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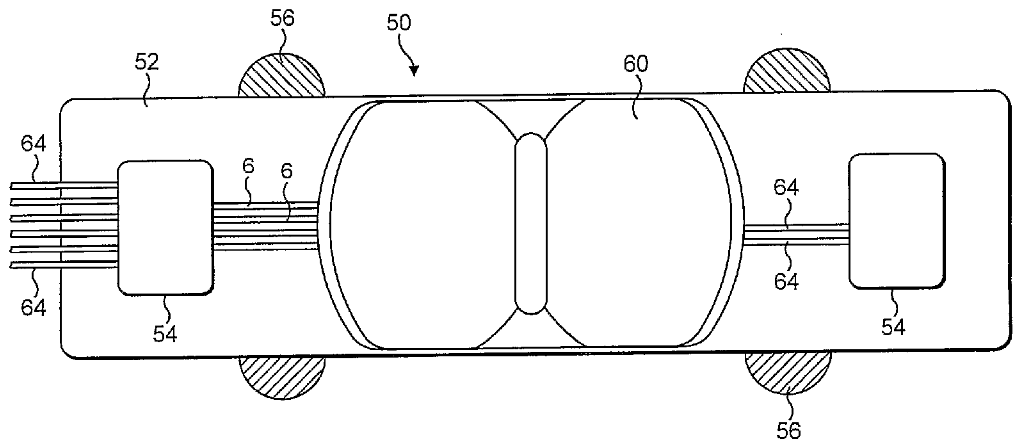

(57) **Abstract:** A physiological sensing device comprises, in combination a sensor (4) for the measurement of the partial pressure of carbon dioxide (pCO_2), a body temperature sensor (5) and a heart rate and oxygen saturation sensor (54). The sensor device can be used to continuously monitor the vital signs of a patient.

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Sensor

The invention relates to a physiological sensor.

A simple sensor particularly suitable for partial pressure of carbon dioxide (pCO_2) measurement, especially as part of a technique for monitoring for ischemias, is described in WO 00/04386.

In addition to the detection of ischemia, it has now been realised that the measurement of pCO_2 may be useful in the diagnosis of severe and potentially life threatening conditions leading to changes in e.g. blood perfusion of tissues, respiration and/or the metabolism, such as shock and sepsis. Thus, it would be advantageous to provide a sensing device which is particularly suited to the monitoring of the hospitalised patient, also outside intensive care units, to detect the onset of sepsis.

Viewed from a first aspect, the present invention provides a physiological sensing device comprising in combination:

a sensor for the measurement of the partial pressure of carbon dioxide (pCO_2);

a body temperature sensor;

a heart rate sensor; and

an oxygen saturation sensor.

Thus, according to the invention a single device can be provided which measures key vital signs such as pCO_2, body temperature, pulse and blood oxygenation. It is believed that the measurement and monitoring of just these four parameters allows a physician to identify the onset of critical and treatment-requiring conditions in a patient such as, for example, sepsis. Consequently, the device according to the invention allows a physician to conveniently and accurately monitor a patient for the onset of sepsis.

In general, the pCO_2 sensor is configured for insertion through a patient's skin. In this way, the sensor may be inserted into the tissue, for example a muscle, of the patient. Thus, the sensor may be dimensioned for insertion into the tissue of a patient with minimal disruption to the tissue. The pCO_2 sensor may be configured to penetrate the patient's skin (and tissue). Consequently, the pCO_2 sensor or the device in general, may be provided with a sharp, for example pointed, tip. Alternatively, the pCO_2 sensor may be configured for insertion into an incision in the patient's tissue.

Viewed from a further aspect, therefore, the invention also provides a physiological sensing device comprising a pCO_2 sensor configured for insertion through a patient's skin and a sharp tip for puncturing a patient's skin on insertion of the pCO_2 sensor.

The sensor device may be provided with an insertion device for inserting the pCO_2 sensor through the patient's skin. In one embodiment, the insertion device is a removable mandrel which is received in a sheath connected to the pCO_2 sensor and engages the pCO_2 sensor to force it through the patient's skin. The mandrel may be removed once the pCO_2 sensor has been inserted in the patient's tissue.

Alternatively, the sensor device may comprise a hollow needle in which the pCO_2 sensor is received for insertion through a patient's skin. The hollow needle may be removable from the sensor device after insertion of the pCO_2 sensor. Advantageously, the cross-section of the needle may be an open curve. This has the advantage that the electrical connections to the pCO_2 sensor can pass through the needle and can be separated from the needle when the needle is removed from the patient. For example, the needle may has a cross-section that is U-shaped, V-shaped or C-shaped.

Advantageously, the device is provided with a self-sealing membrane to close the hole for the needle (or other insertion device) when the needle is removed.

Advantageously, the sensor device and/or the insertion device may be provided with disinfectant, particularly on the pCO_2 sensor, temperature sensor or sharp tip, in order that the sensor device can be applied quickly to a patient, for example in an emergency. Thus, the sensor device may be packaged with disinfectant on those surfaces that will contact the patient.

The pCO_2 sensor may be connected to an electrical cable for communicating signals from the sensor and connected electrically at its distal end to the sensor. The device may comprise a sheath mechanically connected to the pCO_2 sensor and extending with and surrounding at least a portion of the length of the cable. In one arrangement, the sheath comprises a plurality of substantially longitudinally extending flexible portions separated by a plurality of longitudinal slits, such that movement of the proximal end of the sheath towards the distal end of the sheath shortens the distance between the ends of the flexible portions and causes the flexible portions to project outwardly and thereby increase the effective diameter of the sheath in the region of the flexible portions, such that the pCO_2 sensor can be retained in tissue by the projecting flexible portions.

Thus, according to this arrangement, the sensor can be inserted into the patient's tissue and the cable can be pulled to draw the ends of the flexible portions together and cause them to project outwardly. The projecting flexible portions engage with the patient's tissue and retain the pCO_2 sensor in position while the sensor monitors the physiology of the organ. When monitoring is complete, the proximal end of the sheath can be released so that the flexible portions return to their original position flush with the sheath and disengage the tissue. The sensor can then be removed easily from the patient.

The flexible portions may be resilient, for example composed of a resilient material. The flexible portions may be biased into the flush position, for example by their own resilience or by a separate resilient component.

A locking mechanism may be provided, for example at the proximal end of the sheath, to maintain the ends of the sheath in the position in which the flexible members project outwardly.

The device may further comprise a line, for example a Kevlar line, which is mechanically connected to the distal end of the sheath. The line may extend longitudinally with the cable to assist in pulling the distal end of the sheath towards the proximal end of the sheath. Such a line has the advantage that it is not necessary for the cable and/or the electrical connections to the sensor to be strong enough to withstand the forces necessary to bow the flexible members.

It is possible that the cable may be surrounded by a further conduit in addition to the sheath, but this is not preferred. In a simple embodiment, the cable is surrounded only by the sheath.

Advantageously, the sheath may form a carbon dioxide permeable membrane of the pCO_2 sensor. This provides a particularly simple construction. Suitable materials for the sheath in this case are PTFE, silicone rubbers and polyolefins.

The sensor device may be provided with an attachment portion for attaching the device to the surface of the patient's skin. In one convenient embodiment, the attachment portion is an adhesive patch, such as a plaster. In the context of a pCO_2 sensor, this is believed to be a novel aspect of the invention. Thus, viewed from a further aspect, the invention provides a physiological sensing device comprising a pCO_2 sensor configured for insertion through a patient's skin and an adhesive patch for adhering the device to a patient's skin to retain the inserted pCO_2 sensor in position.

The provision of a plaster, as well as retaining the sensor device in position, has several other advantages. In particular, the plaster seals the point at which the pCO_2 sensor is inserted through the patient's skin, thereby reducing the risk of infection. In this regard, the patient-facing side of the plaster may be provided with disinfectant or antibiotics. Furthermore, the plaster may conveniently carry wires, other sensors or a wireless communication device.

Such a device is conveniently applied to the patient and retained in position while the patient is monitored. Desirably, the electrical and mechanical connections to the pCO_2 sensor, such as electrical cables and sheaths are flexible. In this way, the discomfort to the patient when the pCO_2 sensor has been inserted is minimised.

The sensor may comprise a closed chamber bounded, at least partially, by a carbon dioxide permeable membrane; and at least two electrodes within the chamber, with the chamber containing substantially electrolyte-free liquid in contact with the electrodes and the membrane.

By substantially electrolyte-free, it is meant that the liquid has an ionic osmolality no greater than that at 37°C of an aqueous 5 mM sodium chloride solution, preferably no more than that of a 500 μM sodium chloride solution, more especially no more than that of a 10^{-5} to 10^{-6} M HCl solution.

Preferably, the liquid in contact with the electrodes is aqueous and especially preferably it is water, substantially electrolyte-free as defined above. Other solvents that react with CO_2 to increase or decrease their conductance, e.g. by the production or neutralization of ions, may likewise be used. In practice, however, deionized or distilled water with or without the addition of a strong acid (e.g. HCl) to a concentration of 0.1 to 100 μM, preferably 0.5 to 50 μM, more especially about 1 μM, has been found to function particularly well. The function of this small addition of acid is generally to maintain the pH of the liquid at 6 or below to avoid significant contributions to conductance by hydroxyl ions and to maintain the linearity of the measurements of pCO_2.

The liquid may contain a non-ionic excipient. In this way, the osmolarity of the liquid in the chamber can be increased to prevent egress of the liquid across the membrane, without affecting the electrical characteristics of the liquid.

The excipient should have at least isotonic concentration, i.e. should be isosmotic with an aqueous solution of 0.9% w/v NaCl. Preferably, the concentration of the excipient is hypertonic, i.e. is hyperosmotic with 0.9% w/v aqueous NaCl. Thus, the osmolality of the excipient in the chamber may be greater than that of 0.9% w/v aqueous NaCl, preferably greater than that of 1.8% w/v aqueous NaCl (twice isotonic concentration). Osmolalities greater than that of 4.5% w/v aqueous NaCl (five times isotonic concentration), or even greater than that of 9% w/v aqueous NaCl (ten times isotonic concentration) may be used.

Any suitable excipient may be used that is inert to the bicarbonate reaction in the chamber. The excipient should also be soluble in the liquid, for example water. The excipient is also desirably an accepted pharmaceutical excipient for intravenous use and with low viscosity for simple filling of the chamber. The excipient should preferably be sterilizable and storage stable. Desirably, the excipient should inhibit microbiological growth.

A suitable excipient is polyethylene glycol (PEG)and the presently preferred excipient is propylene glycol.

The primary components of the pCO_2 sensor are an electrode chamber, a CO_2-permeable membrane forming at least part of the wall of the electrode chamber, first and second electrodes having surfaces within said chamber (or providing internal surfaces to said chamber), and a liquid (generally substantially electrolyte-free water) in the electrode chamber in contact with the membrane and the first and second electrodes. The sensor includes or is connectable to an AC power supply, a conductance (or resistance) determining device, a signal generator (which may be part of the determining means) and optionally a signal transmitter.

