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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61B 17/39	A1	(11) International Publication Number: **WO 98/40023**
		(43) International Publication Date: 17 September 1998 (17.09.98)

(21) International Application Number: PCT/US98/04172

(22) International Filing Date: 4 March 1998 (04.03.98)

(30) Priority Data:
08/815,819 12 March 1997 (12.03.97) US

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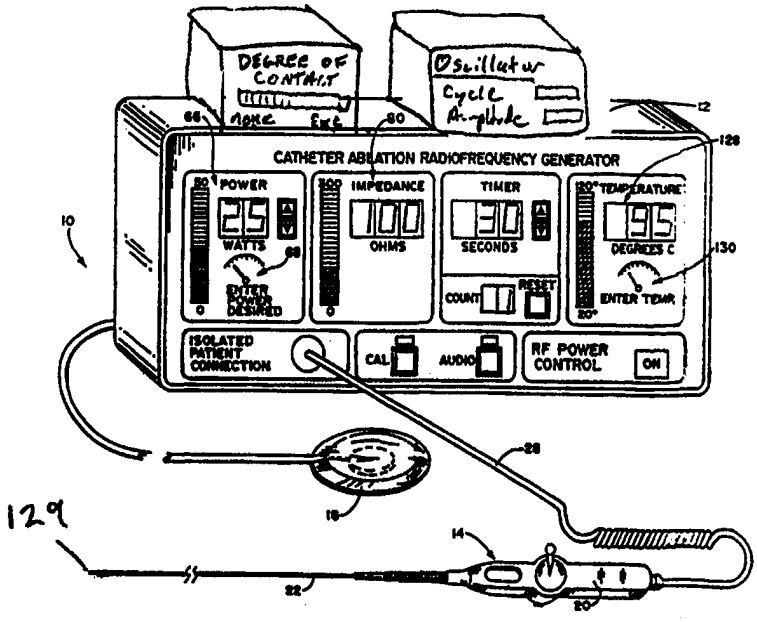
(81) Designated States: JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.

(54) Title: METHOD AND APPARATUS FOR TISSUE ABLATION



(57) Abstract

The present invention is a system for ablating tissue within a body, the system having an energy source providing a level of energy which is non damaging to the cellular structures of the body tissue, a catheter coupled to the energy source, the catheter having an electrode; and means for sensing the temperature of the electrode while also sensing the amount of energy which is non damaging to the cellular structures of the body tissue is delivered to the electrode, the sensing means coupled to the catheter and coupled to the energy source wherein the degree to which the electrode contacts the heart tissue (e.g. no contact, moderate contact, good contact or excellent contact) may be determined.

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METHOD AND APPARATUS FOR TISSUE ABLATION

FIELD OF THE INVENTION

This invention relates generally to the field of devices for cardiac surgery, and more specifically to devices for R-F ablation of cardiac tissue.

BACKGROUND OF THE INVENTION

The present invention is directed toward treatment of tachyarrhythmias, which are excessively fast heart rhythms. In particular, the present invention is directed toward treatment of tachycardias.

Therapies have been developed for treating tachycardias by destroying cardiac tissue containing identified ectopic foci or aberrant conduction pathways. A variety of approaches have been taken, including application of electrical energy or other forms of energy to destroy the undesired cardiac tissue. As examples, ablation of cardiac tissue has been accomplished by means of radio frequency electrical current, microwave energy, heat, electrical pulses, cryothermy, and lasers. At present, ablation using R-F energy is perhaps the most widely practiced in the context of ablation procedures that can be carried out by means of a catheter, inserted into the closed heart.

Most R-F ablation catheters employ electrodes which are intended to contact the endocardium or, in some cases as in U.S. Pat. No. 5,083,565, are intended to penetrate the endocardium, and enter the myocardium. In general, R-F ablation catheters are effective to induce small lesions in heart tissue including the endocardium and inner layers of myocardium, in the immediate vicinity of the electrode.

R-F ablation causes tissue in contact with the electrode to heat through resistance of the tissue to the induced electrical current therethrough. Reliably sensing, however, when the electrode is in actual contact with the heart tissue so that the ablation procedure may begin is required. Many schemes for sensing electrode contact with the tissue have been proposed. For example, ablation systems of Biosense, Inc. detect wall contact through the stability of the sensed EKG. Such an approach is not completely satisfactory.

In patients who have an infarction, for example, the tissue near the infarction often cannot provide an acceptable EKG signal. Ablating near the infarcted area, however, is often times the specific area in which ablation is needed to be performed. Still further, the stability of the EKG actually only indicates the stability of contact during the 50 - 100 ms in which the P or QRS complex is present. The electrode may still bounce against the moving heart wall and still provide a stable EKG signal. Other ablation systems, such as those sold by the CarioRythm division of Medtronic Inc., detect wall contact through impedance. This approach is also not completely satisfactory. Displacement or movement within the heart of the ablation catheter relative to the indifferent skin electrode alters the impedance detected, thus distorting the detection of wall contact. Moreover, such measurements may also vary from patient to patient. Finally, the variations in impedance due to wall contact are often too small to be a reliable indicator of actual wall contact. Thus there exists a need for and ablation system which permits the electrode tissue contact to be reliably indicated.

SUMMARY OF THE INVENTION

The present invention is a system for ablating tissue within a body, the system comprising: an energy source providing a level of energy which is non damaging to the cellular structures of the body tissue, a catheter coupled to the energy source, the catheter having an electrode; the system further having means for sensing the temperature of the electrode while also sensing the amount of energy which is non damaging to the cellular structures of the body tissue (i.e. non ablative) is delivered to the electrode wherein the degree to which the electrode contacts the heart tissue (e.g. no contact, moderate contact, good contact or excellent contact) may be determined. In the preferred embodiment the non-damaging energy delivered to the body is less than 5 Watts and the catheter has a temperature sensor positioned within the distal end.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a system for performing ablation on human tissue that embodies the features of the invention.

FIG. 2 is a sectional view of the distal end or tip of the catheter seen in FIG. 1.

FIG. 3 illustrates a catheter tip having an electrode which is emitting energy into the blood stream and the resulting transmission of heat back into the catheter tip.

FIG. 4 illustrates a catheter tip having an electrode in contact with heart tissue and which is emitting energy into the tissue and the resulting transmission of heat back into the catheter tip.

FIG. 5. illustrates a system for ablating tissue according to the present invention.

FIG. 6 illustrates the change in temperature of the tip electrode as it moves through the blood vessel and contacts heart tissue due to the delivery of a non-ablative amount of energy to the electrode.

FIG. 7 depicts a method of determining heart wall contact of an ablation catheter by delivering an amount of power which is non-damaging to the cellular structures of the body.

FIG. 8 illustrates the change in R-F power required for a 0.5°C temperature rise in the electrode to be maintained as the electrode is moved towards and away from contact with heart tissue.

FIG. 9 illustrates a method of determining heart wall contact of an ablation catheter by supplying a non-damaging amount of power to the electrode to cause a pre-set rise in the temperature of the electrode.

FIG. 10 illustrates the change in heating efficiency of the electrode as it moves into contact with the heart tissue.

FIG. 11 depicts a method of determining heart wall contact by monitoring the heating efficiency of power supplied to the electrode.

FIG. 12 illustrates the operation of a further embodiment of the present invention.

FIG. 13 depicts a method of determining a heart wall contact by supplying a cyclical amount of energy to the electrode and detecting whether there is a corresponding cyclic variation of temperature in the electrode.

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 radio frequency generator 12 that delivers radio frequency energy ("RF energy"). Of course, other types of energy may also be used, such as microwave energy, heat, electrical pulses, cryothermy, and lasers. The specific type of energy delivered is not essential to the invention. The system 10 also includes a steerable catheter 14 carrying a radio frequency emitting tip electrode 129.

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 carries both electrodes.

In the illustrated embodiment, the ablation electrode 129 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 129 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 129 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 portion, which carries the tip electrode 129. 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 radio frequency energy to the ablation electrode 16. The radio frequency heats the tissue to form the lesion.

One or more steering wires 132 (shown in FIG 2) 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 having tip electrode 129 to bend to the left. Also, rotating the steering mechanism 26 to the right pulls on the right steering wire, causing the catheter tip to bend to the right. In this way, the physician steers the tip electrode 129 into contact with the tissue to be ablated.

The generator 12 includes a radio frequency power source 30 connected through a main isolation transformer 32 to first and second conducting lines. In the illustrated embodiment, the power source 30 delivers between 0 - 100 Watts of power at a frequency between 100 KHz - 1 MHz. The first conducting line leads to tip electrode 129. The second conducting line leads to the indifferent patch electrode 18.

FIG. 2 is a sectional view of the distal end or tip of the catheter 14 seen in FIG. 1. As seen catheter tip has electrode 128 mounted on catheter shaft 130. Electrode 128 is electrically coupled to power source (not shown in this FIG) through conductor 129. In the preferred embodiment electrode is a platinum alloy. Positioned within electrode is thermistor assembly 129. Although shown within electrode, thermistor may also be positioned on, adjacent to or separated from electrode. A pair of thermistor leads 131 couple to thermistor assembly and power source. Thermistor assembly is used to sense the temperature of the electrode, although other types of temperature sensors may also be

used, such as a thermocouple for example. As discussed in more detail below, the degree to which the electrode contacts the heart tissue (e.g. no contact, moderate contact, good contact or excellent contact) may be determined by sensing the temperature of the electrode while also sensing the amount of energy which is non damaging to the cellular structures of the body tissue (or "non-ablative") is delivered to the electrode.

