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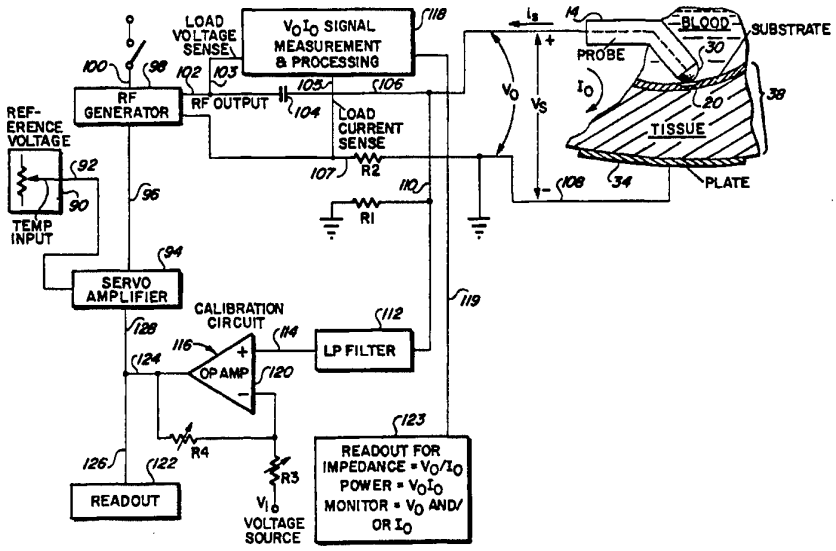

(57) Abstract

A catheter (14) for use in an electrophysiological procedure to ablate a site includes a metallic tip (30) having a first work function and energized by a source of RF energy (10). The RF energy return path is through a relatively large plate (34) of a metallic material having a second work function and disposed at a location removed from the ablation site. The difference in work functions of the tip and the plate, operating in the presence of an electrolyte represented by the intermediate tissue, produces an exchange of electrical charges through chemical reaction to create a galvanic cell. By loading the galvanic cell with a shunt resistor (R1), it becomes a current source providing a current linear with and highly dependent on the tissue temperature at the ablation site. This accurate representation of the tissue temperature at the ablation site is used to regulate the RF energy applied to maintain the tissue at the ablation site at a predetermined temperature during the ablation procedure.

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APPARATUS AND METHOD FOR THERMAL ABLATION

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to catheters and, more particularly, temperature controlled catheter probes for ablating tissue.

2. Background of the Invention

The heart is a four chamber muscular organ (myocardium) that pumps blood through various conduits to and from all parts of the body. In order that the blood be moved in the cardiovascular system in an orderly manner, it is necessary that the heart muscles contract and relax in an orderly sequence and that the valves of the system open and close at proper times during the cycle. Specialized conduction pathways convey electrical impulses swiftly to the entire cardiac muscle. In response to the impulses, the muscle contracts first at the top of the heart and follows thereafter to the bottom of the heart. As contraction begins, oxygen depleted venous blood is squeezed out of the right atrium (one of two small upper chambers) and into the larger right ventricle below. The right ventricle ejects the blood into the pulmonary circulation, which resupplies oxygen and delivers the blood to the left side of the heart. In parallel with the events on the right side, the heart muscle pumps newly oxygenated blood from the left atrium into the left ventricle and from there out to the aorta which distributes the blood to every part of the body. The signals giving rise to these machinations emanates from a

cluster of conduction tissue cells collectively known as the sinoatrial (SA) node. The sinoatrial node, located at the top of the atrium, establishes the tempo of the heartbeat. Hence, it is often referred to as the cardiac pacemaker. It sets the tempo simply because it issues impulses more frequently than do other cardiac regions. Although the sinoatrial node can respond to signals from outside the heart, it usually becomes active spontaneously. From the sinoatrial node impulses race to the atrioventricular (AV) node above the ventricles and speed along the septum to the bottom of the heart and up along its sides. The impulses also migrate from conduction fibers across the overlying muscle from the endocardium to the epicardium to trigger contractions that force blood through the heart and into the arterial circulation. The spread of electricity through a healthy heart gives rise to the familiar electrocardiogram. Defective or diseased cells are abnormal electrically. That is, they may conduct impulses unusually slowly or fire when they would typically be silent. These diseased cells or areas might perturb smooth signalling by forming a reentrant circuit in the muscle. Such a circuit is a pathway of electrical conduction through which impulses can cycle repeatedly without dying out. The resulting impulses can provoke sustained ventricular tachycardia: excessively rapid pumping by the ventricles. Tachycardia dysrhythmia may impose substantial risk to a patient because a diseased heart cannot usually tolerate rapid rates for extensive periods. Such rapid rates may cause hypotension and heart failure. Where there is an underlying cardiac disease, tachycardia can degenerate into a more serious ventricular dysrhythmia, such as fibrillation. By eliminating a reentrant circuit or signal pathway contributing to tachycardia, the source of errant electrical impulses will be eliminated. Ablation of the site attendant such a pathway will eliminate the source of errant impulses and the resulting arrhythmia. Mapping techniques for locating each

of such sites that may be present are well known and are presently used.

Interruption of the errant electrical impulses is generally achieved by ablating the appropriate site. Such ablation has been formed by lasers. The most common technique for use at an ablation site involves the use of a probe energized by radio frequency radiation (RF). Regulation and control of the applied RF energy is through a thermistor located proximate the RF element at the tip of a catheter probe. While such a thermistor may be sufficiently accurate to reflect the temperature of the thermistor, it inherently is inaccurate in determining the temperature of the tissue at the ablation site. This results from several reasons. First, there is a temperature loss across the interface between the ablation site and the surface of the RF tip. Second, the flow of blood about a portion of the RF tip draws off heat from the ablation site which must be replenished by increasing the temperature of the tissue under ablation. However, temperatures above 100°C result in coagulum formation on the RF tip, a rapid rise in electrical impedance of the RF tip, and loss of effective tissue heating. Third, there is a lag in thermal conduction between the RF tip and the thermistor, which lag is a function of materials, distance, and temperature differential. Each of these variables changes constantly during an ablation procedure. To ensure that the ablation site tissue is subjected to heat sufficient to raise its temperature to perform irreversible tissue damage, the power transmitted to the RF tip must be increased significantly greater than that desired for the ablation site in view of the variable losses. Due to the errors of the catheter/thermistor temperature sensing systems, there is a propensity to overheat the ablation site tissue needlessly. This creates three potentially injurious conditions. First, the RF tip may become coagulated. Second, tissue at

the ablation site may "stick to" the RF tip and result in tearing of the tissue upon removal of the probe. This condition is particularly dangerous when the ablation site is on a thin wall of tissue. Third, inadequate tissue temperature control can result in unnecessary injury to the heart including immediate or subsequent perforation.

