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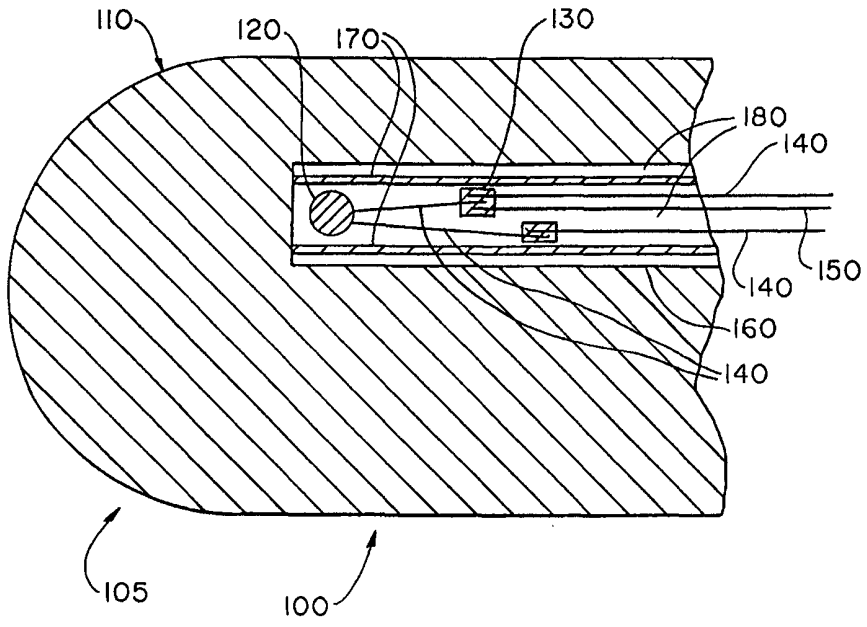

(57) Abstract

An ablation catheter system with dual temperature sensors is disclosed for actively sensing the temperature of a catheter during operation. The sensors detect temperature substantially simultaneously but with varying response times and degrees of accuracy. The relative strengths of the sensors are maximized while relative weaknesses are diminished by utilizing the sensors at the same time and through a method of comparing system variables over time to derive an accurate gauge of actual catheter temperature.

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DUAL SENSOR ABLATION CATHETER

FIELD OF THE INVENTION

The present invention generally relates to ablation catheters. More particularly, the present invention relates to an ablation catheter having dual sensors for monitoring temperature.

BACKGROUND OF THE INVENTION

Ablation catheters are well recognized and important tools for conveying an electrical stimulus to selected locations within the human body. Ablation catheters have been used for many years for the treatment of certain types of cardiac arrhythmia. For example, ablation catheters have been used to interrupt or modify existing conduction pathways associated with arrhythmias within the heart. Ablation procedures are also used for the treatment of atrial ventricular (AV) nodal reentrant tachycardia. Accepted treatments of this condition include ablation of the fast or slow AV nodal pathways. Known cardiac ablation procedures focus on the formation of lesions within the chambers of the heart at selected locations which will either prevent the passage of electrical signals associated with atrial premature contractions or prevent the formation of improper electrical pathways within the heart which can result in atrial arrhythmia.

Radio frequency (RF) catheter ablation has become increasingly popular for many symptomatic arrhythmias such as AV nodal reentrant tachycardia, AV reciprocating tachycardia, idiopathic ventricular tachycardia, and primary atrial tachycardias. Nath, S., et al., "Basic Aspects Of Radio Frequency Catheter Ablation," J Cardiovasc Electrophysiol, Vol. 5, pgs. 863-876, October 1994. RF ablation is also a common technique for treating disorders of the endometrium and other body tissues including the brain.

A typical RF ablation system in its most basic form comprises an RF generator which feeds current to a catheter containing a conductive tip electrode for contacting targeted tissue. The system is completed by a return path to the RF generator, provided through the patient and a large conductive plate, which is in contact with the patient's back.

The standard RF generator used in catheter ablation produces an unmodulated sine wave alternating current at frequencies of approximately 500 to 1000 kHz. The RF energy

is typically delivered into the patient between the conductive tip electrode of the catheter and the large conductive plate in contact with the patient's back. During the delivery of the RF energy, alternating electrical current traverses from the conductive tip through the intervening tissue to the back plate. The passage of current through the tissue results in electromagnetic heating. Heating tissue to temperatures above 500 C is required to cause irreversible myocardial tissue injury. However, heating tissue to temperatures above approximately 1000 C at the electrode/tissue interface can result in boiling of plasma and adherence of denatured plasma proteins to the ablation electrode. The formation of this coagulum on the catheter tip causes a rapid rise in electrical impedance and a fall in the thermal conductivity, resulting in loss of effective myocardial heating. Nath, S., et al., "Basic Aspects Of Radio Frequency Catheter Ablation," J Cardiovasc Electrophysiol, Vol. 5, pgs. 863-876, October 1994. Moreover, such extreme heating of the tissues can damage healthy tissue surrounding the targeted lesion.

Because of the dangers of overheating tissue with ablation catheters, systems for controlling the temperature at the ablation site are necessary. Such systems have been in use for many years. Common ablation systems for controlling the temperature at the ablation site contain an electrode as well as a thermocouple or thermistor at the tip of the catheter. In these systems, a pair of wires from the thermocouple extend back through the body of the catheter to an amplifier in an electrical control portion of the system. An output from the amplifier, is indicative of the temperature of the heated tissue and is used by a control unit to control the duty cycle or power level of the RF generator. This arrangement permits regulating the amount of RF energy delivered to the tissue to control the temperature at the target tissue. An example of a system in which the duty cycle of the ablation catheter is controlled by a temperature sensor is disclosed in U.S. Patent No. 5,122,137 entitled "Temperature Controlled RF Coagulation."