FIG. 3 illustrates a catheter tip having an electrode which is emitting energy into the blood stream and the transmission of heat back into the catheter tip. As discussed above, during RF ablation high frequency current is delivered to the tissue and fluids which contact the electrode. Because these tissues and fluids have some electrical resistivity, heat is generated within the tissues and fluids. This so-called resistive heating thereby causes energy in the form of heat to be transmitted back into the electrode. As seen, RF energy represented by dotted lines 301 is emitted from the electrode 129 of catheter 14. In return, heat, represented by solid lines 302, is created in the surrounding tissues and fluids, in this case the blood stream, and partially radiated back into the electrode. Thus the delivery of RF energy to the tissues or fluids of the body causes the electrode to also heat. In the present example, because the electrode is within the blood, however, less of the heat is radiated back into the electrode and more is carried away from the electrode by the blood flow 305 as compared to if the electrode was in contact with body tissue.

FIG. 4 illustrates a catheter tip which is in contact with body tissue and which is emitting energy into tissue and the transmission of heat back into the catheter tip by the tissue. As seen, when the tip electrode is in contact with tissue, such as heart tissue, less surface area of the tip electrode is exposed to blood. Blood transmits less heat back into the tip electrode from the emitted RF energy than does tissue. Consequently, as illustrated in this FIG., when the tip electrode contacts the heart tissue more heat 302 is

delivered from the heart tissue back to the electrode as compared to when the electrode is completely surrounded by blood. This characteristic provides for three related methods for detecting wall contact. First, assuming constant tip temperature is maintained by the delivery of energy to the electrode, then when the amount of energy required to maintain the constant tip temperature is decreased, the tip is contacting heart tissue. Likewise, assuming the amount of power is kept at a constant, then when the temperature of the tip increases at a constant power setting, the electrode is in contact with the heart tissue. Finally, because the heating efficiency of transmitting energy from the electrode and the resulting transmission of heat back into the electrode is greater the closer electrode is to the wall, then by monitoring the amount of heating efficiency to increase the temperature of the tip electrode, the degree of wall contact may be detected. In each method it is an essential feature of the invention that the power supplied to the electrode and the resultant temperature of the electrode are non-damaging to the cellular structures of the body.

FIG. 5 illustrates a system for ablating tissue according to the present invention. As seen, the system 10 includes a RF generator 12 which is electrically coupled to electrode 128. Electrode is in catheter 14. Temperature sensor 129 is also located within the catheter and is preferably located within the electrode. Controller 500 is coupled to temperature sensor and to RF generator. Through controller, the amount of power delivered by RF generator to electrode may be controlled according to the sensor temperature of the electrode. As discussed above, this control may be aimed so that a constant power to the electrode is maintained, or a constant temperature of the tip electrode is maintained. Controller may also function to detect the heating efficiency of the power delivered to the electrode. Controller may be either a separate device or integral with the R-F generator.

In an alternative embodiment the system may further feature a second temperature sensor 529. In this embodiment the second temperature sensor would be

located remote from the temperature sensor 129 but still in sensory contact with the body so that any variation in the body temperature of the patient during the ablation process may be corrected. Temperature sensor 529 may or may not be positioned along catheter 14. This additional temperature sensor is useful for those patients whose body temperature varies during the ablation catheterization procedure. For example, it is sometimes necessary to deliver a drug, such as isoproteronol, to mimic exercise and, in turn, induce arrhythmias. Such a drug, however, often causes the body temperature to rise 1 or 2 degree Celsius.

In a further alternative embodiment the system may also include display 510 to graphically output data indicating the degree to which the electrode contacts heart tissue (e.g. no contact, medium contact, etc.). Display may also provide data regarding the power delivered, electrode temperature or heating efficiency over time as further discussed below.

In a still further alternative embodiment, an oscillator 511 is either coupled to or provided within controller 500. Oscillator is used to cyclically vary the delivered energy to the electrode at a frequency between
0.01 Hz - 1 Hz discussed below. Other alternative embodiments are also discussed below.

FIG. 6 illustrates the change in temperature of the tip electrode as it moves through the blood and contacts heart tissue due to the delivery of a non-ablative amount of energy to tip electrode by generator. At 600 no energy is delivered to the electrode and the temperature of tip electrode is equal to body temperature, 37 degrees Celsius. As seen at 601, tip electrode has a temperature of approx. 38 degrees Celsius due to the delivery of a non-ablative amount of energy to tip electrode by generator. In the system illustrated the delivery of 1 Watt to an electrode which is 7 French wide and 5 mm long then a temperature rise of smaller than approx. 0.5 degrees Celsius in the tip electrode

while it is in the blood. In the preferred embodiment this non-ablative amount of energy is no more than 5 Watts and is preferably less than 1 Watt. Of course the amount of energy delivered to the electrode and the temperature sensed in the electrode depend on the shape and size of the electrode. The essential aspect of the present invention is that an non damaging amount of energy is delivered to the electrode and the temperature of the electrode is monitored. By monitoring the power delivered or the temperature created or the heating efficiency, then the degree of wall contact may be ascertained. At 603 the tip electrode has been moved into moderate contact with the heart tissue. As seen, due to the increased conduction of heat from tissue to tip electrode as compared to from blood to tip electrode, the temperature of the tip electrode rises. At 609 the tip electrode has been moved into excellent contact with the heart tissue and the temperature of the tip electrode has reached an equilibrium state at a higher temperature. Once tip electrode is removed from excellent contact with the heart tissue and is only in good contact with heart tissue, then the conduction of heat from tissue to tip electrode is relatively decreased and the temperature correspondingly decreases, as seen at 611. At 613 the tip has moved to very good contact with the heart tissue and the temperature of tip has again increased. As illustrated at point 615 an ablative amount of energy is delivered to tip electrode by generator to thereby ablate tissue.

FIG. 7 depicts a method of determining heart wall contact of an ablation catheter and ablating heart tissue using the present invention. As seen at 750 a catheter is inserted into the body and preferably into a blood vessel. Catheter preferably has a tip electrode having a temperature sensor, the electrode and sensor are coupled to a R-F generator having a controller as discussed above. At 752 power which is non-damaging to the cellular structures of the body is supplied to the catheter electrode. At 754 the temperature of the electrode is then sensed. As discussed above the supply of energy to the electrode will cause the electrode to increase in temperature by radiative heating,

although the amount of heating will vary depending upon where the electrode is located, i.e. within the blood vessel or against the heart wall. At 756 the catheter is moved. At 758 the temperature of the electrode is again detected to determine whether it has risen. Assuming a constant amount of power is supplied to the electrode, then the rise in temperature of the electrode will indicate the degree of proximity of the electrode to the heart wall. Steps 756 and 758 are iterative, i.e., they are repeated until a desired result is obtained. Once the catheter is properly located then the ablation procedure may be begun, as depicted at step 760. Of course, the ablation process as depicted includes more than simply increasing the power supplied to the electrode but is also meant to include properly locating the electrode in the specific area of the heart tissue in which the ablative procedure is to be performed.

FIG. 8 illustrates the change in RF power required for a 0.5°C temperature rise in the electrode to be maintained over time. As seen, at 600 tip electrode requires 2.5 Watts to maintain a 0.5°C temperature rise. This would indicate there is no contact of the tip electrode with the heart wall. At 802 the RF power required has decreased to 0.1 watt. This would indicate that the tip electrode now is in very good contact with the heart wall. At 804 the catheter has been further moved and now requires over 0.5 watts to maintain a 0.5°C rise in electrode temperature. This would indicate only moderate contact exists between the tip electrode and the heart wall. Finally, at 806 the RF power requires for a 0.5°C rise in temperature has fallen to approximately 0.3 watts. As seen, this indicates there is now good contact between the heart wall and the tip electrode. Of course, other predetermined increases in temperature other than 0.5° C may be selected, such as 1° C. Any temperature increase which is non ablative may be used.

FIG. 9 depicts a method of determining heart wall contact of an ablation catheter by maintaining a constant temperature rise at the catheter electrode and monitoring the

required power to maintain that rise. The method begins at step 950 by inserting a catheter having an electrode and temperature sensor within the body, preferably within a blood vessel leading to the heart. At 952 an amount of power is supplied to the electrode to cause the temperture of the electrode to rise a preset amount. This preset rise in electrode temperature is no more than a temperature which is non-damaging to the cellular structures of the body. At 954 the catheter is moved. At 956 the amount of power required to maintain the electrode at the preset increase in temperature is detected. If the amount of power required is decreased, then the electrode is in better contact with tissue. Steps 954 and 956 are iterative and should be repeated until an acceptably low power level is required by the electrode. At 958 ablation procedure is begun. As discussed above in regards to FIG. 7 ablation procedure is used in the broadest possible manner and is simply intended to mean that the electrode is now in contact with tissue and a determination must be made whether the specific tissue the electrode is in contact with should be ablated.

FIG. 10 illustrates the change in heating efficiency of the tip electrode as it moves from the blood vessel, contacts the heart tissue and the ablation process is begun. Heating efficiency is the rise in temperature experienced at the tip electrode as compared to the power delivered. As seen at 700 the heating efficiency is very low, roughly 0.25°C/watt. At 702 the efficiency is increased to almost over 5°C/watt. This indicates there is very good contact between the tip electrode and the heart wall. At 704 the catheter has been moved and the heating efficiency is decreased now to 1°C/watt. This would indicate there is only moderate contact between the tip electrode and the heart wall. At 706 the catheter has been further moved and the heating efficiency is increased to roughly 4°C/watt. This would indicate there is good contact between the electrode and the heart wall. Once good contact is made the RF ablation process may be begin as illustrated.

As illustrated the RF ablation process has a constant heating efficiency assuming the contact of the electrode to the tissue is constant. Thus using this method the degree of wall contact of the electrode can be monitored during the R-F ablation.

FIG. 11 depicts a method of determining heart wall contact by measuring the change in heating efficiency of the tip electrode. At 80 a catheter is inserted into the body, preferably a blood vessel leading to the heart. At 82 power is supplied to the electrode. The amount of power supplied is preferably within a range which would not cause damage to the cellular structures of the body. At 84 the temperature of the electrode is detected. At 86 the heating efficiency of the power supplied to the electrode is determined. At 88 the catheter is moved through the blood vessel, preferably towards contact with the heart wall tissue. At 90 whether the heating efficiency of the power supplied to the electrode has increased is detected. Steps 88 and 90 are iterative and should be repeated until the desired heating efficiency is attained. Finally, at 92 the ablation procedure may be begun.

