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(54) Blood oxygen monitoring system

System zur Überwachung des Blutsauerstoffs

Système de surveillance du taux d'oxygène

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Description

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0001] The present invention is directed to a system and lead for monitoring blood oxygen concentration in a patient's venous system.

2. Background

[0002] Blood oxygen concentration is a direct indicator of the physiological status and need of a patient. Other indicators include various cardiac timing signals, blood temperature, respiratory rate and blood pressure measured within the chambers of the heart, blood oxygen saturation, as well as physical rate and acceleration. Physiologically responsive pacemakers and cardioverter/defibrillators, both referred to as cardiac stimulation devices, utilize one or more of such indicators as a control parameter(s) to vary cardiac rate in the process of optimizing a patient's cardiac performance to achieve the correct metabolic rate for providing a high level of patient well being. As is recognized in the art, cardiac stimulation devices provide patients having a chronically malfunctioning heart, with selective cardiac therapy in the form typically, of cardiac stimulation pulses in order to maintain proper metabolic rate. Unlike a healthy heart, a malfunctioning heart normally does not adequately respond to physical activity, exercise, stress or emotion, posture changes and sleep conditions. Normal cardiac reaction to physiological need manifests in adjustment of cardiac stroke volume and heart rate with the natural adjustment of such parameters being responsive to immediate need.

[0003] To remedy the deficiencies of a malfunctioning heart, cardiac stimulation devices have been widely used to control heart rate and thus metabolic rate. Early devices were not rate responsive and provided a pacing regimen that stimulated the heart at a constant rate under all conditions. The drawback of such devices was that under many conditions they did not provide the proper metabolic rate for patient need. For example, under sleep conditions where the required heart rate is low due to minimal physiological need, the device would pace the heart at too high a rate than required. On the other hand, a constant pacing rate did not adequately respond to a patient's metabolic need under high exercise and stress conditions.

[0004] Upon the introduction of rate responsive stimulation devices, a more rapid response to satisfying a patient's physiological need was made available. The intent of such devices was to adjust the patient's cardiac rate on a continual basis for a wide variety of exercise and stress conditions encountered by a patient. A very straightforward technique for controlling cardiac pacing in rate adaptive dual chamber devices is by the use of atrial tracking pacing, especially when the patient has partial or complete AV block. This technique however lacks effectiveness when the patient suffers from atrial fibrillation or sinus bradycardia.

[0005] To address this situation, other techniques utilizing the aforementioned indicators of physiological need have been proposed. For example, the use of venous blood temperature has been described by Cook et al., in U.S. Pat. No. 4,436,092. The shortcomings of this device are, lack of rapid response, coarseness of measurement and susceptibility to non-physiological influences such as the ingestion of cold liquids and fever. A second approach is the use of blood pressure at different locations in the heart. One such device utilizing the blood pressure in the atrium, was described by Cohen in U.S. Pat. No. 3,358,690. However, patients with sinus bradycardia and atrial fibrillation are not amenable to this approach. Other devices utilizing blood pressure have been described by Koning et al. in U.S. Pat. No. 4,566,456 and by Scroeppel in U.S. Pat. No. 4,600,017. These devices however, fall short if the patient suffers from sinus bradycardia or atrial fibrillation. Activity sensing, rate responsive devices as described for example by Anderson et al., in U.S. Pat. No. 4,428,378 and by Thornander et al., in U.S. Pat. No. 4,712,555 provide fast response times and good reliability but often are affected by non activity events. For example, if the patient is riding in a vehicle over a bumpy road, the resulting body movement will be erroneously interpreted as physical activity inducing unnecessary pacing rate increases.

[0006] Still, another class of devices utilizes blood chemistry as physiologic indicators. US 481 5 469 discloses cardiac stimulation leads having an oxygen monitoring circuit in contact with blood, the circuit being driven by pulse trains through the lead conductors. The use of blood oxygen saturation has also been described by Wirtzfeld et al. in U.S. Pat. Nos. 4,202,339 and 4,399,820; by Bornzin in U.S. Pat. No. 4,467,807; by Thompson in U.S. Pat. No. 5,342,406; by Thacker in U.S. Pat. No. 5,438,987; and by Mortazavi in U.S. Pat. Nos. 5,040,538 and 5,411,532. The devices taught by Mortazavi include a light-emitting diode (LED) positioned within a chamber of the heart and arranged such that light emitted from the LED is directed at the blood which then reflects the light to an adjacent light detecting sensor in the form of a phototransistor. Upon delivery of a sensing pulse, the LED commences to emit light and the reflected light is produced in an intensity proportional to the oxygen concentration. Circuitry associated with the phototransistor integrates the voltage proportional to the light's intensity and when the integrated voltage reaches a prescribed value, current is then shunted away from the LED and the integration process is terminated. The time interval from delivery of the sensing pulse to reaching the prescribed value is a measure of the degree of oxygen saturation in the blood. The blood cells change from a blue to a red hue when the hemoglobin in the blood cells is saturated with oxygen. This sensing method does not indicate accurately the percentage of oxygen in the blood

below the saturation point of the hemoglobin. The oxygen sensor circuit includes a diode in series circuit arrangement with a stimulation lead conductor. Pacing pulses are generated having a first polarity, while oxygen sensing pulses are generated having a second polarity opposite to that of the first polarity. Accordingly, this type of arrangement requires a polarity distinction between pacing and sensing pulses. Furthermore, the placement of the sensor is taught to be in the atrium and there is a potential that oxygen monitoring may be compromised if the sensor is located immediately adjacent to or in contact with the atrium wall because there may be an insufficient amount of blood in the area surrounding the sensor to obtain a reliable measure of oxygen concentration.

SUMMARY OF THE INVENTION

[0007] The present invention provides a cardiac stimulation lead as set forth in claim 1.

[0008] Briefly and in general terms, the lead of present invention is preferably for use with a blood oxygen monitoring system that is accurate through the entire oxygen concentration range, and a lead therefor. The system monitors blood oxygen concentration upon the delivery of an oxygen sensing command signal, in the form of a biphasic pulse train, to an oxygen sensor imbedded within a cardiac stimulation lead that is implanted in a patient's venous system. The sensor may also be oriented in the stimulation lead such that it is located in a selected chamber of the heart. The oxygen concentration so determined, may be used as a physiological parameter for controlling the pacing rate of an implanted cardiac stimulation device so as to maintain a patient's proper metabolic rate. The oxygen monitoring circuit is in parallel circuit arrangement with the conductor(s) of a cardiac stimulation lead thereby avoiding the necessity of dedicated polarities for pacing pulses and oxygen monitoring related pulses. Moreover the duration of the oxygen monitoring related pulses are such that they do not induce cardiac muscle contractions akin to those involved in cardiac pacing.

[0009] More specifically, the system is microprocessor controlled and includes a cardiac stimulation lead which is in direct contact with a patient's venous blood system. The cardiac stimulation lead includes at least one electrical conductor and the oxygen monitoring circuit measures the blood oxygen concentration in the venous blood system. An oxygen monitoring pulse generator is coupled to the microprocessor and is configured to generate a biphasic pulse train, which may contain a preselected number of bits comprising at least address bits, control data bits, parameter information bits and stop bits. The pulse train from the oxygen monitoring pulse generator is received by the oxygen monitoring circuit to commence oxygen monitoring. The oxygen monitoring circuit includes an integrated circuit (IC) chip that is preferably hermetically sealed from blood contact and is programmed to undertake the oxygen concentration monitoring functions. The IC chip may be powered by an on board energy storage component that may be recharged from either or both the cardiac stimulation pulses and the oxygen monitoring related pulses.

[0010] The oxygen monitoring circuit may be fabricated on a substrate and may include a working electrode, a counter electrode and a reference electrode. The electrodes may be encased in a gel like oxygen and electrically conductive material. The entire monitoring circuit, as previously mentioned, is imbedded in a cardiac stimulation lead. The lead may have an outer sleeve that is transparent to oxygen and that extends the length of the lead. Oxygen passes through the sleeve as well as the gel like material and eventually reaches the electrodes. In the embodiment of the invention the IC chip is in electrical communication with the electrodes and includes a current source connected between the working electrode and the counter electrode. The IC chip also monitors the voltage between the reference and working electrodes and adjusts the current source in order to keep the voltage between the reference and working electrodes constant at a specific value. The voltage value selected is that value that causes a current to flow that is directly related to the oxygen concentration level. Upon receipt of an oxygen monitoring start signal, the voltage across the reference electrode and working electrode is examined. If the value is other than a required voltage, the IC chip proceeds to change the value of the current generated by the current source until the voltage across the reference electrode and working electrode, returns to the reference value. The value of the current so required, is a measure of the instantaneous blood oxygen concentration level. This value is communicated back to the microprocessor for processing via an information pulse train generated by the IC chip and transmitted back to the microprocessor along the stimulation lead conductor. The information from the IC chip may be in the form of a monophasic pulse train recognizable by the microprocessor. The times at which the oxygen monitoring related pulse trains are transmitted may be during the time interval between the occurrence of a cardiac T-wave and atrial stimulation pulse. From practice, the invention is characterized in that it provides a very accurate, high reliability and relatively low volume physically small oxygen monitoring apparatus and method.

