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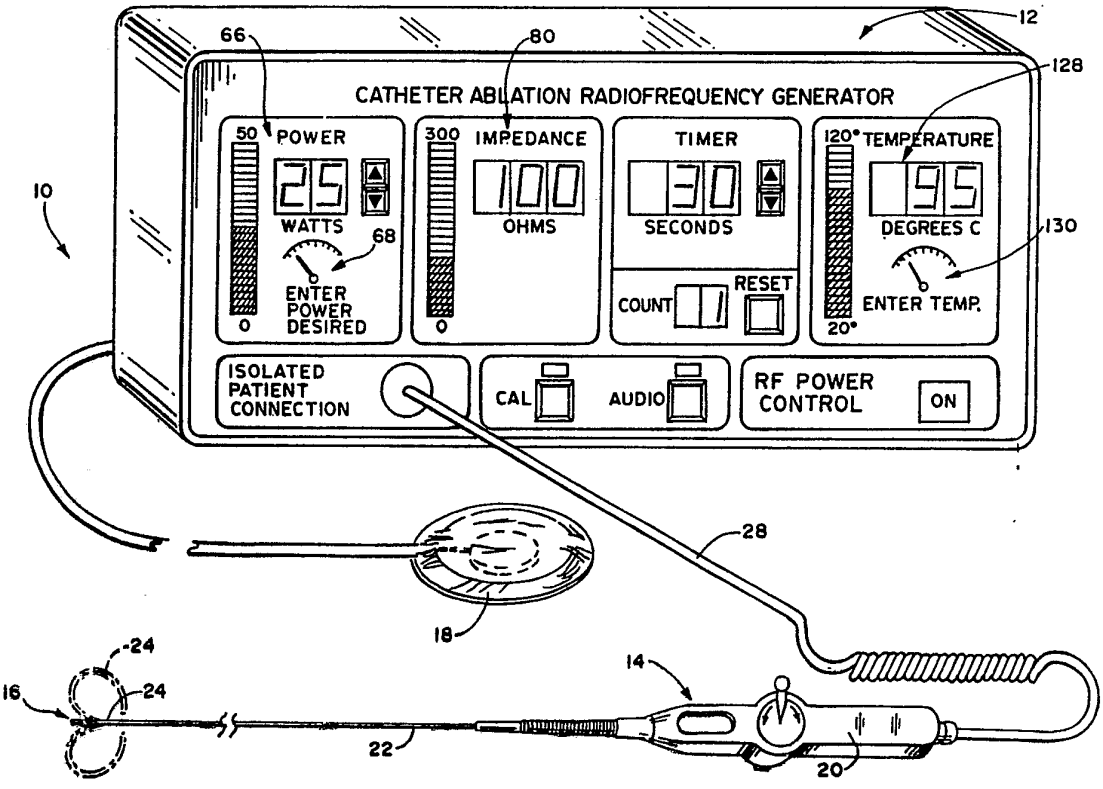
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(54) Title: SYSTEMS AND METHODS FOR ABLATING TISSUE WHILE MONITORING TISSUE IMPEDANCE



(57) Abstract

Systems (10) for ablating tissue measure the current and voltage delivered to the associated electrode assembly (16) and generate measured current and voltage signals. The systems (10) divide the measured voltage signal by the measured current signal to derive a measured tissue impedance signal. The systems (10) perform control functions based upon the measured tissue impedance signal.

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SYSTEMS AND METHODS FOR ABLATING TISSUE WHILE MONITORING TISSUE IMPEDANCE

Field of the Invention

The invention generally relates to catheters and associated power sources. In a more specific sense, the invention relates to ablation catheters that, once steered and manipulated within interior regions of the body, transmit energy to form lesions for therapeutic purposes.

Background of the Invention

Physicians make use of catheters today in medical procedures to gain access into interior regions of the body to ablate targeted tissue areas. It is important for the physician to control carefully and precisely the emission of energy within the body used to ablate the tissue.

The need for careful and precise control over the catheter is especially critical during procedures that ablate tissue within the heart. These procedures, called electrophysiological therapy, are becoming more widespread for treating cardiac rhythm disturbances.

During these procedures, a physician steers a catheter through a main vein or artery (which is

typically the femoral artery) into the interior region of the heart that is to be treated. The physician then further manipulates a steering mechanism to place the electrode carried on the distal tip of the catheter into direct contact with the tissue that is to be ablated. The physician directs radio frequency energy from the electrode tip through the tissue to an indifferent electrode to ablate the tissue and form a lesion.

Cardiac ablation especially requires the ability to precisely monitor and control the emission of energy from the ablation electrode.

Summary of the Invention

The invention provides an improved system for ablating tissue. The system includes source of ablation energy and an electrode assembly connected to the source for emitting the energy at the ablation site.

The system measures the current delivered to the electrode assembly and generates a measured current signal. The system also measures the voltage at the electrode assembly and generates a measured voltage signal.

According to the invention, the system divides the measured voltage signal by the measured current signal to derive a measured tissue impedance signal. The system includes a controller that performs a function based upon the measured tissue impedance signal.

The measured tissue impedance is indicative of certain physiological conditions at the ablation site that might otherwise go undetected.

For example, when the measured tissue impedance signal begins in a predetermined range and, over time, increases beyond it, this suggests the

coagulation of blood on the electrode assembly. The controller generates a control signal when this condition occurs.

As another example, when an incremental increase in the measured tissue impedance signal occurs beyond a prescribed amount, this suggests the onset of coagulation or a sudden shift in the position of the electrode assembly. The controller generates a control signal in response to this condition, too.

As another example, when the measured tissue impedance signal exceeds a predetermined maximum amount, this suggests poor skin contact with the electrode assembly or an electrical problem in the system. The controller generates a control signal.

Depending upon the criteria established by the user, the control signal can serve to interrupt the emission of ablation energy by the electrode assembly. It can also display the measured tissue impedance signal in a user readable format.

In one embodiment, the source generates radiofrequency energy. In this arrangement, the system derives root means squared current and voltage signals based upon the measured radiofrequency current and voltage signals. The system derives the measured tissue impedance signal by dividing the root means squared voltage signal by the root means squared current signal.

Brief Description of the Drawings

Fig. 1 is a perspective view of a system for ablating tissue that embodies the features of the invention;

Fig. 2 is a schematic view of the generator and associated monitor and control circuits for the system;

Fig. 3 is a schematic view of the power mon-

itor and control circuit for the system;

Fig. 4 is a schematic view of the tissue impedance monitor and control circuit for the system;

Figs. 5A and 5B is a schematic view of the tissue temperature monitor and control circuit for the system;

Figs. 6A to C are views of an electrode with thermally insulated temperature sensing element that can be used in associated with the system to measure tissue temperature;

Figs. 7A to C are views of an electrode with multiple thermally insulated temperature sensing elements that can be used in associated with the system to measure tissue temperature; and

Figs. 8A to C are views of an electrode specially shaped to use in heart valve regions and having multiple thermally insulated temperature sensing elements that can be used in association with the system to measure tissue temperature.

Description of the Preferred Embodiments

Fig. 1 shows a system 10 for performing ablation on human tissue that embodies the features of the invention. The system 10 includes a radiofrequency generator 12 that delivers radiofrequency energy. The system 10 also includes a steerable catheter 14 carrying a radiofrequency emitting tip electrode 16.

In the illustrated embodiment, the system 10 operates in a monopolar mode. In this arrangement, the system 10 includes a skin patch electrode that serves as an indifferent second electrode 18. In use, the indifferent electrode 18 attaches to the patient's back or other exterior skin area.

Alternatively, the system 10 can be operated in a bipolar mode. In this mode, the catheter 14 car-

ries both electrodes.

In the illustrated embodiment, the ablation electrode 16 and indifferent electrodes 18 are made of platinum.

The system 10 can be used in many different environments. This specification describes the system 10 when used to provide cardiac ablation therapy.

When used for this purpose, a physician steers the catheter 14 through a main vein or artery (typically the femoral artery) into the interior region of the heart that is to be treated. The physician then further manipulates the catheter 14 to place the tip electrode 16 into contact with the tissue within the heart that is targeted for ablation. The user directs radio frequency energy from the generator 12 into the tip electrode 16 to form a lesion on the contacted tissue.

In the embodiment shown in Fig.1, the catheter 14 includes a handle 20, a guide tube 22, and a tip 24, which carries the tip electrode 16 (which also will be called the ablation electrode). The handle 20 encloses a steering mechanism 26 for the catheter tip 24. A cable 28 extending from the rear of the handle 20 has plugs (not shown). The plugs connect the catheter 14 to the generator 12 for conveying radiofrequency energy to the ablation electrode 16. The radiofrequency heats the tissue to form the lesion.

Left and right steering wires (not shown) extend through the guide tube 22 to interconnect the steering mechanism 26 to the left and right sides of the tip 24. Rotating the steering mechanism 26 to the left pulls on the left steering wire, causing the tip 24 to bend to the left. Also, rotating the steering mechanism 26 to the right pulls on the right steering

wire, causing the tip 24 to bend to the right. In this way, the physician steers the ablation electrode 16 into contact with the tissue to be ablated.

The generator 12 includes a radiofrequency power source 30 connected through a main isolation transformer 32 to first and second conducting lines 34 and 36.