The mechanism by which pCO_2 is determined using the sensor device of the invention is straightforward. In a pure protic solvent, e.g. water, the electrical resistance is high because of the paucity of ionic species. Addition of CO_2 results in formation (with water) of H^+ and HCO^-_3 ions and thus a reduction in the electrical resistance. Since the only factor responsible for reduction in resistance in the sensor is CO_2 passing through the membrane, the change in resistance enables pCO_2 to be measured.

From the equilibrium constant for the $H_2O + CO_2$ to $H^+ + HCO^-_3$ equilibrium, CO_2 concentration is equal to αpCO_2 (where α at 25°C is 0.310). The electrical conductivity for protons is $G_{H+} = 349.8$ S.cm^2/mol, that for hydroxyls is $G_{OH-} = 198.3$ S.cm^2/mol and that for bicarbonate is $G_{HCO3-} = 44.5$ S.cm^2/mol. The concentrations of H^+ and OH^- vary inversely, and the concentrations of H^+ and HCO_3^- are directly proportional to pCO_2. The total conductance of the solution is thus effectively proportional to pCO_2 since the contribution of OH^- is minimal. The conductivity of the solution $G_{solution}$ is thus given by

$$G_{solution} = \theta_{H+}[H^+]G_{H+} + \theta_{OH-}[OH^-]G_{OH-} + \theta_{HCO-3}\,[HCO_3^-]G_{HCO3-}$$

where θ_{H-}, θ_{OH-} and θ_{HC03-} are the activity coefficients for the three ionic species.

Table 1 below shows, by way of example, measured pCO_2 and pH values and corresponding calculated values for H^+, OH^- and HCO_3^- concentrations showing the increase of H^+ and HCO_3^- with increasing pCO_2.

Sample number	pCO_2 (kPa)	pH	$[H^+]$ (mmol/l)	[OH] (mmol/l)	$[HCO_3^-]$ (mmol/l)
1	6.38	5.141	7.23E-06	1.38E-09	7.23E-06
2	9.64	5.060	8.71E-06	1.15E-09	8.71E-06
3	15.37	4.891	1.29E-05	7.78E-10	1.29E-05
4	25.88	4.760	1.74E-05	5.75E-10	1.74E-05
5	31.48	4.664	2.17E-05	4.61E-10	2.17E-05

(pCO_2 and pH measured with a standard blood gas analyser, ABL® System 625 at 37°C)

The electrical conductivity is measured in the solvent film in the pCO_2 sensor of the invention. This can be done by applying a constant voltage (or current) to the electrodes and measuring the current (or voltage) changes which correspond to changes in conductivity as CO_2 enters the solvent through the membrane. Preferably however an alternating sine wave function voltage with a constant peak value is applied and the voltage drop across the electrodes is measured. The solution conductivity is then equal to the current passed through the electrode divided by the voltage drop across the electrodes.

The pCO_2 sensor may function by applying an alternating electrical potential to the electrodes whereby to cause an alternating current in the liquid. The liquid should be reactive with carbon dioxide to alter its conductance. The electrical potential may have a frequency of 20 to 10,000 Hz, preferably 100 to 4,000 Hz.

The pCO_2 sensors of the invention are provided with or are connectable to an electrical power source arranged to apply an alternating electrical potential across the electrodes with a frequency of 100 to 10,000 Hz. The frequency is preferably greater than 1 kHz. The frequency is preferably less than 5 kHz, more preferably less than 2 kHz. At frequencies below 100 Hz, the sensitivity of pCO_2 determination is lower due to electropolarization and moreover the instrument response time becomes overly slow, while at frequencies above 10 kHz sensitivity is again less due to the low impedance of the capacitances in the sensor.

The power source may be an AC power source or alternatively a DC source in conjunction with an oscillator, i.e. a combination which together constitutes an AC power source.

The power supply is preferably such that the maximum current density through the liquid at the electrodes is no more than 50 A/m^2, preferably no more than 30 A/m^2, more preferably no more than 20 A/m^2, in particular no more than 10 A/m^2, and most preferably about 1 A/m^2 or below. Higher current density values of 20 A/m^2 or greater should only be used at the higher frequencies, e.g. 1-10 kHz. The smallest maximum current density is determined by detection limits, but values down to 10^{-8} A/m^2 are usable. The smallest maximum current density however will generally be at least 0.1 μA/m^2.

By operating at such current densities and voltage frequencies, and by appropriate construction, the sensor can determine the conductance/resistance of the liquid into which the CO_2 migrates without any significant loss of accuracy arising as a result of the electropolarization of the electrodes.

For particularly high accuracy, the potential or current across the electrodes (and hence the resistance or conductance of the liquid between the electrodes) is determined using a lock-in amplifier set to the same frequency as that of the voltage generator or electrical power source.

Furthermore it is preferred to incorporate in the detection a high pass filter to screen out current with a frequency less than 100 Hz, preferably less than 150 Hz. The filter is preferably a passive filter, for example a capacitor and a resistor.

The power source and the detector circuitry may, if desired, be included in the sensor of the invention. In this case, if it is desired that the sensor be wireless, it will preferably also be provided with means enabling the signal to be detected remotely, e.g. a transmitter, for example a RF transmitter.

A further electrode may be provided that is electrically connected to the patient, for example to the patient's skin. The signal from this further electrode may be processed with the signal from the sensor in order to compensate for electromagnetic noise from the patient.

Electropolarization effects are considerably reduced by increasing the surface area of the electrodes in contact with the liquid, e.g. by siting the electrodes in wells disposed away from the plane of the membrane or by using non-planar electrode surfaces, e.g. rough or textured surfaces. In general therefore it is desirable to have as large a ratio of surface area of electrode to liquid contact as possible, and as shallow as possible a liquid depth over as much as possible of its area of contact with the membrane. In this way the response time is reduced, electropolarization is reduced, lower frequencies may be used and stray capacitance effects are considerably reduced.

Increased electrical resistance relative to the resistance at the electrodes may be achieved by restricting the cross sectional area of the electrical path through the liquid between the electrodes at a zone in which the liquid is in contact with the membrane, e.g. by decreasing the depth of the liquid for a part of the path between the electrodes, and/or by ensuring a relatively large area of contact between each electrode and the liquid.

The resistance of the liquid at the membrane and between the electrodes may be increased by the use of structural elements to define liquid channels across the membrane between the electrodes, e.g. by disposing the membrane across or adjacent an insulating chamber wall portion in which such channels are formed, for example by etching. Likewise a porous spacer may be disposed between the membrane and the chamber wall to define the depth of the liquid.

Indeed, such spacers are important to use where, under the pressure conditions experienced in use, the membrane is sufficiently flexible and the liquid depth behind the membrane sufficiently small, for the measured conductance to vary with pressure.

In a preferred arrangement, the pCO_2 sensor comprises:

a sensor body having a longitudinal axis;

at least two electrodes spaced in a direction transverse to the longitudinal axis of the sensor body;

a plurality of support members extending outwardly from the axis of the sensor body and defining between adjacent support members at least one liquid channel that provides a fluid pathway between the electrodes; and

a gas-permeable membrane supported by the support members and providing an outer wall of the liquid channel(s).

This arrangement provides a compact configuration of the sensor with a longitudinal geometry that is suited to insertion in the tissue of a patient. Furthermore, the support members are able to provide physical support to the membrane, as well as defining liquid channels of small cross-sectional area that allow accurate measurement.

In order to reduce the electropolarisation effect mentioned above, the electrodes may be located in a recess in the sensor body that has a greater cross-sectional area than the liquid channels. In this way, the current density around the electrodes is reduced by the greater volume for liquid.

The electrodes of the pCO_2 sensor may extend longitudinally, for example parallel to the longitudinal axis of the sensor body.

Similarly, the liquid channel(s) may be transverse, for example perpendicular, to the longitudinal axis of the sensor body. In a preferred arrangement, the pCO_2 sensor comprises a plurality of liquid channels. For example, the sensor may comprise at least three liquid channels.

The support members may be transverse to the longitudinal axis of the sensor body. For example, the support members may be perpendicular to the longitudinal axis of the sensor body in the circumferential direction. In a preferred arrangement, the support members are in the form of rings formed about the longitudinal axis of the sensor body. The cross-section of the support members may be any suitable shape. It has been found in particular that support members with a substantially triangular, in particular sawtooth, cross-section are particularly easily formed by injection moulding. Alternatively, a substantially rectangular cross-section may be used. The support members may be formed integrally with the sensor body, for example by injection moulding. The sensor preferably comprises at least four support members.

The sensor body and/or the pCO_2 sensor may be generally cylindrical. The membrane may be arranged to surround the sensor body.

The described geometry may be applied to any suitable sensor. In the preferred arrangement, the sensor is a pCO_2 sensor.

Where the pCO_2 sensor is constructed with the liquid film in place, the electrodes are preferably of, or plated with, an inert material such that the resistivity of the liquid will not change significantly with storage. Suitable materials include platinum (especially black platinum), gold, silver, aluminium and carbon. Gold is particularly preferred. In general inert electrodes which do not generate solvated ions are preferred.

The membrane may be any material which is permeable to CO_2, and substantially impermeable to the solvent of the liquid, any electrolyte and water. Polytetrafluoroethylene, e.g. Teflon®, silicone rubber, polysiloxane, polyolefins or other insulating polymer films may be used, e.g. at thicknesses of 0.5 to 250 μm. The thicker the membrane, in general the slower the response time of the pCO_2

sensor will be. However the thinner the membrane the greater the risk of non-uniformities or of perforation or other damage. Conveniently, however, the thickness of the membrane will be 1 to 100 µm, preferably 50 to 100 µm.

The walls of the chamber of the pCO_2 sensor of the invention may be of any suitable material, e.g. plastics. Preferably the material should be capable of withstanding conditions normally used in sterilisation, e.g. radiation sterilization (for example using gamma radiation) or thermal sterilization (for example using temperatures of about 121°C as used in autoclave sterilisation). In the case of thermal sterilization, the liquid will generally be sterile filled into the sensor after sterilization. The walls of the chamber and the membrane may be of the same material, e.g. Teflon®, machined to have self-supporting walls and a thinner gas-permeable membrane.

The pCO_2 sensor of the invention is generally relatively inexpensive and so, unlike prior art sensors, may be single-use devices. Moreover the electrode chamber can be made extremely small without difficulty (unlike the prior art glass electrode containing sensors for which miniaturization poses insuperable impedance problems).

The above arrangement provides a pCO_2 sensor, which can be inserted easily into the tissue of an animal, including a human, which can be retained in the tissue during monitoring and which can be removed easily when monitoring is complete.

The pCO_2 sensor is sufficiently small that it will not cause undue disturbance to the tissue to be monitored. Consequently, the sensor may have a maximum diameter of 2 mm, preferably 1 mm.