[0011] The oxygen monitoring circuit may be used with a variety of cardiac stimulation leads including bipolar, unipolar and defibrillation leads. In one embodiment, the lead may be connected between the two conductors of a bipolar lead or between the one conductor of a unipolar lead and the can which houses the cardiac stimulation device.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012]

Fig. 1 is a simplified block diagram of a first embod-

iment in accordance with the present invention including a cardiac stimulation device, and an oxygen monitoring circuit electrically coupled to a bipolar lead;

Fig. 2 is a timing diagram showing the relationship between pacing pulses delivered to a heart by a cardiac stimulation device and the heart's response to these pulses;

Fig. 3 is a perspective view of the electrodes mounted on a substrate used by the oxygen monitoring circuit of the present invention;

Fig. 4A is a cutaway view of the oxygen monitoring circuit of the present invention, including an IC chip, in an encasing silicone sleeve of a cardiac stimulation lead;

Fig. 4B is a simplified block diagram of the IC chip and an energy storage device mounted on the underside of the oxygen monitoring circuit;

Fig. 5A is an electrical circuit diagram of the electrode interconnection of the oxygen monitoring circuit;

Fig. 5B is a graph that depicts the relationship between electrical current delivered to the electrodes of the oxygen monitoring circuit and the voltage between the electrodes as a function of oxygen concentration;

Fig. 5C is a graph that depicts the relationship between the electrical current delivered to the electrodes as a function of oxygen concentration at a fixed reference voltage;

Fig. 6 is a flow chart of the oxygen monitoring method undertaken by the IC chip;

Fig. 7 illustrates a data frame used to communicate between the microprocessor and the oxygen monitoring circuit;

Fig. 8 is a timing diagram that illustrates time multiplexed input and output data within a data frame;

Fig. 9 is an alternate embodiment of the electrical connection of the oxygen monitoring circuit in the cardiac stimulation lead showing a four-wire arrangement;

Fig. 10 is an alternate embodiment of the electrical connection of the oxygen monitoring circuit in the cardiac stimulation lead showing a three-wire arrangement;

Fig. 11 is an alternate embodiment of the electrical connection of the oxygen monitoring circuit in the cardiac stimulation lead showing a two-wire arrangement;

Fig. 12 is an alternate embodiment of the electrical connection of the oxygen monitoring circuit in the cardiac stimulation lead showing a one wire arrangement;

Fig. 13 is a cut away front elevation view of an alternate embodiment of the oxygen monitoring circuit of Fig. 4A showing electrodes mounted directly on the IC chip; and

Fig. 14 is a cut away front elevation view of an alternate embodiment of the oxygen monitoring circuit of Fig. 14 showing two IC chip's mounted in back to back relation.

DETAILED DESCRIPTION OF THE INVENTION

[0013] The following description relates to the best mode presently contemplated for carrying out the invention. This description is not to be taken in the limiting sense, but rather is made merely for the purpose of describing the general principles of the invention. The scope of the invention should be determined with reference to the claims and equivalents thereof.

[0014] Referring to Fig. 1, there is shown in block diagram format, an oxygen monitoring system in accordance with the principles of the present invention. The system 10 includes a cardiac stimulation device 12, a cardiac stimulation lead 14 having a tip electrode 16 and a ring electrode 18. Although stimulation lead 14 is shown as being a bipolar lead, as will be discussed later, other lead configurations such as for example unipolar leads are contemplated by this invention. The stimulation lead 14 is of a typical design known in the art having a silicone outer casing 20 and electrical conductors 22 and 24 that are coupled to tip electrode 16 and ring electrode 18 respectively. The electrodes are adapted to be secured to selected cardiac tissue, such as heart muscle, intended for receipt of stimulation pulses. Mounted within the interior of stimulation lead 14 is oxygen monitoring circuit 25 that is electrically coupled across conductors 22 and 24. The cardiac stimulation device 12 includes an oxygen monitor pulse generator 26, a microprocessor 28, a stimulation pulse generator 30 and a cardiac signal sense circuit 32. The stimulation lead 14 is electrically coupled to the stimulation device 12 by means of connector 34. The type of connector 34 will depend upon the type of stimulation lead used and a single lead connector may be used, for example, when a unipolar lead is employed.

[0015] Aside from the oxygen monitor pulse generator 26, operation of the stimulation device 12 follows conventional principles such as taught, for example, in U.S. Pat. No. 5,342,406 issued to Thompson, U.S. Pat. No. 6,351,672 issued to Park et al., and U.S. Pat. No. 4,712,555 issued to Thomander et al., all of which are incorporated herein by reference in their entireties. Although the present invention is described in conjunction with a cardiac stimulation device being microprocessor based, it is to be understood that it could be implemented in other logic based protocols, such as a state machine mechanization. In such case, the functions undertaken by microprocessor 28 may thus be implemented by the use of the state machine, and in both instances they function as a processor. As is understood, the pulse generator 30, under the control of microprocessor 28, periodically delivers stimulation pulses, via conductors 22 and 24 to selected cardiac sites when it is determined that natural heart contractions have failed to occur. The sense circuit 32 monitors the various cardiac depolarization signals at selected cardiac sites and in the absence of such signals,

the microprocessor 28 directs the pulse generator 30 to deliver appropriate stimulation pulses at the selected sites so as to induce proper cardiac muscle contractions. The sense circuit 32 determines the absence of proper depolarization signals by monitoring the voltage at the various stimulation lead electrodes to detect proper voltage patterns.

[0016] A representative heart cycle and pacing cycle are shown in Fig. 2, where the stimulation pulse labelled "A" is an atrial stimulation pulse and Pp is the atrial depolarization signal or "P" wave and "V" is a ventricular stimulation pulse and Rp is a ventricular depolarization signal or "QRS" complex. The "T" wave represents the repolarization of the ventricles so that they may be in condition to be stimulated again. For purposes of this application, the polarity of Pp and Rp is inverted to distinguish them between a stimulated response and a naturally occurring response. As will be described later, the region between the "T" wave and the "A" pulse (i.e. between consecutive cardiac stimulation pulses) may be utilized by the oxygen monitor pulse generator 26 under the direction of microprocessor 28, for transmitting oxygen monitoring pulses to the oxygen monitoring circuit 25 and for receipt of response data from the oxygen monitoring circuit 25 to microprocessor 28 for blood oxygen content calculations.

[0017] As is shown in Fig. 1, the oxygen monitoring circuit 25 is integrated in stimulation lead 14. The optimum time for placement of the oxygen monitoring circuit 25 in the stimulation lead 14 is during manufacture of the lead. The physical size of the oxygen monitoring circuit 25 is such that no appreciable additional volume is added to the stimulation lead in the region of the sensor placement so as not to interfere with either the stimulation lead's insertion into or retraction from its intended placement in the venous system or with the blood flow in the selected vein. A technique for oxygen sensing in conjunction with a glucose monitoring system, including the system electronics, is described in detail in U.S. Pat. No. 5,497,772, issued to Schulman et al., which is incorporated herein by reference in its entirety. Prior to a discussion of the electronic interface of the oxygen monitoring circuit 25 with the oxygen monitor pulse generator 26 and microprocessor 28, it is informative to understand the physical configuration of the circuit 25. More specifically and with reference to Fig. 3, three metal electrodes, namely a working electrode 36, a counter electrode 38, and a reference electrode 40 are mounted on substrate 42. The substrate is typically a ceramic hermetic material known in the art and the electrodes are metalized sections deposited or etched on the substrate using conventional thin film deposition or etching techniques. The working and counter electrodes may be formed of or coated with platinum and the reference electrode may be formed of or coated with silver chloride. Other suitable metals such as gold may also be used. Extending through the substrate 42 are electrically conductive vias 44, 46, and 48 that are electrically coupled to electrodes 36, 38, and 40 respectively. The vias are also electrically coupled to corresponding electrically conductive pads 50, 52, and 54 respectively.

[0018] As will be discussed below, the pads 50, 52 and 54 are positioned on the opposite side of the substrate 42 with respect to the placement of the electrodes 36, 38, and 40 respectively, for an electrical interface with a signal processing and data receipt and data transmission-integrated circuits (IC) chip 56 (see Fig. 4A). The vias 44, 46 and 48 have a horizontal portion 58, 60, and 62 respectively, as viewed in Fig. 4A, to ensure against any fluid leakage between the opposite sides of the substrate 42 along the via paths through the substrate and also eliminate any noise contributions resulting from fluid contact with the vias. The IC chip 56 further includes at least two additional internal pads, 64 and 66 that connect to external pads 68 and 70 through vias 72 and 74 respectively. As will be discussed later, the pads 68 and 70 are connected to stimulation lead conductors 22 and 24 respectively and carry electrical signals from the leads to the IC chip 56. Surrounding the IC chip 56 is a sealing cap 76 adapted to provide a hermetic seal completely surrounding the IC chip 56. The horizontal portion of vias 72 and 74 (as depicted in Fig. 4A) provide additional insulation against any potential leakage fluids from penetrating into the IC chip 56.

[0019] Another method of providing a hermetic seal is to utilize the IC chip 56 in place of the substrate 42 with the energy storage device included in the IC chip circuit with an overall coating or encapsulation material formed of a thin layer or layers of alumina, zirconia and/or alloys of alumina or zirconia on the IC chip 56 and other components considered as requiring such seal. This construction eliminates the need for the sealing cap 76, wire bonds while the pads 68 and 70 are placed on the opposite side of the IC chip 56, but outside sheath 78. The remainder of the construction remains as shown in Fig. 4B. Encapsulation and hermetic materials and a method of depositing such materials is described in detail in U.S. Patent No. 6, 043,437 issued to Schulman et al. which is incorporated herein in its entirety, by reference.

[0020] Completely surrounding the working electrode 36, the counter electrode 38 and the reference electrode 40 is a sheath 78 formed of an oxygen transmissible material, such as silicone rubber having a thickness in the range of about three mils (0.003 inches). The sheath 78, which is also impervious to fluid flow across its surfaces, is sized to provide a pocket within which is disposed an oxygen and electrically conductive thick gel like substance 80, known as "pHema". Completely surrounding the oxygen monitoring circuit 25 is a thicker sheath 20 made typically of silicone rubber, which is known to allow oxygen to pass through its surfaces. The sheath 20 is the outer casing of stimulation lead 14 and the insulated lead conductors 22 and 24 have their metal wires connected to pads 68 and 70 respectively. The uninsulated connection to pads 68 and 70 are coated with an insulation material such as epoxy. Since the signals carried by

conductors 22 and 24 are digital or large pacing pulses, the small leakage that may occur will only slightly affect their respective amplitudes, but their timing will remain unaltered. When the oxygen monitoring circuit 25 is placed in a patient's venous system, blood oxygen passes through the sheath 20 and then through sheath 78. The gel 80 contains salt water and is capable of allowing such oxygen to come into contact with each of the electrodes 36, 38, and 40. The principles regarding the measurement of glucose in the patient's blood as taught in the previously identified U.S. Patent No. 5,497,772, may be extended here for the measurement of blood oxygen. Accordingly, reference is made to Figs. 5A, 5B and 5C, which represent a schematic of the electrical circuit coupled to the oxygen monitoring circuit 25 for determining the oxygen content in the blood, a graph that qualitatively depicts the relationship between electrical currently delivered and the electrodes of the oxygen monitor circuit 25 and the voltage applied between the electrodes that varies as a function of oxygen content, and a graph that depict the relationship that exists at a fixed electrode voltage between the current flowing through the electrode 38 and the oxygen content, respectively. Referring to Fig. 5A, a trim voltage monitor 86 is coupled between the reference electrode 40 and the working electrode 36 and a current source 84 is coupled between working electrode 36 and counter electrode 38. In the presence of oxygen, current flows through the working electrode 36. The concentration of oxygen in the blood has a direct effect on the level of current flowing through working electrode 36. From Fig. 5B it is observed that the current I and the trim voltage V, vary as a function of the oxygen concentration. For high concentrations of oxygen, a curve 88 establishes a relationship between I and V, and for low concentrations of oxygen, a curve 90 establishes a relationship between I and V. Intermediate values of oxygen concentration produce a family of curves between the high and low oxygen concentration values, each curve representing a different oxygen concentration level.