In the illustrated environment, the power source 30 delivers up to 50 watts of power at a frequency of 500 kHz. The first conducting line 34 leads to the ablation electrode 16. The second conducting line 36 leads to the indifferent patch electrode 18.

Monitoring Actual and Apparent Radiofrequency Power

As Figs. 2 and 3 show, the system 10 includes first monitoring means 38 for measuring the radiofrequency current and radiofrequency voltage delivered by the generator 12 to the patient. The first monitoring means 38 also derives control signals indicative of RMS (root mean squared) voltage (in volts), RMS current (in amps), and actual phase sensitive power (in watts) to support other control functions of the generator 12.

The first monitoring means 38 may be variously configured and constructed. In the illustrated embodiment, the first monitoring means 38 includes current monitoring means 40 for measuring the radiofrequency current passing from the first line 34 through the tissue to the second line 36 (i.e., from the ablation electrode 16 to the indifferent patch electrode 18).

The first monitoring means 38 also includes voltage monitoring means 42. The voltage monitoring means 42 measures the radiofrequency voltage generated between the first and second conducting lines 34 and

36 (i.e., between the ablation electrode 16 and the indifferent patch electrode 18).

The first monitoring means 38 includes three control outputs 44, 46, and 48.

The first control output 44 carries a signal representative of RMS current conducted by the ablation electrode 16.

The second control output 46 carries a signal representative of the RMS voltage between the ablation electrode 16 and the indifferent patch electrode 18.

The third control output 48 carries a signal representative of actual phase sensitive power transmitted by the ablation electrode 16.

In the illustrated embodiment (as Figs. 2 and 3 show), the current monitoring means 40 includes an isolated current sensing transformer 50 connected in the second conducting line 36. In this arrangement, the current sensing transformer 50 directly measures the radiofrequency current passing through the ablation electrode 16 to the indifferent patch electrode 18.

The measured value is a radiofrequency signal varying at the selected rate, which in the illustrated embodiment is 500 kHz.

The current sensing transformer 50 is connected to the first control output 44, which derives RMS current. The first control output 44 includes an integrated circuit RMS converter 52 to do this function. The RMS current converter first squares the radiofrequency current input signal from the current sensing transformer 50, and then averages the squared signal over a user prescribed period (which in the illustrated embodiment is about once every 0.01 second). The RMS current converter 52 then takes the

square root of the average squared value. The resulting output represents RMS current.

The RMS current signal takes the form of a relatively slowly varying signal, compared with the rapidly varying radiofrequency current input signal.

As Figs. 2 and 3 show, the voltage monitoring means 42 includes an isolated voltage sensing transformer 54 that is connected between the first and second conducting lines. In this arrangement, the voltage sensing transformer 54 directly measures the radiofrequency voltage across the body tissue between the ablation electrode 16 and the indifferent patch electrode 18.

Like the value measured by the current sensing transformer 50, the measured voltage value is a radiofrequency signal varying at the selected 500 kHz rate.

The voltage sensing transformer 54 is connected to the second control output 46, which derives RMS voltage. The second control output 46 includes an integrated circuit RMS converter 56 to do this function. The RMS voltage converter 56 squares the radiofrequency voltage input signal and then averages it over the same user prescribed period used by the current converter 52. The RMS voltage converter 56 then takes the square root of the average squared voltage value.

The resulting RMS voltage signal (like the RMS current signal) takes the form of a relatively slowly varying signal.

The voltage sensing transformer 54 is also connected to the third control output 48, which derives actual phase sensitive power. The third control output 48 includes an analog multiplier integrated circuit 58 to do this function. The multi-

plier circuit 58 receives as one input the radiofrequency input current signal directly from the current sensing transformer 50. The multiplier circuit 58 also receives as a second input the radiofrequency input voltage signal directly from the voltage sensing transformer 54.

The output of the multiplier circuit 58 is the product of these two inputs, which represents the actual radiofrequency power transmitted by the ablation electrode 16.

The power value is (like its component current and voltage inputs) a radiofrequency signal varying at a relatively high radiofrequency rate.

The third control output 48 also includes a low pass filter 60. In the illustrated embodiment, which operates with a radiofrequency rate of 500 kHz, the cut off frequency of the filter 60 selected is about 100 Hz. The rapidly varying measured input power value is low pass filtered by the filter 60 into a relatively slowly varying signal.

This signal represents the actual phase sensitive power signal of the radiofrequency energy that the ablation electrode 16 delivers to the targeted tissue.

The first, second, and third control outputs 44, 46, and 48 each includes appropriate inline scaling circuits 62. The scaling circuits 62 scale the RMS current signal, the RMS voltage signal, and the actual phase sensitive power signal to a specified voltage range that can be usable by the remainder of generator 12 circuitry. In the illustrated embodiment, the scaled range is 0.0 to 5.0 volts.

The first monitoring means 38 also includes an analog to digital converter 64. The converter 64 digitizes a selected one or more of the analog RMS

current output signal, RMS voltage output signal, and the actual phase sensitive power signal.

The digital output(s) of the converter 64 can be used to display measurement results. In the illustrated embodiment, the system 10 includes a first digital display 66 on the generator 12 to show the user the actual phase sensitive power signal.

The digital output(s) of the converter 64 also can be used to control operation of the generator 12. In the illustrated embodiment, the system 10 uses the digitized outputs in a feedback loop that maintains radiofrequency output voltage within a desired range or at a constant value to control radiofrequency power at the ablation electrode 16. By controlling the power delivered by the generator 12, the physician can reproducibly form lesions of the desired depth during an ablation procedure.

In this arrangement, the system 10 includes an input 68 for the user to enter an operating value desired for the actual phase sensitive power for the generator 12. The system 10 includes power control means 70 that includes comparator 71 to compare desired power with actual phase sensitive power. The output of the comparator varies the output voltage of radiofrequency power source 30 to maintain minimum error between the measured actual power and the set point power.

In the illustrated embodiment, the power control means 70 also monitors phase differences between radiofrequency voltage and current. The power control means 70 does this function by computing apparent power and by comparing the computed apparent power to the actual phase sensitive power. If the radiofrequency voltage and current signals are exactly in phase, the apparent power and actual phase sensi-

tive power will be the same. However, if there is a phase difference, actual phase sensitive power will differ from the apparent power by a factor that represents the cosine of the phase angle.

In the illustrated embodiment, the power control means 70 includes a multiplier circuit 72 that obtains the product of the RMS current and RMS voltage. The resulting output of the multiplier circuit 72 forms the apparent (i.e., not phase sensitive) power of the system 10. The power control means 70 includes a comparator 74 to compare the derived apparent power with the actual phase sensitive power. The magnitude of the output of the comparator 74 quantifies the amount of the phase shift.

If the output of the phase shift comparator 74 exceeds a preselected amount, the power control means 70 generates a warning signal to show that a phase shift between the radiofrequency voltage and current has occurred. The system 10 may include a flashing light and audible alarm (not shown) to warn the user.

The power control means 70 operates to maintain a constant set power when the output of the phase shift comparator 74 remains within an allowable range above the threshold amount. The power control means 70 operates to reduce the output voltage of the source 30 when the output of the phase shift comparator 74 increases beyond this range. If the output of the phase shift comparator 74 shows a phase shift beyond a maximum threshold value, the power control means 70 generates a signal to shut off all power to the ablation electrode 16.

Monitoring Tissue Impedance

As Fig. 4 shows, the system 10 further includes second monitoring means 76 for deriving the im-

pedance of the tissue undergoing ablation. The second monitoring means 76 derives tissue impedance not only in absolute terms, but it also serves to record changes in tissue impedance over time.

The second monitoring means 76 generates appropriate control signals based upon observed absolute values of tissue impedance as well as sensed changes according to preprogrammed criteria.

The second monitoring means 76 may be variously configured and constructed. In the illustrated embodiment, the second monitoring means 76 includes a microprocessor 78. The microprocessor 78 samples the digitized outputs of the analog-to-digital converter 64 at prescribed intervals (for example, every 20 milliseconds, which represents a 50 Hz sampling rate).

The microprocessor 78 also divides the sampled digitized RMS voltage signal by the sampled digitized RMS current signal. The digital result is the tissue impedance (in ohms) for the sample. Preferably, the system 10 includes a second display 80 on the generator 12 that shows the user the sampled tissue impedance.

The microprocessor 78 also maintains a record of sampled tissue impedances over time. From this record, the microprocessor 78 calculates the changes in tissue impedance during a selected interval and generates appropriate control signals based upon predetermined criteria.

The predetermined criteria under which the microprocessor 78 generates the control signals based upon tissue impedance can vary. Preferably, the tissue impedance control signals are used to augment the monitoring and control functions of the power control means 70 just described.

In the illustrated embodiment, if measured tissue impedance falls outside a predetermined set range, the microprocessor 78 generates a command signal to shut off power to the ablation electrode 16, whatever the actual phase sensitive power level sensed. The set range for tissue impedance for a cardiac ablation procedure is believed to be about 50 to 300 ohms.

When tissue impedance begins in the set range and, over time, increases beyond it, the most likely cause is the coagulation of blood on the ablation electrode 16. A sudden rise in tissue impedance over the set range suggests the sudden onset of coagulation or a sudden shift in the position of the ablation electrode 16. Rapid fluctuations of the tissue impedance also could suggest poor contact between the ablation electrode 16 and the targeted tissue. All require prompt response; for example, withdrawal and cleaning of the ablation electrode 16, or repositioning of the ablation electrode 16.