The temperature sensor may be applied to the patient's skin, in use of the sensor device. However, in one embodiment of the invention, the temperature sensor is configured for insertion through the patient's skin. In particular, the temperature sensor and the pCO_2 sensor may be incorporated into a single sensor unit. In other words, the pCO_2 sensor may include the temperature sensor.

Blood oxygen saturation levels may be measured by pulse oxymetry. Thus, the device may comprise a pulse oxymetry sensor. In pulse oxymetry, the saturation of oxyhaemoglobin in a patient's blood is determined by measuring the absorption of light by the haemoglobin. The degree of absorption differs depending on whether the haemoglobin is saturated or desaturated with oxygen. The blood oxygenation sensor according to the present invention may, in particular, be a reflectance pulse oxymetry sensor. In other words, the sensor may be configured to illuminate the patient's skin with light of a specified wavelength or wavelengths and measure the reflectance of these wavelengths in order to determine the degree of oxygen saturation of the patient's blood. Conveniently, therefore, the blood oxygenation sensor may be configured to be retained against the patient's skin by the adhesive patch.

The sensor device may comprise a dedicated heart rate sensor. Conveniently, however, the oxygen saturation sensor and heart rate sensor are provided by a pulse oxymetry sensor.

The sensor device may comprise a plurality of sensors for respective physiological parameters. For example, the device may comprise an array of sensors. Such sensors may measure one or more of the partial pressure of carbon dioxide, the partial pressure of oxygen, temperature, pH or glucose concentration, for example. The sensors may be provided, for example, on the plaster or adhesive patch. In the presently preferred embodiment, the device comprises a temperature sensor, a pCO_2 sensor, a heart rate sensor and a blood oxygenation sensor.

The pCO_2, oxygenation and temperature determined by the sensor device may be a quantified value or may simply be an indication that the values are above or below one or more threshold values indicative of sepsis, values which may be varied according to the location of the measurement site.

The sensor device may be used for a single measurement or, more preferably, may be used for continuous or repeated monitoring, e.g. in emergency and intensive care settings or in the ward or nursing homes of any risk patient for fast detection and immediate treatment of changes in vital signs.

Although the sensor has been described in relation to the detection of sepsis, it may be used to detect any condition that will cause either hypocarbia or hypercarbia in the tissue, i.e. any condition that will either change the respiratory pattern of the patient, or conditions that will increase the production of or reduce the elimination of CO_2. Conditions where hypocarbia is likely to be found include sepsis, fever of origin other than sepsis per se, moderate cardiac failure, pulmonary oedema, acute respiratory distress syndrome (ARDS) and hyperventilation of any cause. Conditions where hypercarbia is likely to be found include ischemia at the place where the sensor is located, circulatory shock of haemorrhagic, cardiac or septic origin and respiratory insufficiency, acute or chronic, such as ARDS or chronic obstructive lung disease (COLD).

An embodiment of the invention will now be described, by way of example only, with reference to the accompanying drawings, in which:

Figure 1 is a schematic diagram of a complete sensing system incorporating the sensor device of the invention;

Figure 2 is a schematic diagram illustrating the measurement principle for the pCO_2 sensor in the system of Figure 1;

Figure 3 is a partially cutaway view of a pCO_2 sensor according to the invention;

Figure 4 is a cross-sectional view along line A-A of Figure 3;

Figure 4a is a magnified view of the detail indicated by the circle in Figure 4;

Figure 5 is a view of the pCO_2 sensor of Figure 3 with the membrane removed;

Figure 6 illustrates a variant of the pCO_2 sensor of Figure 3 wherein the attachment mechanism is visible;

Figure 7 is a plan view of a sensor device according to an embodiment of the invention;

Figure 8 is a side view, partially in section, of the sensor device of Figure 7;

Figure 9 is a side view of the sensor device of Figures 7 and 8 in the position of use;

Figure 10 is an enlarged view of the pCO_2 and temperature sensor of the sensor device of Figures 7 to 9;

Figure 11 shows a sensor device according to an alternative embodiment of the invention;

Figure 12 is a perspective view, partially in section, of the sensor device of Figure 11;

Figure 13 is a sectional view of a details of the sensor device of Figures 11 and 12;

Figure 14 is a plan view of the sensor device of Figures 11 to 13 without the insertion needle; and

Figure 15 is a perspective view of the sensor device in the position of Figures 14.

In accordance with the invention, a pCO_2 sensing system comprises a sensor device 50, an electronic surface unit 2, and a monitor unit 3, as shown in Figure 1. The sensor device 50 comprises a combined pCO_2 and temperature sensor unit 1 and two pulse oxymetry sensors 54.

Figures 7 to 10 show the sensor device 50 according to an embodiment of the invention. The device 50 comprises a self-adhesive strip 52 onto which are mounted two reflection pulse oxymetry sensors 54 and a sensor unit 1 which will be described in detail below. The pulse oxymetry sensors may be of the type commercially available from Nellcor of Pleasanton, California as MAX FAST adhesive forehead sensors. The self-adhesive strip 52 is provided with a release strip 56 which can be peeled from the adhesive strip 52 to reveal the adhesive surface of the adhesive strip 52 for application to a patient's skin. The sensor device 50 is provided packaged with the sensor unit 1 in a tube (not shown) filled with a sterile aqueous isotonic solution of propylene glycol to prevent any damage, contamination or evaporation.

The sensor device 50 includes a mandrel 58 provided with a finger grip 60. The mandrel 58 is received in a flexible sheath (or catheter) 62 which contains the cable connections 6 from the sensor unit 1. As shown in Figure 10, at its distal end, the mandrel 58 engages the sensor unit 1 and allows the pointed sensor unit 1 to be driven through a patient's skin by the application of manual pressure to the finger grip 60 of the mandrel 58. In this way, the sensor unit 1 is located in the patient's muscle, for example in the patient's underarm.

When the pCO_2 sensor unit 1 has been located correctly in the patient's muscle, the mandrel 58 is withdrawn from the flexible sheath 62 leaving the sensor device 50 in the configuration shown in Figure 9. The sheath 62 and cables 6 that are connected to the sensor unit 1 are sufficiently flexible that the patient feels little, if any, discomfort with the sensor unit 1 in position.

The sensor unit 1 is held in position in the muscle by the adhesive strip 52 adhering to the patient's skin. At the same time, the adhesion of the adhesive strip

52 to the skin brings the pulse oxymetry sensors 54 into their position of use against the patient's skin. The pulse oxymetry sensors 54 measure the reflectance of specified wavelengths of light from the patient's skin in order to determine the oxygen saturation level in the patient's blood.

As shown most clearly in Figure 7, electrical connections 64 from the pulse oxymetry sensors 54 and from the sensor unit 1 run longitudinally along the adhesive strip 52 for connection to the electronic surface unit 2. Alternatively, as shown in Figure 9, the sensor device 50 may be provided with a wireless device 70 for communication with the electronic surface unit 2 or the monitor unit 3.

The sensor device 50 is delivered packaged and sterilised. It includes a membrane-protected conductometric sensor 4 with a diameter of less than 1 millimetre, and a temperature probe 5 integrated in the sensor unit 1. Wires 6 connect the sensor 4 and probe 5 electrically by means of a connector to the electronic surface unit 2.

The electronic surface unit 2 sends and receives signals to and from the sensor device 50. It is placed on the patient's skin, performs signal processing on signals from the sensor unit 1 and transmits the conditioned signal to the monitor unit 5.

The monitor unit 3 is based on a portable personal computer 7 with PCMCIA input/output card 8 and Labview software (available from National Instruments Corporation of Austin, Texas).

The pCO_2 sensor 4 is used for measurements of the level (partial pressure) of CO_2 (pCO_2) in tissue, according to the measurement principle illustrated in Figure 2. The measurement chamber consists of two small cavities 9 with one electrode 10 positioned in each. The two cavities 9 are connected by one or more passageways 11 enclosed by a semi-permeable membrane 12, i.e. a membrane that only allows transport of CO_2 in and out of the volume of the sensor 4. The whole volume is filled with de-ionised water and 5% propylene glycol . The conductivity in the water depends upon the pCO_2, and by measuring the conductivity between the electrodes 10 in the volume, information about pCO_2 may be extracted.

As shown in Figures 3 to 5, the sensor unit 1 comprises an injection moulded plastics support 23, which is substantially cylindrical and surrounded by the semi-permeable membrane 12. The support 23 has a pointed tip 24 at its distal end and a body portion 25 which extends proximally from the tip 24. On the body portion 25 are mounted, by gluing, two gold electrodes 10. The electrodes 10 extend longitudinally along opposed sides of the body portion 25 and are received in respective recesses in the body portion 25.

Between the tip 24 and the body portion 25, a frustoconical projection 26 is provided for securing the membrane 12 by frictional fit. A corresponding projection 26 is provided at the proximal end of the body portion 25. The membrane 12 may be glued to the support 23, but it is important that the glue used to secure the membrane 12 and electrodes 10 is selected such that it does not bleed ions into the water-filled chamber formed between the body portion 25 of the support 23 and the membrane 12. Furthermore, the sealing faces of the support 23 may be made selectively hydrophobic in order to avoid the formation of a water film into which ions may bleed.

The membrane 12 may also be secured to the support 23 by means of crimp connection and a soft gasket, if necessary. The membrane 12 may act as the gasket, particularly where the membrane 12 is formed of silicone rubber. A heat shrink sleave may be used to form the crimp connection, as is the case in Figure 6. Alternatively, metal crimp rings may be used in locations corresponding to those of the sealing projections 26.

The body portion 25 of the support 23 is provided with a plurality of ribs 27, which are formed with a saw tooth profile for easy moulding. The ribs 28 provide mechanical support to the membrane 12 and also define the fluid passageways 11 required for the sensor 4 to function effectively. Between each electrode 10 and the fluid passageways formed between the ribs 27 is provided a reservoir 9 formed by the recess in which the electrode 10 is located. The reservoir 9 provides a region of relatively low current density around the electrodes 10 in order to reduce electropolarisation effects.

During manufacture, the membrane 12 is fixed onto the support 23, while immersed in the de-ionised water and propylene glycol solution, so that the chamber bounded by the membrane 12, the electrodes 10, and the ribs 27 is completely filled with liquid. Thus, this chamber forms a pCO_2 sensor as shown schematically in Figure 2.

It is possible for the sensor 1 to include more than one sensing chamber. For example, two parallel electrodes 10 separated by a wall member may be provided on each side of the support 23. A sensing chamber is thereby formed between one electrode 10 on one side of support 23 via the fluid passageways 11 between the ribs 27 on the top of the support 23 to one of the electrodes 10 on the other side of the support 23. A corresponding sensing chamber is provided between the remaining electrodes 10 and the fluid passageways 11 on the bottom of the support 11. An electrode 10 from each of these chambers may be electrically connected to the corresponding electrode from the other chamber, such that the electrical signal from the sensor reflects the conductivity of both chambers.