[0021] In practice, to measure the blood oxygen concentration, it is required to maintain the trim voltage V at a constant or fixed value, which is typically in the range of about 0.3 to 0.7 volts and preferably at 0.5 volts. This is accomplished by varying the current I until the trim voltage (V) is measured to be 0.5 volts. As will be described below, the feedback control system to maintain the trim voltage at a constant value is undertaken in the IC chip 56. From Fig. 5C is it recognized that the relationship between the current I and the oxygen concentration are substantially linear, so that the oxygen concentration at the working electrode 38 is simply related to the amount of current required to maintain the trim voltage V, at a constant value. Accordingly, to determine the oxygen concentration in the blood, it is necessary simply to measure the current I delivered by current source 84.

[0022] Referring now to Fig. 6, there is shown a flow chart of the signal processing regimen undertaken by the IC chip 56. As shown in Fig. 1, pacing pulses, oxygen monitor pulse generator signals and oxygen concentration signals, are transmitted via stimulation lead conductors 22 and 24. Accordingly at block 92, a pulsatile signal existing on the stimulation lead conductors is monitored. The pulsatile signal is analyzed in block 94 to determine whether it is a cardiac stimulation pulse or a pulse train containing a request to monitor the current value of the blood oxygen concentration. The form of the pulse train signal will be discussed in detail later. If the IC chip 56 determines that no request exists for the determination of the current value of the blood oxygen concentration, then in block 96 the pulsatile signal is ignored and no further action is taken by the IC chip 56. However if a request to monitor the current oxygen concentration exists, the current value of the trim voltage V_T is monitored in block 98 and in block 100, if it determined that the value of V_T is equal to V_{T-1}, indicating that the blood oxygen concentration has not changed between successive determinations, the IC chip 56 sends a pulse train S_{T-1} representative of the value of the current I_{T-1} generated by the current source 84 during the prior oxygen concentration determination to the microprocessor 28. However, if V_T does not equal V_{T-1}, then in block 104 the IC chip 56 adjusts the value of the current generated by the current source 84 until the present trim voltage V_T equals 0.5 volts. In block 106, a pulse train S_T representative of the present value of the current I_T required to return the trim voltage V_T to 0.5 volts is sent to the microprocessor 28. Although the microprocessor 28 is not contained in IC chip 56, the process undertaken by the microprocessor 28 of converting the pulse train data to the present value of the blood oxygen concentration is depicted in block 108.

[0023] An additional advantage of the present invention is that IC chip 56 is coupled to an energy storage device 110, such as an electrical storage cell, a rechargeable battery or a capacitor (see Fig. 4B) that provides power to the chip so it can undertake the voltage monitoring, current generation, pulsatile signal recognition and generation and other functions necessary to carry out the electrical aspects of the invention. Although the energy storage device has been described as a rechargeable battery, it is to be understood those other energy storage devices, such as a capacitor, are within the contemplation of the present invention. Furthermore, as an alternate embodiment to that shown in Fig. 4B, the energy storage device may be included in the IC chip providing the potential of eliminating the use of a substrate. The pulsatile signals appearing on conductors 22 and 24 are used to recharge the battery 110. To facilitate the recharge function, the battery 110, which is coupled to the IC chip 56 through conductive pads 65 and 67 connected to respective internal pads 64 and 66, may include a half-wave or full-wave rectifier circuit and storage capacitors and in this manner can utilize pulses of both polarities whether they are cardiac stimulation puls-

es or oxygen interrogation request pulse trains, for the recharge process. The use of the IC chip 56, including programming its functions, especially in view of the specific teachings of this invention, are considered to be within the realm of capabilities of one skilled in the art. Similarly, the use of energy storage devices such as the rechargeable battery, and rectifier circuits are considered within the capabilities of one skilled in the art.

[0024] An example of the pulse train used by the oxygen monitor pulse generator 26 is shown in U.S. Pat. No. 5,917,346 issued to Gord. More specifically and with reference to Figs. 7 and 8, there is shown the oxygen monitor pulse generator 26 data signal sent over conductors 22 and 24 under the control of microprocessor 28. The data frames are of length T3 and within each data frame, a predetermined number N bits of data are found, where N is an integer typically in the range from 8 to 64. A representative assignment of the data bits included in the data frame is shown in Fig. 7. It is noted that the data bits contain a start bit, address bits, OP code bits, control data bits, a parity bit, transmit data bits and a stop bit. The "transmit data bits" portion of the data frame includes parameter information bits relating to the nature, status or value of the respective parameter. As shown in Fig. 7, there are three assigned address bits to provide for eight sensors. However, it is to be understood that additional address bits may be used to provide for a greater number of sensors. The distribution of the bits complies with accepted convention and within the capabilities of one skilled in the art for implementing the signal processing procedures for reading and writing such data frames. The parity bit is used to check for a possible error in the command due to noise. If more than one bit of error might occur, then several bits can be used for checking this possibility. Because the input comprises biphasic data that occurs at a regular interval or rate, e. g., every T1 seconds, the energy contained in such pulse, as described previously, may be utilized to provide the operating power or battery recharge necessary for the operation of the circuits contained within the oxygen monitor circuit 25 and IC chip 56. The typical widths of the pulses are in the range from 0.1 to 1000 microseconds (and may be in the range of about 0.1 to 100 microseconds and have a magnitude in the range of from approximately 0.5 to 10 volts. The voltages used depend on the specific IC technology used. For example, 0.5 micron technology requires from about 3 to 5 volts and 0.08 micron technology requires about 0.5 volts.

[0025] A binary or logical "1" is represented by a biphasic pulse of one phase, that is, a positive pulse followed by a negative pulse, whereas a binary or logical "0" is represented by a biphasic pulse of the opposite phase that is, commencing with a negative pulse followed by a positive pulse. As an alternate form for the data information returned by the IC chip 56 to the microprocessor 28, a monophasic pulse train may be employed. As is shown in Fig. 2, the interval between the T wave and the atrial stimulation pulse A, is available for use for the transmission and receipt of oxygen related data frames.

[0026] One method of generating a monophasic pulse train is to generate a positive pulse to represent a binary or logical "1" and a binary or logical "0" by the absence of a pulse. The pulse train requesting the data can act as the clocking circuit for the oxygen detector and thus determine when a return pulse should be present. Such technique may be used by the present invention and the microprocessor 28 may be programmed to recognize the absence of a pulse as a binary or logical "1". For example and with reference to Fig. 8, the logical "1" appearing at a time T2 after an input data logical "0", is identified as data existing as output data, whereas the logical "0" at a T2 time after the next input data logical "0" is identified as no output data existing In this manner, output data may be identified and transmitted to the microprocessor for processing. It should be noted that pulse widths in the range of from 1 to 10 microseconds, as contemplated by this invention, will have a little or no possibility in stimulating the heart because of the relatively slow cardiac muscle reaction time, thus permitting the use of the conductors 22 and 24 for carriers of both cardiac stimulation and oxygen related pulses. Similarly, circuit design features may be used, if needed, in the IC chip 56, to shield the chip from the effects of relatively long duration high voltage cardiac stimulation pulses.

[0027] Although the invention has been described with reference to a bipolar lead, it is to be understood that other lead configurations are contemplated by the invention. Accordingly reference is made to Fig. 9 through Fig. 12. showing such other configurations. Fig. 9 shows a bipolar lead 112 having a second pair of conductors 114 devoted exclusively to oxygen monitoring circuit 25. In this manner, the delivery of the oxygen monitoring related pulse trains is independent of cardiac stimulation pulse delivery timing. Fig. 10 shows a bipolar lead 116 having a third conductor 118 functioning as a return for oxygen monitoring circuit 25. Fig. 11 shows a unipolar lead 120 having a second conductor 122 functioning as a return for oxygen monitoring circuit 25. Fig. 12 shows a unipolar lead 124 having a conductive element 126 on the surface of the lead that is connected to oxygen monitoring circuit 25 and that acts as a return through the patient's anatomy in much the same fashion as does the return for a unipolar lead.

[0028] An alternate embodiment of the oxygen monitoring circuit of Fig. 4A is shown in Fig. 13 as monitoring circuit 25'. The monitoring circuit 25' comprises the IC chip 56, with the electrodes 36, 38 and 40 mounted directly on one side of the IC chip. The electrically conductive vias 128, 130 and 132 interconnect the electrodes 36, 38 and 40 respectively, to corresponding terminals on the IC chip 56. The electrodes are immersed in a gel 80 which is encased by a sheath 20, all as previously described. The pads 68 and 70 provide and interface connection between the IC chip 56 and conductors 22 and 24 respectively. With the exception of the sheath78

and pads 68 and 70, the IC chip 56 is encased by a hermetic sealing cap as previously described or coated by a fluid impervious hermetic material 134. The material 134 also extends around the electrodes 36, 38 and 40 in such a manner so as to insulate the IC chip 56 from the gel 80. An appropriate candidate for such material is aluminum oxide (alumina) as described in U.S. Patent 6,259,937. Moreover, a waterproof material 136 and 138 encases the pads 68 and 70 respectively. The waterproof material forms a fluid tight seal around the pads and is preferably, but not restricted to, an epoxy material.

[0029] A still further embodiment of the oxygen monitoring circuit of Fig. 4A is shown in Fig. 14 wherein two IC chips (each IC chip being descried above in conjunction with Fig. 13) are arranged such that the underside 135 of each monitoring circuit 25' is in registration and in abutting relationship. As shown in Fig. 14, pads 68 and 70 of each IC chip 56 are electrically connected to conductors 22 and 24 respectively. The connection is insulated with an epoxy 136 and 138 or other waterproof insulating material. Since the timing of the blood oxygen interrogation pulses is the measurement parameter rather than the magnitude of such pulses, a slight amount of leakage in the area of the epoxy insulating material is tolerable. The IC chips are sized small enough such that one or two chips as discussed, fit within a cardiac stimulation lead. An advantage of the embodiment of Fig. 14 is the increased oxygen monitoring capability of two "sensors" over one "sensor".