When radio frequency current is conducted through tissue, as might occur during a procedure of ablating a tissue site on the interior wall (endocardium) of the heart with a radio frequency energized catheter, heating occurs preliminarily at the interface of the tip of the catheter and the myocardial tissue. Given a fixed power level and geometry of the catheter probe, the temperature gradient from the probe interface and a distance, r, into the tissue is proportional to $1/r^4$. Heating is caused by the resistive (OHMIC) property of the myocardial tissue and it is directly proportional to the current density. As may be expected, the highest temperature occurs at the ablation site which is at the interface of the RF tip and the tissue.

When the temperature of the tissue at the ablation site approaches 100°C, a deposit is formed on the RF tip that will restrict the electrical conducting surface of the RF tip. The input impedance to the RF tip will increase. Were the power level retained constant, the interface current density would increase and eventually arcing and carbonization would occur. At these relatively extreme temperatures, the RF tip will often stick to the surface of the tissue and may tear the tissue when the RF tip is removed from the ablation site.

To effect ablation, or render the tissue nonviable, the tissue temperature must exceed 50°C. If the parameters of the RF tip of a catheter are held constant, the size and depth of the lesion caused by ablation is directly

proportional to the temperature at the interface (assuming a time constant sufficient for thermal equilibrium). In order to produce lesions of greatest depth without overheating of the tissues at the interface, critical temperature measurement techniques of the RF tip are required.

The current technology for measuring the temperature of an RF tip embodies a miniature thermistor(s) located in the RF tip of the probe. The present state of the art provides inadequate compensation for the thermal resistance that exists between the thermistor and the outer surface of the RF tip or between the outer surface of the RF tip and the surface of the adjacent tissue. Because of these uncertainties contributing to a determination of the specific temperature of the tissue at the interface, apparatus for accurately measuring the interface temperature would be of great advantage in performing an electrophysiological procedure to ablate a specific site(s) of the myocardial tissue.

SUMMARY OF THE INVENTION

A catheter probe having a tip energized by an RF generator radiates RF energy as a function of the RF energy applied. When the tip is placed adjacent tissue at an ablation site, the irradiating RF energy heats the tissue due to the ohmically resistive property of the tissue. The catheter tip placed adjacent the ablation site on tissue in combination with an electrically conducting plate in contact with tissue at a location remote from the ablation site and an electrolyte defined by the intervening tissue create a galvanic cell when the tip and plate have different work functions because of migration of electrical charges therebetween. By loading the galvanic cell, the DC output current is a linear function of the temperature of the ablation site heated by the RF energy. The DC output current of the galvanic cell is used to regulate the output of the RF generator applied to the catheter tip to control the current density at the ablation site and hence maintain the ablation site tissue at a predetermined temperature.

It is therefore a primary object of the present invention to provide regulation of RF energy radiated from a catheter tip during an ablation procedure.

Another object of the present invention is to provide an output signal representative of the tissue temperature at an ablation site for regulating the RF radiation power level of a probe performing an ablation procedure.

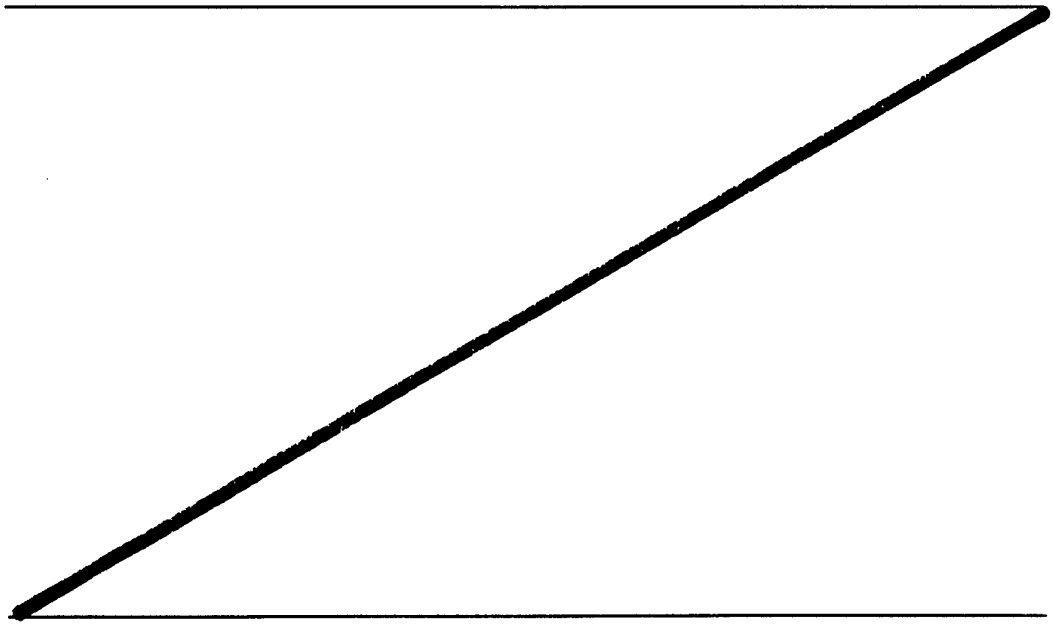
Yet another object of the present invention is to generate a signal representative of the actual tissue temperature at an ablation site to control heating of the ablation site by regulating irradiating RF energy from an ablating RF tip despite heat dissipating variables that may be present.

Still another object of the present invention is to provide a catheter for ablating cardiac impulse pathways at a predetermined temperature.

A further object of the present invention is to provide a self-regulating catheter mounted RF radiating element controlled by the tissue temperature at an ablation site for ablating a site on the endocardium of a heart suffering tachycardia dysrhythmia to destroy a pathway of errant electrical impulses at least partly contributing to the tachycardia dysrhythmia.

A still further object of the present invention is to provide a method for heating and ablating an ablation site at a predetermined and controllable temperature.

These and other objects of the present invention will become apparent to those skilled in the art as the description thereof proceeds.