FIG. 12 illustrates the operation of further embodiment of the present invention. As discussed above, the temperature of the patient's body may vary during the ablation process. This may provide problems with indicating the quality of wall contact of the tip electrode. In this alternative embodiment this problem is overcome through the use of a cyclic delivery of non-damaging amount of RF energy to the tip electrode and the corresponding sensing of the temperature in the tip electrode. As seen at 852 a cycle of RF energy between 0-0.2 watts is delivered to the electrode. At this time the electrode temperature undergoes a slight change in temperature as illustrated at 850. Once wall contact is achieved, then the sensed electrode temperature will also undergo a cyclic variation as illustrated at 854. Moreover, there will be a phase shift between the sensed temperature of the electrode and the delivery of the RF energy while any contact is

maintained. This phase shift will result from the lag in time of the power being delivered to the tissue, the tissue heating, and the radiation of the tissue heat back into the tip electrode and the sensing of this heat by the temperature sensor. If the electrode is further moved and only moderate contact is made between the tip electrode and the heart tissue, then the amplitude of the temperature variation of the electrode will decrease as seen at 860. Once good or better contact is satisfactorily achieved, then the amplitude of the temperature variation at the tip electrode will increase again as illustrated at 862.

FIG. 13 depicts a method of determining heart wall contact through the use of a cyclic delivery of a non-damaging amount of energy to the electrode and the corresponding sensing of the temperature variation in the tip electrode. At 81 the catheter having a tip electrode is inserted into the body, preferably a blood vessel lead to the heart. At 83 an amount of power which is non-damaging to the cellular structures of the body is supplied to the electrode in a cyclic or oscillatory manner. At 85 the temperature of the tip electrode is detected. At 87 whether the temperature of the tip electrode has risen and fallen in a cycle which corresponds to the oscillatory supply of power is detected. Steps 85 and 87 are iterative and should be repeated until a temperature variation in the electrode which is in a cycle corresponding to the power supplied and which also shows a sufficient amplitute of temperature variance is achieved. At 89 the ablation process is begun.

Although the invention has been described in detail with particular reference to a preferred embodiment and alternate embodiments thereof, it will be understood variations and modifications can be effected within the scope of the following claims. Such modifications may include substituting elements or components which perform substantially the same function in substantially the same way to achieve substantially the same result for those described herein.

CLAIMS:

1. A system for ablating tissue within a body, the system accessing the body tissue through the blood vessels of the body comprising:

an energy source providing a level of energy which is non damaging to the cellular structures of the body tissue,

a catheter coupled to the energy source, the catheter having an electrode; and

means for sensing the temperature of the electrode while also sensing the amount of energy which is non damaging to the cellular structures of the body tissue is delivered to the electrode, the sensing means coupled to the catheter and coupled to the energy source wherein the degree to which the electrode contacts the heart tissue (e.g. no contact, moderate contact, good contact or excellent contact) may be determined.

2. The system according to claim 1 wherein the level of energy which is non damaging to the cellular structures of the body tissue is less that 5 Watts

3. The system according to claim 1 wherein the means for sensing temperature comprises a thermistor positioned adjacent the electrode

4. The system according to claim 1 wherein the means for sensing the temperature of the electrode while also sensing the amount of energy which is non damaging to the cellular structures of the body tissue is delivered to the electrode comprises means for controlling the amount of energy delivered to the electrode so that the electrode temperature is raised no more than 5 degrees Celsius.

5. The system according to claim 4 wherein the means for controlling the amount of energy delivered to the electrode so that the electrode temperature is raised no more than 5 degrees Celsius comprises means for controlling the amount of energy delivered to the electrode so that the electrode temperature is raised no more than one half degrees Celsius.

6. The system according to claim 4 wherein the means for sensing the temperature of the electrode while also sensing the amount of energy which is non damaging to the cellular structures of the body tissue is delivered to the electrode comprises means for delivering a constant amount of non-damaging energy to the body tissue and means for detecting when the constant non-damaging energy is delivered directly to the body tissue as compared to delivered to the blood within the blood vessels of the body.

7. The system according to claim 6 wherein the catheter has a distal end, a temperature detector positioned adjacent the distal end, the temperature detector indicating when the temperature increases above a pre determined level, the pre determined level being non damaging to body tissue.

8. The system according to claim 7 wherein the pre determined level is no more than 5 degrees Celsius and wherein the energy source is an RF generator.

9. The system according to claim 8 wherein the RF generator provides between 100KHz -1 MHz and 0 -100 Watts.

10. A system for ablating tissue within a body, the system accessing the body tissue through the blood vessels of the body comprising:

an energy source providing a level of energy which is non damaging to the cellular structures of the body tissue,

a catheter coupled to the energy source, the catheter having an electrode; and

means for sensing the relation between the power delivered to the electrode and the rise in temperature of the tip electrode and indicating the degree of contact between the electrode and tissue, the indicating means coupled to the sensing means

11. The system according to claim 10 wherein the means for sensing the relation between the power delivered to the electrode and the temperature of the tip electrode comprise means for delivering a constant amount of non-damaging energy to the body tissue and means for detecting when the constant non-damaging energy is delivered directly to the body tissue as compared to delivered to the blood within the blood vessels of the body.

12. The system according to claim 10 wherein the means for sensing the relation between the power delivered to the electrode and the temperature of the tip electrode comprise means for delivering an amount of energy to the electrode to cause the electrode to increase a pre set amount of temperature, wherein the amount of energy to the electrode to cause the electrode to increase a pre set amount of temperature is greater when the electrode is further from body tissue as compared to in contact with the body tissue

13. The system according to claim 10 wherein the means for sensing the relation between the power delivered to the electrode and the temperature of the tip electrode comprise means for detecting the heating efficiency of the electrode.

14. The system according to claim 13 wherein the means for detecting the heating efficiency comprise means for detecting the increase in the heating efficiency of the electrode.

15. A system for ablating tissue within a body, the system accessing the body tissue through the blood vessels of the body comprising:

an energy source,

a catheter coupled to the energy source, the catheter having means for delivering non-damaging energy to the body tissue, and means for detecting when the non-damaging energy is delivered directly to the body tissue as compared to delivered to the blood within the blood vessels of the body.

16. The system according to claim 15 wherein the catheter has a distal end, a temperature detector positioned adjacent the distal end, the temperature detector indicating when the temperature increases above a pre determined level, the pre determined level being non damaging to body tissue.

17. The system according to claim 15 wherein the pre determined level is 1 degree Celsius wherein the energy source is an RF generator.

18. The system according to claim 17 wherein the RF generator provides between 100khz -1MHz and 0 -100 Watts.

19. A system for ablating tissue within a body, the system accessing the body tissue through the blood vessels of the body comprising:

an energy source,

a catheter coupled to the energy source, the catheter having means for delivering non-damaging energy to the body tissue, and means for detecting when the non-damaging energy is delivered directly to the body tissue as compared to delivered to the blood within the blood vessels of the body.

20. A system for ablating tissue within a body, the system accessing the body tissue through the blood vessels of the body comprising:

a catheter having an electrode and a temperature sensor,

a generator coupled to the catheter, the generator having means for delivering to the electrode a non damaging amount of energy

a controller coupled to the temperature sensor and the generator, the controller having means for controlling the amount of energy delivered to the electrode so that the electrode temperature is raised no more than 5 degrees Celsius.

21. A method of detecting contact between an ablation catheter and a heart wall comprising the steps of:

inserting an ablation catheter having an electrode and an electrode temperature sensor into a blood vessel leading to a heart wall, the blood vessel having a stream of blood therein;

supplying a power to the electrode, the power being non-damaging to the cellular structure of the body tissue;

detecting the temp of electrode in blood stream due to the supply of power to the electrode;

moving catheter along the blood vessel;

sensing the temperature of the electrode while also sensing the amount of energy which is non damaging to the cellular structures of the body tissue is delivered to the electrode; and

determining the degree to which the electrode is in contact with heart tissue.

22. The method of claim 21 wherein the step of supplying the pre set amount of power to the electrode comprises supplying the power in an cycle, the cycle having a first amplitude and a second amplitude

23. The method of claim 21 wherein the cycle has a frequency of 0.01 Hz - 1 Hz.

24. The method of claim 23 wherein the first amplitude is less than second but greater than zero

25. A method of detecting contact between an ablation catheter and a heart wall comprising the steps of:

inserting catheter having an electrode and an electrode temperature sensor into a blood vessel leading to a heart wall, the blood vessel having a stream of blood therein;

supplying power to the electrode to cause the electrode temperature to rise a pre set amount, the pre set amount of temperature rise being non-damaging to body tissue;

moving catheter along the blood vessel;

detecting whether the amount of power supplied to the electrode to cause the electrode temperature to rise a pre set amount has decreased, if the power has decreased, then electrode is closer to the heart wall and the ablation procedure may begin, otherwise, continue moving catheter along the blood vessel.

26. The method of claim 25 wherein the step of supplying the pre set amount of power to the electrode comprises supplying the power in a cycle, the cycle having a first amplitude and a second amplitude

27. The method of claim 26 wherein the cycle has a frequency of 0.01 Hz - 1 Hz.

28. The method of claim 26 wherein the first amplitude is less than second but greater than zero.

29. The method of claim 26 wherein the step of detecting whether temp of electrode has risen comprises detecting whether the temperature of the electrode has risen in cycle which corresponds to the cycle of the supply of power to the electrode.