Claims

1. A cardiac stimulation lead (14) for use with a cardiac stimulation device (12), the device comprising, a processor (28), a cardiac stimulation pulse generator (30) coupled and responsive to the processor and configured to deliver cardiac stimulation pulses via the cardiac stimulation lead (14) to selected cardiac sites, an oxygen monitoring pulse generator (26) coupled to the processor and configured to generate a biphasic pulse train for application to the cardiac stimulation lead (14) between consecutive cardiac stimulation pulses, the stimulation lead (14) comprising:

   at least one electrical conductor (22,24), said lead (14) being, in contact with a patient's blood stream and selected cardiac sites; and
   an oxygen monitoring circuit (25) electrically coupled to said at least one electrical conductor (22,24) and adapted to be in contact with the patient's blood stream, said oxygen monitoring circuit (25) configured to monitor the oxygen concentration of the patient's blood, wherein the oxygen monitoring circuit (25) interrogates the patient's blood during an interval between consecutive stimulation pulses to measure the blood oxygen concentration utilizing the biphasic pulse train for carrying commands and parameter information between the processor (28) and oxygen monitoring circuit (25).

2. The lead (14) of claim 1, wherein the oxygen monitoring circuit (25) comprises:

   a working electrode (36), a counter electrode (38) and a reference electrode (40);
   an integrated circuit chip (56) electrically coupled to said electrodes (36,38,40) and programmed to undertake an oxygen concentration measurement process;
   a current source (84) controlled by said integrated circuit chip (56) and coupled between the working electrode (36) and the counter electrode (38) and configured to supply current between the working and counter electrodes (36,38);
   a voltage monitor (86) arranged to detect the voltage across the reference electrode (40) and working electrode (36); wherein the integrated circuit chip (56) is programmed to control the level of current supplied by the current source (84) and to monitor the detected voltage such that upon exposure of the electrodes to varying levels of oxygen concentration, varying levels of current is caused to flow between the working electrode (36) and counter electrode (38) and wherein the detected voltage is caused to change and further wherein the integrated circuit chip (56) causes the current source (84) to generate a current of a magnitude to return the detected voltage to a preselected reference value, said current magnitude being a direct measure of oxygen concentration.

3. The lead (14) of claim 1 or 2, wherein the lead (14) is encased in an oxygen transmissible sheath (78).

4. The lead (14) of claim 1 or 2 wherein the lead (14) is encased in a silicone sheath (20) extending the length thereof.

5. The lead (14) of claim 4, wherein the electrodes are encased in an oxygen conductive gel (80).

6. The lead (14) of claim of 5, wherein the oxygen conductive gel (80) is pHema.

7. The lead (14) of claim 2, wherein said working electrode (36), counter electrode (38) and reference electrode (40) are mounted on one face of a ceramic substrate (42) and the integrated circuit chip (56) is mounted on an opposing face of the substrate (42) and wherein there are electrical conductors (46,44,48) passing through the substrate intercon-

necting the electrodes (36,38,40) with corresponding terminals (50,52,54) of the integrated circuit chip (56), the conductors having a first portion extending through the substrate in a first direction and a second portion (58,69,62) traversing through the substrate at a second direction being substantially orthogonal to the first direction.

8. The lead (14) of any one of claims 1 to 7, wherein the oxygen monitoring circuit (25) includes a rechargeable energy source (110) and wherein said cardiac stimulation pulses are utilized to recharge the energy source (110).

9. The lead (14) of any one of claims 1 to 7, wherein the oxygen monitoring circuit (25) includes a rechargeable energy source (110) and wherein biphasic pulses generated by the oxygen monitoring pulse generator (26) are utilized to recharge the energy source (110).

10. The lead (14) of any one of claims 1 to 9, wherein the oxygen monitoring circuit (25) includes circuitry to generate a pulse train responsive to the oxygen monitoring pulse train in a format consistent therewith to provide the processor with the results of the interrogation request.

11. The lead (14) of claim 10, wherein the pulse train generated by the oxygen monitoring circuit (25) is monophasic.

12. The lead (14) of any one of claims 1 to 11, wherein the cardiac stimulation pulse generator (30) is housed in an electrically conductive can in contact with a patient's tissue, and wherein the oxygen monitoring circuit (25) is electrically coupled to the at least one electrical conductor (22,24) and the patient's tissue.

13. The lead (14) of any one of claims 1 to 12, wherein the at least one electrical conductor (22,24) includes a pacing conductor and a return conductor wherein the oxygen monitoring circuit (25) is electrically coupled between the pacing conductor and the return conductor.

14. The lead (14) of any one of claims 1 to 12, wherein the at least one electrical conductor (22,24) comprises a pair of pacing conductors and a second pair of conductors, the oxygen monitoring circuit (25) being electrically coupled across the second pair of conductors, said second pair of conductors in electrical communication with the stimulation device.

15. The lead (14) of any one of claims 1 to 12, wherein the at least one electrical conductor (22,24) comprises two pacing conductors and a return conductor, wherein the oxygen monitoring circuit (25) is electrically coupled between one of the pacing conductors and the return conductor.

16. The lead (14) of any one of claims 1 to 12, wherein the at least one conductor comprises two conductors and the oxygen monitoring circuit (25) is electrically coupled across said two conductors.

Patentansprüche

1. Herzstimulationskatheter (14) zur Verwendung mit einer Herzstimulationsvorrichtung (12), wobei die Vorrichtung Folgendes umfasst: einen Prozessor (28), einen Herzstimulationsimpulsgeber (30), der mit dem Prozessor verbunden ist, in Bezug auf den Prozessor responsiv ist und konfiguriert ist, um über den Herzstimulationskatheter (14) Herzstimulationsimpulse an ausgewählte Stellen im Herzen zuzuführen, einen Sauerstoffüberwachungsimpulsgeber (26), der mit dem Prozessor verbunden und konfiguriert ist, um eine biphasische Impulsfolge zu erzeugen, die zwischen aufeinander folgenden Herzstimulationsimpulsen an den Herzstimulationskatheter (14) angelegt wird, wobei der Stimulationskatheter (14) Folgendes umfasst:

zumindest einen elektrischen Leiter (22, 24), wobei der Katheter (14) mit dem Blutstrom eines Patienten und ausgewählten Stellen im Herzen in Kontakt steht; und
eine Sauerstoffüberwachungsschaltung (25), die elektrisch mit dem zumindest einen Leiter (22, 24) verbunden ist und geeignet ist, um mit dem Blutstrom des Patienten in Kontakt zu stehen, wobei die Sauerstoffüberwachungsschaltung (25) konfiguriert ist, um die Sauerstoffkonzentration im Blut des Patienten zu überwachen, wobei die Sauerstoffüberwachungsschaltung (25) das Blut des Patienten während eines Intervalls zwischen aufeinander folgenden Stimulationsimpulsen untersucht, um die Blutsauerstoffkonzentration unter Verwendung der biphasischen Impulsfolge zu messen, um Befehle und Parameterinformationen zwischen dem Prozessor (28) und der Sauerstoffüberwachungsschaltung (25) zu transportieren.

2. Katheter (14) nach Anspruch 1, worin die Sauerstoffüberwachungsschaltung (25) Folgendes umfasst:

eine Arbeitselektrode (36), eine Gegenelektrode (38) und eine Bezugselektrode (40);
einen Chip (56) mit integriertem Schaltkreis, der elektrisch mit den Elektroden (36, 38, 40) verbunden ist und programmiert ist, um ein Sauerstoffkonzentrationsmessverfahren durch-

zuführen;
eine Stromquelle (84), die durch den Chip (56) mit integriertem Schaltkreis gesteuert wird und zwischen der Arbeitselektrode (36) und der Gegenelektrode (38) geschaltet ist und konfiguriert ist, um Strom zwischen der Arbeits- und der Gegenelektrode (36, 38) zuzuführen;
einen Spannungswächter (86), der angeordnet ist, um die Spannung zwischen der Bezugselektrode (40) und der Arbeitselektrode (36) zu detektieren; worin der Chip (56) mit integriertem Schaltkreis programmiert ist, um den durch die Stromquelle (84) eingespeisten Strompegel zu steuern und die detektierte Spannung zu überwachen, sodass bewirkt wird, dass variierende Strompegel zwischen der Arbeitselektrode (36) und der Gegenelektrode (38) fließen, wenn die Elektroden unterschiedlichen Sauerstoffkonzentrationswerten ausgesetzt sind, und worin eine Änderung der detektierten Spannung bewirkt wird und worin ferner der Chip (56) mit integriertem Schaltkreis bewirkt, dass die Stromquelle (84) einen Strom mit einer Stärke erzeugt, um die detektierte Spannung auf einen vorab ausgewählten Bezugswert zurückzuführen, wobei die Stromstärke ein direktes Maß der Sauerstoffkonzentration darstellt.

3. Katheter (14) nach Anspruch 1 oder 2, worin der Katheter (14) in einer sauerstoffdurchlässigen Hülle (78) eingeschlossen ist.

4. Katheter (14) nach Anspruch 1 oder 2, worin der Katheter (14) in einer Silikonhülle (20) eingeschlossen ist, die sich in dessen Längsrichtung erstreckt.

5. Katheter (14) nach Anspruch 4, worin die Elektroden in einem sauerstoffleitfähigen Gel (80) eingeschlossen sind.

6. Katheter (14) nach Anspruch 5, worin das sauerstoffleitfähige Gel (80) pHema ist.

7. Katheter (14) nach Anspruch 2, worin die Arbeitselektrode (36), die Gegenelektrode (38) und die Bezugselektrode (40) auf einer Fläche eines Keramiksubstrats (42) angebracht sind und der Chip (56) mit integriertem Schaltkreis auf einer gegenüberliegenden Fläche des Substrats (42) angebracht ist und worin elektrische Leiter (46, 44, 48) durch das Substrat hindurch verlaufen und die Elektroden (36, 38, 40) mit entsprechenden Anschlüssen (50, 52, 54) des Chips (56) mit integriertem Schaltkreis verbinden, wobei die Leiter einen ersten Abschnitt, der sich in eine erste Richtung durch das Substrat hindurch erstreckt, und einen zweiten Abschnitt (58, 69, 62) aufweisen, der in einer zweiten Richtung durch das Substrat hindurch verläuft, die im Wesentlichen im rechten Winkel auf die erste Richtung steht.

8. Katheter (14) nach einem der Ansprüche 1 bis 7, worin die Sauerstoffüberwachungsschaltung (25) eine wiederaufladbare Energiequelle (110) umfasst und worin die Herzstimulationsimpulse genutzt werden, um die Energiequelle (110) wiederaufzuladen.