The system 10 preferably includes flashing lights and an audible alarm (not shown) to transmit a warning to the user when these conditions occur.

A very high tissue impedance value could suggest poor skin contact with the indifferent electrode 18, or an electrical problem in the system 10. Again, this calls for prompt corrective action.

If tissue impedance remains within the set range, but rises beyond a prescribed amount within the range, the second monitoring means 76 generates a control signal that reduces but does not interrupt, the power output. In this arrangement, a relatively tight range of tissue impedance can be established (for example, 80 to 150 ohms) to maintain relatively constant power within this range.

Monitoring Tissue Temperature

As Fig. 5 shows, the system 10 includes third monitoring means 82 for sensing the temperature of the tissue in contact with the ablation electrode 16. The third monitoring means 82 includes temperature sensing means 84 carried in the ablation electrode 16. The system 10 also includes control means 86 for the generator 12 that is responsive to the sensed tissue temperature for performing generator control functions.

Thermal insulation means 88 thermally isolates the temperature sensing means 84 from the thermal mass of the ablation electrode 16. Thus, the temperature sensing means 84 does not add to or serve as a part of the thermal mass of the ablation electrode 16. It serves to show the true temperature of the tissue with which it is in contact, without adding to the thermal mass of the ablation electrode 16 and without being influenced by the temperature of the surrounding thermal mass of the ablation electrode 16.

In the embodiment illustrated in Figs. 6A to C, the ablation electrode 16 includes an interior well 90 at its tip end 92. The temperature sensing means 84 occupies this well.

In this arrangement, the thermal insulating means 88 isolates the temperature sensing means 84 from the interior surface of the well 90 and the rest of the thermal mass of the ablation electrode 16.

In Figs. 6A to C, the temperature sensing means 84 includes a small bead thermistor 94 with two associated lead wires 96 and 98. The temperature sensing tip of the thermistor 94 is exposed at the tip end 92 of the ablation electrode 16 for tissue contact.

In the illustrated embodiment (see Figs. 6A

to C), the third monitoring means 82 includes means 132 for calibrating the thermistor 94 to account for deviations in nominal resistance among different thermistors 94. During manufacture of the catheter 10, the resistance of thermistor 94 is measured at a known temperature; for example, 75 degrees C. A calibration resistor 134 equal to the measured value is incorporated into the catheter handle 20. The leads of the calibration resistor 134 are connected to the third monitoring means 82.

The thermistor 94 of the type shown is commercially available from the Fenwal Co. (Massachusetts) under the trade designation 111-202CAK-BD1. The lead wires 96 and 98 comprise #36 AWG signal wire Cu+ clad steel (heavy insulation).

Potting compound 100 encapsulates the thermistor 94 and lead wires 96 and 98 within the electrode well. Insulating sheathes 102 also shields the encapsulated lead wires 96 and 98. Together, the compound 100 and sheathes 102 electrically insulate the thermistor 94 from the surrounding ablation electrode 16.

The potting compound 100 and insulation sheathes 102 can be made with various materials. In the illustrated embodiment, loctite adhesive serves as the potting compound 100, although cyanoacrylate adhesive or RTV adhesive and the like could be used. The sheathes 102 are made from polymide material, although other conventional electrical insulating materials also can be used.

In the illustrated embodiment, the thermal insulating means 88 comprises a tube 104 that envelopes the encapsulated thermistor 94 and lead wires 96 and 98. The thermal insulation tube 104 is itself adhesive bonded to the interior wall of the well 90.

The thermal insulating material of the tube 104 can vary. In the illustrated embodiment, it is a polymide material having a wall thickness of about .003 inch. Other thermal insulating materials like mylar or kapton could be used.

The lead wires 96 and 98 for the thermistor 94 extend from the electrode well 90 through the guide tube 22 and into the catheter handle 20. There, the lead wires 96 and 98 electrically couple to the cable 28 extending from the handle 20. A cable plug (not shown) connects to the generator 12 and transmits the temperature signal from the thermistor 94 to the third monitoring means 82.

Figs. 7A to C show an alternate embodiment of an ablation electrode 16 having an array of temperature sensing means 84. At least one temperature sensing means 84, and preferably all of them, are thermally isolated from the ablation electrode 16 in the manner shown in Figs 6A to C.

As Figs. 7A to C show, the ablation electrode 16 in the multiple array version includes an interior core well 106. Five branch wells 108A to E extend from the core well 106. The branch wells 108A to E open at the surface of the ablation electrode 16. One branch well 108A opens at the tip of the ablation electrode 16, like the single temperature sensing means 84 shown in Figs. 6A to C. The other four branch wells 100B to E extend at an angle from the core well 106 at arcuate intervals of 45 degrees. The four branch wells 108B to E open at the side of ablation electrode 16 and encircle the tip well branch 100A.

A temperature sensing means 84 occupies each branch well 108A to E. In the illustrated and preferred embodiment, a thermal insulating means 88

isolates each temperature sensing means 84 from the interior surface of the associated branch well 108A to E and the remaining thermal mass of the ablation electrode 16.

As in the embodiment shown in Figs. 6A to C, each thermal sensing means 84 includes a small bead thermistor 94 with two associated lead wires 96 and 98. The temperature sensing tips of the thermistors 94 are exposed at the tip of the ablation electrode 16 for multiple contact with the tissue. The associated lead wires 96 and 98 are bundled within the center core well 106 and pass through the guide tube 22 to the handle 20.

As in the embodiment shown in Figs. 6A to C, potting compound 100 encapsulates each thermistor 94 and its lead wires 96 and 98 within the associated branch well. Insulating sheathes 102 also shield the encapsulated lead wires 96 and 98. Together, the compound 100 and sheathes 102 electrically insulate each thermistor 94 from the surrounding ablation electrode 16.

As in the embodiment shown in Figs. 6A to C, a thermal insulating tube 104 envelopes each electrically encapsulated thermistor 94 and its lead wires 96 and 98. And, as in the Figs 6A to C embodiment, adhesive bonds each thermal insulation tube 104 to the interior wall of each branch well 108A to E.

Figs. 8A to C show another alternate embodiment of an ablation electrode 16 having multiple temperature sensing means 84.

In the arrangement shown in Figs. 8A to C, the ablation electrode 16 includes a forward electrode region 110 and a rear electrode region 112. The forward electrode region 110 and the rear electrode re-

gion 112 are generally spherical in shape.

An electrical and thermal insulating sleeve 114 separates the forward electrode region 110 and the rear electrode region 112. The sleeve 114 is generally cylindrical in shape. The resulting "peanut" shape is well suited for use within the valve regions of the heart.

In the illustrated embodiment, the forward electrode region 110 and the rear electrode region 112 are made of platinum. The sleeve 114 is made of a polysulfone material.

Multiple temperature sensing means 84 occupy the surface of each forward and rear electrode region 110 and 112. At least one, and preferably all, the temperature sensing means 84 are thermally isolated from the remainder of the surrounding body of the associated electrode region 110 and 112.

Each electrode region 110 and 112 includes an interior core well 116 and branch wells 118 that open at the surface of the associated electrode region 110 and 112. A temperature sensing means 84 occupies each well branch. In the illustrated and preferred embodiment, thermal insulating means 88 also isolates each temperature sensing means 84 from the interior surface of the associated branch well 116 and 118 and the rest of the thermal mass of the electrode region 110 and 112.

As in the embodiment shown in Figs. 6A to C, each thermal sensing means 84 includes a small bead thermistor 94 with two associated lead wires 96 and 98. The temperature sensing tips of the thermistors 94 are exposed at the surface of the associated electrode regions 110 and 112 for multiple contact with the tissue. The associated lead wires 96 and 98 are bundled in the center core well 116, passing

through the guide tube 22 to the handle 20.

As in the previous embodiments, potting compound 100 encapsulates each thermistor 94 and its lead wires 96 and 98 within the associated branch well 116 and 118. Insulating sheathes 102 also shield the encapsulated lead wires 96 and 98. Also as in the previous embodiments, a thermal insulating tube 104 envelopes each electrically encapsulated thermistor 94 and its lead wires 96 and 98. Adhesive bonds the thermal insulation tube 104 to the interior wall of each branch well 116 and 118.

The number and arrangement of possible arrays of multiple temperature sensing means 84 can, of course, vary from the specific configurations shown in Figs. 6, 7, and 8. For example, one or more temperature sensing means 84 can occupy the side region of the ablation electrode 16, below its tip. The branch wells holding the temperature sensing means 84 also can extend from the center well at various angles, acute, obtuse, or perpendicular. Not all the temperature sensing means 84 need be thermally isolated from the electrode 16, but preferable they all are.

As Fig. 5 shows, the third monitoring means 82 can perform different display and control functions in response to sensed temperature conditions according to different prescribed criteria.

Preferably, the third monitoring means 82 responds to sensed tissue temperature not only in absolute terms, but it also serves to record changes in tissue temperature over time and respond to these changes as well.

In the illustrated embodiment, the third monitoring means 82 includes a control output 120 for each temperature sensing means 84 carried by the as-

sociated ablation electrode 16.