Known RF ablation systems that use temperature control mechanisms have numerous disadvantages. For example, known systems using thermocouples suffer from voltage and current noise problems. The transmission of a low voltage signal from the thermocouple to the amplifier, which is indicative of the temperature, must be transmitted accurately over a long distance in order to appropriately limit the temperature. Maintaining an accurate transmission is very difficult because the low voltage signals from the thermocouple are being transmitted by wires directly adjacent the wire used to provide the high voltage signal for ablating. The low voltage signals from the

thermocouple are typically swamped by the high voltages and high frequencies used for the ablation, thereby causing temperature signals to be very noisy and less likely to give accurate temperature readings. Additionally, accuracy of thermocouple systems are not perfect. Typically, accuracy for a standard thermocouple is on the order of one degree Celsius. Systems using thermistors, while having greater accuracy than those using thermocouples, suffer from slow response times.

Other devices have attempted to address the above-listed disadvantages by utilizing a thermocouple and a thermistor within a single assembly. Two attempts to make such improvements are found in U.S. Patent No. 5,066,140, to Shigezawa et al. and U.S. Patent No. 5,161,892, to Beran. Therein, thermocouple temperature sensing devices employ the passive use of a thermistor. In the devices of the '140 Patent and the '892 Patent, the thermocouple actively senses temperature at a first location. The thermistor is placed adjacent the "cold-junction" of the thermocouple at a second location removed from the thermocouple. The thermistor does not actively sense temperature, but rather, assists in compensating and correcting the measurements sensed by the thermocouple by subtracting the room temperature signal. The thermistor, thus, merely functions in a passive state, assisting in the determination of temperature based solely upon the thermocouple temperature readings. Such devices fail to properly address the underlying accuracy shortcomings of thermocouple temperature sensing, and fail to fully utilize the strengths of a thermistor. Thus, there remains an acute need for a device that combines the strengths of both a thermocouple and a thermistor while at the same time compensating for the weaknesses of each of the devices alone.

SUMMARY OF THE INVENTION

The present invention provides an apparatus and method for accurately sensing the temperature of a catheter during operation. According to one embodiment, a plurality of temperature sensors are utilized to substantially simultaneously sense the temperature of the catheter during operation. From the sensed temperatures, a control signal is generated with which to communicate data to the operator or to an automated frequency generator to facilitate the more efficient and safe use of the catheter. Temperature sensing within the catheter is done on a substantially continual basis during operation.

According to an embodiment of the invention, a thermistor and a thermocouple are utilized as the temperature sensors. The relative strengths of each of the different sensors

is combined and taken advantage of to more accurately detect the operating temperature of the catheter through a substantially continuous comparison of temperature readings and other system parameters. Thus, the respective weaknesses of the thermocouple and the thermistor are minimized. The comparison and monitoring of the system results in a more accurate and dependable determination of catheter temperature at any given moment in time.

According to a further embodiment of the invention, a method is employed wherein the temperature data sensed by a thermistor and a thermocouple are compared, calibrated, and analyzed to take advantage of their respective strengths and to minimize their respective weaknesses. The circuitry located in the catheter performs an algorithm to determine, based on temperature reading and design constraints, whether to utilize the thermistor, thermocouple or both to gauge the temperature at a tip electrode of the catheter. The algorithm is performed during operation of the catheter, thus, minimizing the likelihood of overheating tissue.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a schematic diagram of a known ablation catheter system.

Figure 2 is a cross-sectional view of a distal end of a catheter according to an embodiment of the present invention.

Figure 3 is a schematic diagram of the circuitry utilized in an embodiment of the present invention.

Figure 4 is a schematic diagram of the circuitry utilized in an alternative embodiment of the present invention.

Figure 5 is a diagram comparing a sine wave versus an input signal from the circuit depicted in Figure 4.

Figure 6 is a diagram depicting the actual and detected temperatures about the distal end of a catheter according to an embodiment of the present invention.

Figure 7 is a flowchart illustrating the operation of an embodiment of the present invention.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

The present invention provides an ablation catheter having dual sensors for monitoring temperature. Ablation catheters are well recognized and important tools for

conveying an electrical stimulus to selected locations within the human body. Figure 1 illustrates a schematic drawing of a known basic RF ablation catheter system 10. System 10 includes an RF signal generator 12, a catheter 14, a tip electrode 16 and a backplate 18. An electrical conductor 20 within catheter 14 extends between and electrically connects electrode 16 to RF generator 12. In operation, RF generator 12 feeds a current to catheter 14 via conductor 20. During the delivery of RF energy, alternating electrical current traverses from tip electrode 16 through the intervening tissue 19 of the patient to backplate 18. The passage of current through the tissue results in resistive (joule) heating. When using an ablation system, the targeted tissue must be heated to temperatures above approximately 50° C for effective ablation. However, temperatures at and above approximately 100° C at the electrode/tissue interface can result in boiling of plasma and adherence of denatured plasma proteins to the ablation electrode. The formation of the coagulum on the catheter tip causes a rapid rise in electrical impedance and a fall in the thermal conductivity resulting in loss of effective myocardial heating. Because of the dangers of overheating tissue with ablation catheters, systems for controlling the temperature at the ablation site are necessary and such systems have been in use for many years. Embodiments of the present invention are particularly useful when used as or in combination with temperature and/or current limiting ablation catheters.

The present invention provides an ablation catheter which utilizes two or more different types of temperature sensors to detect the temperature of the catheter. Referring now to Figure 2, a dual sensor catheter 100 according to the present invention is illustrated having a tip electrode 110 at a distal end 105. Electrode 110 is electrically connected via conductors (not shown) to a power source at the proximal end of catheter 100. Thermocouple 130 and thermistor 120 are positioned within catheter 100 as illustrated in Figure 2. Thermistor 120 has a slower relative response time than thermocouple 130, thus, thermistor 120 is advantageously positioned distally of thermocouple 130.