9. Katheter (14) nach einem der Ansprüche 1 bis 7, worin die Sauerstoffüberwachungsschaltung (25) eine wiederaufladbare Energiequelle (110) umfasst und die durch den Sauerstoffüberwachungsimpulsgeber (26) erzeugten biphasischen Impulse genutzt werden, um die Energiequelle (110) wiederaufzuladen.

10. Katheter (14) nach einem der Ansprüche 1 bis 9, worin die Sauerstoffüberwachungsschaltung (25) Schaltkreise umfasst, um eine Impulsfolge zu erzeugen, die in Bezug auf die Sauerstoffüberwachungsimpulsfolge responsiv ist und ein damit übereinstimmendes Format aufweist, um dem Prozessor die Ergebnisse der Untersuchungsabfrage bereitzustellen.

11. Katheter (14) nach Anspruch 10, worin die durch die Sauerstoffüberwachungsschaltung (25) erzeugte Impulsfolge monophasisch ist.

12. Katheter (14) nach einem der Ansprüche 1 bis 11, worin der Herzstimulationsimpulsgeber (30) in einer elektrisch leitfähigen Dose aufgenommen ist, die mit dem Gewebe des Patienten in Kontakt steht, und worin die Sauerstoffüberwachungsschaltung (25) mit dem zumindest einen elektrischen Leiter (22, 24) und dem Gewebe des Patienten elektrisch verbunden ist.

13. Katheter (14) nach einem der Ansprüche 1 bis 12, worin der zumindest eine elektrische Leiter (22, 24) einen Schrittmacherleiter und eine Rückleitung umfasst, wobei die Sauerstoffüberwachungsschaltung (25) elektrisch zwischen dem Schrittmacherleiter und der Rückleitung geschaltet ist.

14. Katheter (14) nach einem der Ansprüche 1 bis 12, worin der zumindest eine elektrische Leiter (22, 24) ein Paar Schrittmacherleiter und ein zweites Paar an Leitern umfasst, wobei die Sauerstoffüberwachungsschaltung (25) elektrisch an das zweite Leiterpaar angeschlossen ist, wobei das zweite Leiterpaar in elektrischer Kommunikation mit der Stimulationsvorrichtung steht.

15. Katheter (14) nach einem der Ansprüche 1 bis 12, worin der zumindest eine elektrische Leiter (22, 24) zwei Schrittmacherleiter und eine Rückführungsleitung umfasst, wobei die Sauerstoffüberwachungs-

schaltung (25) elektrisch zwischen den Schrittmacherleitern und der Rückleitung geschaltet ist.

16. Katheter (14) nach einem der Ansprüche 1 bis 12, worin der zumindest eine Leiter zwei Leiter umfasst und die Sauerstoffüberwachungsschaltung (25) elektrisch an die beiden Leiter angeschlossen ist.

Revendications

1. Fil de stimulation cardiaque (14) pour utilisation avec un dispositif de stimulation cardiaque (12), le dispositif comprenant un processeur (28), un générateur d'impulsions de stimulation cardiaque (30) couplé et réagissant au processeur et configuré pour délivrer des impulsions de stimulation cardiaque par le fil de stimulation cardiaque (14) à des sites cardiaques sélectionnés, un générateur d'impulsions de surveillance d'oxygène (26) couplé au processeur et configuré pour produire un train d'impulsions biphasiques pour l'application au fil de stimulation cardiaque (14) entre des impulsions de stimulation cardiaque consécutives, le fil de stimulation (14) comprenant:

au moins un conducteur électrique (22, 24), ledit fil (14) étant en contact avec le courant sanguin du patient et des sites cardiaques sélectionnés; et
un circuit de surveillance d'oxygène (25) électriquement couplé audit au moins un conducteur électrique (22, 24) et apte à être en contact avec le courant sanguin du patient, ledit circuit de surveillance d'oxygène (25) étant configuré pour surveiller la concentration de l'oxygène du sang du patient, où le circuit de surveillance d'oxygène (25) interroge le sang du patient durant un intervalle entre des impulsions de stimulation consécutives pour mesurer la concentration de l'oxygène dans le sang en utilisant le train d'impulsions biphasiques pour porter des commandes et des informations de paramètre entre le processeur (26) et le circuit de surveillance d'oxygène (25).

2. Fil (14) selon la revendication 1, dans lequel le circuit de surveillance d'oxygène (25) comprend:

une électrode de travail (36), une contre-électrode (38) et une électrode de référence (40);
une puce de circuit intégré (56) électriquement couplée auxdites électrodes (36, 38, 40) et programmée pour entreprendre un processus de mesure de concentration de l'oxygène;
une source de courant (84) commandée par ladite puce de circuit intégré (56) et couplée entre l'électrode de travail (36) et la contre-électrode (38) et configurée pour fournir le courant entre l'électrode de travail et la contre-électrode (36, 38);
un organe de surveillance de tension (86) agencé pour détecter la tension à l'électrode de référence (40) et à l'électrode de travail (36); où la puce de circuit intégré (56) est programmée pour commander le niveau de courant fourni par la source de courant (84) et pour surveiller la tension détectée de sorte que lors de l'exposition des électrodes à des niveaux variants de concentration d'oxygène, des niveaux variants de courant est amené à s'écouler entre l'électrode de travail (36) et la contre-électrode (38), et où la tension détectée est amenée à changer, et en outre où la puce de circuit intégré (56) amène la source de courant (84) à produire un courant d'une grandeur pour ramener la tension détectée à une valeur de référence présélectionnée, ladite grandeur de courant étant une mesure directe de la concentration de l'oxygène.

3. Fil (14) selon la revendication 1 ou 2, où le fil (14) est renfermé dans une gaine (78) transmissible à l'oxygène.

4. Fil (14) selon la revendication 1 ou 2, où le fil (14) est renfermé dans une gaine en silicone (20) s'étendant sur sa longueur.

5. Fil (14) selon la revendication 4, où les électrodes sont renfermées dans un gel conducteur d'oxygène (80).

6. Fil (14) selon la revendication 5, dans lequel le gel conducteur d'oxygène (80) est pHema.

7. Fil (14) selon la revendication 2, dans lequel ladite électrode de travail (36), contre-électrode (38) et électrode de référence (40) sont montés sur une face d'un substrat céramique (2), et la puce de circuit intégré (56) est montée sur une face opposée du substrat (42), et où il y a des conducteurs électriques (46, 44, 48) passant à travers le substrat interconnectant les électrodes (36, 38, 40) avec des bornes correspondantes (50, 52, 54) de la puce de circuit intégré (56), les conducteurs ayant une première portion s'étendant à travers le substrat dans une première direction et une seconde portion (58, 69, 62) traversant à travers le substrat à une seconde direction sensiblement orthogonale à la première direction.

8. Conducteur (14) selon l'une quelconque des revendications 1 à 7, dans lequel le circuit de surveillance d'oxygène (25) comporte une source d'énergie rechargeable (110), et où lesdites impulsions de stimulation cardiaque sont utilisées pour recharger la source d'énergie (110).

9. Fil (14) selon l'une quelconque des revendications 1 à 7, dans lequel le circuit de surveillance d'oxygène (25) comporte une source d'énergie rechargeable (110), et où des impulsions biphasiques produites par le générateur d'impulsions de surveillance d'oxygène (26) sont utilisées pour recharger la source d'énergie (110).

10. Fil (14) selon l'une quelconque des revendications 1 à 9, dans lequel le circuit de surveillance d'oxygène (25) comporte des circuits pour produire un train d'impulsions réagissant au train d'impulsions de surveillance d'oxygène en un format correspondant à celui-ci pour fournir au processeur les résultats de la requête d'interrogation.

11. Fil (14) selon la revendication 10, dans lequel le train d'impulsions produit par le circuit de surveillance d'oxygène (25) est monophasé.

12. Fil (14) selon l'une quelconque des revendications 1 à 11, dans lequel le générateur d'impulsions de stimulation cardiaque (30) est logé dans une boîte électriquement conductrice en contact avec le tissu du patient, et où le circuit de surveillance d'oxygène (25) est couplé électriquement à au moins un conducteur électrique précité (22, 24) et au tissu du patient.

13. Fil (14) selon l'une quelconque des revendications 1 à 12, dans lequel le au moins un conducteur électrique (22, 24) comporte un conducteur de régulation et un conducteur de retour, où le circuit de surveillance d'oxygène (25) est couplé électriquement entre le conducteur de régulation et le conducteur de retour.

14. Fil (14) selon l'une quelconque des revendications 1 à 12, dans lequel le au moins un conducteur électrique (22, 24) comprend une paire de conducteurs de régulation et une seconde paire de conducteurs, le circuit de surveillance d'oxygène (25) étant couplé électriquement à la deuxième paire de conducteurs, ladite deuxième paire de conducteurs étant en communication électrique avec le dispositif de stimulation.

15. Fil (14) selon l'une quelconque des revendications 1 à 12, dans lequel le au moins un conducteur électrique (22, 24) comprend deux conducteurs de régulation et un conducteur de retour, où le circuit de surveillance d'oxygène (25) est couplé électriquement entre un des conducteurs de régulation et le conducteur de retour.

16. Fil (14) selon l'une quelconque des revendications 1 à 12, dans lequel le au moins un conducteur comprend deux conducteurs, et le circuit de surveillance d'oxygène (25) est couplé électriquement aux deux conducteurs précités.