30. A method of detecting contact between an ablation catheter and a heart wall comprising the steps of:

inserting catheter having an electrode and an electrode temperature sensor into the blood vessel leading to a heart wall, the blood vessel having a stream of blood therein;

supplying power to the electrode to cause the electrode temperature to rise a pre set amount, the pre set amount of temperature rise being non-damaging to body tissue;

moving catheter along the blood vessel;

detecting whether the amount of power supplied to the electrode to cause the electrode temperature to rise a pre set amount has decreased, if the power had decreased, then electrode is closer to the heart wall and the ablation procedure may begin, otherwise, continue moving catheter along the blood vessel.

31. The method of claim 30 wherein the step of supplying power to the electrode to cause the electrode temperature to rise a pre set amount comprises supplying the power in a cycle such that the temperature of the electrode rises to a preset amount in a corresponding cycle.

32. The method of claim 26 wherein the cycle has a frequency of 0.01 Hz - 1Hz.

33. The method of claim 26 wherein the first amplitude is less than second but greater than zero

34. The method of claim 30 wherein the step of detecting whether the amount of power supplied to the electrode to cause the electrode temperature to rise a pre set amount has decreased comprises detecting whether the power and temperature oscillate at the same frequency.

35. A method of detecting contact between an ablation catheter and a heart wall comprising the steps of:

inserting catheter having an electrode and an electrode temperature sensor into a blood vessel leading to a heart wall, the blood vessel having a stream of blood therein;

supplying power to the electrode and measuring the heating efficiency of the supplied power, the power supplied being non-damaging to the cellular structure of the body tissue;

moving catheter along the blood vessel;

detecting whether the heating efficiency of the power supplied to the electrode has increased, if the heating efficiency has increased, then electrode is closer to the heart wall and the ablation procedure may begin, otherwise, continue moving catheter along the blood vessel.

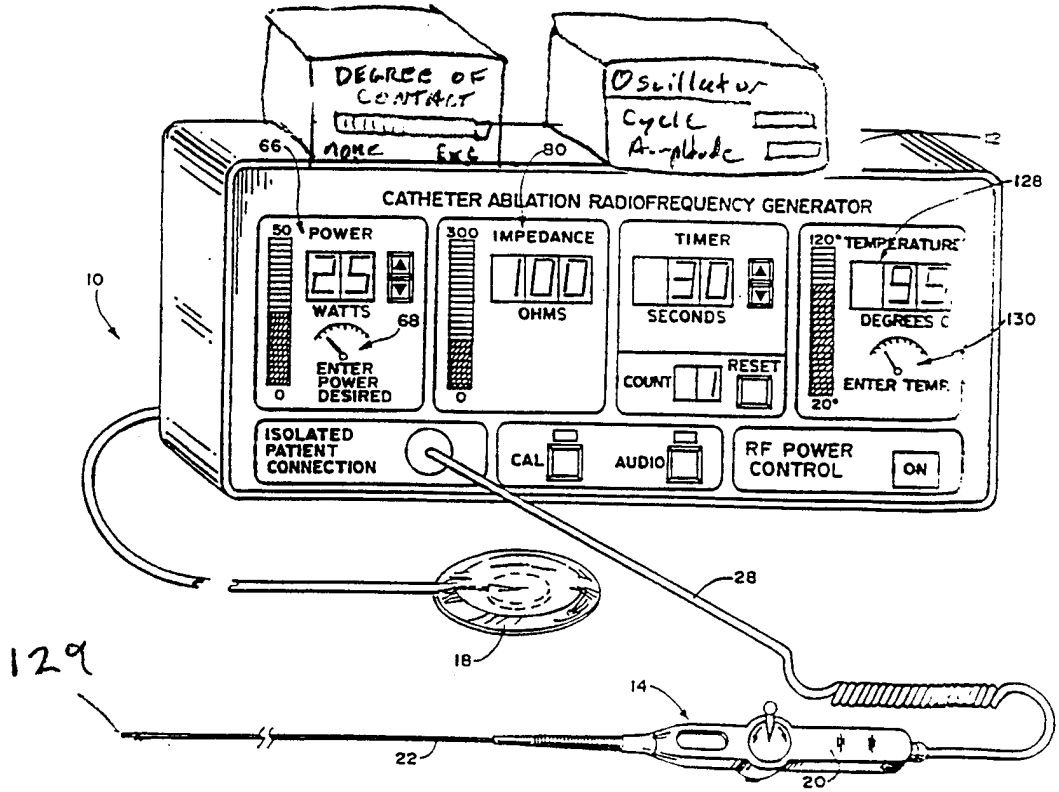

DEGREE OF CONTACT
Oscillator
Cycle
Amplitude
CATHETER ABLATION RADIOFREQUENCY GENERATOR
POWER
WATTS
ENTER POWER DESIRED
IMPEDANCE
OHMS
TIMER
SECONDS
TEMPERATURE
DEGREES C
ENTER TEMP.
COUNT
RESET
ISOLATED PATIENT CONNECTION
CAL
AUDIO
RF POWER CONTROL
ON
10
12
18
20
22
28
66
68
80
128
129
130
14