In an alternate embodiment, Resistance Temperature Detector (RTD) sensors utilizing metals such as platinum, tungston, nickel, nickel alloys, or similar material can be used in place of thermistor 120 and/or thermocouple 130. RTD sensors provide significant benefits in that they are the most stable, accurate, and linear sensors currently available. Disadvantages of RTD sensors include increased expense, the requirement of a current source, the propensity to self-heat, and the generation of a relatively small output signal.

In yet a further embodiment, integrated circuit (IC) sensors are contemplated in place of thermistor 120 and/or thermocouple 130. Use of IC sensors yields high accuracy and output at a relatively low cost. IC sensors, however, are limited in their configuration and limited by a maximum temperature range, require a power supply and provide relatively slow response.

Copper wire 140 and constantan wire 150 complete a circuit between thermistor 120 and thermocouple 130 which extends to a power source at a connector (not shown) as described above. While copper and constantan wires 140, 150 are the preferred types of wires for the present invention, other types of non-matching wires may also be used without departing from the spirit or scope of the present invention. For example, a copper wire and a platinum alloy wire could be used. Thermistor 120 and thermocouple 130 are electrically isolated from tip electrode 110 at distal end 105 of catheter 100 by an insulation barrier or casement 160. Casement 160 is preferably comprised of microtubing 170 and thermally conductive epoxy 180. Thus, as tip electrode 110 is heated, thermocouple 130 and thermistor 120 are positioned to sense the temperature of catheter 100 at the selected location in the human body.

The circuitry of one embodiment of catheter 100 is depicted in Figure 3. The circuitry is located substantially in RF generator 12 or an adaptor cable system. In this embodiment, thermocouple 130 is connected across the input terminals of amplifier 190. In the preferred embodiment of the present invention, amplifier 190 is a "cold junction compensating" amplifier which subtracts the parasitic voltage introduced at the input of amplifier 190. It should be noted that other types of amplifiers may also be used without departing from the spirit or scope of the present invention.

Thermistor 120 is connected to resistors R1, R2, and R3. The combination of thermistor 120 and resistors R1, R2, and R3 are configured as a bridge circuit 121 having a differential output V_0 connected to amplifier 210. If $(R1)\cdot(R3) = (R2)\cdot(R_{Therm})$, where R_{therm} is the resistance of thermistor 120, then the differential output of bridge 121 equals zero. However, as thermistor 120 varies, the current flowing through the legs of bridge 121 will vary, thus creating a differential voltage at the input of amplifier 210.

According to the embodiment illustrated in Figure 3, thermocouple 130 produces a voltage that is linearly related to the temperature. The voltage difference is amplified by amplifier 190, which produces a thermocouple voltage signal V_{TC}, representative of the voltage of thermocouple 130. Constantan wire 150 eventually contacts copper wire 140

again at amplifier 190. This second junction of wire 140 with wire 150, in a sense, creates a second thermocouple which contributes a parasitic voltage. "Cold-junction compensating" is performed at amplifier 190 to remove the parasitic voltage, that is introduced at near-room temperatures, from the thermocouple voltage, resulting in V_{TC}.

Thermistor 120 comprises a variable resistor where resistance is determined by the temperature. As previously described, a differential voltage is provided to amplifier 210 by bridge circuit 121 which results in a thermistor voltage signal V_{TH}, representative of the thermistor voltage. According to the embodiment illustrated in Figure 3, both thermocouple 130 and thermistor 120 actively detect and communicate the temperature of catheter 100 with the use of three wires.

According to a further embodiment of the present invention, a more sophisticated circuit, as depicted in Figure 4, may be used in which only two wires are necessary to read the temperature of catheter 100. As shown in Figure 4, thermocouple 130 is connected on one side to thermistor 120 and on the other side to node 231. A signal generator 232 is provided and is connected to node 231 through resistor R4. Node 231 is also connected to input terminal 233. An amplifier 240 is provided having one input connected to node 231 and the other input connected to ground. The output of amplifier 240 is the thermocouple output voltage V_{TC}.

Thermistor 120 is connected between thermocouple 130 and ground. Amplifier 245 is provided with one input connected to input terminal 233 and the other input connected to ground. A high pass filter circuit 250 is provided and is connected to the output of amplifier 245. High pass filter circuit is comprised of capacitor C1 and resistor R5. An amplifier 260 is provided having one input connected to filter circuit 250 and a second input connected to ground. Rectifying diode D1 is provided having its anode connected to the output of amplifier 260 and its cathode connected to filter circuit 270. Filter circuit 270 is comprised of resistor R6 and capacitor C2. The output of filter 270 is connected to amplifier 280 which is connected as a voltage follower having one input connected to filter circuit 270 and the other input connected to its output. The output of amplifier 280 is the thermistor output V_{TH}.

In operation, current is introduced into the circuit through signal generator 232. The thermocouple voltage, V_{TC}, is not significantly influenced by resistor R_4, nor by the series resistance of thermistor 120 and in essence acts as a DC signal. The thermocouple

voltage is directed into amplifier 240, thereby producing V_{TC} . As previously stated, "cold-junction compensation" is performed at amplifier 240, or elsewhere.

With respect to the operation of thermistor 120, AC generator 232 impresses an alternating current onto thermistor 120. The voltage drop across thermistor 120 is affected by the thermistor resistance which is affected by the temperature. As can be seen in Figure 5, an AC signal 300 from AC generator 232 is a conventional, balanced, non-distorted sine wave. An input signal 310, is applied to input terminal 233 which is fed to amplifier 245. As can also be seen in Figure 5, input signal 310 has a similar curve as AC signal 300, however, it has a smaller amplitude, and wavelength, which is partly as a result of the voltage division between thermistor 120 and resistor R_4. Additionally, the DC voltage from thermocouple 130 tends to "lift" up signal 310 such that it is asymmetrical with the x-axis.