The lead wires 96 and 98 for each thermistor 94 provide the input for the control outputs 120. Alternatively, when the ablation electrode 16 carries multiple thermistors 94, the number of lead wires 96 and 98 traversing the guide tube 22 can be minimized by providing an integrated circuit 122 within the third monitoring means 82 for multiplexing the input signals of the thermistors 94.

In the illustrated embodiment, the third monitoring means 82 includes a converter 124 to obtain an average temperature for each grouped array of thermistors 94 during a user prescribed period (which in the illustrated embodiment is about once every 0.01 second).

The embodiment shown in Figs. 6A to C includes one thermistor 94, so the input signal and the average will be the same.

The embodiment shown in Figs. 7A to C includes a single grouped array of five thermistors 94 clustered at the tip of the ablation electrode 16. For this array, the converter adds the individual input signals and divides by five.

The embodiment shown in Figs. 8A to C includes two grouped arrays, one having five thermistors 94 on the forward electrode region 110, the other having four thermistors 94 on the rear electrode region 112. The converter 124 adds the input signals for each grouped array and divides by the associated number of thermistors 94 in each grouped array to obtain an average for the forward electrode region 110 and a separate average for the rear electrode region 112.

The third monitoring means 82 includes an analog to digital converter 126. The converter 126

digitizes the sensed temperature average(s) for the system 10.

The converter 126 also digitizes the value of the calibration resistor 134. The thermistor resistance value is divided by the calibration resistor value to get a normalized resistance for the thermistor 94. This value is the input to a read only memory (ROM) 136 (see Fig. 5B) containing stored thermistor temperature data. The ROM 136 output is the actual measured tissue temperature (in degrees C), taking into account deviations in the nominal resistance of the thermistor 94.

Although not shown in the drawings, the embodiments having multiple thermistors 94 would include an equal number of calibration resistors 134, one for each thermistor 94.

The digital output(s) of the converter can be used to display measurement results. In the illustrated embodiment, the system 10 includes a third digital display 128 on the generator 12 to show the user the average sensed temperature.

If the "peanut" type electrode shown in Figs. 8A to C is used, the system 10 includes a separate display for the forward and rear electrode region 110 and 112.

The digital output(s) of the converter 126 also can be used to control operation of the generator 12. Preferably, the temperature control signals of the third monitoring means 82 also are used to further augment the function of the first and second monitoring means 38 and 76 previously described.

In the illustrated embodiment, the system 10 uses the digitized temperature outputs in a feedback loop that maintains radiofrequency output voltage within a desired range or at a constant value to con-

trol radiofrequency power at the ablation electrode 16. By controlling the power delivered by the generator 12 based upon temperature, the physician is able to control the size of the lesion generated.

For this purpose, the system 10 includes an input 130 for the user to enter an operating value desired for the tissue temperature.

If tissue temperature remains within a preset range, but deviates a prescribed amount within the range, the third monitoring means 82 generates a control signal that either increases or reduces but does not interrupt, the power output. If the tissue temperature rises, the control signal reduces the power output. If the tissue temperature falls, the control signal increases the power output. If measured tissue temperature falls outside the preset range, the third monitoring means 82 generates a command signal to shut off power to the ablation electrode 16. A representative set range for tissue temperature for cardiac ablation is believed to be about 40 degrees to 100 degrees C.

When temperature begins in the set range and, over time, fall outside it, the most likely cause is the coagulation of blood on the ablation electrode 16, requiring withdrawal and cleaning of the ablation electrode 16. A sudden change in tissue temperature outside the set range suggests a shift in the position of the ablation electrode 16, requiring repositioning of the ablation electrode 16.

The system 10 preferably includes flashing lights and an audible alarm (not shown) to transmit a warning to the user when these temperature- based conditions occur.

The system 10 as described can provide precise control over the ablation procedure. The moni-

toring and control of actual phase sensitive power assure the effective distribution of radiofrequency to the ablation electrode 16. The monitoring and control of tissue impedance and tissue temperature, either separately or in combination, set safe physiological limits in terms of lesion size and detection of coagulation. Monitoring and control of tissue impedance and/or tissue temperature also provide information regarding orientation of the ablation electrode 16.

Claims:

We Claim:

1. A system for ablating tissue comprising a source of ablation energy,

electrode means electrically connected to the source for emitting the energy at the ablation site,

current monitoring means for measuring the current delivered to the electrode means and generating a measured current signal,

voltage monitoring means for measuring voltage at the electrode means and generating a measured voltage signal,

means for dividing the measured voltage signal by the measured current signal to derive a measured tissue impedance signal, and

control means for performing a function based upon the measured tissue impedance signal.

2. A system according to claim 1

wherein the control means calculates changes in the measured tissue impedance signals during a selected interval and generates control signals based upon predetermined criteria.

3. A system according to claim 1

wherein the control means generates a command signal to interrupt energy to the electrode means when the measured tissue impedance signal falls outside a predetermined range.

4. A system according to claim 3

wherein the predetermined range is about 50 to 300 ohms.

5. A system according to claim 1

wherein the control means generates a control signal when the measured tissue impedance signal begins in a predetermined range and, over time,

increases beyond it, suggesting coagulation of blood on the electrode means.

6. A system according to claim 1

wherein the control means generates a control signal in response to an incremental increase in the measured tissue impedance signal beyond a prescribed amount, suggesting the onset of coagulation or a sudden shift in the position of the electrode means.

7. A system according to claim 1

wherein the control means generates a control signal when the measured tissue impedance signal exceeds a predetermined maximum amount, suggesting poor skin contact with the electrode means or an electrical problem in the system.

8. A system according to claim 1

wherein the source generates radiofrequency energy,

and further including

means for deriving a root means squared current signal based upon the measured radiofrequency current signal,

means for deriving a root means squared voltage signal based upon the measured radiofrequency voltage signal, and

wherein the measured tissue impedance signal is derived by dividing the root means squared voltage signal by the root means squared current signal.

9. A system according to claim 1

wherein the control means includes display mean for indicating the measured tissue impedance signal in a user readable format.

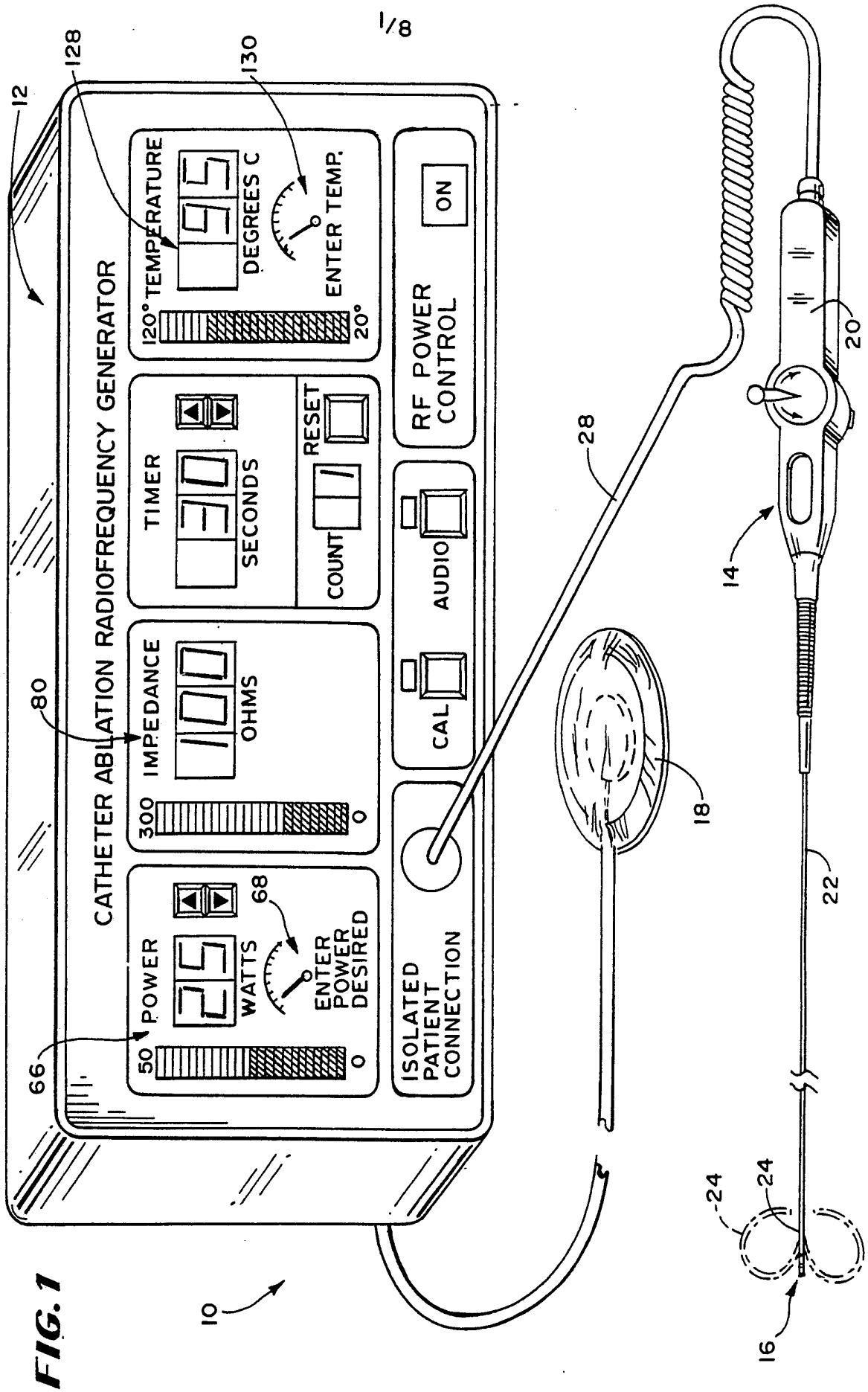

CATHETER ABLATION RADIOFREQUENCY GENERATOR
120° TEMPERATURE
95
DEGREES C
ENTER TEMP.
20°
TIMER
30
SECONDS
RESET
COUNT
1
RF POWER CONTROL
ON
IMPEDANCE
100
OHMS
300
0
CAL
AUDIO
POWER
25
WATTS
ENTER POWER DESIRED
50
0
ISOLATED PATIENT CONNECTION
12
128
130
80
66
68
10
28
18
14
20
22
24
24
16