BRIEF DESCRIPTION OF THE DRAWINGS

The present invention may be described with greater specificity and clarity with reference to the following drawings, in which:

Figure 1 illustrates a simplified representation of the present invention;

Figure 2 illustrates the current density at an ablation site during an ablation procedure;

Figure 3 illustrates a representation of a catheter probe embodying a thermistor useful in the present invention;

Figure 4 illustrates representatives curves for calibrating the temperature of an ablation site through use of a probe embodying a thermistor;

Figure 5 is a block diagram illustrating the circuitry attendant the present invention; and

Figure 6 illustrates a catheter probe for sequentially mapping the endocardium, identifying a site to be ablated and ablating the site without relocating the probe.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Two electrodes of different metals having different work functions in the presence of an electrolyte, such as blood, a saline solution or living tissue, will produce an exchange of electrical charges and an electromotive force (emf) is generated. This emf generator is known as a galvanic cell. A technical discussion of the history of galvanic cells is set forth in Chapter 1.3, entitled "Basic Electrochemistry" (pages 12-31) in a textbook entitled Modern Electrochemistry, authored by John O'M. Bockris, published by Plenum Press., New York, dated 1970. Detailed technical discussions of galvanic cells can be found in: Chapter 4, entitled "Reversible Electrode Potentials" (pages 73-100) of a textbook entitled Electrochemistry Principles and Applications, authored by Edmund C. Potter, published by Cleaver-Hume Press, Ltd., dated 1956; Chapter 4 entitled "Electrodes and Electrochemical Cells" (pages 59-89) of a textbook entitled Introduction to Electrochemistry, authored by D. Bryan Hibbert, published by MacMillan Press Ltd., dated 1993; and Chapter 12 entitled "Reversible Cells" (pages 282-311) of a textbook entitled Electrochemistry of Solutions, authored by S. Glasstone, published by Methuen & Co. Ltd., London, dated 1937 (Second Edition). These technical discussions are incorporated herein by reference.

The magnitude of the potential of a galvanic cell is a function of the electrolyte concentrates and the metals' work functions. The open circuit voltage of the galvanic cell is essentially constant despite temperature changes at the interface between the electrodes and the electrolyte. However, by loading the galvanic cell with a fixed value shunt resistance it simulates a current generator which has an output signal directly proportional to the temperature of the metal and electrolyte interface. The output signal of the current generator can be calibrated as a function of the temperature at the interface. A simple method for

calibration is that of referencing the output of the current generator with the output of a thermistor embedded in the electrode at steady state power and temperature conditions at an initial or first temperature and at a second temperature. This will provide two data points for the power/temperature curve of the current generator. Since the output of the current generator is linear, the curve can be extended to include all temperatures of interest.

The present invention is directed to apparatus for ablating an errant cardiac conduction pathway responsible for or contributing to arrhythmia of the heart. The ablation process is performed by heating the ablation site tissue to a temperature typically exceeding 50°C, sufficient to cause ablation of the cells contributing to the errant impulse pathway. The ablation is effected by irradiating the ablation site tissue with radio frequency (RF) energy. For this purpose, a catheter probe tip is positioned adjacent the ablation site, which site has been previously determined by mapping procedures well known to physicians and those skilled in the art. Upon positioning of the probe tip at the ablation site, a source of RF energy is actuated to transmit RF energy through a conductor to the tip of the probe. The RF energy radiates from the tip into the ablation site tissue. The current density at the ablation site is a function of the power of the RF energy irradiating the ablation site and the surface area defining the interface between the tip and the ablation site tissue. Control of the tissue temperature at the interface is of significant importance to control the area and depth of ablation in order to perform the degree of ablation necessary, to prevent coagulation on the tip, to prevent the tip from sticking to the tissue, to prevent avoidable injury to adjacent tissue, to prevent perforation of the tissue, and to avoid unnecessary heating of the blood flowing in and about the tip.

Catheter probes having a thermistor embedded at the tip have been used to perform an ablation procedure and the amount of RF energy applied has been regulated as a function of the temperature sensed by the thermistor. Such temperature sensing is inherently inaccurate in determining the temperature at the ablation site due to the numerous variables present. First, there exists a temperature loss through the interface between the ablation site and the surface area of the tip in contact with tissue. Second, there exists a thermal conductivity lag between the surface area of the tip in contact with the ablation site and the thermistor. Third, the orientation of the tip with respect to the ablation site will vary with a consequent variation of heating of the ablation site. Finally, the blood flowing about the tip area not in tissue contact will draw off heat as a function of both flow rate and orientation of the tip with respect thereto. By experiment, it has been learned that the differences between the tissue temperature at the ablation site and the temperature registered by a thermistor may range from 10°C to 35°C. Such temperature excursion may result in unnecessary injury without a physician being aware of the injury caused at the time of the ablation procedure. Where ablation is being performed upon a thin wall myocardium, puncturing can and does occur with potentially disastrous results.

The present invention is shown in simplified format in Figure 1. An RF generator 10 serves as a source of RF energy. The output of the RF generator is controlled by an input signal identified as J_1. The RF energy, as controlled by J_1, is transmitted through a conductor 12 to a catheter probe 14. This probe is depicted as being lodged within a blood filled chamber 16 of a heart. The chamber may be the right or left atrium or the right or left ventricle. Probe 14 is lodged adjacent, for instance, tissue 18 at an ablation site 20 representing a reentrant circuit to be

ablated. As represented, blood continually flows through chamber 16 about and around probe 14.

Probe 14 includes a tip 30 electrically connected to conductor 12 to irradiate ablation site 20 with RF energy. Typically, the frequency may be in the 350kHz to 1200kHz range. Such irradiation of the ablation site will result in heating of the ablation site as a function of the current density at the ablation site. The current density is determined by the energy level of the irradiating RF energy and the surface area of the ablation site. More specifically, the heat generated is proportional to the current density squared. This may be expressed as: $T(r) = kPd = kI^2R = (J_o^2/r^4)\ R$, where T=temperature, r=distance from the interface, J_o=current density at the interface, Pd= power dissipated, I= current at the interface, and R= resistance at the interface. The return path to RF generator 10 is represented by conductor 32. Conductor 32 is electrically connected to a relatively large sized plate 34 placed adjacent the patient's skin, preferably a large surface area of the patient's back. To ensure good electrical contact, an electrically conducting salve may be disposed intermediate plate 34 and patient's back 36. The fluid and tissues of the patient intermediate tip 30 and plate 34, represented by numeral 38, constitutes, in combination, an electrolyte and therefore an electrically conductive path between the tip and the plate. The DC current flow is represented by i_s and the DC voltage is represented by v_s.