Referring again to Figure 4, input signal 310 is directed through first amplifier 245 and high-pass filtered by filter circuit 250 to remove the DC offset imparted by thermocouple 130 and to restore the symmetry of signal 310 about the x-axis. The resultant signal is then amplified by amplifier 260 and rectified by diode D1. The signal is then filtered by filter circuit 270 which senses the peak level. The signal is then passed through voltage follower 280 to produce the thermistor voltage signal V_{TH}.

By using the circuit illustrated in Figure 4, both the thermistor voltage signal, V_{TH}, and thermocouple voltage signal, V_{TC} are generated through the use of a common pair of wires. This reduces the cost of the catheter because the manufacturing time is reduced and also allows for a narrower and more flexible catheter by reducing the number of wires required.

Referring now to Figure 6, the actual temperature of catheter 100 versus the sensed temperatures by thermistor 120 and thermocouple 130 are shown. Figure 6 is broken down into segments which represent temperature during periods of non-operation 500, temperature during warm up and cool down processes 510, and temperature during operation 520, of catheter 100. Actual temperature is depicted by piece-wise linear curve 320 depicting temperature before and during an ideal ablation catheter operation. Jagged curve 340 depicts the temperature sensed by thermocouple 130. Curve 340 assumes its jittery formation because the thermocouple voltage signal is relatively small and is highly sensitive to voltage and current noise which is typical during RF ablation. The need for the previously mentioned cold-junction compensation precludes use of an amplifier at

thermocouple 130, thus, the design of catheter 100 exposes the full length of thermocouple wiring 140, 150 to such noise and other interference which account for the noisy signal. As depicted, the inaccuracy of curve 340 results in an error shift below the actual temperature shown by curve 320. Typical accuracy for a standard thermocouple 130 is on the order of one degree Celsius. Smooth curve 330, depicting the temperature sensed by thermistor 120, is more accurate, however, it possesses a significantly slower response time as shown by the longer slope of signal 330 in segments 510 and 520 of Figure 6.

As previously stated, an important object of the present invention is to combine the above-mentioned relative strengths of thermocouple 130 and thermistor 120 and to minimize their respective weaknesses. One method of combining the strengths of thermistor 120 and thermocouple 130 is depicted in Figure 7. Operation of the circuit begins initially at block 400, wherein the standard deviation, or sigma (σ), of thermocouple voltage signal, V_{TC}, and thermistor voltage signal V_{TH} are calculated over a trailing ten-second time interval. Next, as shown at decision block 410, it is determined whether the sigmas of V_{TC} and V_{TH} are less than one degree Celsius. If the answer is "yes," the system has reached a substantially stable state and some system calibration can be undertaken. If stable, the system determines if both V_{TH} and V_{TC} are less than 41 degrees Celsius as shown at decision block 420. In an alternate embodiment of the present invention, the inquiry could be whether both signals are greater than 35 degrees Celsius, a typical temperature within a living human body where the ablation occurs.

If the answer to the question posed in decision block 420 is "no," a control signal is calculated by averaging V_{TC} and V_{TH} in block 430. In the situation where V_{TC} and V_{TH} are greater than 41 degrees Celsius, the control signal is derived by averaging V_{TC} and V_{TH} because the situation suggests that catheter 100 is at a very high, yet stable, temperature, thus, the averaging of two stable readings provides a good estimate of the actual temperature.

Alternatively, if the temperature in decision block 420 is less than 41 degrees Celsius, then a corrected thermocouple voltage signal V'_{TC}, is calibrated from V_{TH} as depicted in block 440. V'_{TC} is calculated by using the smooth thermistor signal V_{TH} and calculating the error between V_{TH} and V_{TC}. The error is then added to V_{TC} to derive V'_{TC}, which is a faster responding thermocouple voltage that has its offset error removed. As depicted in block 450, V'_{TC} is used as the control signal for the system and the system then returns to the beginning of the routine at block 400.

If the system lacks stability, as is the case if the sigmas of V_{TC} and V_{TH} are not less than one degree Celsius, as asked in decision block 410, the system must determine which signal is more accurate to derive an appropriate control signal. If sigma V_{TC} and sigma V_{TH} are greater than one degree Celsius, then the system determines whether the sigma V_{TH} is greater than one degree Celsius in block 460. If yes, this suggests that there is either a rapid temperature increase due to RF heating or a rapid temperature decrease due to a sudden loss of RF which is depicted within segment 510 of the temperature curve of Figure 6. Accordingly, V'_{TC} is then used as the control signal for the system because of the faster response time and greater accuracy of thermocouple 130.

Alternatively, if sigma V_{TH} is less than one degree Celsius, V_{TH} is used as the control signal as shown in block 470. Use of V_{TH} as the control signal occurs when thermistor voltage curve 330 is not changing rapidly, for example, after the ablation procedure has reached its normal operating temperature, as depicted in segment 520 of Figure 6.

The control signal generated by the circuit, through the performance of the algorithm, is utilized to limit the temperature at tip electrode 110 beneath a predetermined limit such as 100° C, thus, preventing the formation of coagulum on electrode 110 and/or tissue overheating. The control signal acts as an input signal to a frequency generator, or other suitable device connected to catheter 100, to perform the temperature limiting function. Typically, the frequency generator is designed to have an operator controllable automatic shutoff in relation to the temperature.