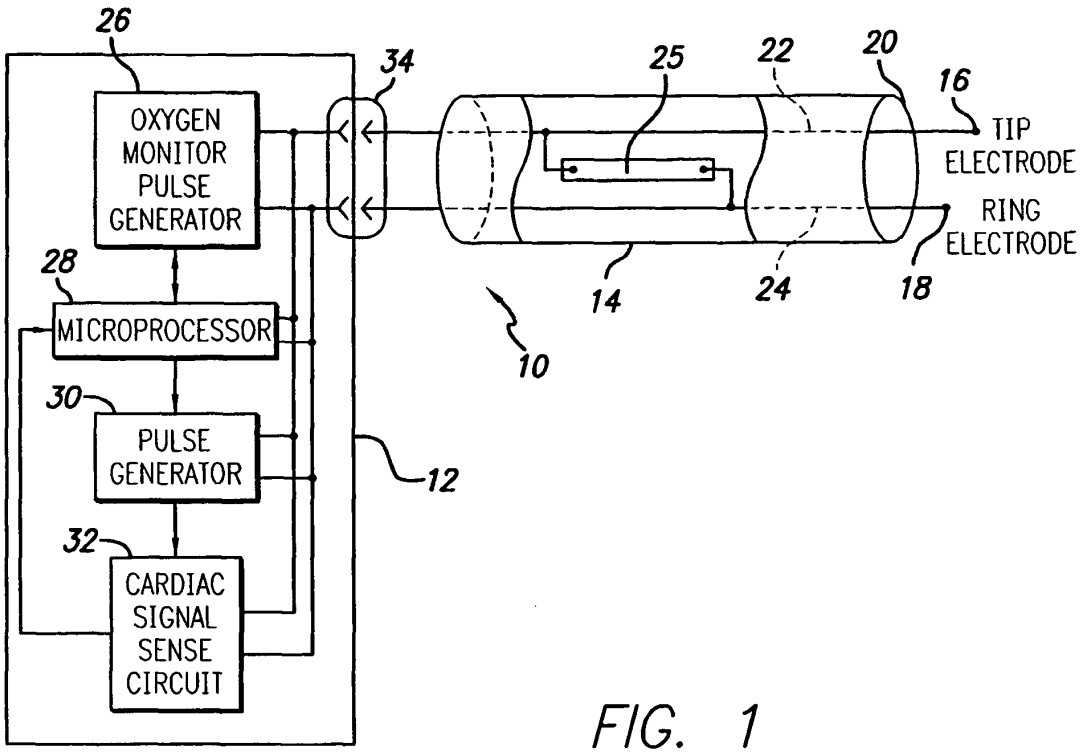

26
OXYGEN MONITOR PULSE GENERATOR
28
MICROPROCESSOR
30
PULSE GENERATOR
32
CARDIAC SIGNAL SENSE CIRCUIT
34
12
25
22
20
16
TIP ELECTRODE
RING ELECTRODE
14
24
18
10