As more particularly illustrated in Figure 2, ablation site 20 has a relatively high concentration of current paths, representatively depicted by diverging lines identified with numerals 42, 44, 46, 48, 50, and 52. These current paths are in close proximity with one another at the ablation site. The resulting high current density will

produce heating of the ablation site as a function of the current density. The depth of the ablated tissue is representatively illustrated by line 54. The current density proximate back 36 of the patient adjacent plate 34 is relatively low. With such low current density, essentially no heating of the skin adjacent plate 34 will occur. It is to be appreciated that Figure 2 is not drawn to scale and is intended to be solely representative of relative current densities resulting from irradiation of an ablation site by tip 30.

Ablation with tissue temperature control permits the physician to optimize the ablation process by allowing the ablation to occur at maximum temperature that is below a temperature conducive to formation of coagulation on the tip. Since such temperature is a function of the RF energy irradiating the ablation site tissue, control of the amount of RF energy transmitted via conductor 12 to the tip is necessary. A presently available type of catheter probe 60 is illustrated in Figure 3. This probe includes a tip 62 for radiating RF energy received through conductor 64 from a source of RF energy. A thermistor 66 is embedded in tip 62 or in sufficient proximity with the tip to be responsive to the temperature of the tip. A pair of conductors 68 and 70 interconnect thermistor 66 with a signal detection circuit to provide an output signal representative of the temperature sensed. Furthermore, probe 60 may include mapping electrodes 72, 74 and 76. These electrodes may be used in conjunction with manipulation of probe 60 within the heart to detect and identify errant impulse pathways causing cardiac arrhythmia. Conductors 78, 80 and 82 connect electrodes 72, 74 and 76, respectively, to circuitry associated with the mapping functions, as is well known.

As stated above, thermistor 66 is incapable of providing an accurate representation of the temperature at

the ablation site. In summary, these causes are due to heat loss through the interface between tip 30 and ablation site 20 (see Figure 2), thermal lag between the area of tissue in contact with the tip and the sensing element of the thermistor, and heat loss resulting from flow of blood about the tip area not in contact with the tissue.

By experimentation, it has been learned that the combination of tip 30, plate 34 and body 38 perform in the manner of a galvanic cell provided that the tip and the plate are metallic and of different work functions since body 38 acts as an electrolyte; the body is permeated by fluids having electrical properties similar to a saline solution. Experiments indicate that a preferable material for tip 30 is platinum and a preferable material for plate 34 is copper. The open circuit voltage (v_s) of this galvanic cell is essentially independent of the temperature of ablation site 20. However, if the galvanic cell is heavily loaded with a shunt resistor, the galvanic cell serves as a current source and the magnitude of the current (i_s) is linear as a function of the tissue temperature at the ablation site through the 37°C to 100°C temperature range of interest. The temperature of the tissue adjacent plate 34 is the body temperature since the current density is insufficient to generate heat of any consequence. Thus, the galvanic cell created by the apparatus illustrated in Figure 2 provides an output signal representative of the tissue temperature at ablation site 20 and irrespective of the temperature of tip 30.

One method for calibrating the galvanic cell will be described, but other methods may be used which do not require the presence of a thermistor at the tip. A thermistor is embedded in the tip of a catheter probe, such as probe 60. For reasons set forth above, the output of the thermistor is inherently inaccurate with respect to the

actual tissue temperature at the ablation site; moreover, the temperature sensed by the thermistor as a function of the power applied is generally nonlinear. However, within a temperature range from a quiescent standby state to a small temperature increase at the ablation site (small increase in power applied), the output signal of the thermistor is essentially linear. By matching the output curve of the thermistor with the generally linear response curve of the galvanic cell, two coincident reference points can be determined. Referring to Figure 4, there is illustrated a thermistor response curve and a galvanic cell response curve manipulated to be coincident from a point 0 to a point 1. By correlating the temperature indication of the thermistor at these two points, with the current output (i_s) of the galvanic cell, the temperature response can be linearly extrapolated to obtain a temperature reading correlated with the current output of the galvanic cell. That is, for any given current output of the galvanic cell, the tissue temperature of the ablation site can be determined. Thus, if probe 14 illustrated in Figures 1 and 2 is of the type shown in Figure 3, calibration of the probe at the ablation site can be readily determined. Other methods for calibrating the current output with temperature can also be employed, as set forth above.

Referring to Figure 5, there is illustrated a block diagram of the major components necessary to control the power applied to a catheter probe for ablating an errant impulse pathway at an ablation site. Figure 5 shows a temperature input circuit 90 for setting a reference voltage equivalent to the tissue temperature sought for an ablation site at which an ablation procedure is to be performed. The resulting output signal is transmitted through conductor 92 to a servo amplifier 94. The servo amplifier provides an output signal on conductor 96 to control the output power of RF generator 98. A switch 100 controls operation of the RF

generator. The RF energy output is impressed upon conductor 102. A blocking capacitor 104 is representative of a high pass filter and blocks any DC component of the signal on conductor 102. Conductor 106 interconnects the blocking capacitor with tip 30 of probe 14 and transmits RF energy to the tip. Tip 30 irradiates ablation site 20 of an endocardium, wall, membrane, or other living tissue to be irradiated with RF energy. Tip 30 is of a substance, such as platinum or other metal, having a first work function. Plate 34 displaced from tip 30, is of a substance, such as copper or other metal, having a second work function which is different from the first work function. Plate 34 is in electrical contact with a mass of tissue 38 intermediate tip 30 and the plate. This tissue, being essentially a liquid and having electrical characteristics of a saline solution, serves in the manner of an electrolyte interconnecting tip 30 and plate 34. The resulting galvanic cell formed, as discussed above, provides a DC output voltage v_s across conductors 106 and 108. Shunt impedance R1 heavily loads the galvanic cell formed to convert the galvanic cell to a current source (i_s) to provide an output signal reflective of the tissue temperature at ablation site 20. The output signal from the galvanic cell is transmitted through conductor 110 to a lowpass filter 112. The output of the lowpass filter is conveyed via conductor 114 to an operational amplifier 120 of a calibration circuit 116. Additionally, a signal measurement and processing circuit 118, connected to conductor 102 through conductor 103 to provide sampling of the output load voltage (V_0). It is also connected to conductor 107 through conductor 105 to provide an input signal of the load output) current (I_0) sensed, processes the input signals to provide an indication of the impedance, power, and voltage and current levels. A readout 123, connected through conductor 119 to signal measurement and processing circuit 118 provides each of a

plurality of indications of impedance, power, voltage level, current level, etc.