FIG 1

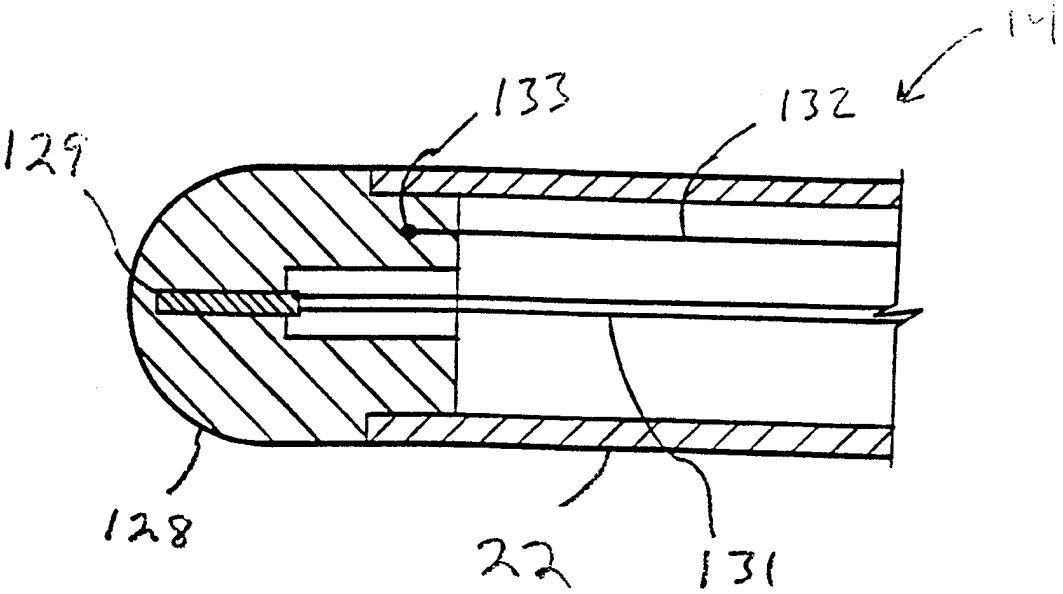

129
133
132
131
128
22

FIG 2

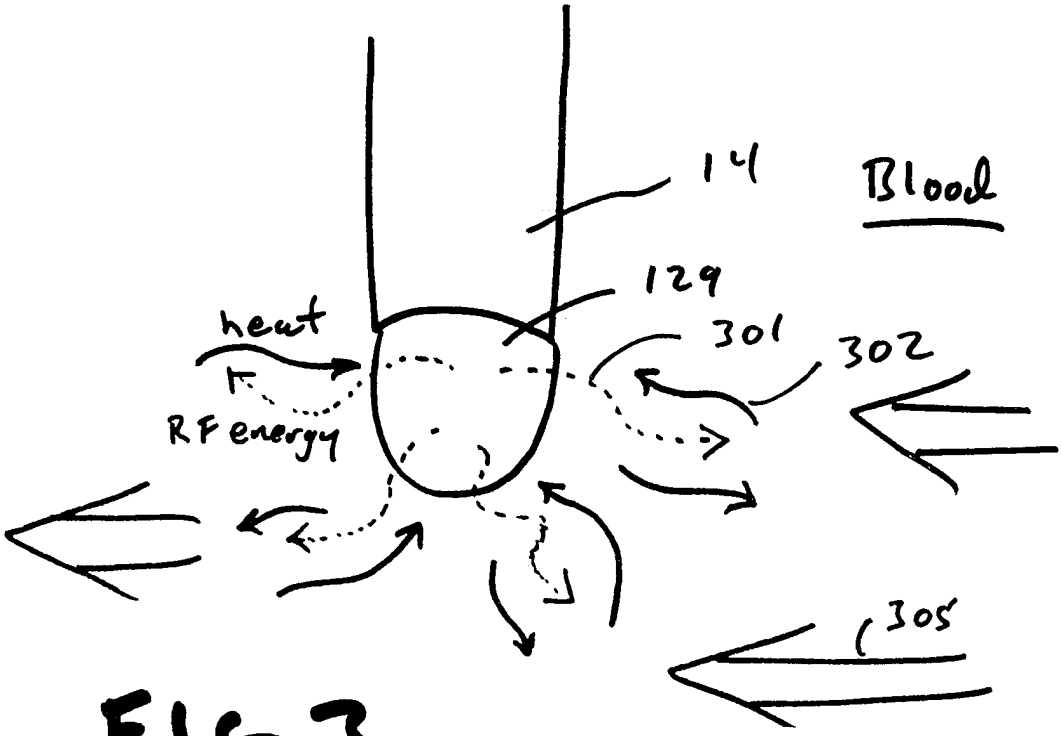

14
Blood
129
heat
301
302
RF energy
305

FIG 3

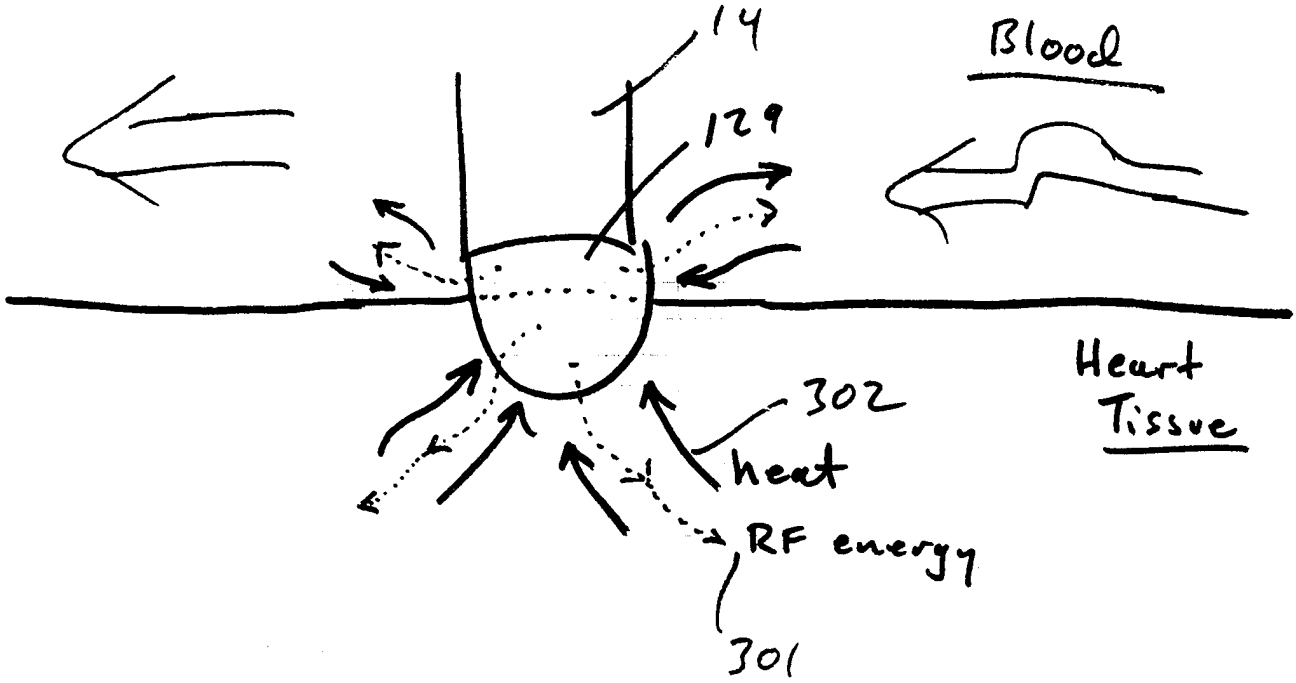

14
Blood
129
Heart
Tissue
302
heat
RF energy
301

FIG 4

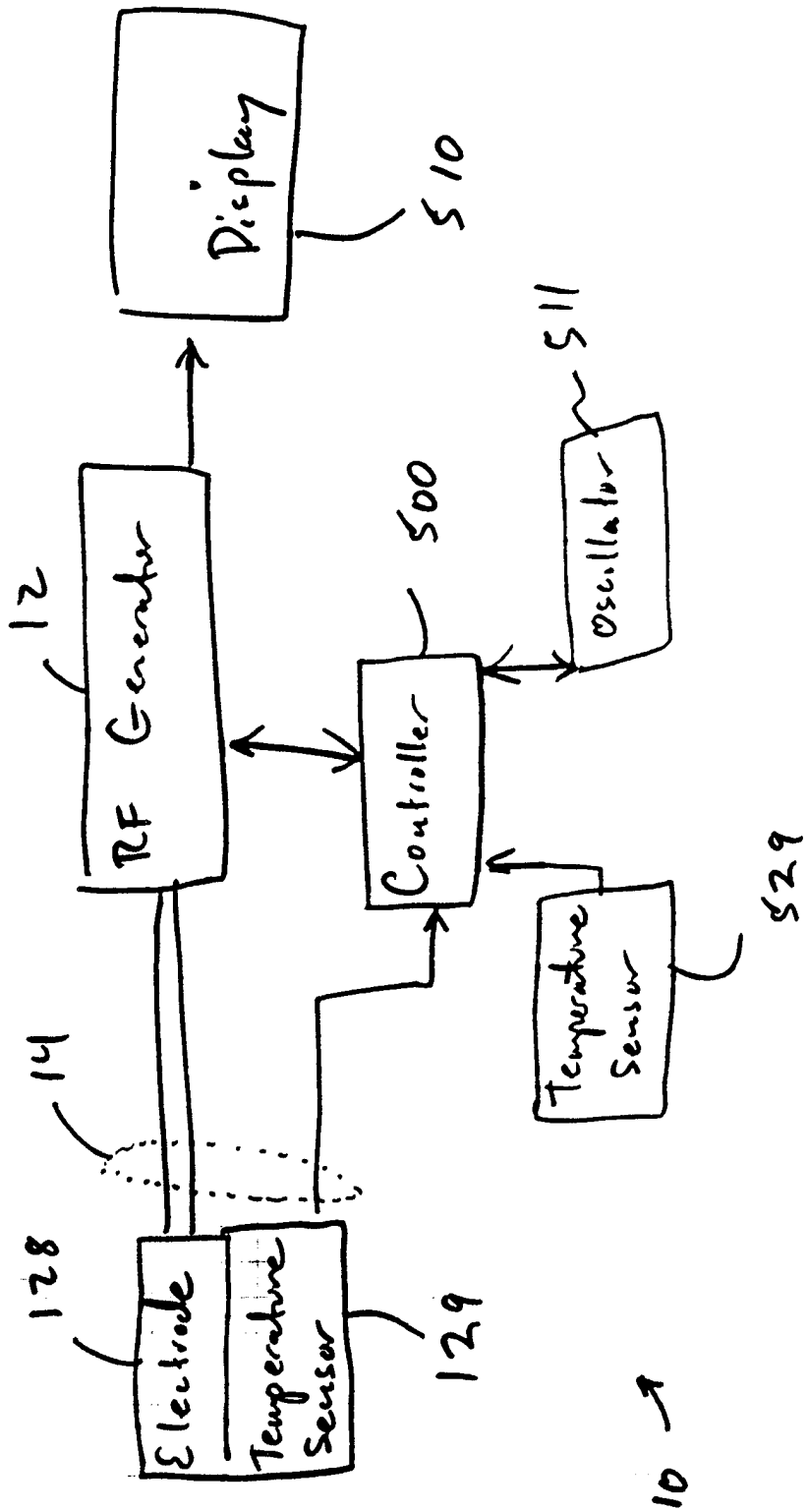
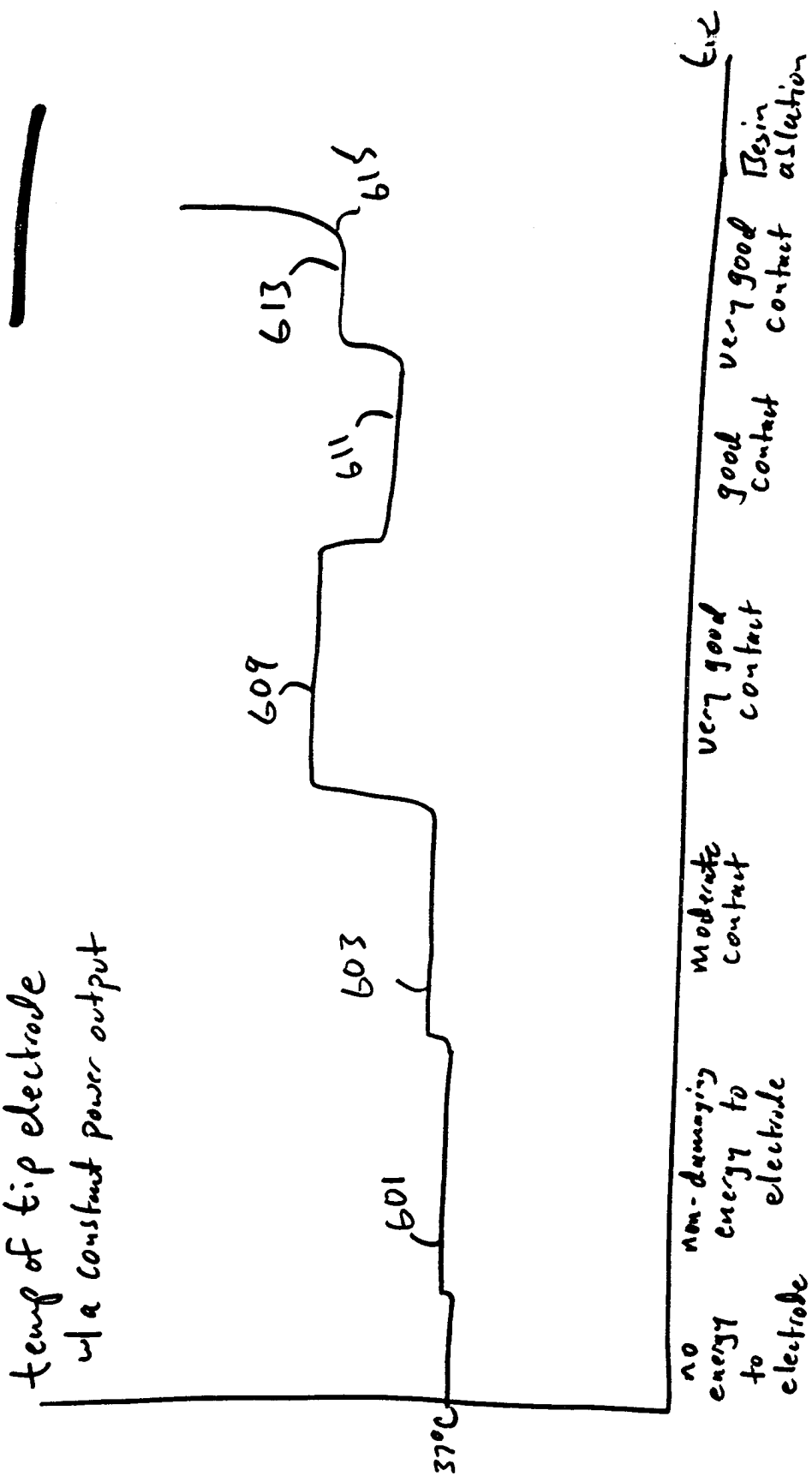