Embedded in the proximal end of the support 23 is a temperature sensor 5 in the form of a thermocouple. The temperature sensor 5 is used both for pCO_2 corrective calculations and for the measured tissue temperatures to be displayed on the monitor 3, which is informative for medical diagnosis. The temperature sensor 5 has a minimum measuring range of 33-42°C and a minimum accuracy of +/- 0.2°C.

A ribbon cable 6 is electrically and mechanically connected to the electrodes 10 and the temperature sensor 5. The electrodes 10 are formed as extensions of the conductors of the ribbon cable 6. Alternatively, the electrodes may be formed by plating onto the support 23. Where the cable 6 and the connection to the support 23 are sufficiently strong, the cable 6 can be used to pull the sensor unit 1 from its position of use. Alternatively, a Kevlar line may be provided, for example incorporated with the ribbon cable 6, to provide a strong external mechanical connection.

The membrane 12 may extend proximally from the support 23 with the cable 6 to form a catheter around the cable 6. Alternatively, a separate catheter 28 may be provided. In this case, the catheter 28 is bonded to the support 23 proximally of the electrodes 10 and the membrane 12.

As shown in Figure 6, the catheter 28 may be provided with a plurality of slits 29 in order to fix the sensor unit 1 in position in tissue. The slits 29 are arranged such that when the catheter 28 is pushed distally (in the direction of the arrow B in Figure 6), relative to the cable 6 (or Kevlar line) the portions 30 of the catheter 28 between the slits 29 are forced outwardly and assume the shape shown in phantom in Figure 6. The radially projecting portions 30 of the catheter 28 retain the sensor unit 1 in the tissue in which it is embedded. The relative position of the catheter 28 and the cable 6 can be maintained with a locking mechanism (not shown) until it is time for the sensor unit 1 to be removed from the tissue. At this time, the locking mechanism can be released and the portions 30 of the catheter 28 will return to their relaxed position so that the sensor unit 1 can be removed from the tissue.

The catheter tip with the integrated sensor 4 is placed 0.5 - 4 cm into tissue to measure pCO_2 to detect and monitor the effect of treatment of the diseases and conditions mentioned above during a period of up to four weeks.

The sensor unit 1 has a maximum diameter of 1 mm and the maximum distance from the catheter tip to the sensor element is 2 mm. The sensor 4 has a minimum pCO_2 measuring range of 2-25 kPa, with a minimum detectable pCO_2 difference of 0.2 kPa. The maximum response of the sensor 4 is 20 seconds. The maximum allowable measurement current is in any area of the fluid chamber is such that $j<1mA/cm^2$ while the measuring input voltage is not more than 50 mV RMS.

The electrodes 10 are gold plated and their total area is approximately 0.3 mm^2. The measurement frequency f_{meas} should be higher than 100 Hz. At lower frequencies, polarisation effects in the measurement chamber dominate the measurements. At frequencies above 10 kHz, the low impedance of the capacitances become a significant issue. The measurement resistance $R\_{measure}$ is in the range of 500 kOhm to 7 MOhm.

The sensor 4 is electrically connected to an electronic surface unit 2 located on the patient skin by the ribbon cable 6, which has a length between 5 cm and 1 metre. The maximum diameter of the cable/catheter is 1 mm. The cable/catheter is soft and flexible so that it does not excessively disturb the neighbouring tissue. The cable/catheter and its connections are also sufficiently robust to withstand any pulling forces which may be caused by both normal and "abnormal" use.

During sterilisation, storage and transport the sensor unit 1 is covered by deionised, sterile and endotoxin-free water to make sure that there is substantially no net loss of water from the sensor reservoir.

Figures 11 to 15 show a sensor device 50 according to an alternative embodiment of the invention. Except where otherwise indicated, the configuration of this embodiment is the same as that of the sensor device described in relation to Figures 7 to 10. As in the previous embodiment, the device 50 comprises a self-adhesive strip 52 onto which are mounted two reflection pulse oxymetry sensors 54 and a sensor unit 1 as described above. The self-adhesive strip 52 is provided with a release strip 56 which can be peeled from the adhesive strip 52 to reveal the adhesive surface of the adhesive strip 52 for application to a patient's skin. The sensor device 50 is provided packaged with the sensor unit 1 in a sterile water-filled tube 72 filled with a sterile aqueous isotonic solution of propylene glycol to prevent any damage, contamination or evaporation.

The sensor device 50 includes a U-section insertion needle 74 provided with a finger grip 60. In the packaged sensor device 50, the sensor unit 1 and the associated cable connections are received in the U-shaped channel in the insertion needle 74. With the protective tube 72 removed, the insertion needle 74 can be driven through a patient's skin by the application of manual pressure to the finger grip 60. The insertion needle 74 can then be removed from the sensor device 50 leaving the sensor unit 1 located in the patient's muscle in the general configuration shown in Figure 14. The U-shape of the insertion needle 74 allows the needle to be disengaged from the cable connections 6 to the sensor unit 1 as it is withdrawn.

Figure 13 shows the detail of the connections between the insertion needle 74 and the sensor device 50. As shown in Figure 13, the U-section insertion needle 74 is moulded into the finger grip 60. The sensor device 50 is provided with a plastic housing 76 which is located over and engages with an orifice defined in the self-adhesive strip 52. The plastic housing 76 is bonded to the self-adhesive strip 52. In the centre of the plastic housing 76 is defined a hole through which the insertion needle 74 passes. Above the hole in the plastic housing 76 a metal guide 78 in the form of a disc with a central hole for the insertion needle 74 is bonded to the plastic housing 76. The central hole in the metal guide 78 has a U-shape corresponding to the cross-section of the insertion needle 74 and acts to hold the needle 74 in position so that it cannot rotate and cause damage to the cable connections 6 to the sensor unit 1. The cable connections 6 from the sensor unit 1 pass from the insertion needle 74 between the metal guide 78 and the plastic housing 76 and are surrounded by a protective sheath 62 which is glued to the metal guide 78. The holes through the metal guide 78 and the plastic housing 76 are closed by a silicone membrane 80 provided over the metal guide and through which the insertion needle 74 passes. The silicone membrane 80 elastically deforms to seal the holes when the insertion needle 74 is removed.

As shown in Figure 13, a beaded rim 82 of the cover tube 72 snap fits into a corresponding recess in the plastic housing 76 to seal the tube 72 to the sensor device 50. The tube 72 is removed from the sensor device 50 to expose the insertion needle 74 when the sensor unit 1 is to be inserted in the patient's muscle.

As shown in Figures 1 and 2, the electronic surface unit 2 comprises a sine generator 13 which provides a voltage of at least 5 Volts and a current supply of 50mV, and is powered by batteries 14. A filter 15 is provided for filtering or averaging the input of the lock-in amplifier 16. A passive filter can be used which reduces the current consumption. A pre-amplifier 17 is combined with a servo mechanism to remove DC current from the signal to reduce electrolysis effects. According to the servo arrangement, the output of the pre-amplifier is fed back to its input via a low pass filter. Thus, only DC components of the output are fed back and cancel any DC current drawn through the pCO_2 sensor. In this way, it is ensured that there is no DC current through the pCO_2 sensor which would degrade the electrodes. The op-amp used in this stage consumes minimal current and has a large CMMR value. At the same time, the bias current is minimal. A lock-in amplifier 16 amplifies the AC signal from the sensor 4. This may be built with op-amps or using an IC package with at least 1% accuracy for the signal detection at frequencies lower than 1kHz. A galvanic division 19 such as an optocoupler or a coil coupler is provided to prevent noise transfer from the monitor unit 3 and associated cabling 18. The optocoupler is normally favoured due to the noise signal ratio. A temperature signal amplification and conditioning unit 20 is provided to amplify the signal from the temperature sensor 5. The electronic unit 2 is powered by a rechargeable and changeable standard type battery 14. The battery capacity is sufficient for 14 days continuous monitoring. The surface unit 2 is also provided with an on/off indicator LED 21, and a battery status indicator (not shown). Communication between the surface unit 2 and the monitor 3 is analogue through a shielded cable 18. However, the surface unit 2 may include an analogue to digital converter such that communication between the surface unit 2 and the monitor 3 may be digital, for example by digital wire transmission or digital wireless transmission. The cable 18 is at least 4 m long and light and flexible.

As shown in Figures 1 and 2, an AC current is generated by sine generator 13 and fed to one of the pCO_2 sensor electrodes 10 and to a lock-in amplifier 16. The high-pass signal from the other pCO_2 electrode 10 is passed through a filter 15 to a low noise amplifier 17 and from there to the lock-in amplifier 16 where it is compared to the reference signal generated by the sine generator 13. Out of phase components, i.e. undesired components, of the signal are rejected and the remaining portion of the signal is amplified. The amplified signal is proportional to pCO_2 (or conductance) and is passed on for recordal or further manipulation to the monitor 3.

The surface unit 2 may also be electrically connected to a reference electrode (not shown) that is electrically connected to the patient's skin. The signal from the reference electrode can be used to compensate the signals from the sensor unit 1 for the effect of electromagnetic noise generated by the patient.

A single surface unit 2 may receive signals from several sensor units 1 and provide a multiplexed output to the monitor unit 3.

The monitor unit 3 comprises a portable PC 7 including CD RW and IR port, and a PCMCIA I/O card 8 which can collect signals from at least 4 different surface units 2 simultaneously. The PCMCIA card 8 may have an integrated non-galvanic coupling. The power supply 22 for the monitor unit 3 is of a medically approved type operating on both 110V and 230V.

The software functions of the monitor unit 3 may be implemented in Labview, a software package available from National Instruments of Austin, Texas and capable of handling up to 4 different surface units simultaneously. The software provides the facility for calibration of the sensor(s) with three calibration points and a second order calibration function. The software can be modified to support any other number of calibration points and type of calibration function. The software also has the facility to smooth the signal from the sensor device 50 over defined time intervals. It is possible to have at least two alarm levels for the measurement values and two alarm levels for their gradients. The measurement value gradients are calculated for individually defined time intervals. The alarm is both visible and audible. It is possible to stop an alarm indication while keeping the other alarms active. The monitor 3 can log all measured values, parameter settings and alarms throughout a session. With a 30 second logging interval there should be a storage capacity for at least 10 two week sessions on the hard disc. The session log can be saved to a writeable CD in a format readably by Microsoft Excel.

The sensor device 50 according to this embodiment of the invention is able to provide, in a single device, measurement of pCO_2, temperature and blood oxygenation of the patient's muscle. With this information, a physician can identify, amongst other conditions, the onset of sepsis in the patient quickly and accurately.

Although the sensor device has been described herein with particular reference to the measurement of pCO_2, the general configuration of the sensor device may be used for other physiological sensors, for example body temperature, partial pressure of oxygen, pH or glucose concentration.