FIG. 1

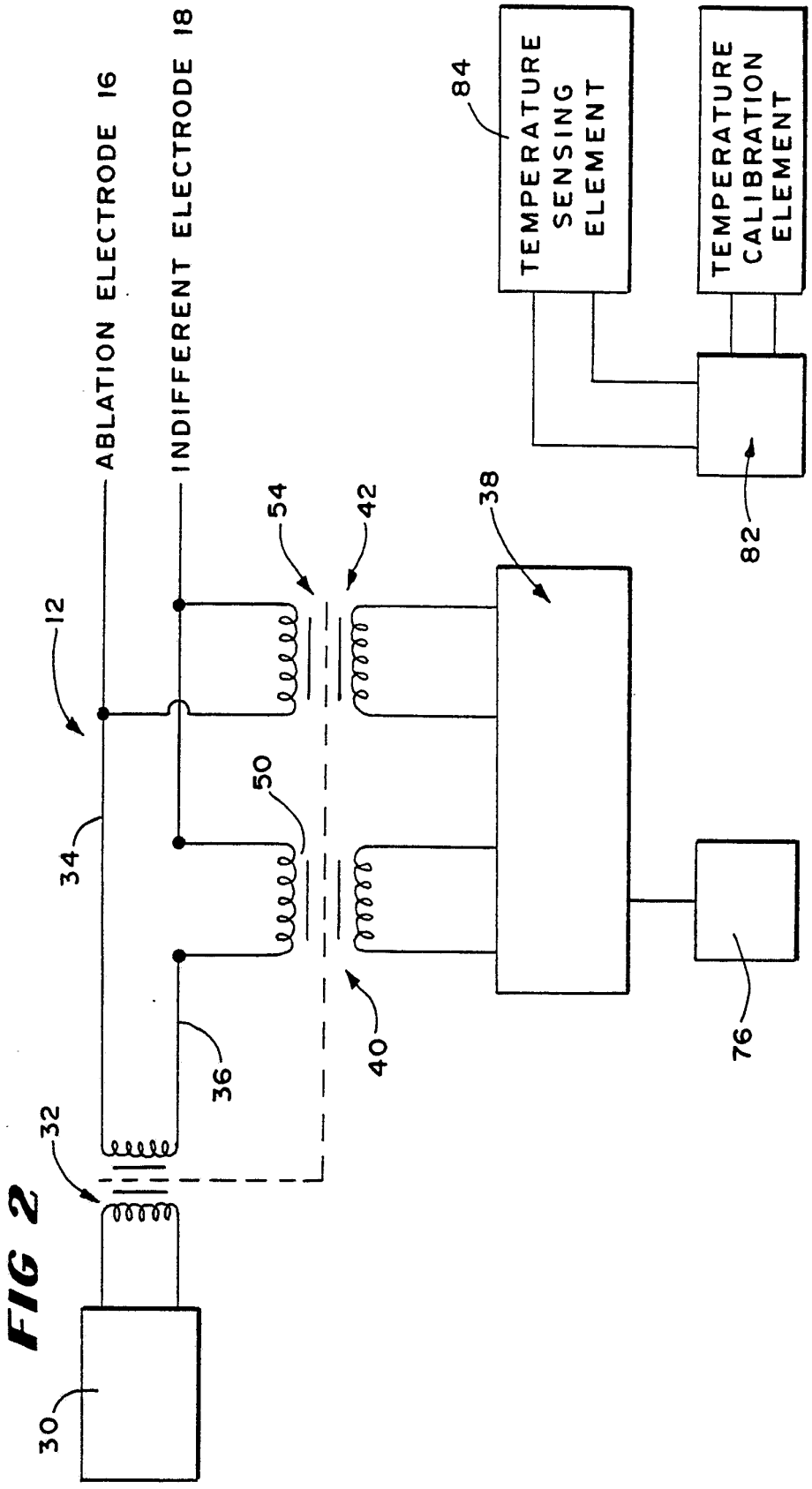

ABLATION ELECTRODE 16
INDIFFERENT ELECTRODE 18
TEMPERATURE SENSING ELEMENT
TEMPERATURE CALIBRATION ELEMENT
84
82
38
54
42
12
50
34
36
40
32
30
76

FIG 2

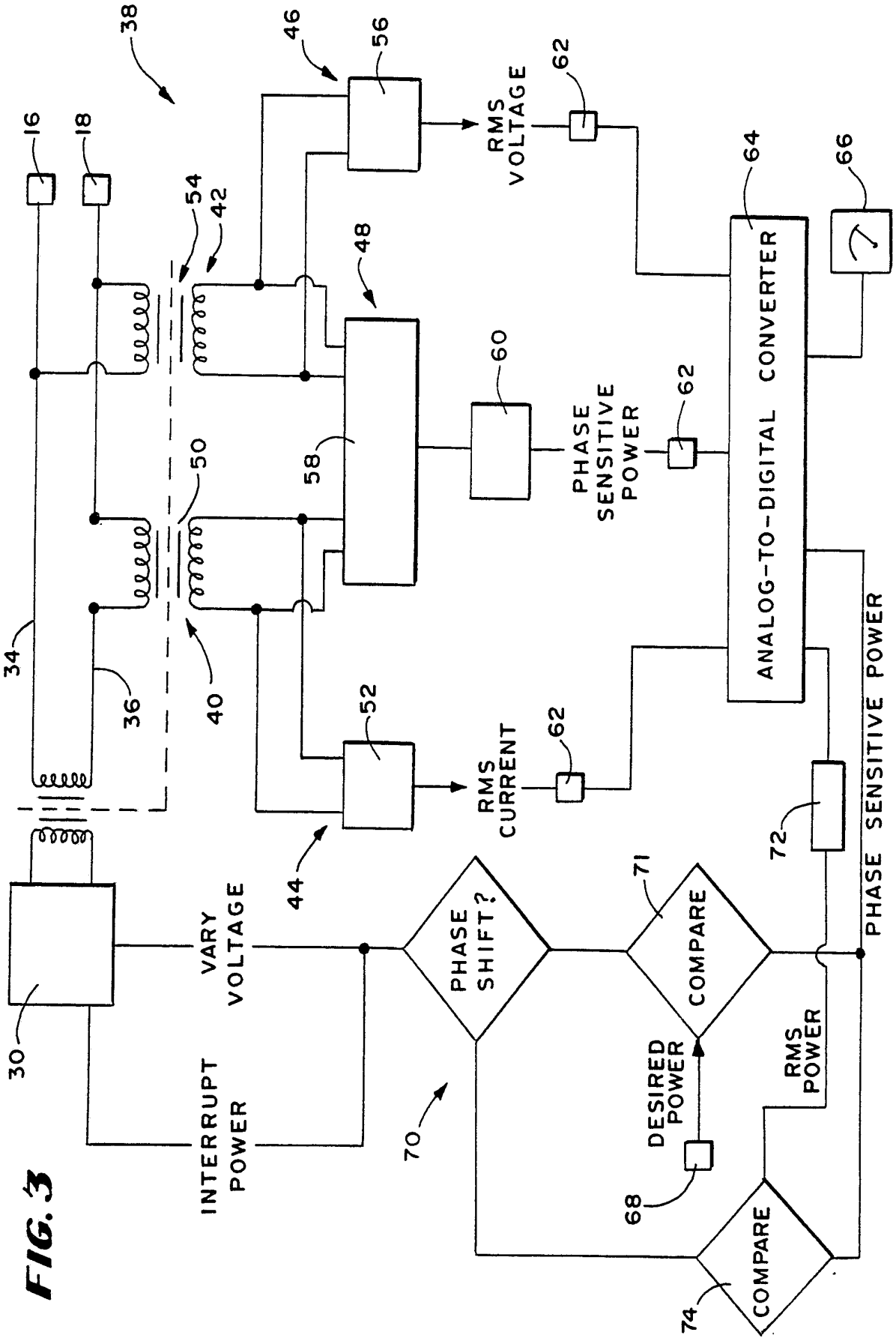

38
46
56
RMS VOLTAGE
62
16
18
54
42
48
64
66
ANALOG-TO-DIGITAL CONVERTER
60
PHASE SENSITIVE POWER
62
58
50
34
36
40
52
RMS CURRENT
62
72
PHASE SENSITIVE POWER
44
71
VARY VOLTAGE
PHASE SHIFT?
COMPARE
30
INTERRUPT POWER
70
DESIRED POWER
RMS POWER
68
COMPARE
74