Variable resistors R3 and R4, in combination with operational amplifier 120, are representative of adjustments to be made to correlate the output current (i_s) of the galvanic cell with the tissue temperature of ablation site 20. Calibration circuit 116 can perform the above-described correlation of the thermistor indicated temperature with the current output signal of the galvanic cell to obtain a tissue temperature indication of the ablation site as a function of the current (i_s) generated by the galvanic cell. A readout 122, connected via conductors 124,126 with the calibration circuit, may be employed to provide an indication of the tissue temperature of the ablation site. An output signal from the calibration circuit is also conveyed via conductors 124 and 128 to servo amplifier 94. This output signal is reflective of the tissue temperature at the ablation site. Thereby, the servo amplifier receives an input signal reflective of the tissue temperature at the ablation site. Circuitry of servo amplifier 94 will determine whether to raise or lower the tissue temperature of the ablation site or to maintain it at its preset temperature. A command signal to increase, to decrease, or to maintain the power output of the RF generator is transmitted from servo amplifier 94 through conductor 96 to the RF generator.

Referring to Figure 6, there is illustrated a variant of probe 14 useable with the present invention. The combination of first mapping a site of interest and then ablating the site is a lengthy procedure. Were it possible to ablate a site identified during a mapping procedure without relocating the probe or without replacing the mapping probe with an ablating probe, significant time would be saved. Figure 6 illustrates a catheter probe 130, which

may be sufficiently flexible to position all or some of its length in contacting relationship with the surface of the myocardial tissue to be mapped. A tip 132, which may be similar to tip 30 of probe 14, is disposed at the distal end. A plurality of mapping electrodes, such as rings 134, 136, 138, 140 and 142 are disposed proximally along the probe from tip 132. These rings serve a function of mapping the tissue of interest to identify and locate a site to be ablated to destroy the circuit responsible for errant impulses. For these rings to work in the manner of tip 30, as described with reference to Figures 1-5, the rings are preferably metallic and have a work function different from that of plate (or electrode) 34. One of a plurality of conductors 144, 146, 148, 150, 152 and 154 interconnect the respective tip and rings with the output of a switching circuit(s) 160. A data acquisition circuit 162 is selectively interconnected through switching circuit 160 to each of rings 132-142 and possibly tip 132. The data acquisition circuit collects data sensed by the rings and/or tips to map the tissue surface traversed by the probe. Upon detection of a site to be ablated to destroy an impulse pathway (circuit), switch circuit 160 switches to interconnect the respective ring (or tip) with RF generator 164. Upon such interconnection, the respective ring (or tip) will irradiate the identified site with RF energy and the ablation function, as described above along with the tissue temperature control function, will be performed.

From this description, it is evident that upon detection of a site located by performing a mapping function, ablation of the site can be performed immediately without further movement or manipulation of the catheter probe. Furthermore, the ablation function can be performed with the circuitry illustrated in Figure 5 to heat and maintain the tissue at a predetermined temperature until ablation is completed.

Empirically, it has been determined that the circuit and apparatus for ablating tissue, as illustrated in Figure 5, provides to a physician a very accurate indication of the tissue temperature at the ablation site. With such accuracy, ablation procedures are capable of being performed on thin wall tissue without fear of coagulation of the tip, adhesion of tissue to the tip or puncture, which fears exist with presently used ablation performing apparatus. Furthermore, accurate representation of the temperature at the ablation site is no longer critically dependent upon the orientation of the probe at the ablation site nor upon the extent of the depression of the tissue in response to the pressure exerted by the probe tip. Because of these very difficult to control variables, complete ablation of the errant impulse pathway was not always achieved if the physician were overly cautious. Tip coagulation, sticking tissue and sometimes excessive injury to and puncture of the tissue occurred if the physician were more aggressive. These results were primarily due to the inaccuracy of the information conveyed to the physician during the procedure and not so much due to poor technique.

As will become evident from the above description, tip 30 (and tip 132) does not need a thermistor or a thermocouple to set or determine the temperature of the ablation site. Therefore, the probe can be smaller and more versatile than existing probes. Moreover, the probe can be manufactured at a substantially reduced cost because it is more simple than existing devices. Rings (or other electrodes) located on the catheter can be used for mapping sites of errant impulses and any of the rings (or other electrodes) can be used to irradiate the tissue at such site after identification of the site and without repositioning of the catheter.

While the invention has been described with reference to several particular embodiments thereof, those skilled in the art will be able to make the various modifications to the described embodiments of the invention without departing from the true spirit and scope of the invention. It is intended that all combinations of elements and steps which perform substantially the same function in substantially the same way to achieve the same result are within the scope of the invention.

WHAT IS CLAIMED IS:

1. Apparatus for ablating tissue at an ablation site in the heart of a human being, said apparatus comprising in combination:

(a) a source of RF energy for irradiating the tissue at the ablation site to cause a temperature rise of the tissue at the ablation site;

(b) a catheter tip for contactingly engaging the ablation site and for irradiating the tissue with RF energy to heat the tissue at the ablation site, said tip comprising a first electrode of material having a first work function;

(c) transmission means for conveying RF energy from said source to said tip;

(d) a second electrode displaced from said first electrode and of material having a second work function different from the first work function for electrically contacting an area of tissue of the human being;

(e) a galvanic cell formed by said first electrode, said second electrode and the tissue of the human being serving as an electrically interconnecting electrolyte for generating an electrical current corresponding with the temperature rise of the tissue at the ablation site; and

(f) a control circuit responsive to said electrical current generated by said galvanic cell for regulating the operation of said source of RF energy to control RF irradiation of the ablation site and thereby control the temperature of the tissue at the ablation site.

2. The apparatus of Claim 1 wherein the material of said first electrode is platinum and the material of said second electrode is copper.

3. The apparatus of Claim 2 including a catheter mounted probe for supporting said tip.

4. The apparatus of Claim 3 wherein said probe includes a thermistor for sensing the temperature of said tip.

5. The apparatus of Claim 4 including a calibration circuit receiving an input signal from said thermistor for correlating said electrical current generated by said galvanic cell with the temperature of the ablation site.

6. The apparatus of Claim 5 wherein the material of said first electrode is platinum and the material of said second electrode is copper.

7. The apparatus of Claim 1 wherein said second electrode is a plate.

8. The apparatus of Claim 1 wherein said second electrode is a plate adapted to electrically contact the skin on the back of the human being.