FIG. 1

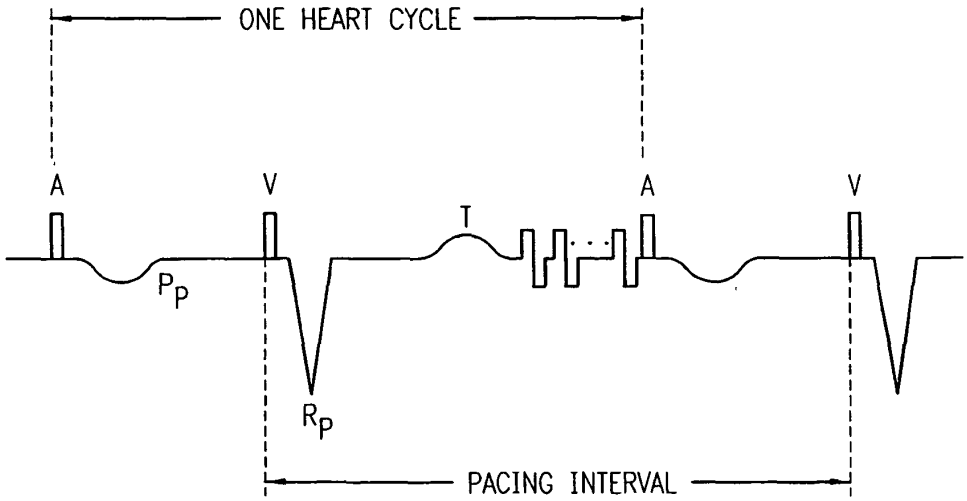

ONE HEART CYCLE
A
V
A
V
T
P_P
R_P
PACING INTERVAL

FIG. 2

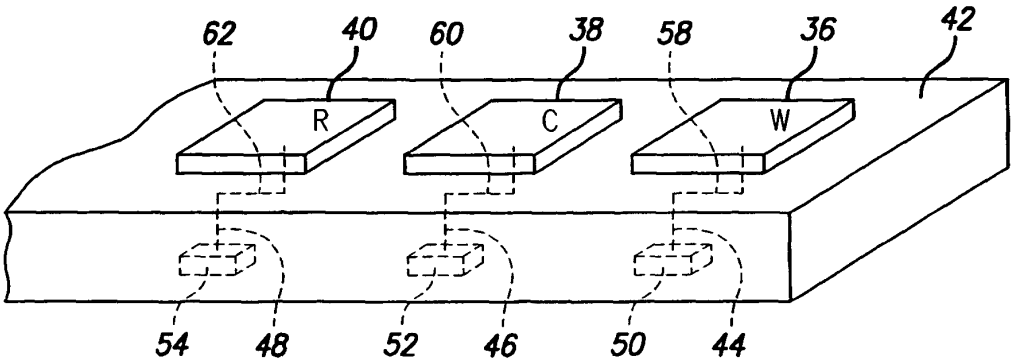

62
40
60
38
58
36
42
R
C
W
54
48
52
46
50
44

FIG. 3

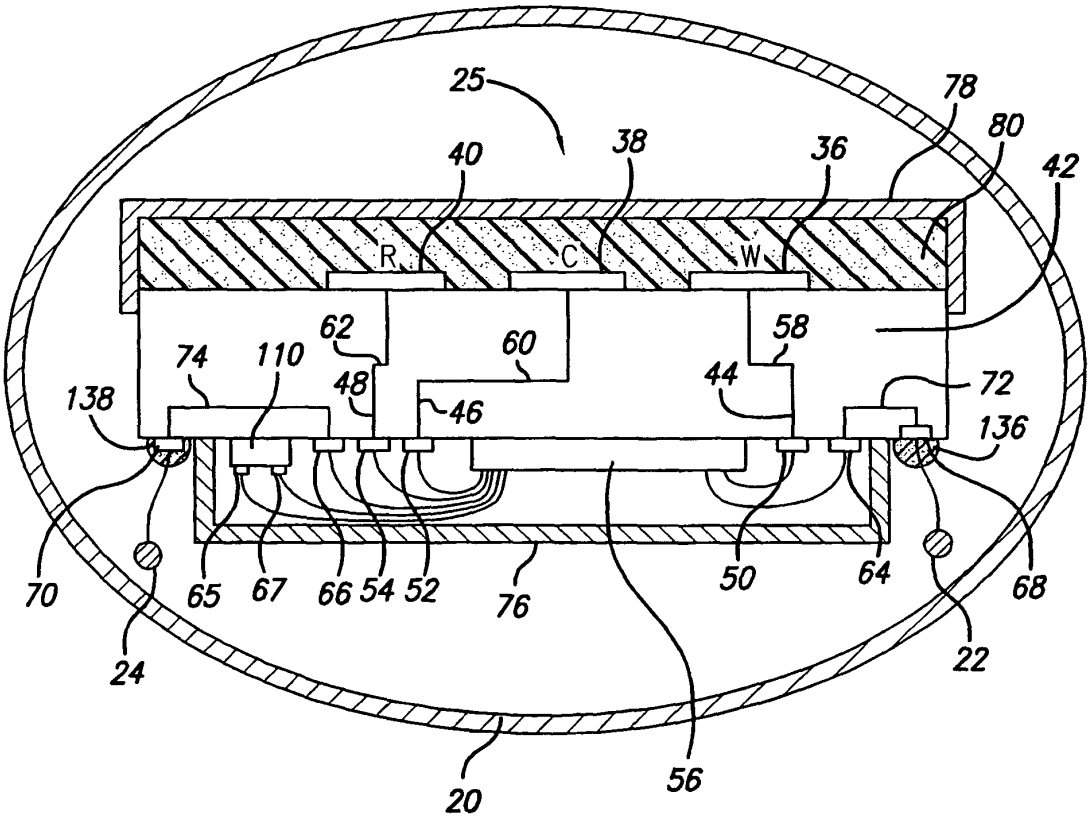

25
78
80
42
40
38
36
R
C
W
62
60
58
74
110
48
46
44
72
138
136
70
65
67
66
54
52
76
50
64
68
24
22
20
56

FIG. 4A

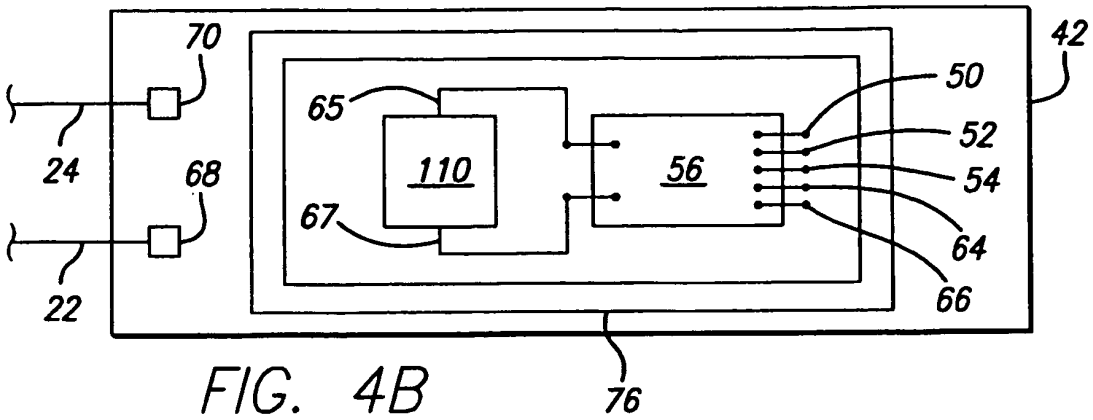


FIG. 4B

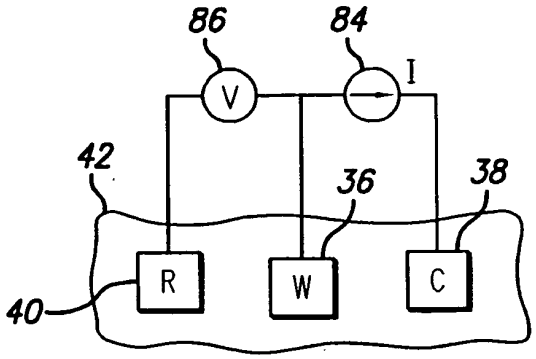


FIG. 5A

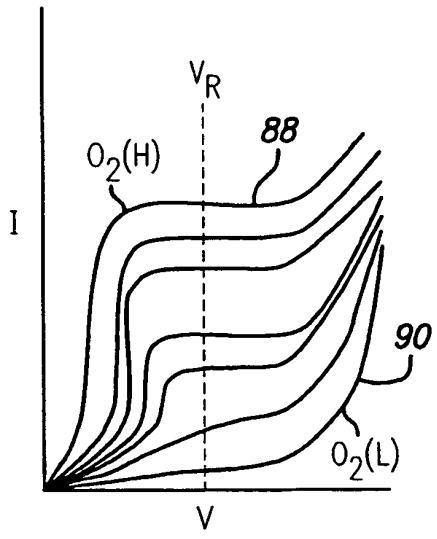


FIG. 5B

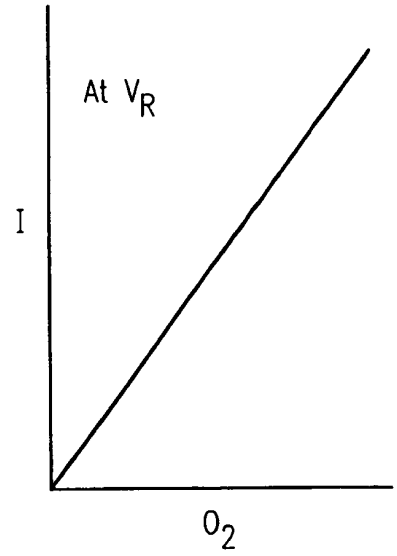


FIG. 5C

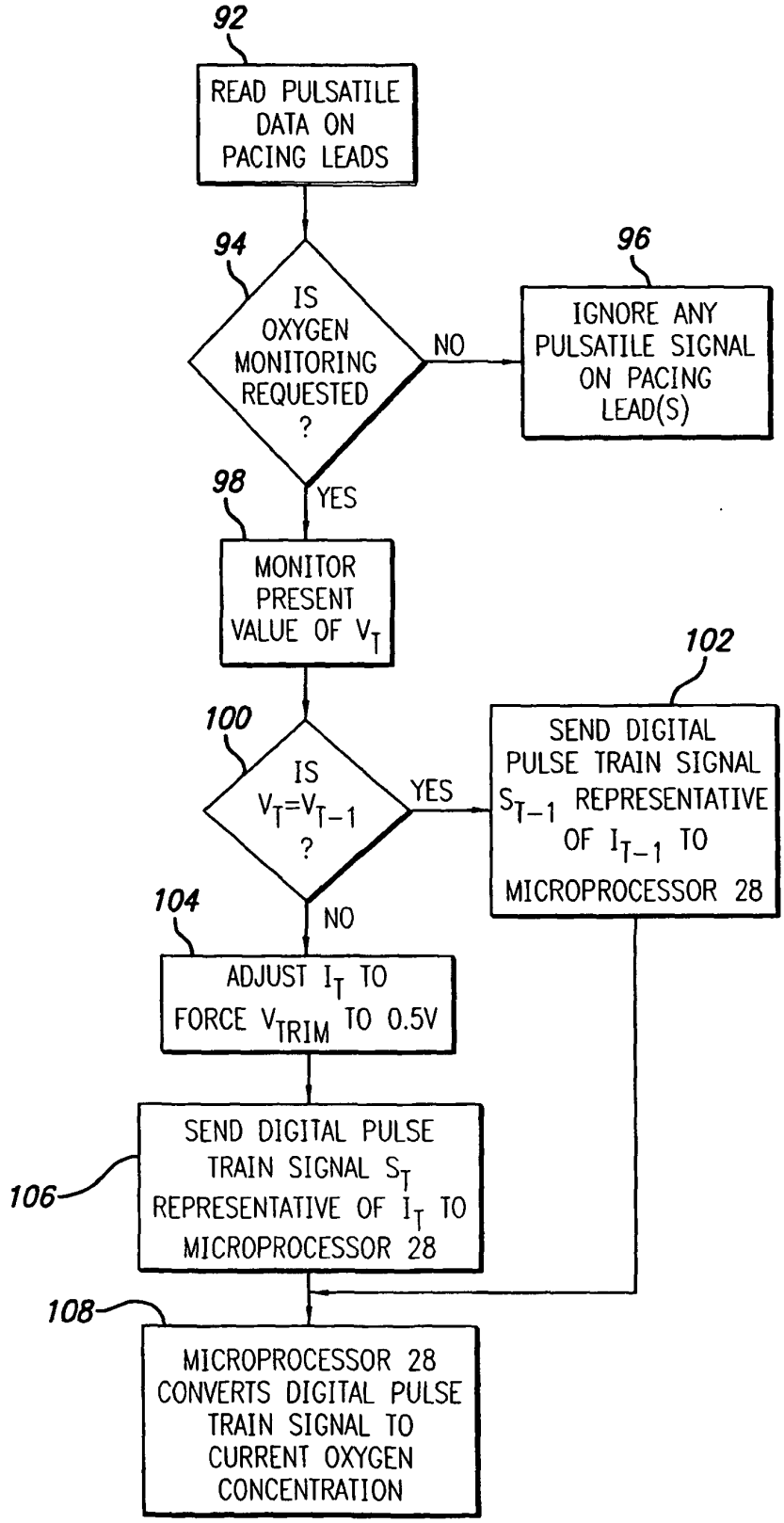

92
READ PULSATILE DATA ON PACING LEADS
94
IS OXYGEN MONITORING REQUESTED ?
NO
96
IGNORE ANY PULSATILE SIGNAL ON PACING LEAD(S)
YES
98
MONITOR PRESENT VALUE OF V_T
100
IS $V_T=V_{T-1}$?
YES
102
SEND DIGITAL PULSE TRAIN SIGNAL S_{T-1} REPRESENTATIVE OF I_{T-1} TO MICROPROCESSOR 28
NO
104
ADJUST I_T TO FORCE V_{TRIM} TO 0.5V
106
SEND DIGITAL PULSE TRAIN SIGNAL S_T REPRESENTATIVE OF I_T TO MICROPROCESSOR 28
108
MICROPROCESSOR 28 CONVERTS DIGITAL PULSE TRAIN SIGNAL TO CURRENT OXYGEN CONCENTRATION

FIG. 6

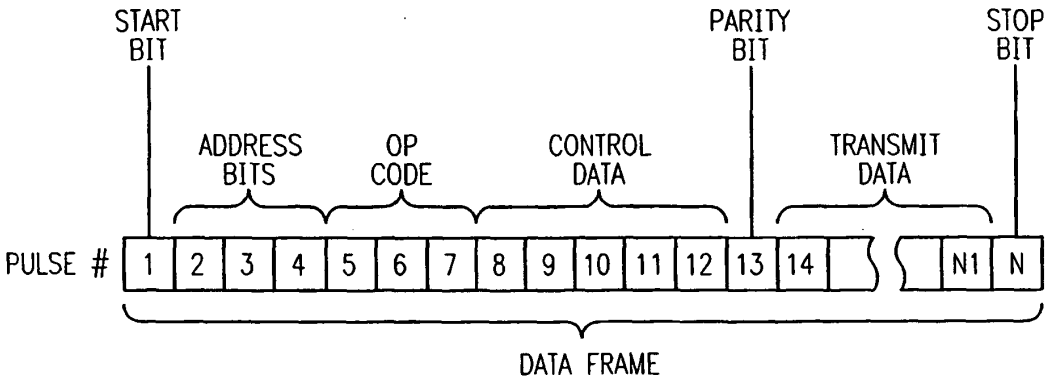

START BIT
PARITY BIT
STOP BIT
ADDRESS BITS
OP CODE
CONTROL DATA
TRANSMIT DATA
PULSE #
1
2
3
4
5
6
7
8
9
10
11
12
13
14
N1
N
DATA FRAME

FIG. 7

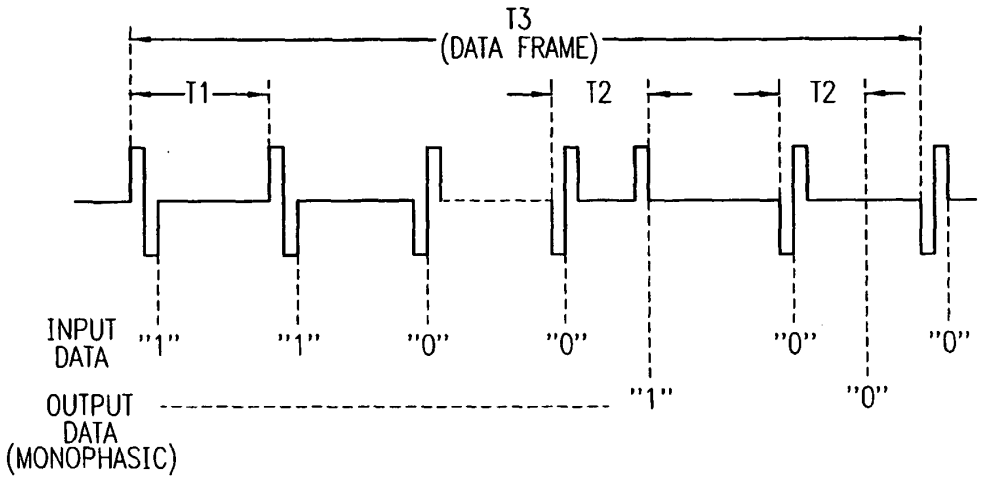

T3
(DATA FRAME)
T1
T2
T2
INPUT DATA
"1"
"1"
"0"
"0"
"0"
"0"
OUTPUT DATA (MONOPHASIC)
"1"
"0"