Display
510
RF Generator
12
500
Oscillator
511
Controller
Temperature Sensor
529
14
128
Electrode
Temperature Sensor
129
10

Fig 5

FIG 6


temp of tip electrode
w/a constant power output
37°C
601
603
609
611
613
615
no energy to electrode
non-damaging energy to electrode
moderate contact
very good contact
good contact
very good contact
Begin ablation
time

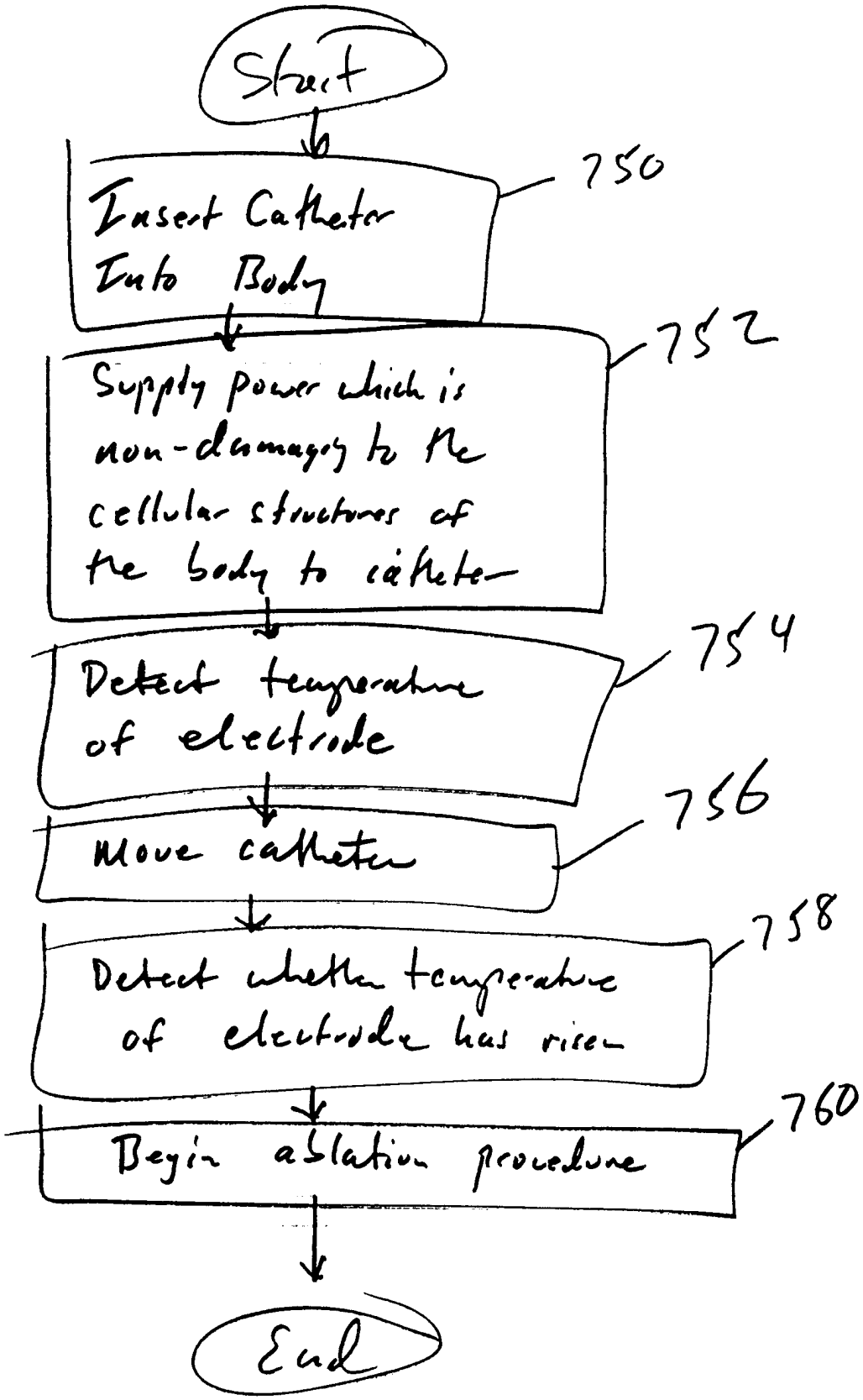
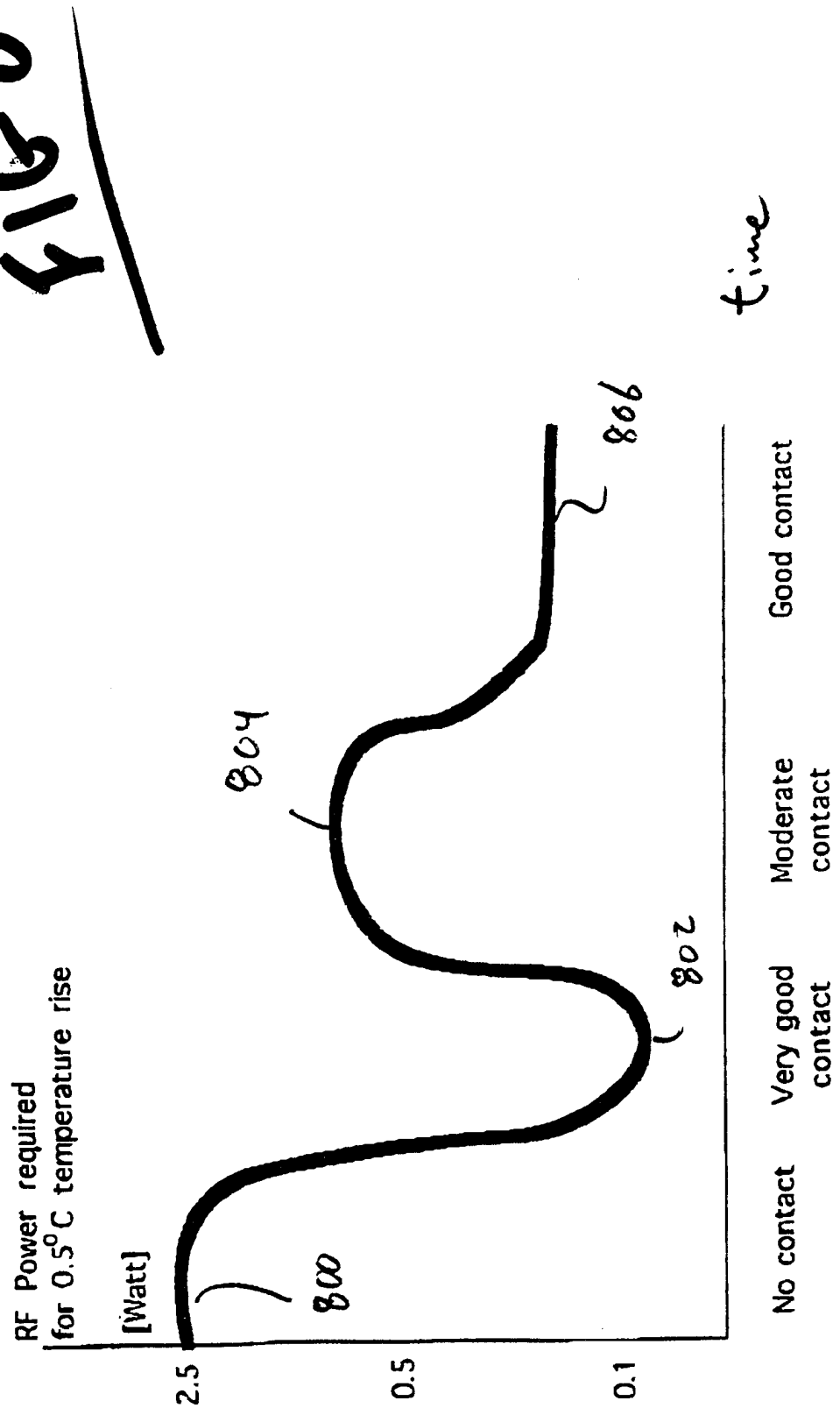


FIG 7

constant power
temp rise

FIG 8


RF Power required
for 0.5°C temperature rise
[Watt]
2.5
0.5
0.1
800
802
804
806
time
No contact
Very good contact
Moderate contact
Good contact