9. The apparatus of Claim 1 including an indicator for indicating the temperature of the ablation site.

10. A catheter assembly for irradiating tissue at an ablation site of a living being to raise the temperature of the ablation site to a predetermined range and to maintain the temperature of the ablation site within the predetermined range for a period of time, said catheter assembly comprising in combination:

(a) a tip being locatable at the ablation site, said tip being formed of a material having a first work function;

(b) an electrode displaced from said tip and located in electrical contact with the tissue of the living being, said electrode being formed of a material having a second work function different from the first work function;

(c) a galvanic cell formed by said tip, said electrode, and the tissue of the living being serving as an electrolyte intermediate said tip and said electrode for generating a current corresponding to the temperature of the tissue at the ablation site;

(d) an RF generator interconnected with said tip and said electrode for applying RF energy through said tip to the tissue at the ablation site to heat the tissue at the ablation site; and

(e) a control circuit for regulating said RF generator as a function of the current generated by said galvanic cell to control the temperature of the tissue at the ablation site.

11. The catheter assembly of Claim 10 wherein the material of said electrode is copper.

12. The catheter assembly of Claim 10 wherein the material of said tip is platinum.

13. The catheter assembly of Claim 10 wherein said electrode is a plate locatable in electrical contact with and in overlying relationship to the skin of the living being.

14. The catheter assembly of Claim 10 including a temperature input circuit for setting the temperature of the ablation site.

15. The catheter assembly of Claim 14 including an indicator for indicating the temperature of the ablation site.

16. The catheter assembly of Claim 10 including a calibration circuit for calibrating the current generated by said galvanic cell with the temperature of the ablation site.

17. The catheter assembly of Claim 10 wherein the contact area between said tip and the ablation site tissue is less than the contact area between said electrode and the tissue of the living being to provide a higher current density at the ablation site.

18. The catheter assembly of Claim 10 wherein the current density and temperature rise is greater at the ablation site tissue than at the interface between said electrode and the tissue of the living being.

19. The catheter assembly of Claim 10 wherein said galvanic cell includes a load resistor for generating the current reflective of the temperature rise of the ablation site tissue.

20. Apparatus for ablating tissue at an ablation site, said apparatus comprising in combination:

(a) a first electrode having a first work function locatable at the ablation site tissue;

(b) a second electrode having a second work function different from the first work function locatable in electrical contact with tissue for creating a galvanic cell in combination with said first electrode and the tissue acting as an electrolyte to provide a current output signal corresponding with the temperature at the ablation site tissue;

(c) an RF generator for applying RF energy to the ablation site tissue through said first and second electrodes to heat the ablation site tissue; and

(d) a control circuit for regulating the RF energy generated by said RF generator as a function of said current output signal to regulate the temperature of the ablation site.

21. The apparatus of Claim 20 wherein said first and second electrodes are metallic.

22. The apparatus of Claim 21 wherein said first electrode is platinum and wherein said second electrode is copper.

23. The apparatus of Claim 20 including an indicator for indicating the temperature of the ablation site tissue.

24. The apparatus of Claim 20 including a temperature input circuit for setting the temperature of the ablation site tissue.

25. The apparatus of Claim 20 including means for correlating said current output signal with the temperature of the ablation site tissue.

26. Apparatus for ablating tissue at an ablation site, said apparatus comprising in combination:

(a) an RF generator for applying RF energy to the ablation site to heat the ablation site tissue;

(b) a probe in contact with the ablation site tissue for irradiating the ablation site tissue with RF energy;

(c) a transmission line for conveying RF energy from said RF generator to said probe;

(d) a temperature sensor for sensing the temperature of the ablation site tissue and for producing a signal reflective of the temperature sensed, said temperature sensor comprising said probe, an electrode

displaced from said probe and an electrolyte in electrical contact with said probe and said electrode; and

(e) a control circuit responsive to said signal produced by said temperature sensor for regulating the RF energy applied to said probe to establish the temperature at the ablation site tissue within a predetermined range.

27. The apparatus of Claim 26 including a temperature input circuit for setting the temperature of the ablation site tissue.

28. The apparatus of Claim 26 including an indicator for indicating the temperature of the ablation site tissue.

29. A method for ablating tissue at an ablation site in the heart of a human being, said method comprising the steps of:

(a) generating RF energy from a source of RF energy;

(b) irradiating the tissue at the ablation site with RF energy through a tip in contact with the ablation site to heat the tissue at the ablation site, the tip comprising a first electrode of material having a first work function;

(c) conveying RF energy from the source to the tip;

(d) electrically contacting an area of tissue of the human being with a second electrode displaced from the first electrode and of material having a second work function different from the first work function;

(e) generating an electrical current corresponding with the temperature rise of the tissue at the ablation site by a galvanic cell formed by the first electrode, the second electrode and the tissue of the human

being serving as an electrically interconnecting electrolyte; and

(f) regulating the operation of the source of RF energy with a control circuit responsive to the electrical current generated by said generating step to control RF irradiation of the ablation site and thereby control the temperature of the tissue at the ablation site.

30. A method for ablating tissue at an ablation site, said method comprising the steps of:

(a) generating RF energy with an RF generator;

(b) irradiating the ablation site with RF energy through a probe proximate the ablation site;

(c) conveying RF energy from the RF generator to the probe through a transmission line;

(d) sensing the temperature at the ablation site tissue with a temperature sensor and producing a signal reflective of the temperature sensed, the temperature sensor comprising the probe, an electrode displaced from the probe and an electrolyte in electrical contact with the probe and the electrode; and

(e) regulating the output of the RF generator with a control circuit responsive to the signal produced by said sensing step to establish the temperature at the ablation site tissue within a predetermined range.

31. Apparatus for mapping tissue to locate a site to be ablated and for ablating the site located, said apparatus comprising in combination:

(a) a probe having a plurality of electrodes disposed therealong for placement adjacent the tissue to be mapped;

(b) a data acquisition circuit for performing mapping functions in response to signals generated by the

tissue proximate each electrode of said plurality of electrodes to identify and locate a tissue site to be ablated;

(c) an RF generator for generating RF energy to ablate a located ablation site;

(d) a switching circuit for selectively interconnecting said data acquisition circuit and said RF generator to each electrode of said plurality of electrodes; and

(e) a plurality of conductors interconnecting said switching circuit with said plurality of electrodes.

32. The apparatus of Claim 31 wherein each electrode of said plurality of electrodes has a first work function and including a further electrode having a second work function different from the first work function, said further electrode being locatable in electrical contact with tissue for creating a galvanic cell in combination with said plurality of electrodes and the tissue acting as an electrolyte to provide a current output signal corresponding with the located site to be ablated and a control circuit for regulating the RF energy generated by said RF generator as a function of said current output signal to regulate the temperature of the site being ablated.

33. The apparatus of Claim 32 including a temperature input circuit for setting the temperature of the site to be ablated.