FIG. 8

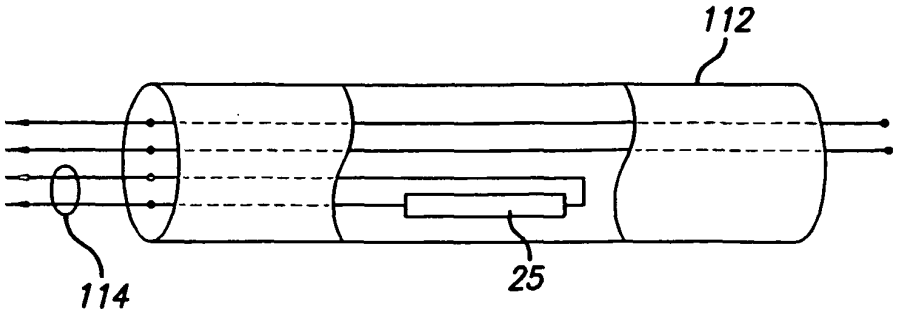


FIG. 9

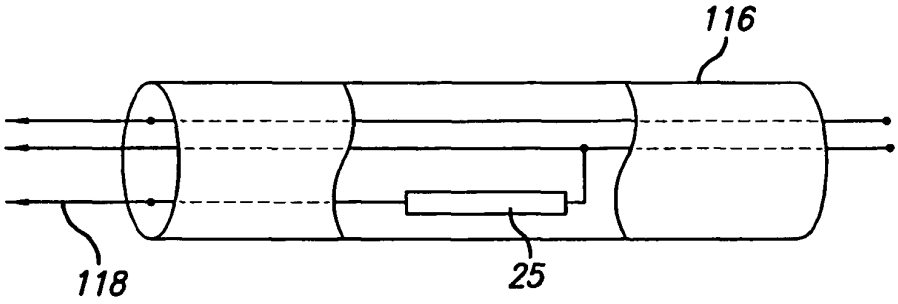


FIG. 10

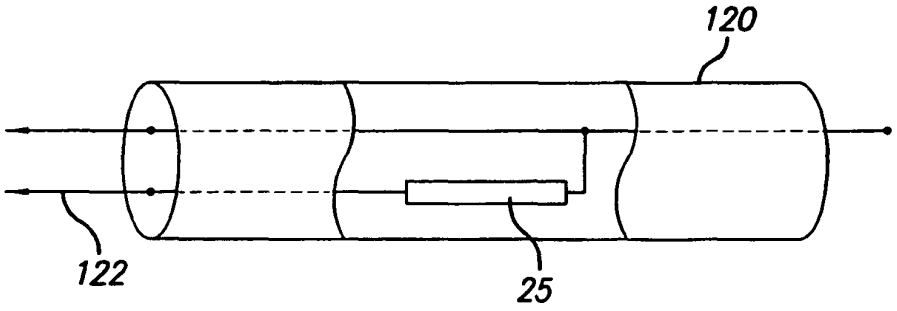


FIG. 11

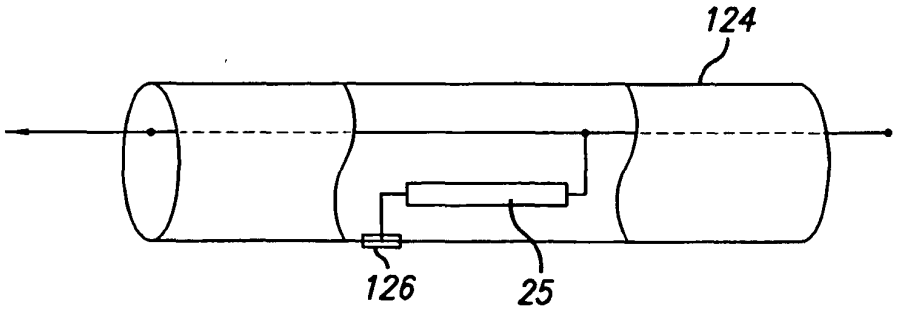
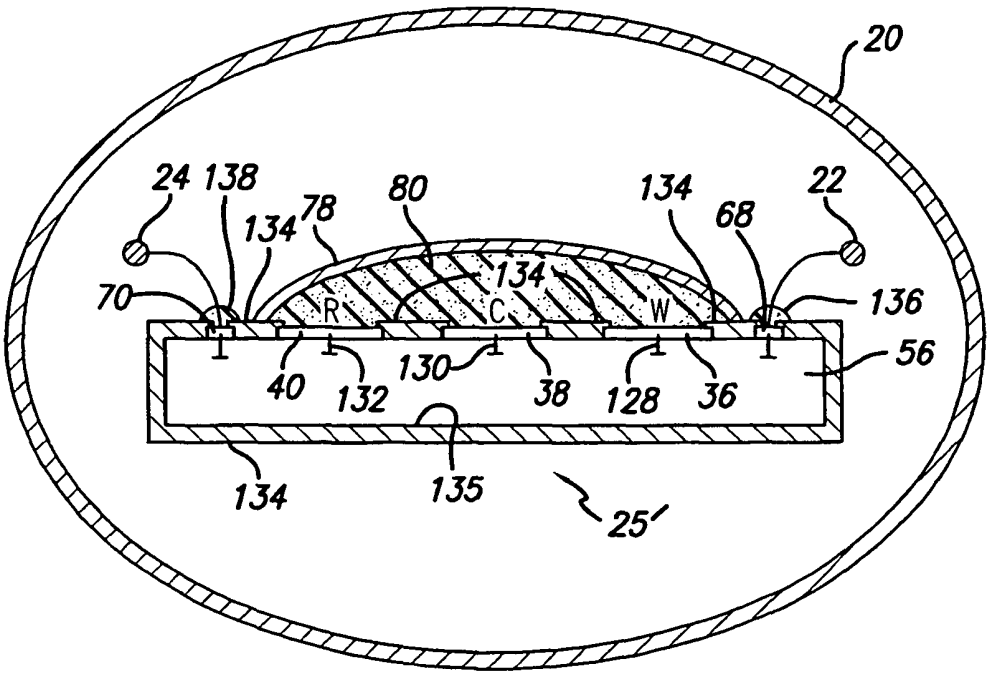


FIG. 12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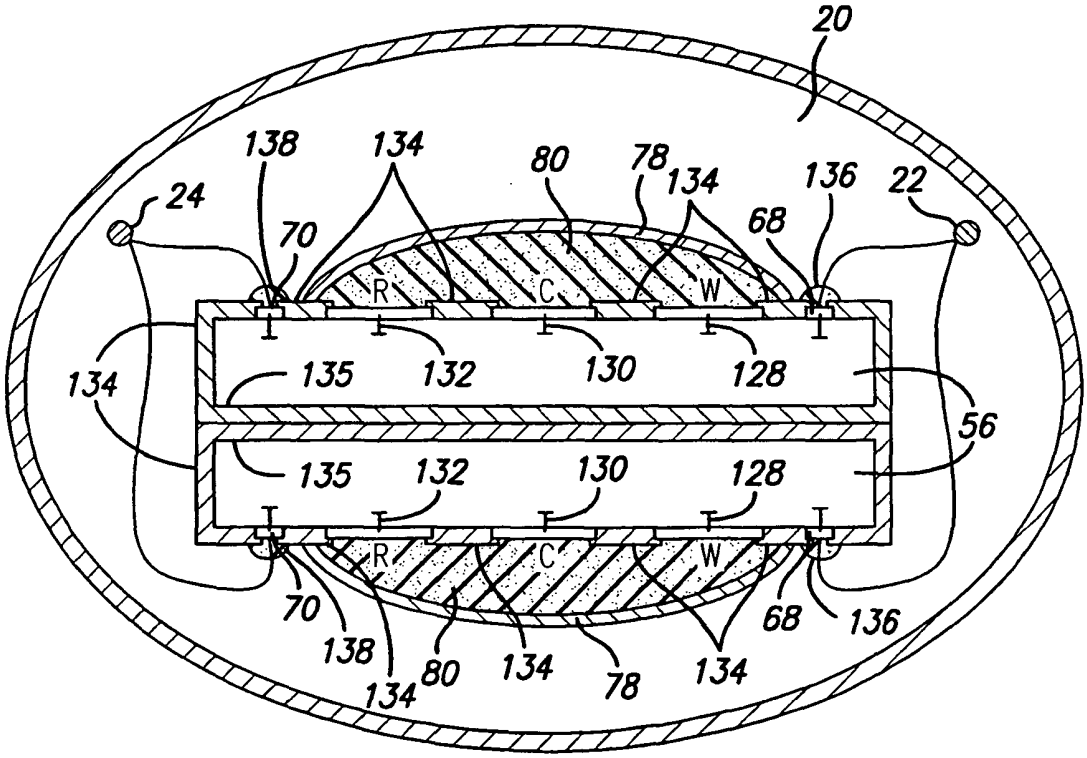
138
134
78
80
134
68
22
70
R
C
W
136
56
40
132
130
38
128
36
134
135
25'

FIG. 13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80
78
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136
22
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C
W
134
135
132
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128
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135
132
130
128
R
C
W
70
68
136
138
134
80
134
78
134

FIG. 14

REFERENCES CITED IN THE DESCRIPTION

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专利名称(译)	血氧监测系统		
公开(公告)号	EP1468641B1	公开(公告)日	2011-03-23
申请号	EP2004251684	申请日	2004-03-24
申请(专利权)人(译)	艾尔弗雷德·E·曼基金会为科研		
当前申请(专利权)人(译)	艾尔弗雷德·E·曼基金会为科研		
[标]发明人	SCHULMAN JOSEPH H		
发明人	SCHULMAN, JOSEPH H.		
IPC分类号	A61B5/00 A61N1/365 G01N33/49		
CPC分类号	A61N1/36557 G01N33/4925		
代理机构(译)	佩吉特，HUGH CHARLES EDWARD		
优先权	10/418860 2003-04-16 US		
其他公开文献	EP1468641A3 EP1468641A2		
外部链接	Espacenet		

摘要(译)

氧气监测系统测量患者血液中的氧气浓度，以用作速率响应起搏中的生理控制参数。氧气监测系统包括嵌入心脏刺激引线中的氧气监测电路，并监测患者静脉系统中通过并进入引线的血氧。氧监测电路包括工作电极，对电极，参比电极和电连接在电极之间的IC芯片，并被编程以执行氧浓度测量过程。围绕电极的氧气导致电流在电极之间流动，并且IC芯片改变耦合在工作电极和对电极之间的电流源产生的电流值，以保持工作电极和参考电极之间的电压预先选定值。电流源值的变化是血氧浓度的直接量度。氧监测电路可以包括安装在基板一侧的IC芯片，并且在其背面安装有电极或IC芯片，电极直接安装在IC芯片上。此外，可以使用具有适当绝缘的IC芯片代替衬底。可以使用至少两个绝缘IC芯片，例如以背对背布置，以提高整体灵敏度或冗余度。

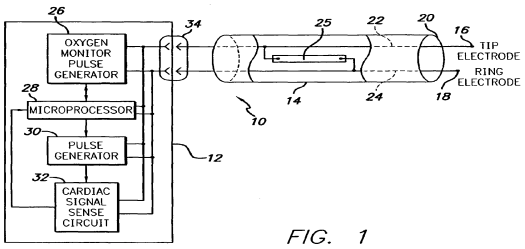

FIG. 1

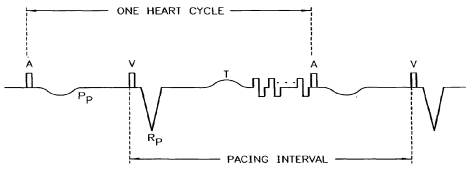

FIG. 2