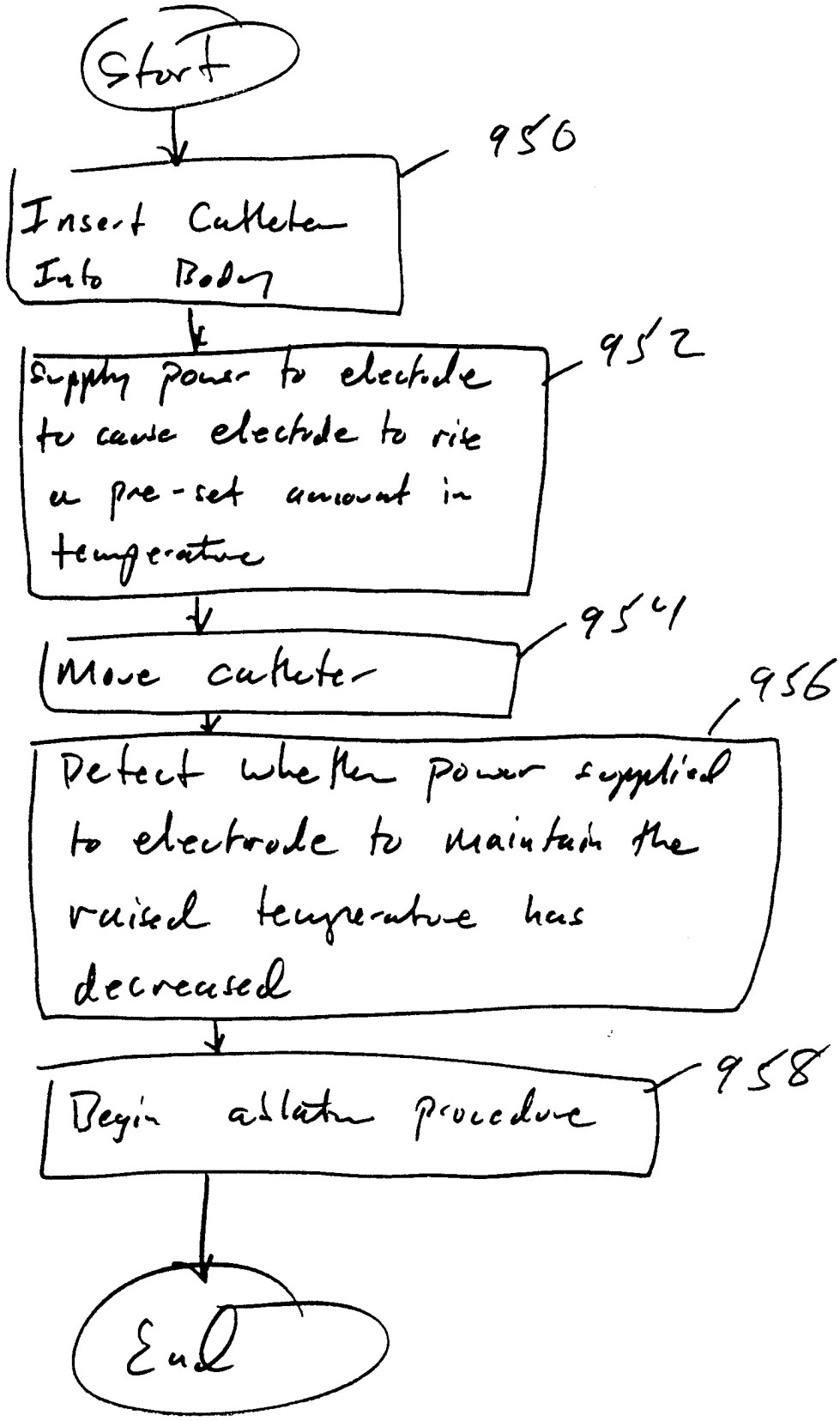
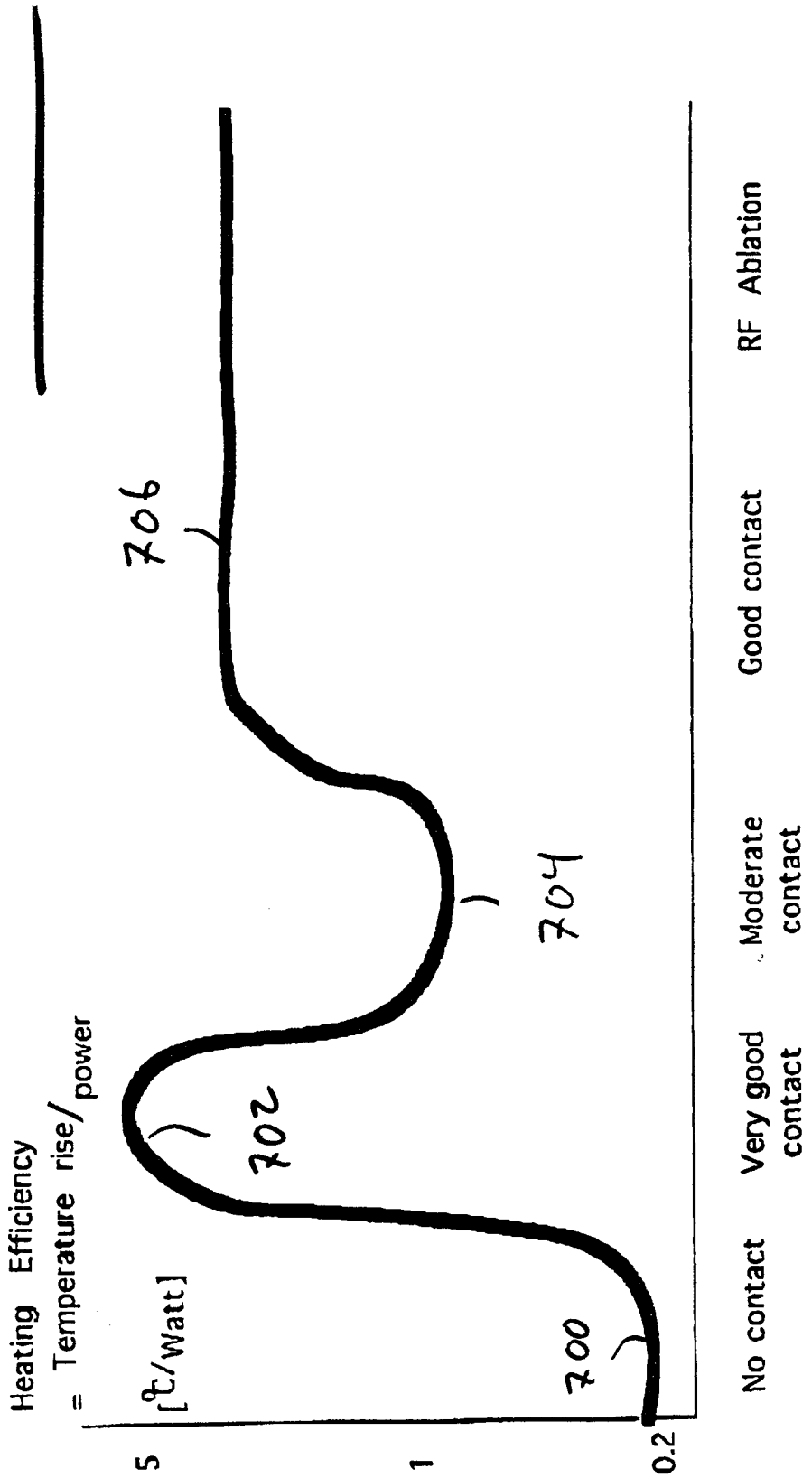
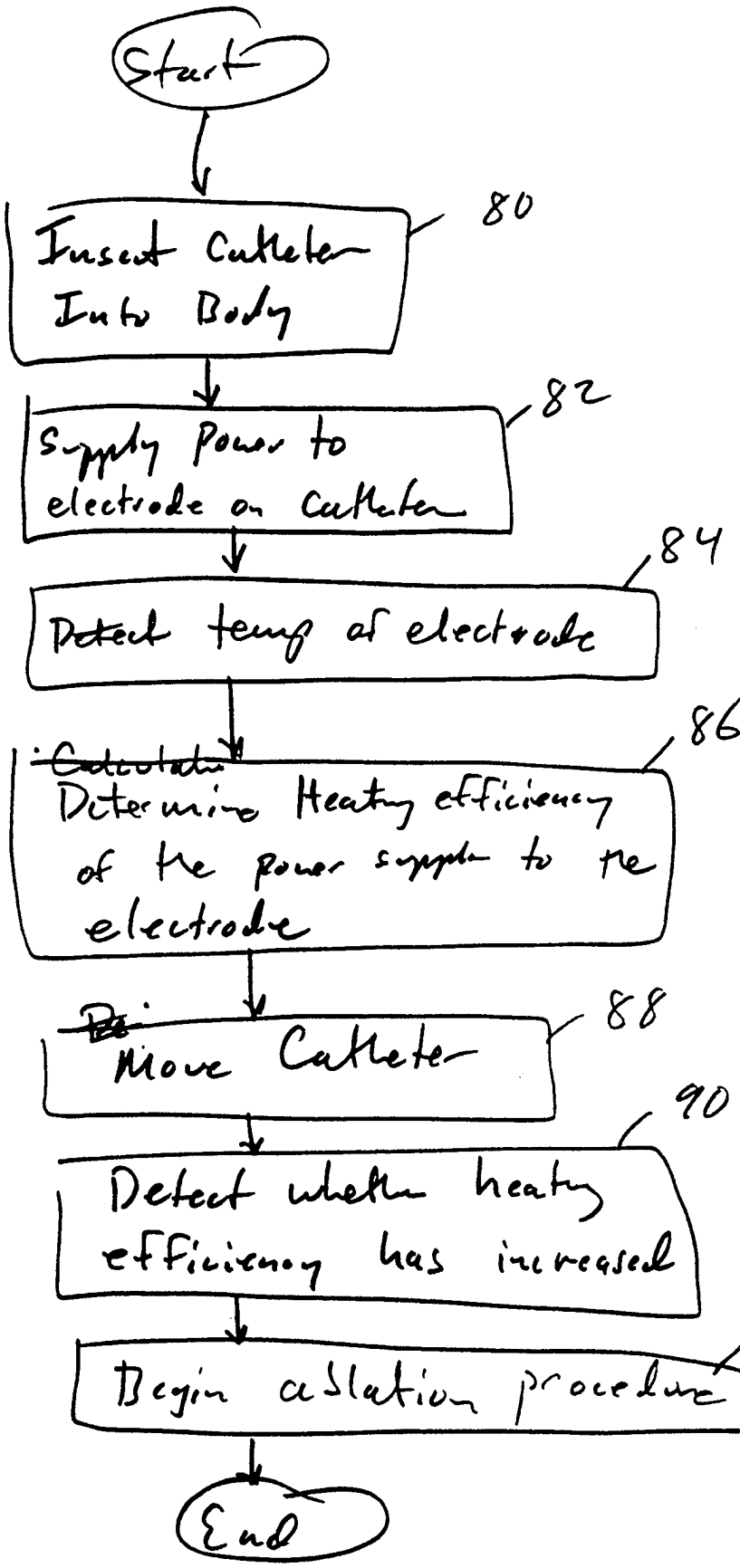