The positioning of thermistor 120 and thermocouple 130 or other temperature sensors, including resistance temperature detectors, and IC sensors, within catheter 100 as well as the amount of insulation provided by casement 160 and the mass of thermocouple 130 and thermistor 120, respectively, will significantly impact the determination of response times of the temperature sensors. The present invention contemplates an embodiment wherein, by manipulation of the aforementioned variables, the response time of thermocouple 130 is made slower than the response time of thermistor 120. In such a situation, the preceding discussion centered around Figure 7 is still applicable.

While the present invention has been described and illustrated with reference to particular preferred embodiments, the invention is not limited to the specific temperature sensors or examples given. For example, an RTD or IC sensor may be combined with a thermistor or thermocouple in a variety of configurations to obtain desired manufacturing

and performance benefits. Various other modifications will occur to those of ordinary skill in the art, and other embodiments and modifications can be made without departing from the spirit and scope of the invention as defined in the following claims.

CLAIMS:

1. An ablation catheter having a proximal end and a distal end, the catheter comprising:

a flexible conductor extending from the proximal end of the catheter to the distal end of the catheter;

an electrode attached about the distal end of the catheter, the electrode being electrically connected to the conductor; and

a plurality of temperature sensors communicatively coupled adjacent the proximal end of the catheter.

2. The ablation catheter of claim 1, wherein the plurality of temperature sensors comprises:

a first temperature sensor electrically connected to the conductor; and

a second temperature sensor electrically connected to the conductor;

wherein the second temperature sensor is a different type of temperature sensor than the first temperature sensor.

3. The ablation catheter of claim 2, wherein the first temperature sensor is a thermistor.

4. The ablation catheter of claim 3, wherein the second temperature sensor is a thermocouple.

5. The ablation catheter of claim 2, wherein the first temperature sensor is a thermocouple.

6. The ablation catheter of claim 2, further comprising a casement positioned about the first and second temperature sensors.

7. The ablation catheter of claim 6, wherein the casement is substantially thermally conductive and electrically isolating.

8. The ablation catheter of claim 1, wherein the plurality of temperature sensors substantially simultaneously measure temperature.

9. The ablation catheter of claim 1, wherein an at least one of the temperature sensors comprises an integrated circuit sensor.

10. The ablation catheter of claim 1, wherein at least one of the temperature sensors comprises a resistance temperature detector.

11. An ablation catheter comprising:

a housing having a proximal end and a distal end;

a plurality of conductors extending from the proximal end of the housing to the distal end of the housing;

an electrode located at the distal end of the housing, the electrode being electrically connected to the plurality of conductors; and

a plurality of temperature sensors electrically connected to the plurality of conductors and the electrode for substantially simultaneously measuring temperature data of the catheter.

12. The ablation catheter of claim 11, wherein the plurality of temperature sensors comprises:

a thermocouple; and

a thermistor, the thermistor being electrically connected to the thermocouple.

13. The ablation catheter of claim 12, wherein the plurality of conductors comprise two wires.

14. The ablation catheter of claim 12, wherein the plurality of conductors comprise three wires.

15. The ablation catheter of claim 12, wherein the thermocouple is substantially adjacent the electrode and wherein the thermistor is connected in series with the thermocouple.

16. The ablation catheter of claim 11, further comprising a barrier located between the plurality of conductors and the temperature sensors.

17. A method of measuring catheter temperature with a catheter having both a thermocouple and a thermistor, the method comprising:

sensing first temperature data with a thermistor; and

sensing second temperature data with a thermocouple substantially simultaneously with the sensing of the first temperature data.

18. The method of claim 17, further comprising calculating a control signal by averaging the first temperature data and the second temperature data.

19. The method of claim 17, further comprising:

comparing the first temperature data and the second temperature data to a first preset value;

comparing the first temperature and the second temperature data to a second preset value; and

calculating a control signal.

20. The method of claim 19, wherein the calculation of the control signal is based on the relationship of the second temperature data to the first preset value.

21. The method of claim 19, wherein the calculation of the control signal is based on the relationship of the second temperature data to the second preset value.

22. The method of claim 17, wherein the sensing of first and second temperature data further comprises treating at least one of the first and second temperature data essentially as an AC signal.

23. The method of claim 17, wherein the sensing of first and second temperature data further comprises treating at least one of the first and second temperature data essentially as a DC signal.

Fig. 1

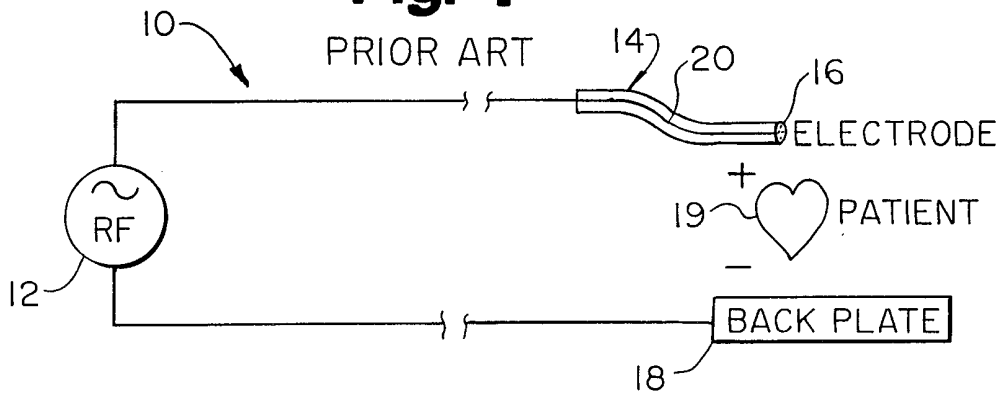
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Fig. 2