Claims

1. A physiological sensing device comprising in combination:
a sensor for the measurement of the partial pressure of carbon dioxide (pCO_2);
a body temperature sensor;
a heart rate sensor; and
an oxygen saturation sensor.

2. A sensing device as claimed in claim 1, wherein the pCO_2 sensor is configured for insertion through a patient's skin.

3. A sensing device as claimed in claim 1 or 2, wherein the temperature sensor is configured for insertion through a patient's skin.

4. A sensing device as claimed in any preceding claim, wherein the temperature sensor and the pCO_2 sensor are provided by a sensor unit for insertion through a patient's skin.

5. A sensing device as claimed in any of claims 2 to 4 wherein the device comprises a sharp tip for puncturing a patient's skin on insertion of the pCO_2 sensor.

6. A physiological sensing device comprising a pCO_2 sensor configured for insertion through a patient's skin and a sharp tip for puncturing a patient's skin on insertion of the pCO_2 sensor.

7. A sensing device as claimed in claim 5 or 6, wherein the sharp tip is provided by a removable hollow needle in which the pCO_2 sensor is located for insertion through a patient's skin.

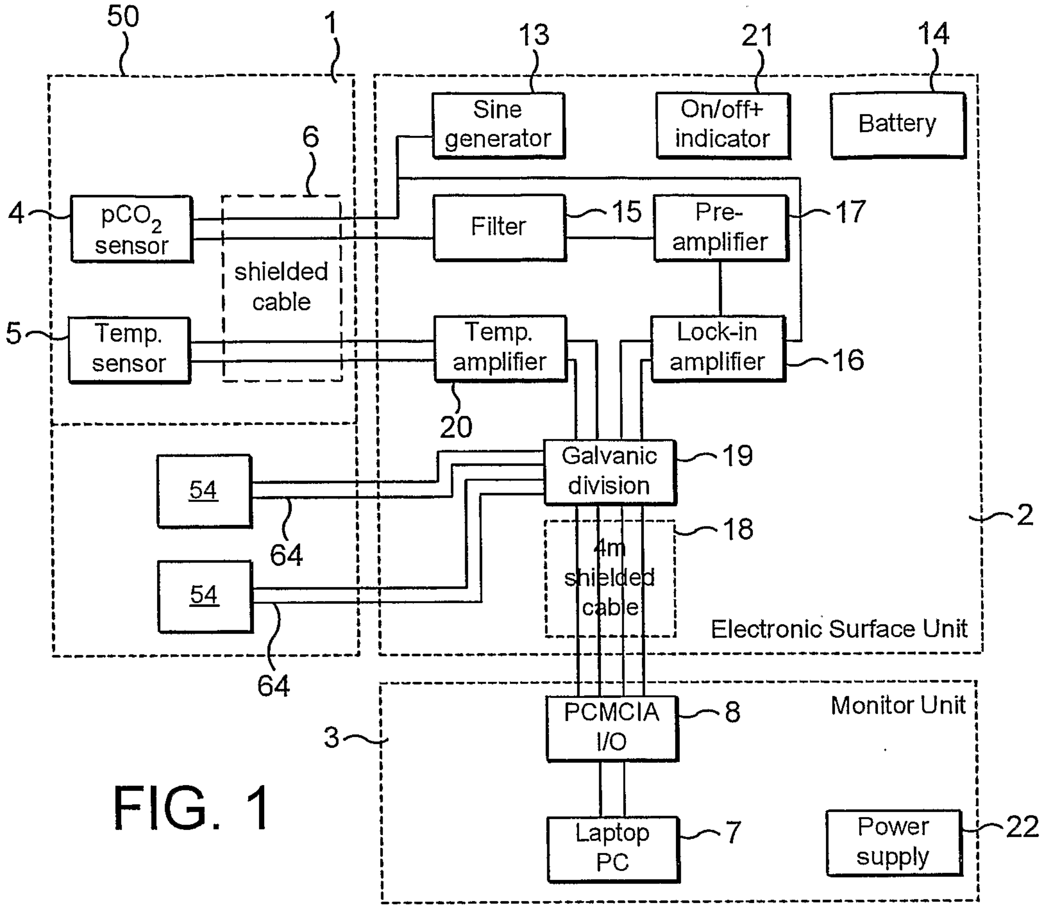
8. A sensing device as claimed in any preceding claim, wherein the oxygen saturation sensor is configured for application to the surface of a patient's skin.

9. A sensing device as claimed in claim 8, wherein the heart rate sensor and the oxygen saturation sensor are provided by a pulse oxymetry sensor.

10. A sensing device as claimed in any preceding claim comprising an adhesive patch for adhering the device to a patient's skin.

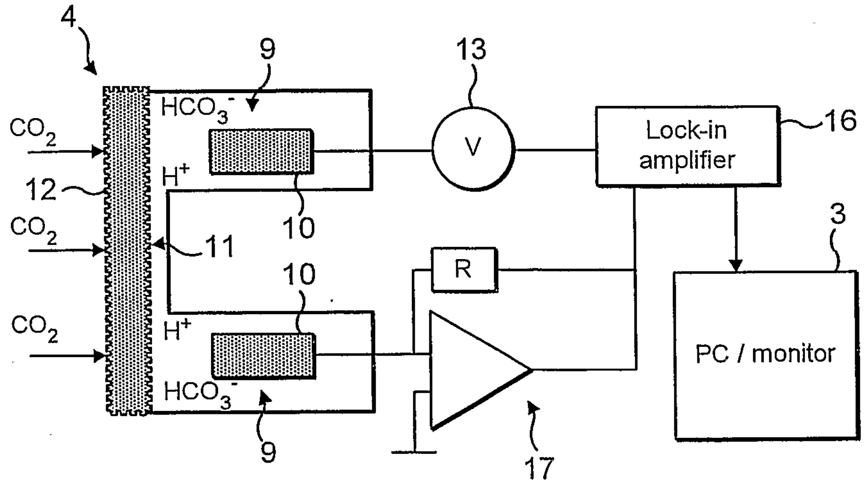
11. A physiological sensing device comprising a pCO_2 sensor configured for insertion through a patient's skin and an adhesive patch for adhering the device to a patient's skin to retain the inserted pCO_2 sensor in position.

12. A sensing device as claimed in any preceding claim, wherein the pCO_2 sensor comprises a chamber bounded, at least in part, by a carbon dioxide permeable membrane and containing a substantially electrolyte-free liquid and at least two electrodes.



50
1
13
21
14
Sine generator
On/off+ indicator
Battery
6
4
pCO2 sensor
Filter
15
Pre-amplifier
17
shielded cable
5
Temp. sensor
Temp. amplifier
Lock-in amplifier
16
20
Galvanic division
19
54
64
4m shielded cable
18
2
54
Electronic Surface Unit
64
PCMCIA I/O
8
Monitor Unit
3
Laptop PC
7
Power supply
22

FIG. 1



4
9
13
CO2
HCO3-
V
Lock-in amplifier
16
H+
12
10
3
CO2
11
10
R
CO2
H+
PC / monitor
HCO3-
9
17