FIG. 3

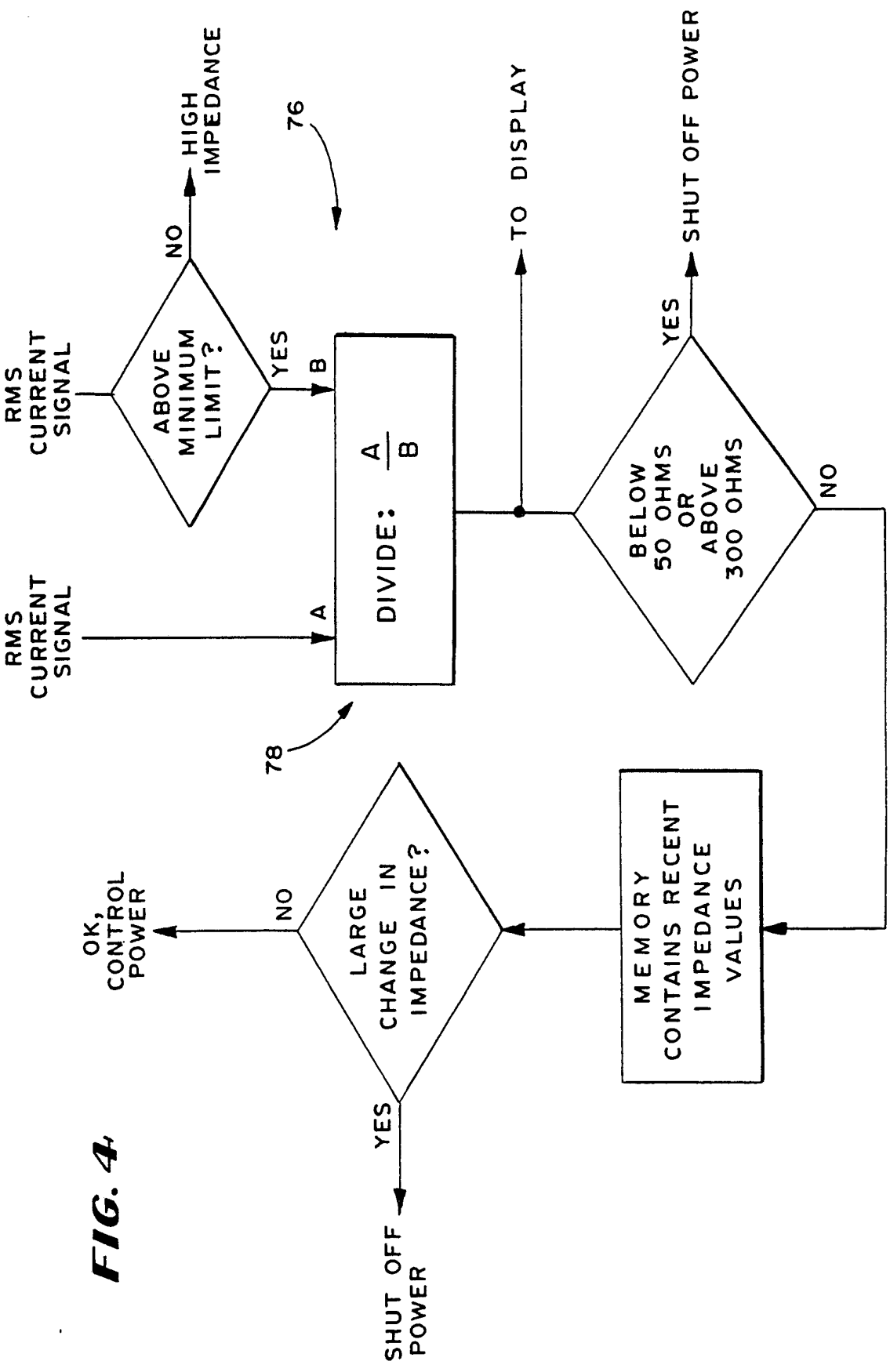

RMS CURRENT SIGNAL
ABOVE MINIMUM LIMIT?
NO
HIGH IMPEDANCE
YES
B
76
RMS CURRENT SIGNAL
A
DIVIDE: A/B
78
TO DISPLAY
BELOW 50 OHMS OR ABOVE 300 OHMS
YES
SHUT OFF POWER
NO
MEMORY CONTAINS RECENT IMPEDANCE VALUES
LARGE CHANGE IN IMPEDANCE?
NO
OK, CONTROL POWER
YES
SHUT OFF POWER

FIG. 4

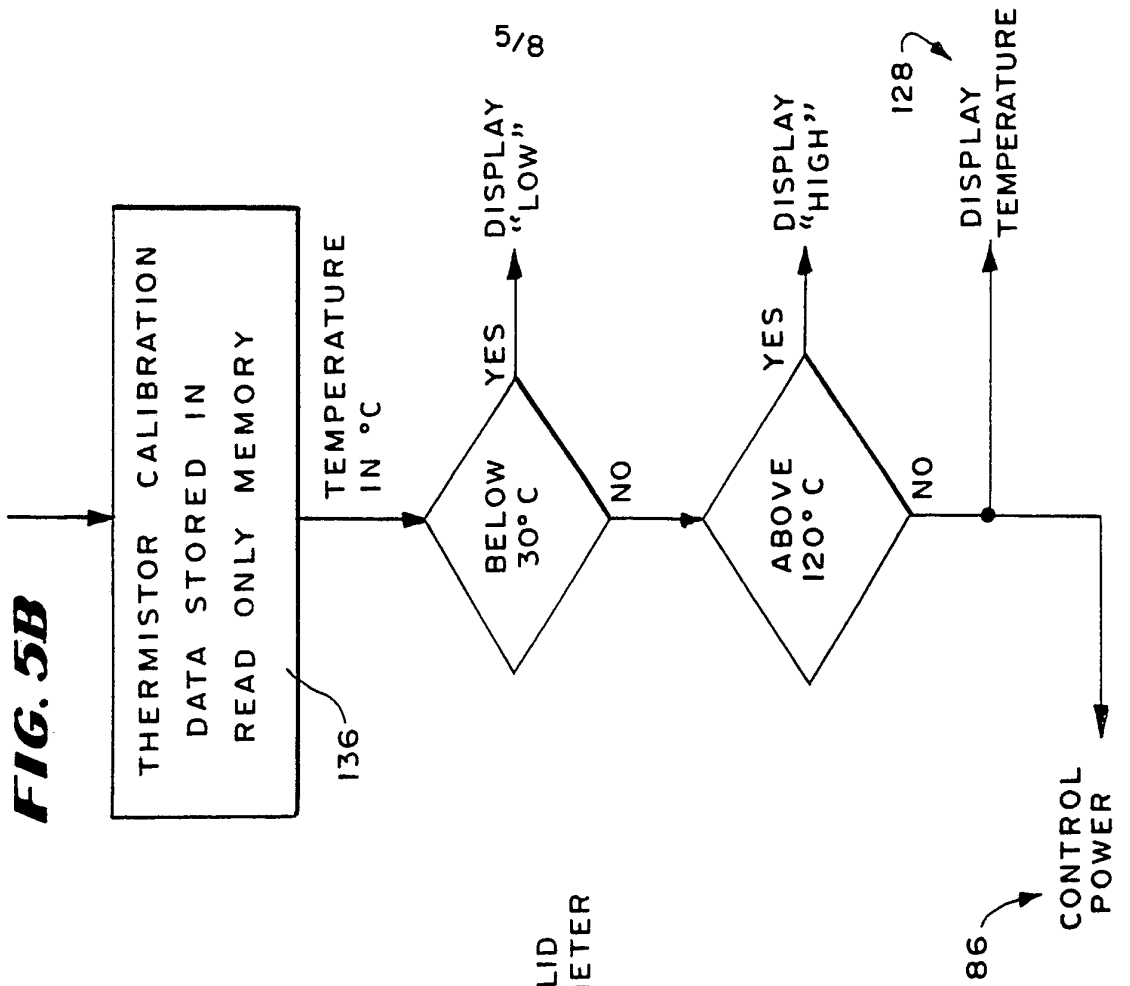

THERMISTOR CALIBRATION DATA STORED IN READ ONLY MEMORY
136
TEMPERATURE IN °C
BELOW 30° C
YES
DISPLAY "LOW"
NO
ABOVE 120° C
YES
DISPLAY "HIGH"
NO
128
DISPLAY TEMPERATURE
CONTROL POWER
86