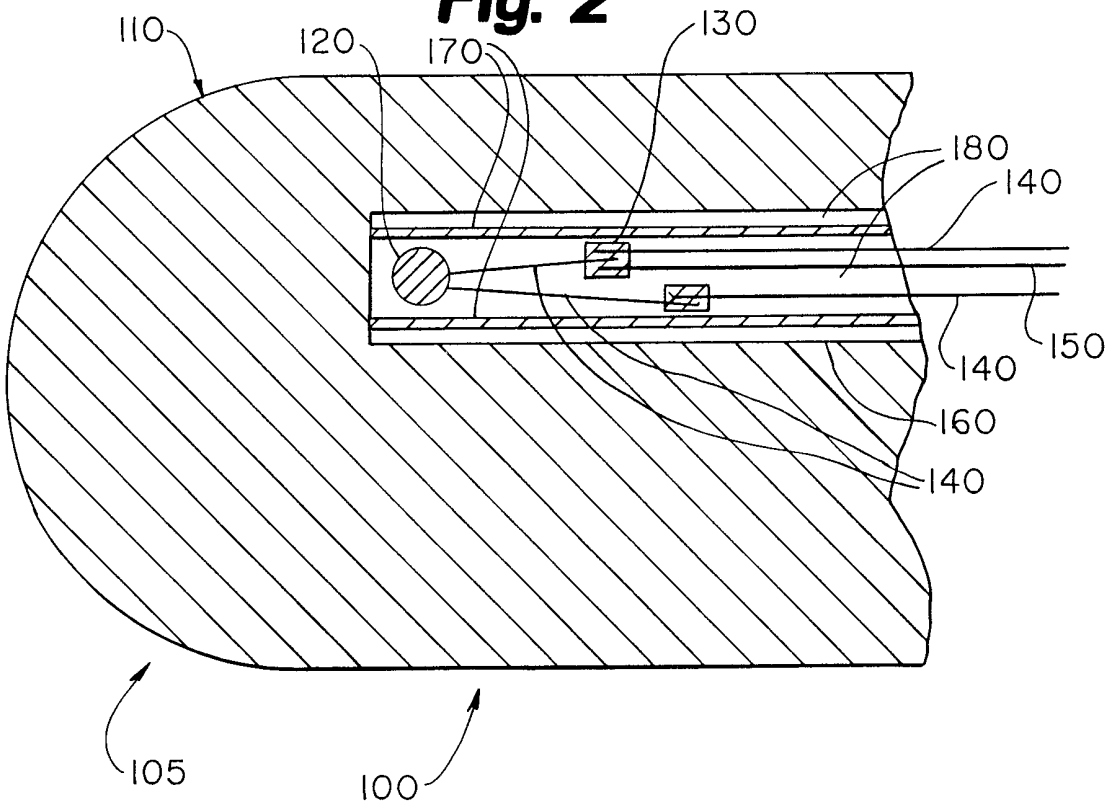
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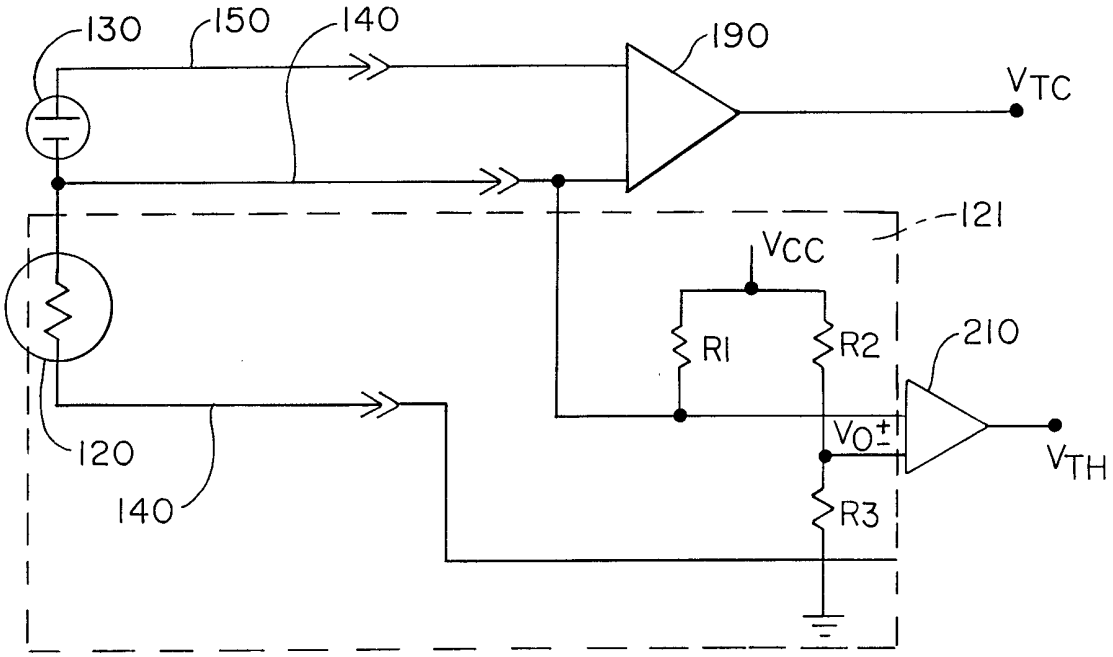
Fig. 3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R3