34. The apparatus of Claim 33 including an indicator for indicating the temperature of the site during ablation.

35. The apparatus of Claim 31 wherein said plurality of electrodes includes a plurality of rings disposed in spaced apart relationship along said probe.

36. The apparatus of Claim 35 wherein said plurality of electrodes includes a tip electrode disposed at the distal end of said probe.

37. The apparatus of Claim 36 wherein said switching circuit interconnects only one of the ring of said plurality of rings and said tip electrode whichever corresponds with the site to be ablated.

38. The apparatus of Claim 31 wherein said probe remains stationary adjacent the tissue after the mapping function performed has identified and located the site to be ablated and remains stationary during interconnection of said RF generator to ablate the located site.

39. The apparatus of Claim 38 wherein said switching circuit interconnects only the electrode of said plurality of electrodes which corresponds with the site to be ablated.

40. The apparatus of Claim 31 wherein said switching circuit interconnects only the electrode of said plurality of electrodes which corresponds with the site to be ablated.

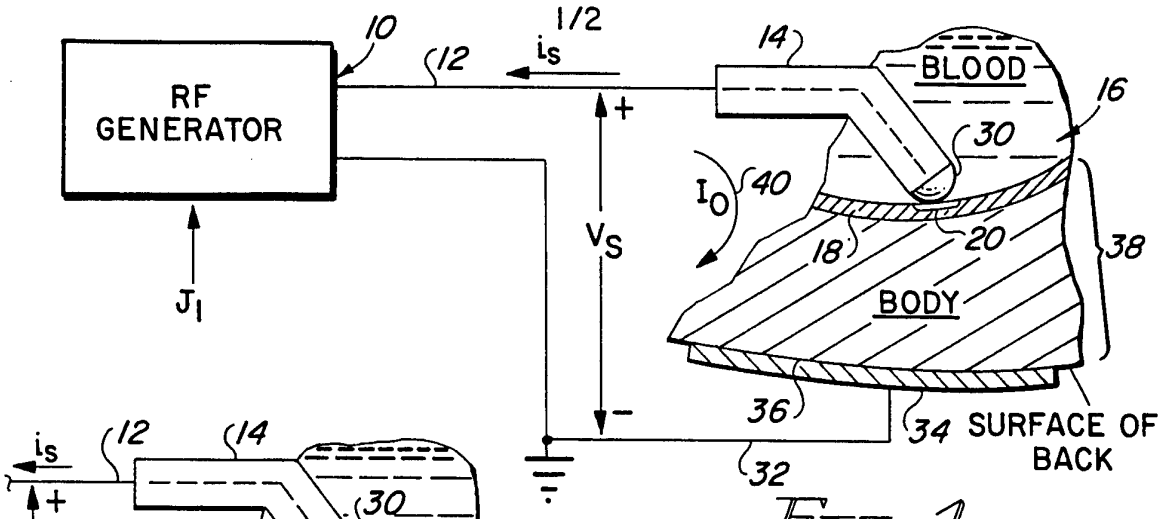


FIG-1

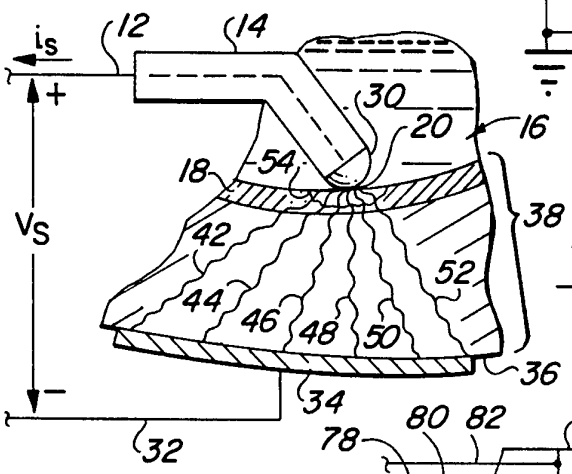


FIG-2

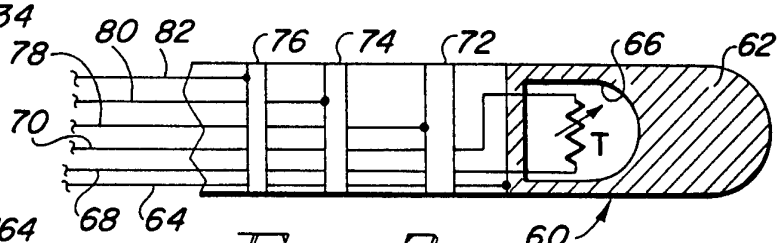


FIG-3

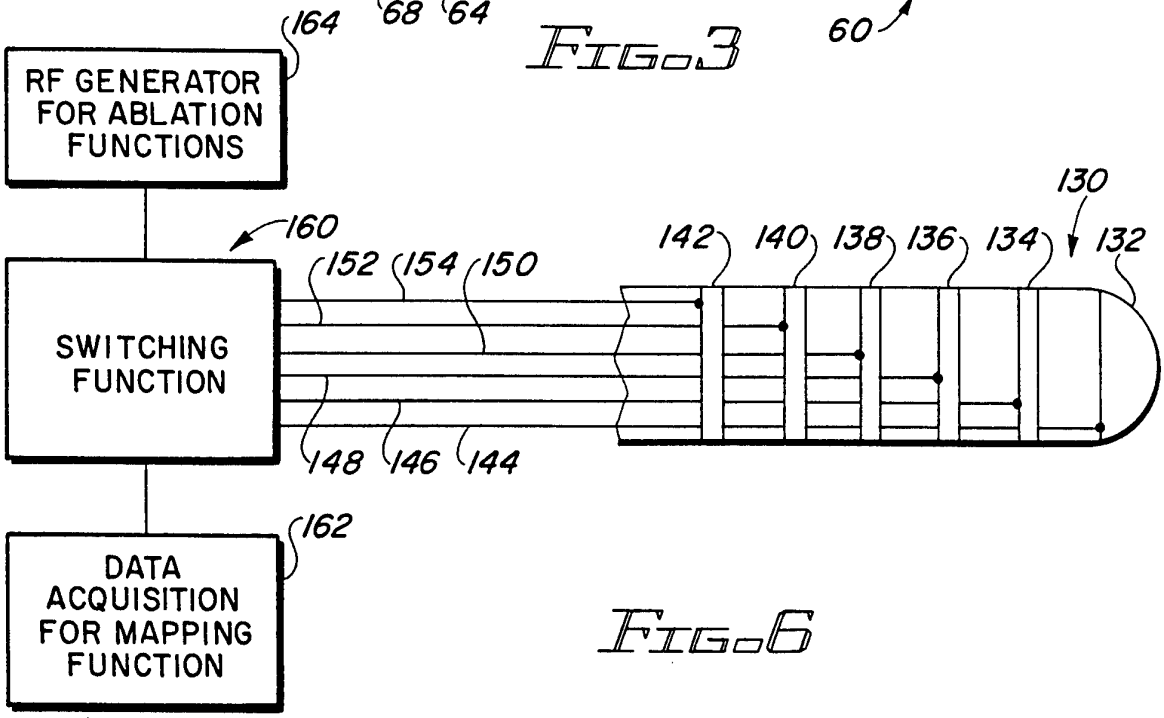


FIG-6

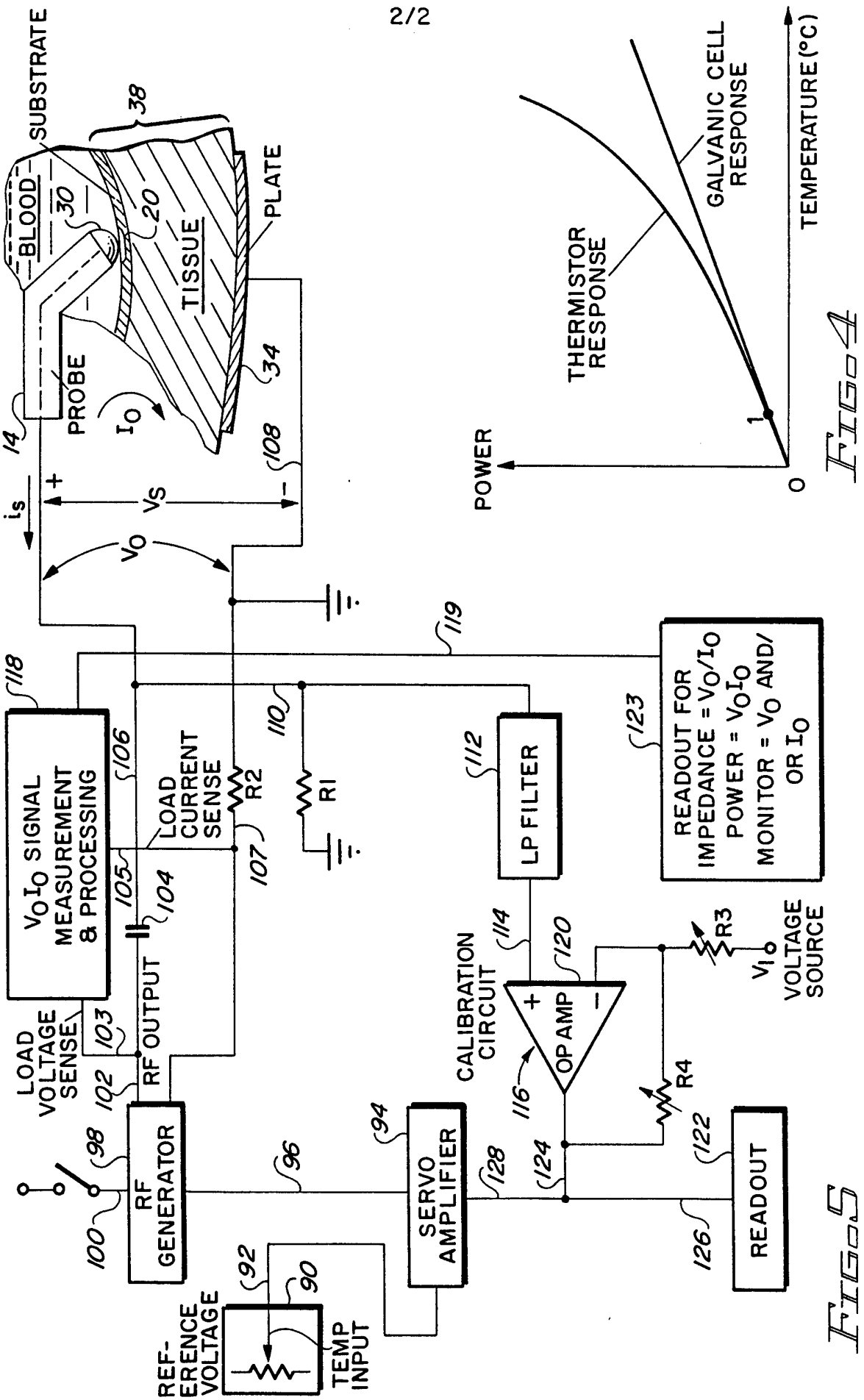

SUBSTRATE
38
BLOOD
30
20
TISSUE
PLATE
PROBE
34
14
108
I_O
i_S
+
V_S
−
V_O
119
118
$V_O I_O$ SIGNAL MEASUREMENT & PROCESSING
106
LOAD CURRENT SENSE
R2
110
R1
107
105
104
LOAD VOLTAGE SENSE
103
RF OUTPUT
102
98
100
RF GENERATOR
96
94
SERVO AMPLIFIER
128
92
90
REF-ERENCE VOLTAGE
TEMP INPUT
112
LP FILTER
123