FIG. 2

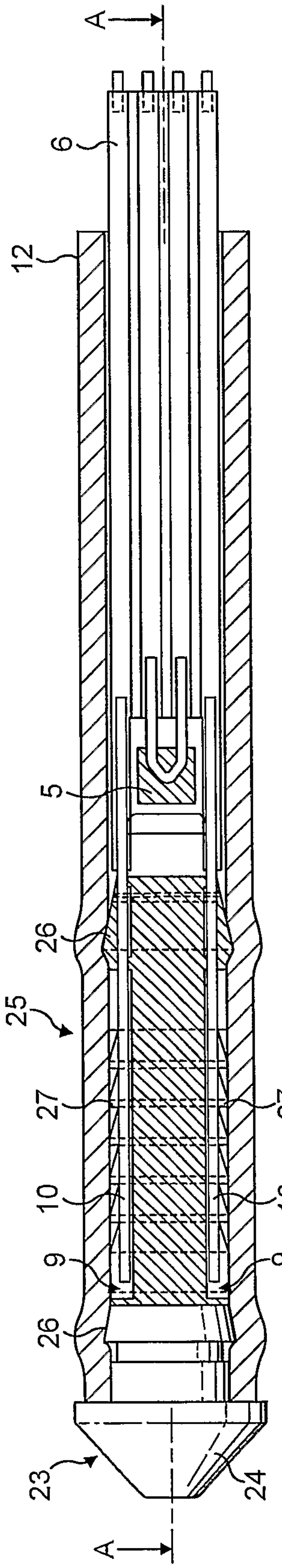


FIG. 3

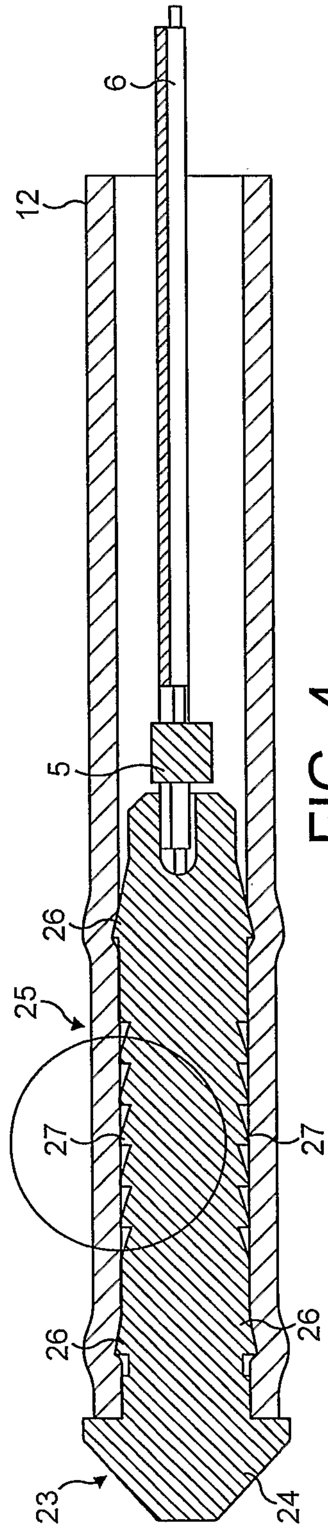


FIG. 4

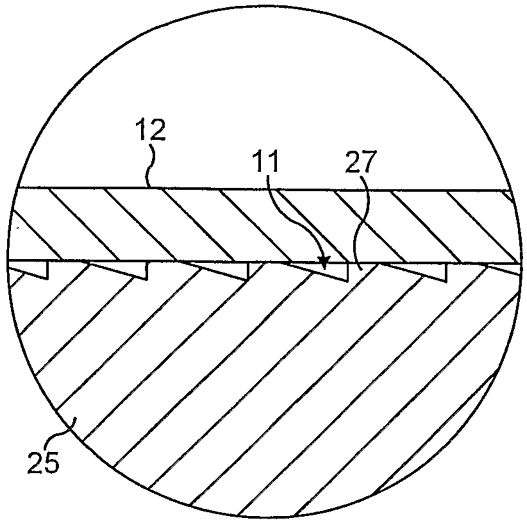


FIG. 4a

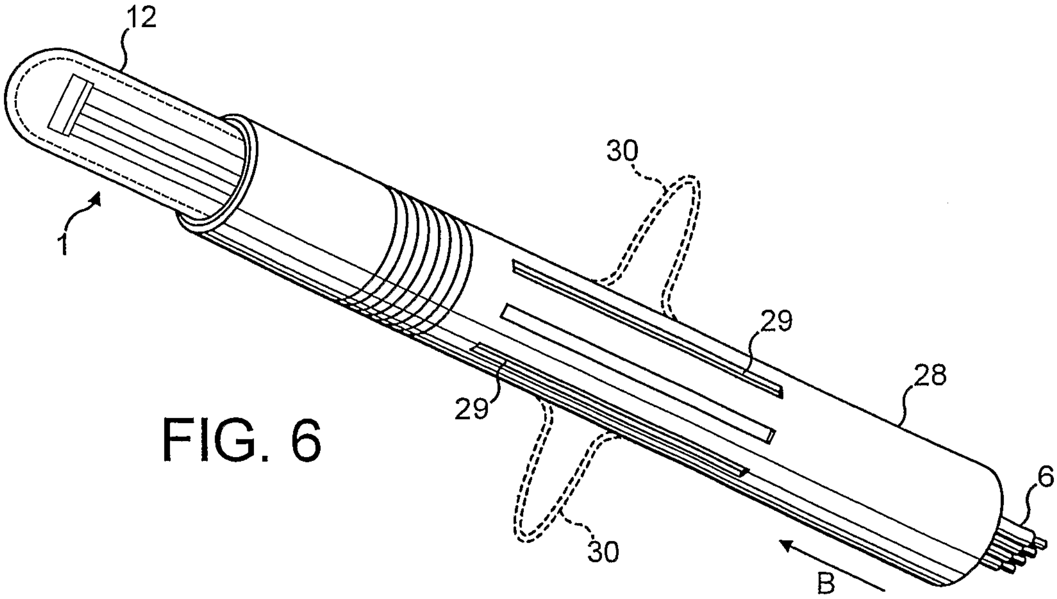


FIG. 6

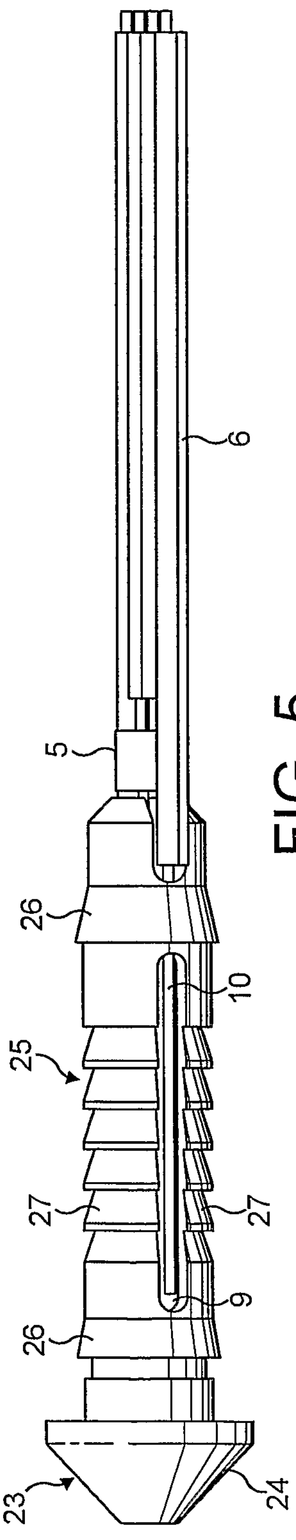


FIG. 5

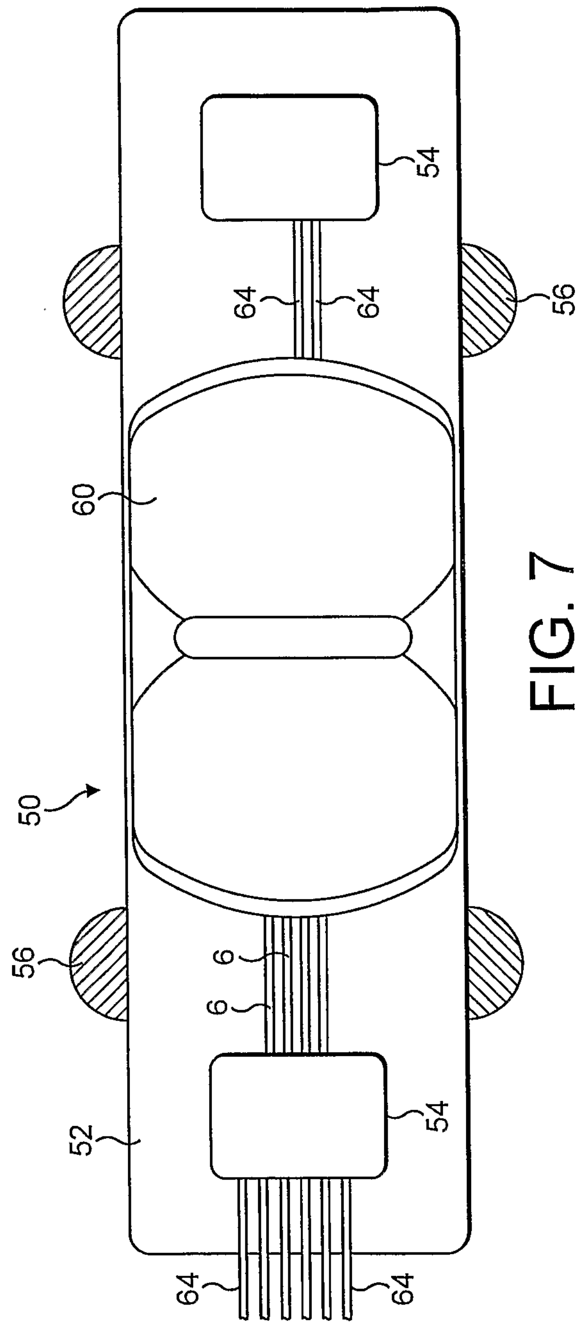


FIG. 7

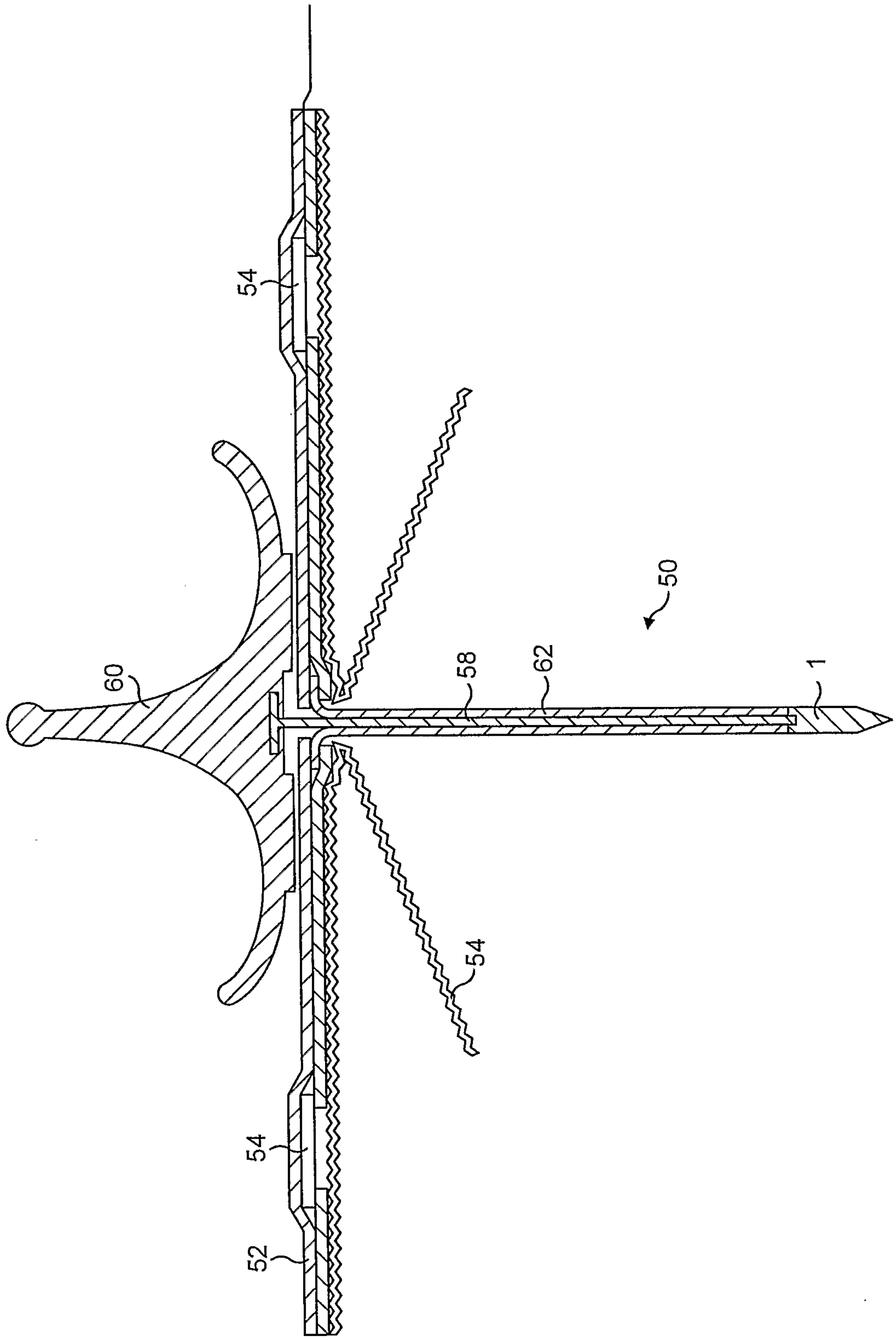


FIG. 8

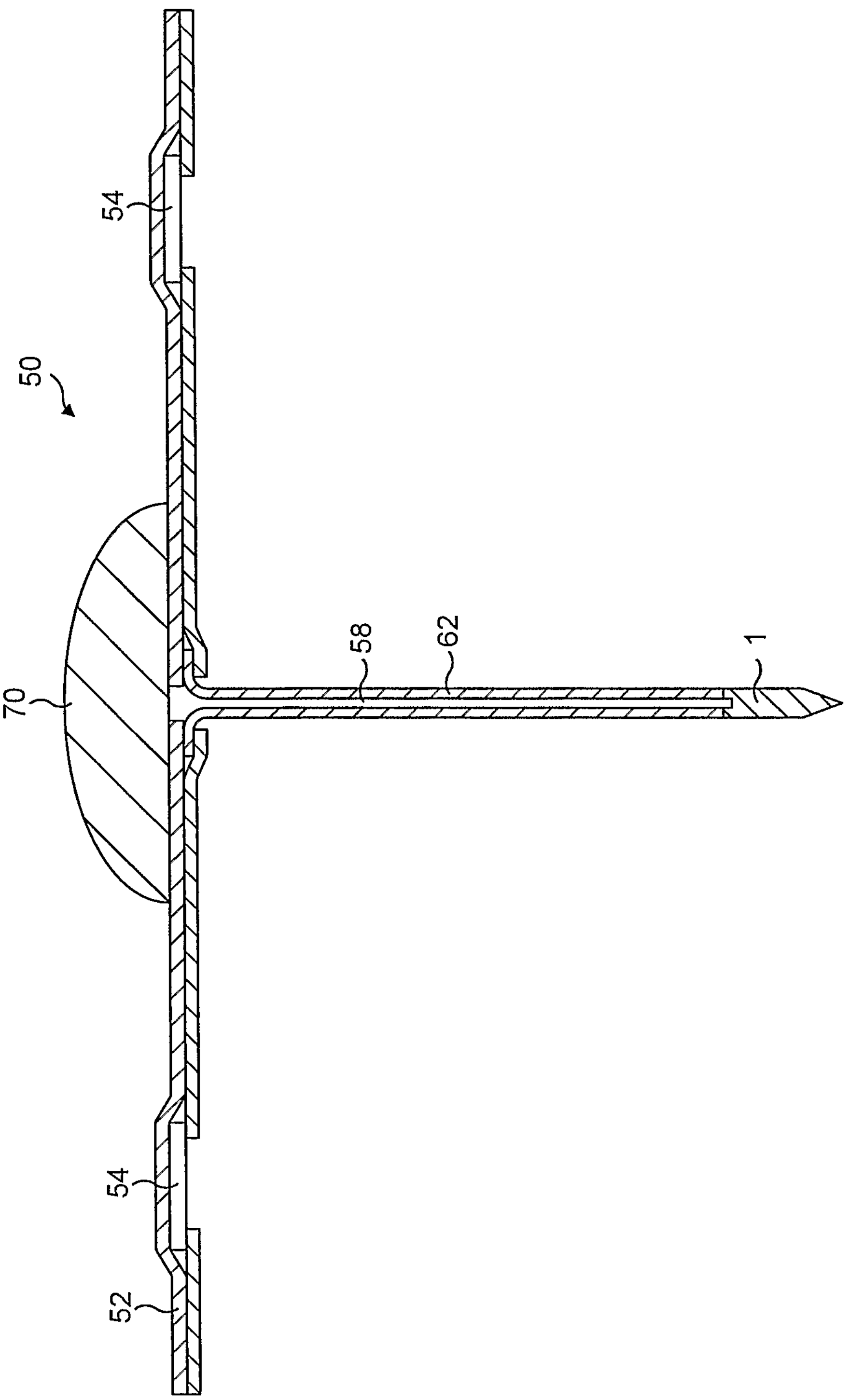


FIG. 9

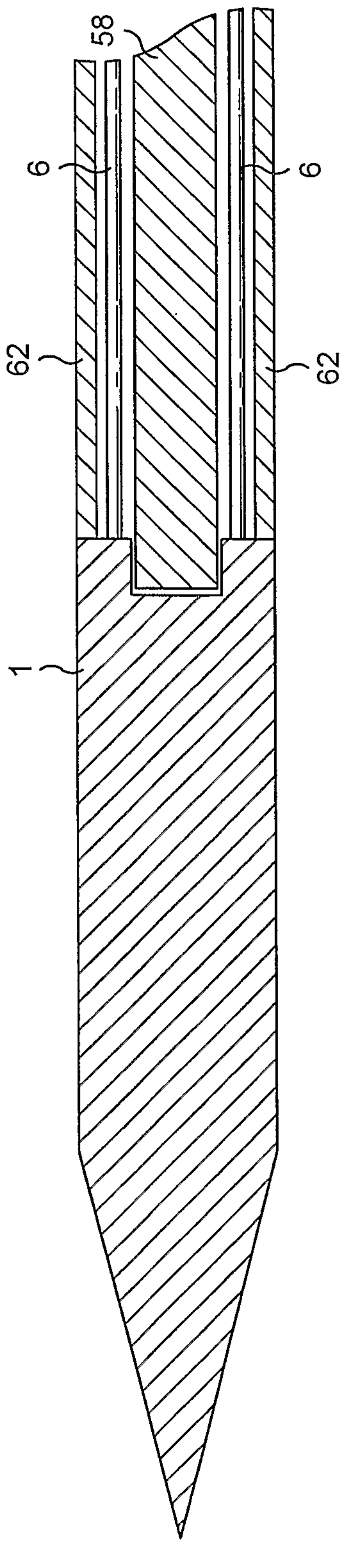


FIG. 10

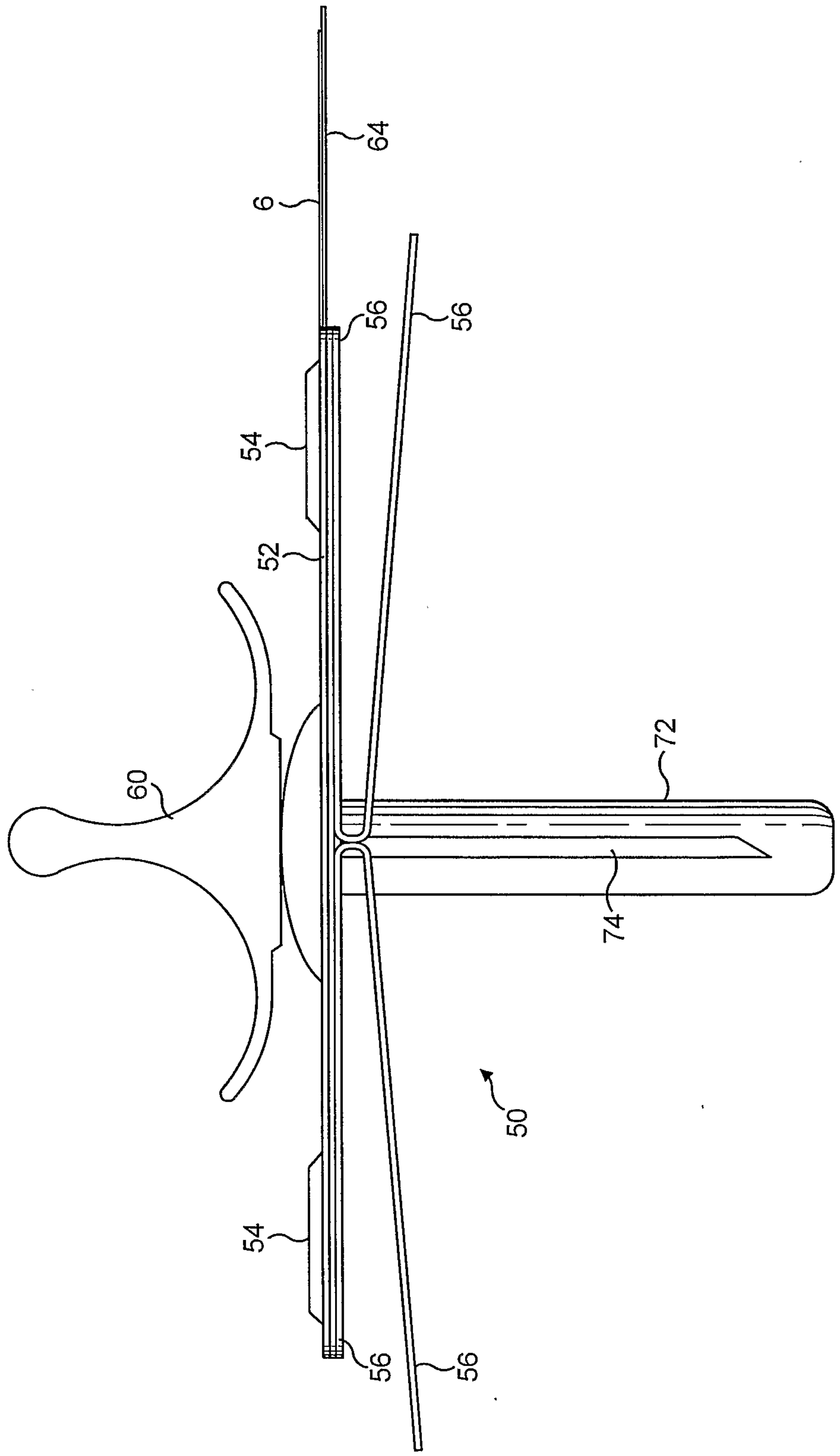


FIG. 11

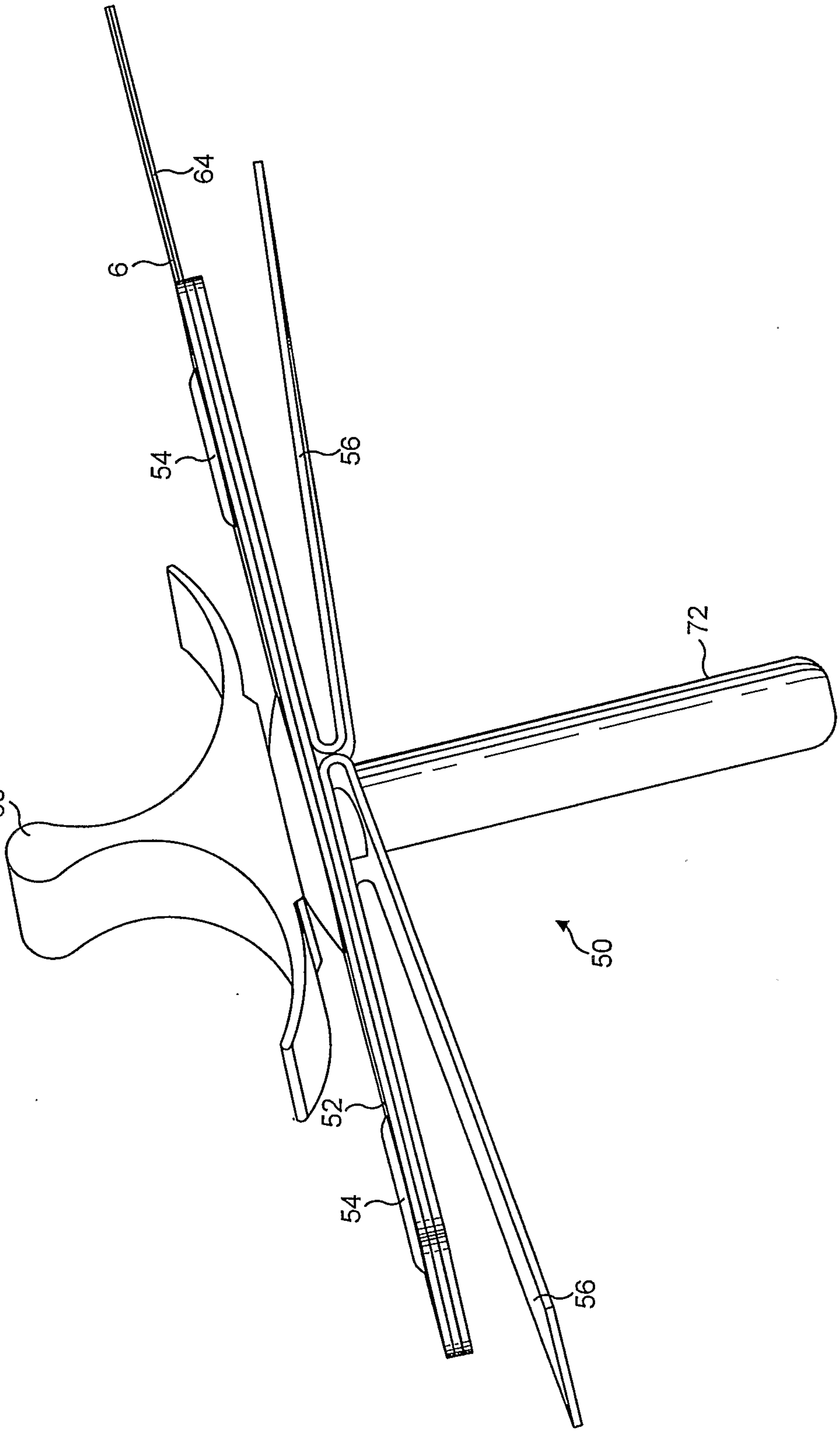


FIG. 12

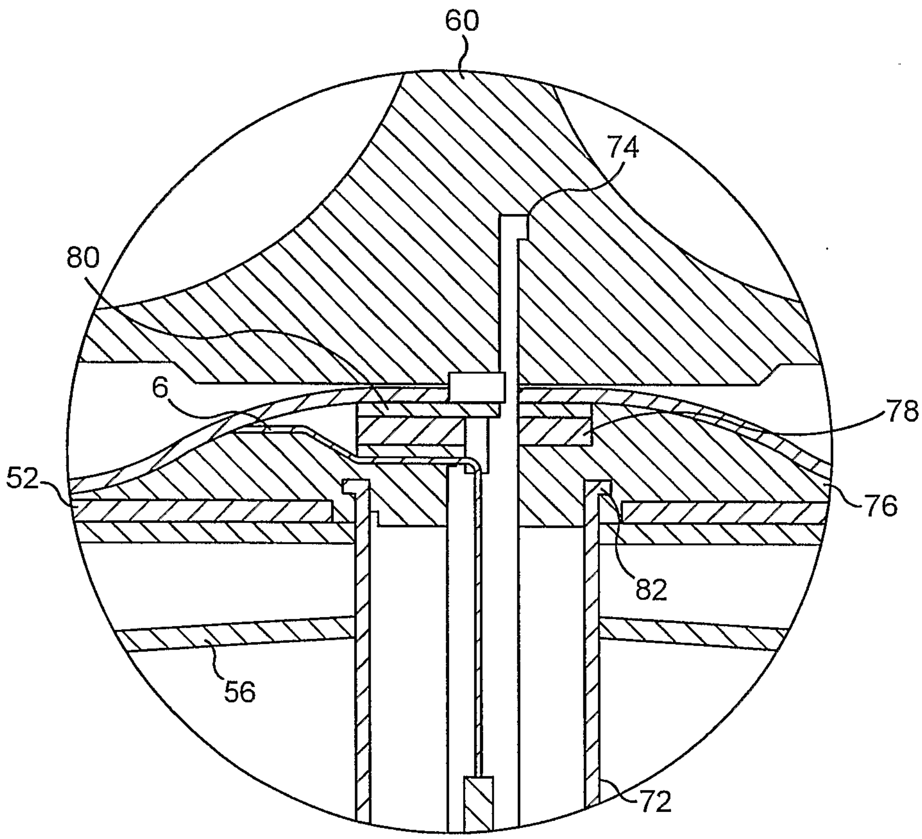


FIG. 13

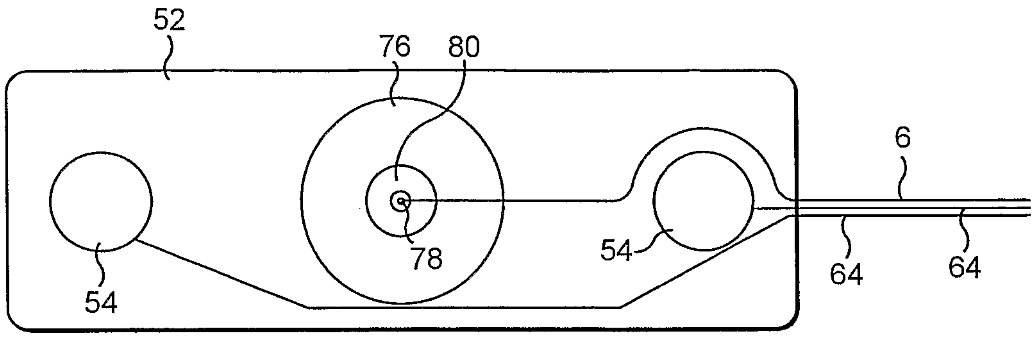


FIG. 14

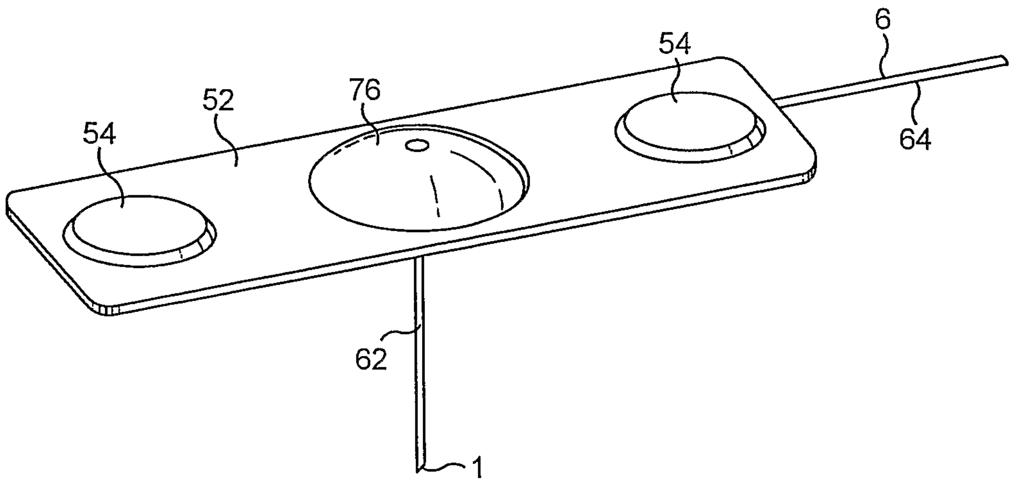


FIG. 15

INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB2005/003461

A. CLASSIFICATION OF SUBJECT MATTER
A61B5/02 A61B5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
X Y	US 5 375 604 A (KELLY ET AL) 27 December 1994 (1994-12-27) column 4, line 49 - column 13, line 61; claims 1,17,19	1 2-5
Y	US 6 264 611 B1 (ISHIKAWA AKIRA ET AL) 24 July 2001 (2001-07-24) column 9, line 1 - column 10, line 46; claim 1; figure 11	2-5
X	US 2004/152961 A1 (CARLSON SVEN-ERIK ET AL) 5 August 2004 (2004-08-05) paragraph '0064!; claims 1,3	1
X	US 2004/111014 A1 (HICKLE RANDALL S) 10 June 2004 (2004-06-10) paragraphs '0013!, '0029!, '0030!, '0043!	1
	-/--	

[X] Further documents are listed in the continuation of box C

[X] Patent family members are listed in annex