FIG. 5B

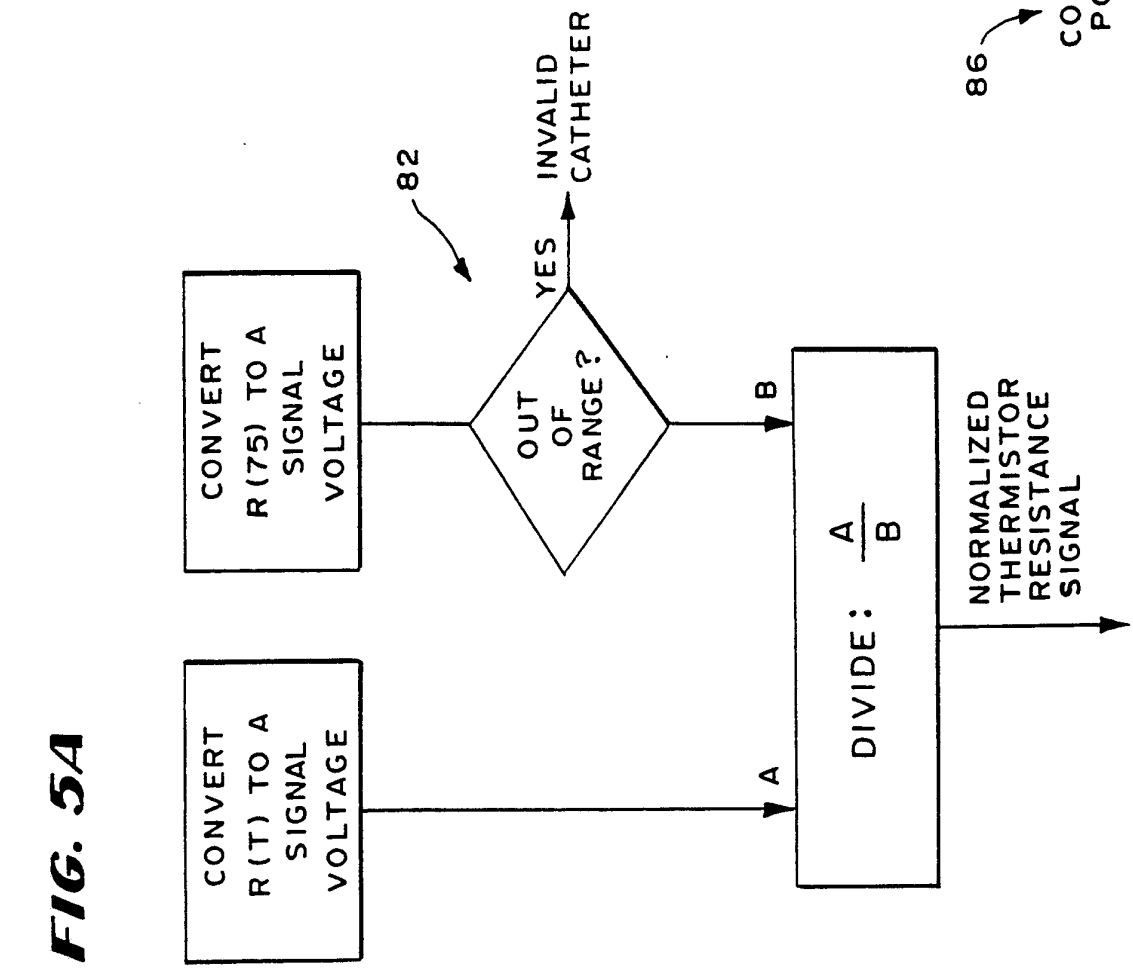

CONVERT R(T) TO A SIGNAL VOLTAGE
CONVERT R(75) TO A SIGNAL VOLTAGE
82
OUT OF RANGE?
YES
INVALID CATHETER
A
B
DIVIDE: A/B
NORMALIZED THERMISTOR RESISTANCE SIGNAL