Fig 9

constant temp
Decrease power

FIG 10

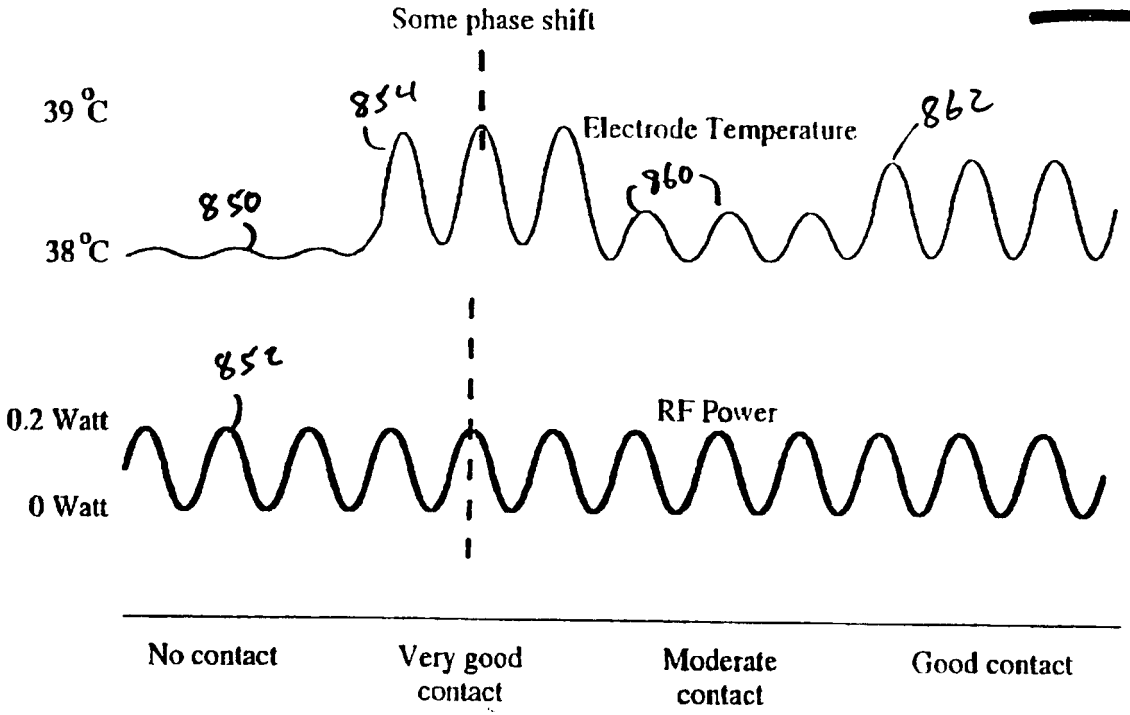

Heating Efficiency
= Temperature rise/power
[°C/Watt]
5
1
0.2
700
702
704
706
No contact
Very good contact
Moderate contact
Good contact
RF Ablation



Heating Efficiency

FIG 11

FIG 12



method to eliminate need for body temp meas

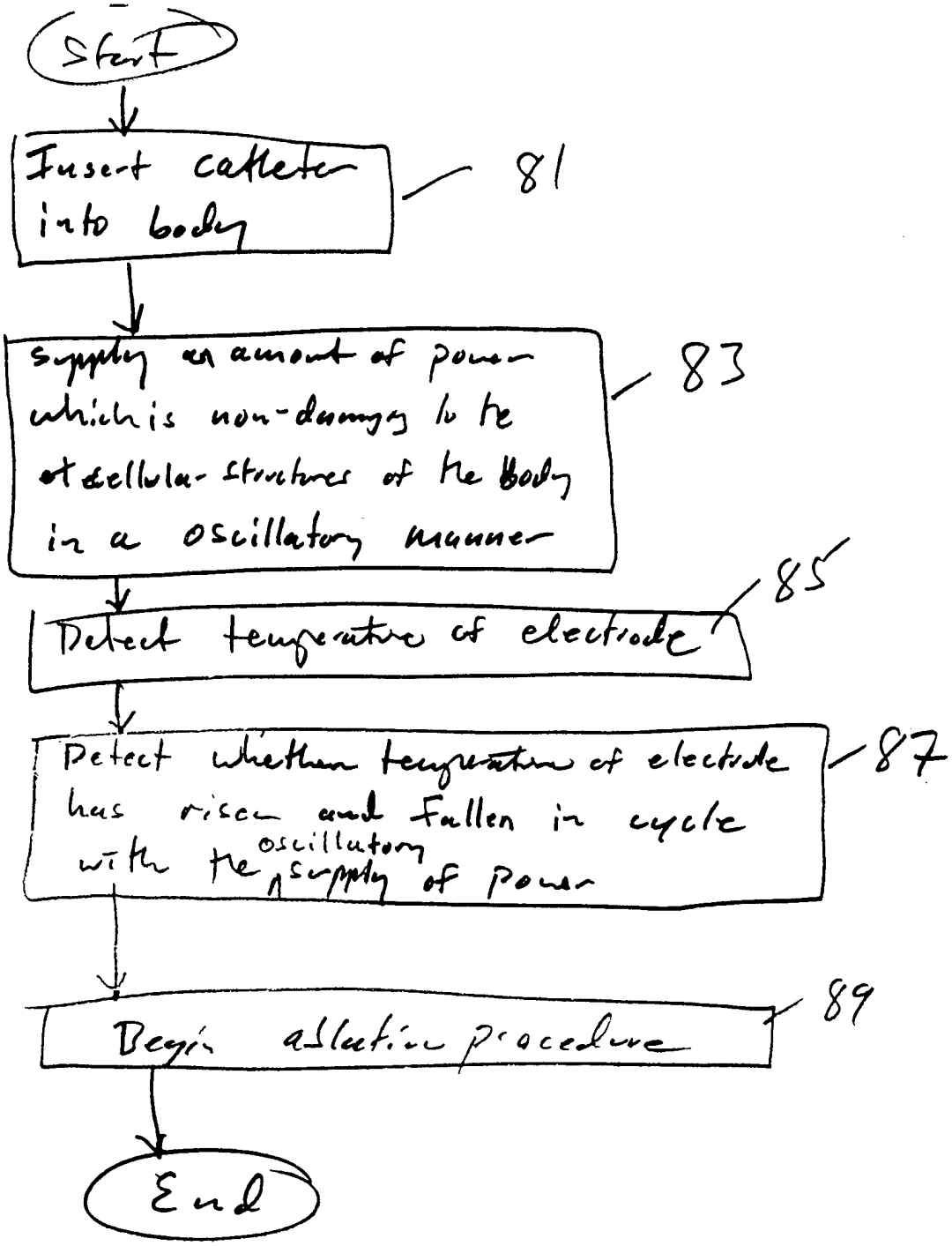

Start
Insert catheter into body
81
Supply an amount of power which is non-damaging to the cellular structures of the body in a oscillatory manner
83
Detect temperature of electrode
85
Detect whether temperature of electrode has risen and fallen in cycle with the oscillatory supply of power
87
Begin ablation procedure
89
End

FIG 13

INTERNATIONAL SEARCH REPORT

Interi nal Application No
PCT/US 98/04172

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/39

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 6 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.
A	WO 95 10978 A (EP TECHNOLOGIES INC) 27 April 1995 see page 4, line 8 - line 16 see page 9, line 26 - page 12, line 24; figures 2,6	1,10,15, 19,20
A	US 5 562 721 A (MARCHLINSKI FRANCIS E ET AL) 8 October 1996 see abstract; figures 1,2	1,10,15, 19,20
A	US 5 341 807 A (NARDELLA PAUL C) 30 August 1994 see abstract; figure 1	1,10,15, 19,20
A	WO 90 07303 A (ANGIOPLASTY SYSTEMS INC) 12 July 1990 see page 12, line 23 - page 13, line 7	1,10,15, 19,20

-/--

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

[X] Patent family members are listed in annex.

° Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
11 June 1998	25. 06. 98

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	Hansen, S

1

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

INTERNATIONAL SEARCH REPORT

Inter nal Application No
PCT/US 98/04172

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 96 00040 A (EP TECHNOLOGIES INC) 4 January 1996 see page 20, line 19 - page 21, line 11; figure 6B	1,10,15, 19,20
A	US 5 122 137 A (LENNOX CHARLES D) 16 June 1992 see abstract; figure 2	1,10,15, 19,20

1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 98/04172

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

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

1. [X] Claims Nos.: 21-35
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

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

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

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

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

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

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

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

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter ›nal Application No
PCT/US 98/04172

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9510978 A	27-04-1995	NONE	
US 5562721 A	08-10-1996	US 5447529 A	05-09-1995
		AU 1435895 A	15-08-1995
		CA 2179058 A	03-08-1995
		WO 9520361 A	03-08-1995
		US 5673704 A	07-10-1997
US 5341807 A	30-08-1994	CA 2139312 A	06-01-1994
		EP 0648087 A	19-04-1995
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		WO 9400050 A	06-01-1994
WO 9007303 A	12-07-1990	AU 4945490 A	01-08-1990
		US 5454809 A	03-10-1995
		US 5626576 A	06-05-1997
		US 5749914 A	12-05-1998
WO 9600040 A	04-01-1996	US 5755715 A	26-05-1998
		US 5702386 A	30-12-1997
US 5122137 A	16-06-1992	CA 2081464 A	28-10-1991
		EP 0528868 A	03-03-1993
		JP 6500476 T	20-01-1994
		WO 9116859 A	14-11-1991