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
16 January 2006	20. 02. 2006

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel (+31-70) 340-2040, Tx 31 651 epo nl, Fax (+31-70) 340-3016	Chopinaud, M

Form PCT/ISA/210 (second sheet) (January 2004)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB2005/003461

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
X	US 5 665 477 A (MEATHREL ET AL) 9 September 1997 (1997-09-09) abstract	1
A	US 6 289 238 B1 (BESSON MARCUS ET AL) 11 September 2001 (2001-09-11) claim 1	1-5
A	EP 1 238 626 A (NIHON KOHDEN CORPORATION) 11 September 2002 (2002-09-11) the whole document	1-4
X	US 5 353 792 A (LUEBBERS ET AL) 11 October 1994 (1994-10-11) claims 1,4,5,7; figure 1	6-8
X	EP 0 381 612 A (O.C.T. OPTICAL CHEMICAL TECHNOLOGIES LIMITED) 8 August 1990 (1990-08-08) claim 1; figure 1	6-8
X	US 6 058 321 A (SWAYZE ET AL) 2 May 2000 (2000-05-02) column 9, line 42 - column 10, line 14; figure 11	6-8
X	US 2004/138688 A1 (GIRAUD JEAN PIERRE) 15 July 2004 (2004-07-15) column 12, line 29 - line 44; claim 1	6-8
X	US 4 615 340 A (CRONENBERG ET AL) 7 October 1986 (1986-10-07)	6-8,10
A	the whole document	9
Y	DE 101 41 732 A1 (FRANKENBERGER, HORST; HUFNAGEL, HEIKE; KERNER, WOLFGANG; KRAHWINKEL, M) 6 March 2003 (2003-03-06) abstract; claim 1; figure 13	11
Y	US 2003/055353 A1 (WEBBER MARGARET R ET AL) 20 March 2003 (2003-03-20) abstract	11
A	US 5 338 435 A (BETTS ET AL) 16 August 1994 (1994-08-16) the whole document	11,12

Form PCT/ISA/210 (continuation of second sheet) (January 2004)

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2005/003461

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons.

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6 4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2 ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos..

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos

Remark on Protest

☐ The additional search fees were accompanied by the applicant s protest

☒ No protest accompanied the payment of additional search fees

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-5

Sensing device comprising :
a sensor for measuring pC02;
a body temperature sensor;
a heart rate sensor; and
an oxygen saturation sensor.

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2. claims: 6-10

A sensing device comprising a pC02 sensor for inserion through a patient's skin and having a sharp tip for puncturing the skin.

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3. claims: 11-12

A sensing device comprising a pC02 sensor for insertion into the patient's skin and having an adhesive patch for adhering the device to a patient's skin

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INTERNATIONAL SEARCH REPORT

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patsnap

专利名称(译)	传感器		
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外部链接	Espacenet		

摘要(译)

生理传感装置包括用于测量二氧化碳分压（pCO 2 ）的传感器（4），体温传感器（5）和心率和氧饱和度传感器的组合（54）。传感器装置可用于连续监测患者的生命体征。