READOUT FOR IMPEDANCE = V_O/I_O POWER = $V_O I_O$ MONITOR = V_O AND/ OR I_O
114
CALIBRATION CIRCUIT
116
OP AMP
120
R3
V_I
VOLTAGE SOURCE
R4
124
122
READOUT
126
THERMISTOR RESPONSE
GALVANIC CELL RESPONSE
TEMPERATURE (°C)
POWER
1
0

Fig 5

Fig 4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/09818

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 5/0402; A61N 1/05
US CL :128/642, 606/41; 607/75, 99, 122
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)

U.S. : 128/642; 606/41; 607/75, 99, 122

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 practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 4,896,671 (CUNNINGHAM ET AL.) 30 January 1990, see entire document.	1-40
X, P	US, A, 5,454,370 (AVITALL) 03 October 1995, see column 3 line 29 to column 5 line 44.	31, 35-40
X, P	US, A, 5,462,545 (WANG ET AL.) 31 October 1995, see column 3 line 25 to column 8 line 48.	31, 35-40

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"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
"A"	document defining the general state of the art which is not considered to be part of particular relevance	"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
"E"	earlier document published on or after the international filing date	"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
"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)	"&"	document member of the same patent family
"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		

Date of the actual completion of the international search 03 SEPTEMBER 1996	Date of mailing of the international search report 26 SEP 1996
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3590	Authorized officer LEE COHEN Telephone No. (703) 308-2998

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