Fig. 4

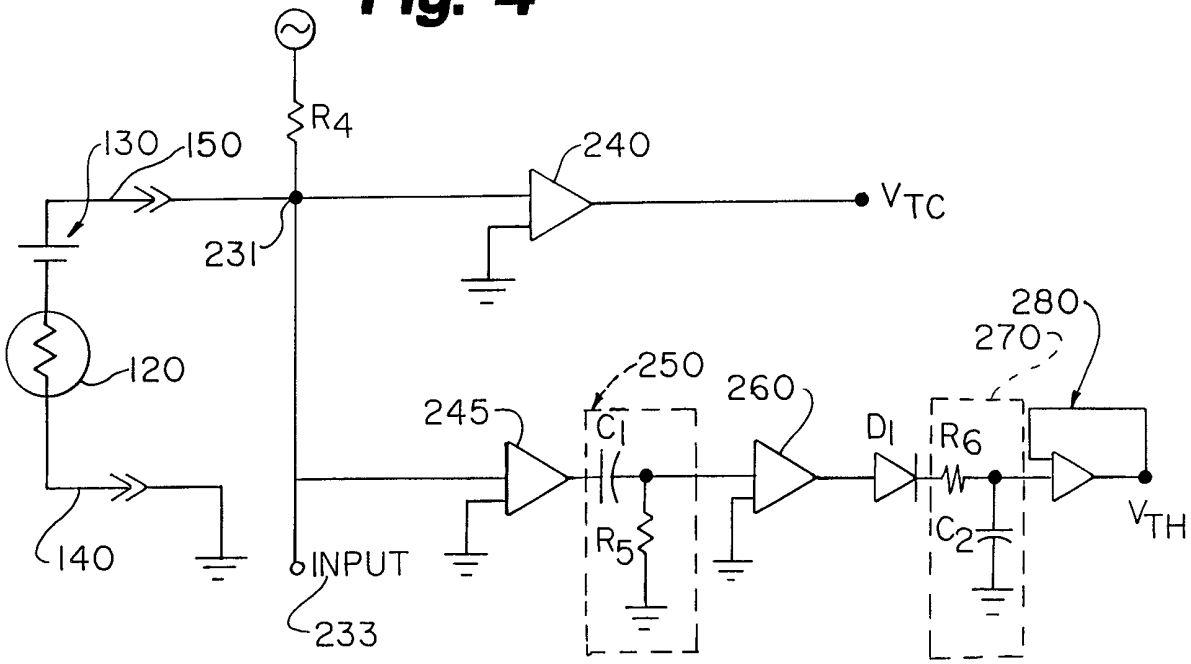

R4
130
150
240
VTC
231
120
280
270
250
260
245
C1
D1
R6
R5
C2
VTH
140
INPUT
233

Fig. 5

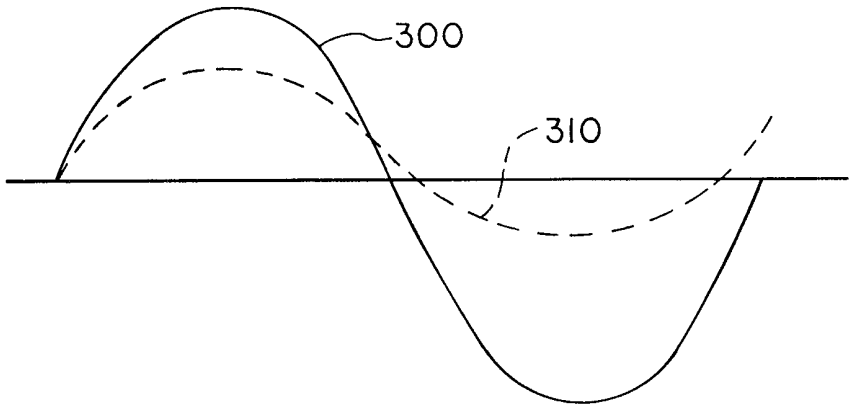


Fig. 6

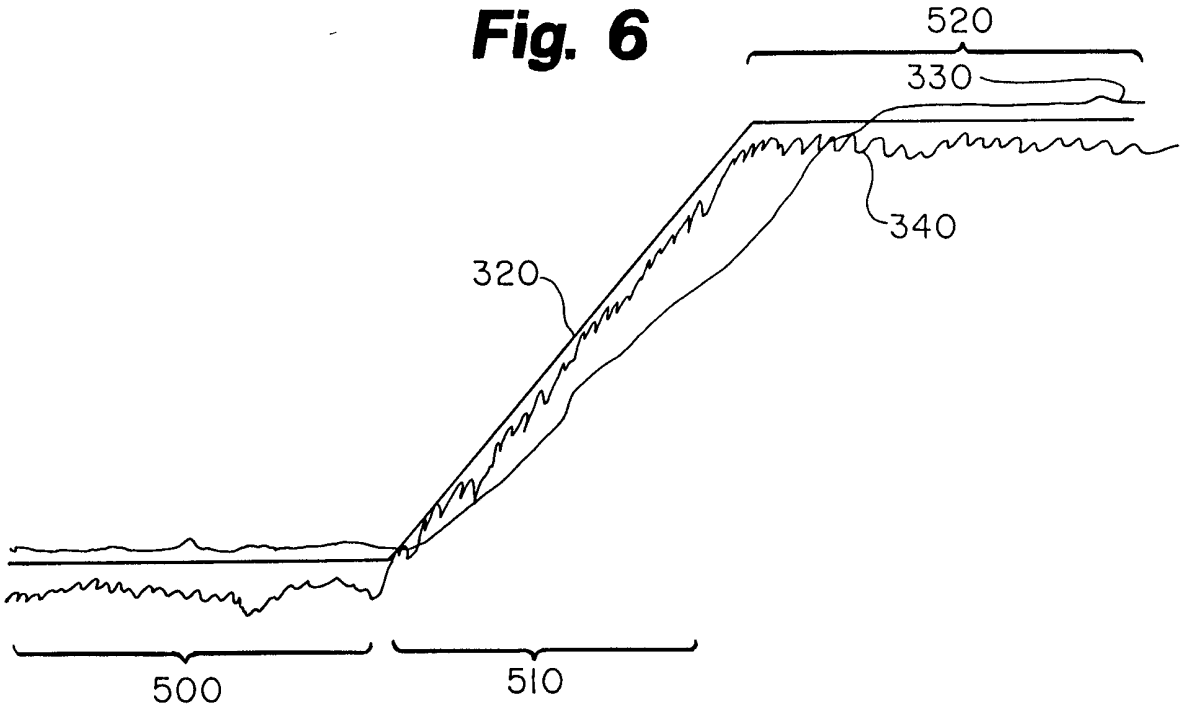
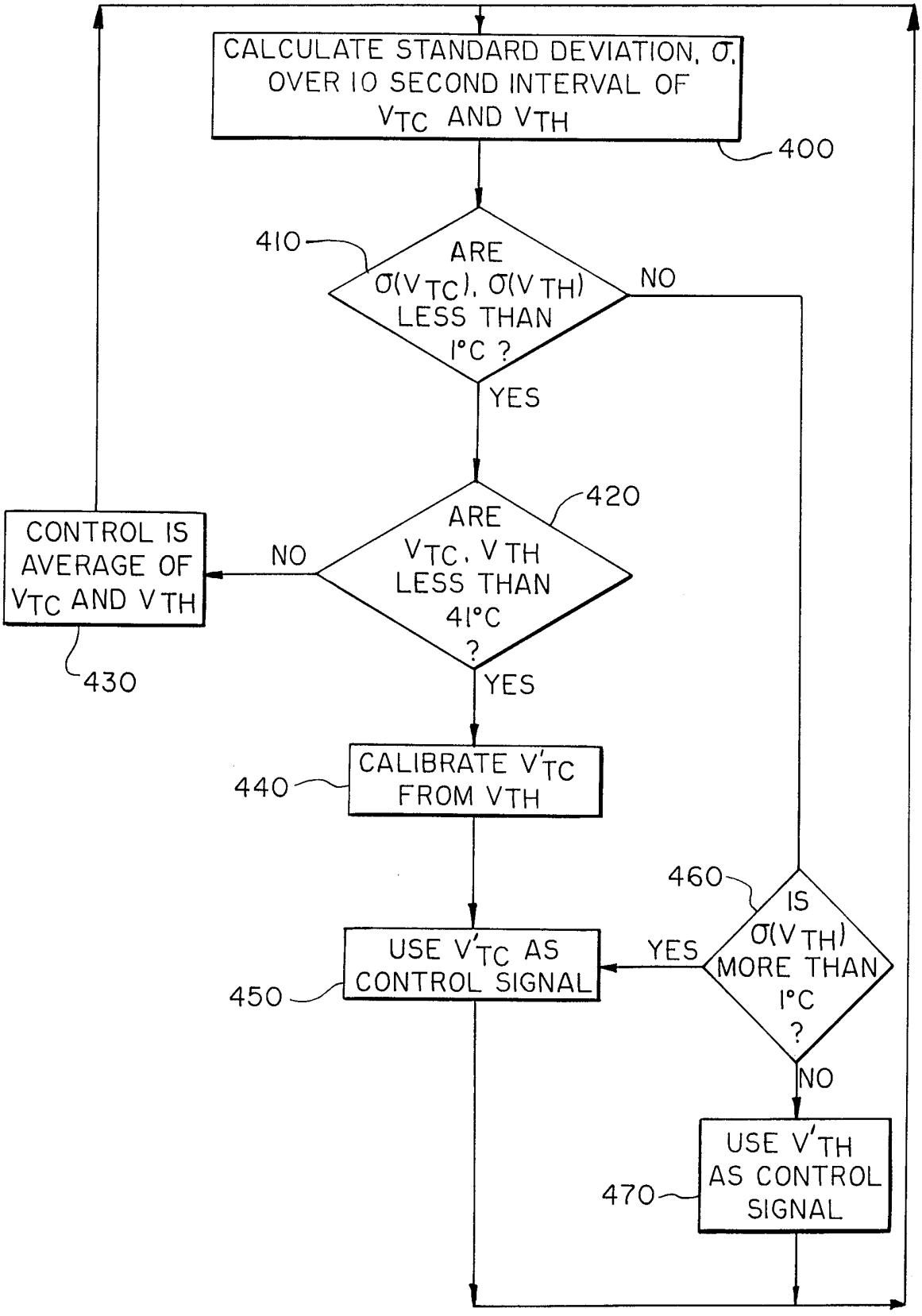


Fig. 7


CALCULATE STANDARD DEVIATION, σ, OVER 10 SECOND INTERVAL OF VTC AND VTH
400
410
ARE σ(VTC), σ(VTH) LESS THAN 1°C ?
NO
YES
420
ARE VTC, VTH LESS THAN 41°C ?
NO
YES
CONTROL IS AVERAGE OF VTC AND VTH
430
CALIBRATE V'TC FROM VTH
440
460
IS σ(VTH) MORE THAN 1°C ?
YES
NO
USE V'TC AS CONTROL SIGNAL
450
USE V'TH AS CONTROL SIGNAL
470

INTERNATIONAL SEARCH REPORT

Inte. .onal Application No
PCT/US 99/31002

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B18/14

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)
IPC 7 A61B

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 833 688 A (OSLAN ALAN ET AL) 10 November 1998 (1998-11-10) see "summary of the invention abstract	1,11-13, 17
A	US 5 596 995 A (SHERMAN MARSHALL L ET AL) 28 January 1997 (1997-01-28)	
A	US 4 403 296 A (PROSKY HOWARD S) 6 September 1983 (1983-09-06)	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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"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

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Date of the actual completion of the international search	Date of mailing of the international search report
22 May 2000	31/05/2000

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

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INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter ›nal Application No
PCT/US 99/31002

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5833688 A	10-11-1998	AU 6179898 A WO 9836697 A	09-09-1998 27-08-1998
US 5596995 A	28-01-1997	WO 9634558 A	07-11-1996
US 4403296 A	06-09-1983	NONE	