FIG. 5A

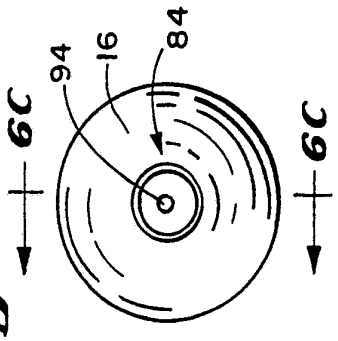


FIG. 6B

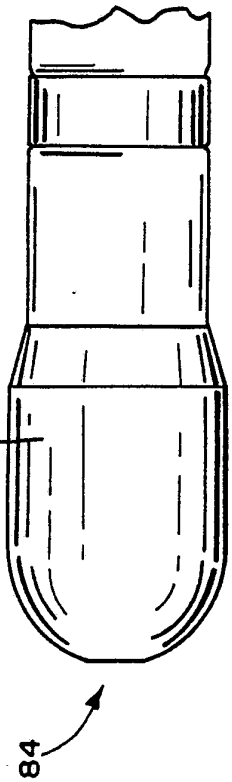


FIG. 6A

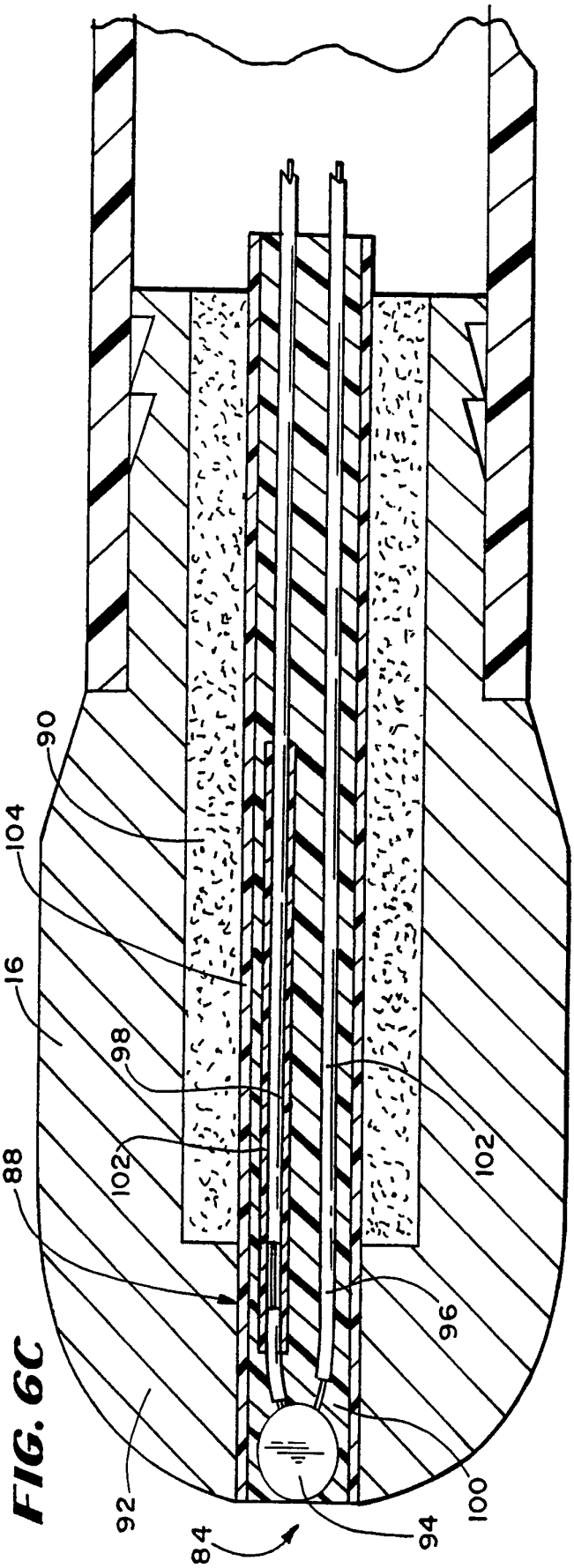


FIG. 6C

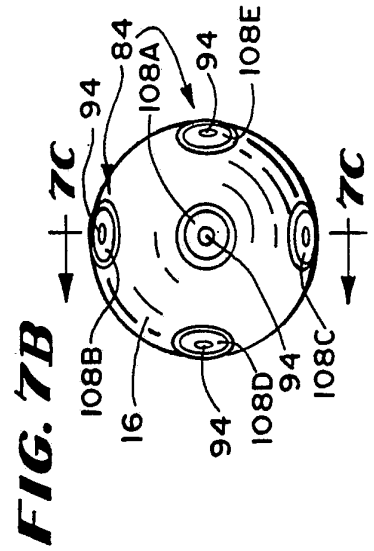


FIG. 7B

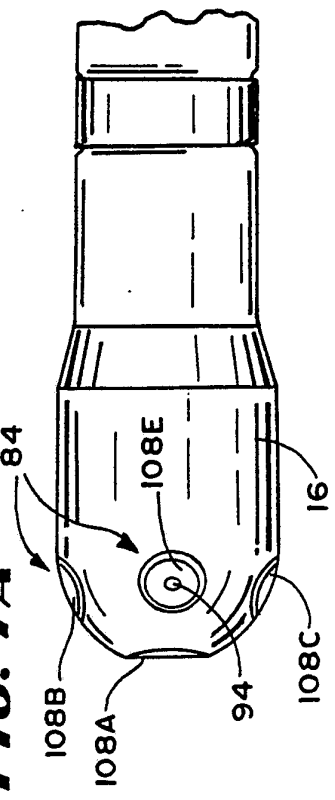


FIG. 7A

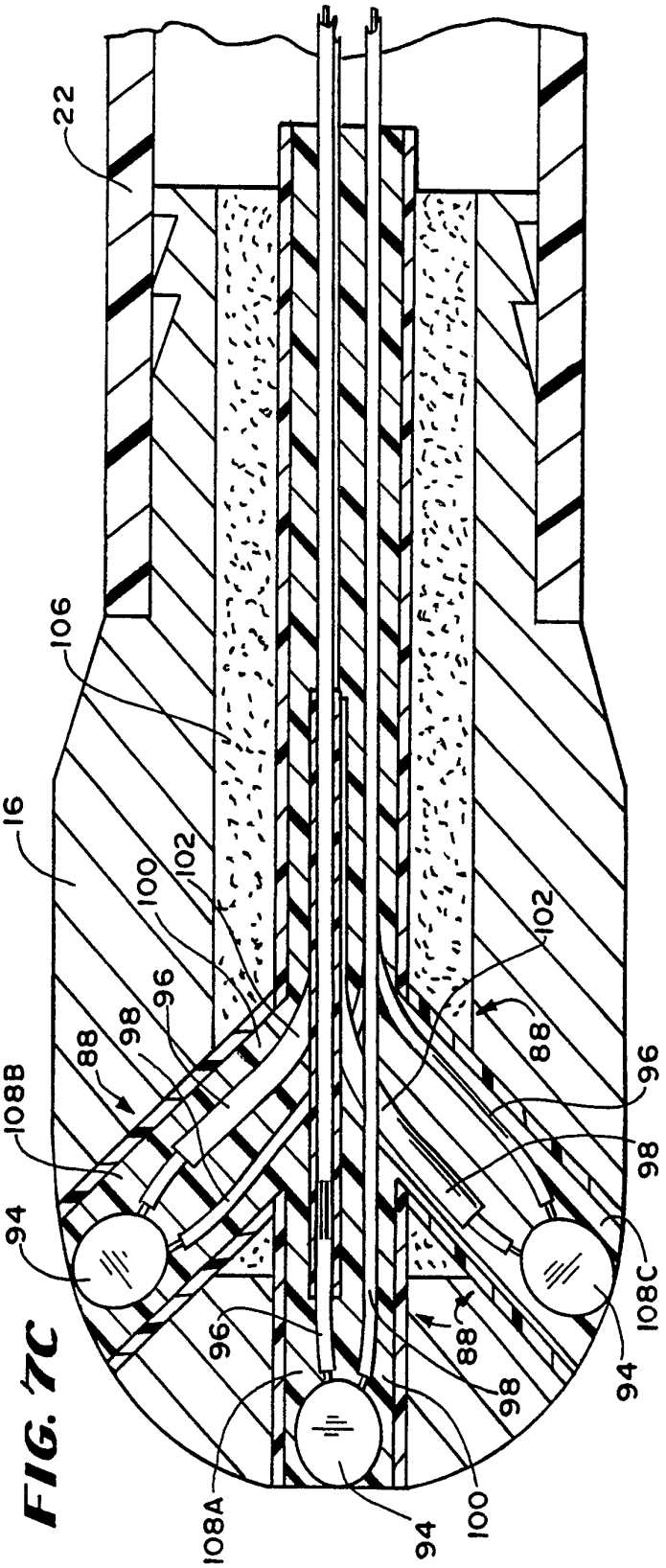


FIG. 7C

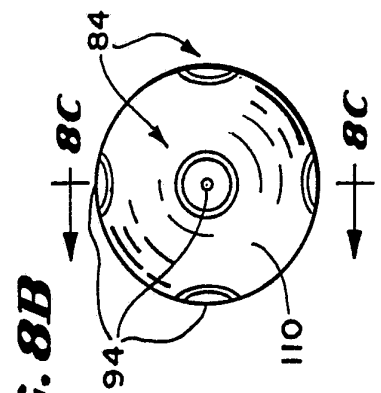


FIG. 8B

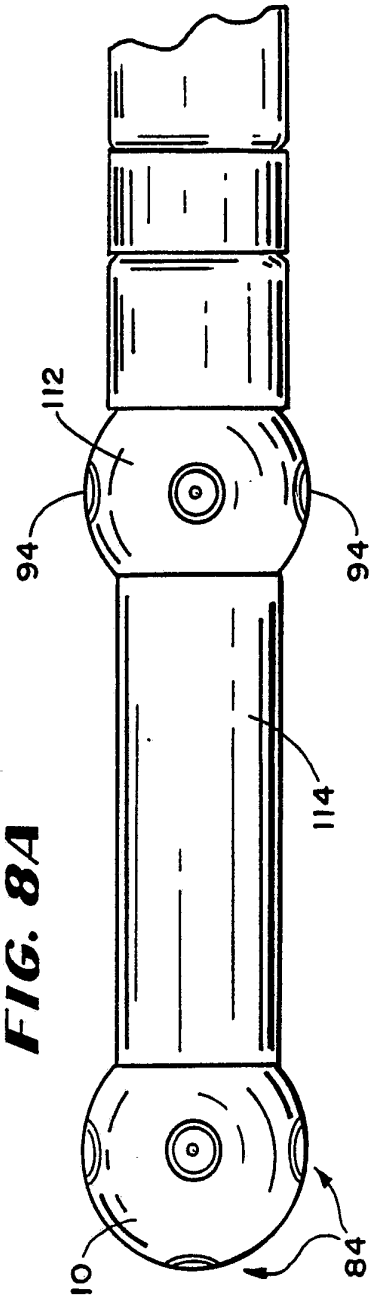


FIG. 8A

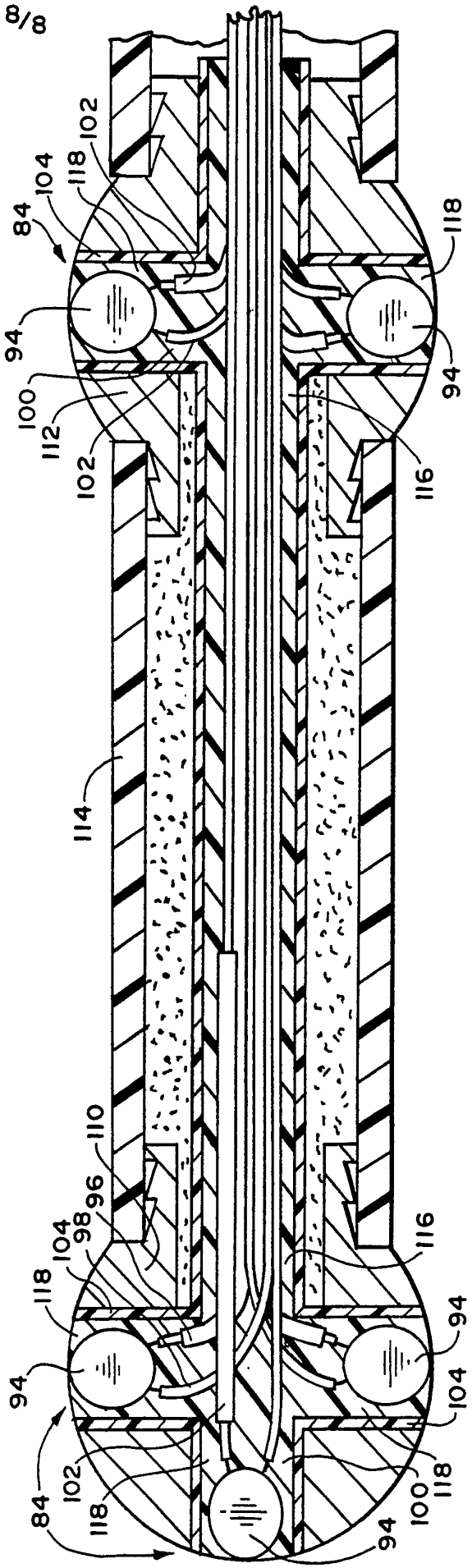


FIG. 8C

INTERNATIONAL SEARCH REPORT

PCT/US92/09557

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61B 17/39
US CL :364/482; 324/692; 128/734
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. : 364/482, 483, 551.01; 324/692; 128/734; 364/482; 324/692; 128/734

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)

Please See Extra Sheet.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 4,966,597 (COSMAN) 30 October 1990 See Fig. 1; col. 1, lines 18-44; col. 3, lines 20-46; col. 4, lines 5-11	1-9
Y	US, A, 4,907,589 (COSMAN) 13 March 1990 See Fig. 1; col. 1, lines 45-49	1-9
Y	US, A, 4,805,621 (Heinze et al) 21 February 1989 See Fig. 1 and Fig. 2; col. 1, lines 12-24;	1-9
A	US, A, 4,692,685 (BLAZE) 08 September 1987 See col. 1, lines 12-19; col. 4, lines 53-57	1-9
A	US, A, 4,945,912 (LANGBERG) 07 August 1990 See Fig. 3 and 4; col. 1, lines 21-27; col. 3, lines 22-30	1-9

☐ 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	Date of mailing of the international search report
21 JANUARY 1993	16 FEB 1993
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. NOT APPLICABLE	Authorized officer MICHAEL ZANELLI Telephone No. (703) 305-9756

Form PCT/ISA/210 (second sheet)(July 1992)*

B. FIELDS SEARCHED
Electronic data bases consulted (Name of data base and where practicable terms used):

APS

1020 S 364/482, 483, 551.01/CCLS
78 S 324/692/CCLS
251 S 128/734/CCLS
1318 S L1 OR L2 OR L3
171 S ABLAT###(5A)TISSUE#
15 S TISSUE#(5A)IMPEDENCE#
0 S L5 AND L6
0 S L5 AND IMPEDENCE#
0 S L4 AND L5
47 S L5 AND ELECTRODE#
0 S TISSUE#(P)ABLAT###(P)IMPEDENCE
25 S L5 AND CURRENT AND VOLTAGE
0 S L6 AND L12
12 S IMPEDENCE(3A)TISSUE#
0 S L14 AND ABLAT?