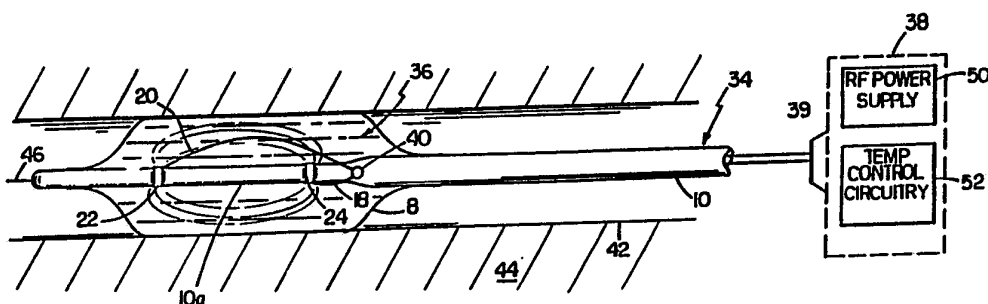




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(54) Title: HEATED BALLOON CATHETERS AND THE LIKE



(57) Abstract

A device and a method for heating tissue, the device having a catheter shaft (10) for insertion into a patient's body, a chamber formed by a collapsible balloon (8) mounted on the shaft and filled with an electrically conductive fluid (36). A power supply (50) applies an electrical potential to two or more contacts (22, 24) within the chamber via conductors (18, 20). The fluid is heated on the basis of I^2R losses by a radio frequency electric current flowing between electrodes, and in turn heat the surrounding tissue. According to the method, the device is inserted into a patient's body, the chamber is filled with the fluid, and an electrical potential is applied to the contacts. The device acts as a temperature source, and a thermistor (26) in the balloon or in contact with tissue responds to the heating effect to control application of the current.

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HEATED BALLOON CATHETERS AND THE LIKE

Background of the Invention

This invention relates to balloon catheters and similar devices useful to apply heat within a patient's body, e.g., for angioplasty, hyperthermal treatment of
5 tumors, and other medical procedures.

Prior proposals for application of heat internally of the body have often had drawbacks. The devices have been too large for certain procedures or have otherwise been
10 difficult to insert, remove and/or control. In some cases, the devices have been too complex in construction or have been too expensive.

We have conceived of an approach that, in a number of circumstances, can overcome such drawbacks.

Summary of the Invention

According to one aspect of the invention, a device for heating tissue comprises a chamber constructed for insertion into a patient's body, an electrically conductive fluid preselected for resistive heating for filling the
20 chamber, a plurality of spaced electrical contacts enclosed within the chamber and a corresponding plurality of conductors for connecting the electrical contacts to a power supply for applying a radio frequency electrical potential to the contacts, the contacts being exposed to the fluid-
25 containing space of the chamber so that the radio frequency electrical potential can cause current to flow through fluid between the contacts, the chamber and the contacts being cooperatively constructed and arranged to cause the current to be substantially confined to the fluid within the
30 chamber, whereby, on the basis of I^2R losses of the radio frequency electric current flowing between the electrical contacts, the fluid can be heated and the fluid in turn can

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heat the surrounding tissue by thermal conduction through a wall of the chamber.

Preferred embodiments of this aspect of the invention may include one or more of the following features.

5 The chamber is defined by an expandable wall and is adapted to be empty and the expandable wall collapsed at the time of introduction into the patient and wherein a conduit is adapted to fill the chamber with the fluid after introduction of the chamber into a patient's body. The
10 device in the form of a catheter, and further comprising a catheter shaft constructed for insertion into a patient's body, the chamber being defined by a wall which at least in part is expandable, and the chamber being associated with a lumen for fluid flow between the chamber and a fluid source
15 outside of the body, the chamber being fillable after placement in the body with an electrical conductive fluid preselected to produce resistive heating. The chamber is defined by an inflatable balloon. The spaced contacts are mounted directly upon the catheter shaft within the chamber.
20 The conductors are enclosed within the shaft along its length. The chamber has the form of an inflatable balloon mounted upon the shaft. The electrical contacts are radiopaque and serve as radiopaque markers. The impedance between a pair of electrodes, when the chamber is filled
25 with the preselected fluid, is less than 1000 ohms, preferably in the range of 50 to 500 ohms. The device includes a power supply constructed to operate at a frequency between 100 kHz and 100 MHz. The electrical potential applied across the contacts by the power source is
30 about 100 volts or less. The device further comprises a temperature sensor, and a temperature control circuit for controlling the output of the power supply in response to information received from the temperature sensor. A

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temperature sensor constructed to sense the temperature of the fluid for controlling the application of the electrical potential to the contacts is located within the chamber. The device associated with an temperature sensor located
5 outside the chamber in contact with tissue surrounding the chamber for controlling the application of electrical potential to the contacts is located within the chamber. The chamber is filled with a saline solution. The chamber is filled with a fluid that is radiopaque. The device is
10 sized and constructed for insertion into a blood vessel, or for insertion into the body to apply heat to the prostate gland. The chamber is coated with a coating that prevents it from sticking to tissue. The device includes a power supply adapted to apply current at a level sufficient to
15 cause localized boiling of the fluid at the electrical contacts, to cause mixing of the fluid in the chamber and produce uniform heating of the chamber wall. The device includes a pressure transducer exposed to sense fluid pressure in the chamber and means constructed and arranged
20 to control the energy applied to the electrical contacts in response to information received from the pressure transducer. The device is associated with a power supply controlled by a thermistor sensor, and a control constructed and arranged to operate alternately in a power application
25 mode in which RF potential is applied to the contacts and a sensing mode during which application of RF potential to the contacts is disrupted. The device includes a thermistor exposed to fluid in the chamber, the thermistor connected to one of the electrical contacts, the device adapted to be
30 used with a power supply controlled to alternately apply potential to the electrical contacts and to sense the temperature of the fluid in the absence of RF potential on the contacts.

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According to another aspect of the invention, a method for heating tissue comprises inserting into a patient's body a chamber containing electrically conductive fluid preselected for resistive heating, there being a plurality of spaced electrical contacts enclosed within the chamber and a corresponding plurality of conductors for connecting the electrical contacts to a power supply for applying a radio frequency electrical potential to the contacts, the contacts being exposed to the fluid-containing space of the chamber so that the radio frequency electrical potential can cause current to flow through fluid between the contacts, the chamber and the contacts being cooperatively constructed and arranged to cause the current to be substantially confined to the fluid within the chamber, and applying radio frequency potential to the electrical contacts, whereby, on the basis of I^2R losses of the radio frequency electric current flowing between the electrical contacts, the fluid is heated and the fluid in turn heats the surrounding tissue by thermal conduction through a wall of the chamber.

Preferred embodiments of this aspect of the invention may include one or more of the following features. The radio frequency potential applied across the contacts is at frequency in the range between about 100 kHz and 100 MHz. The method includes controlling the electrical current between the electrical contacts to induce localized boiling at the contacts.

According to still another aspect of the invention, a method for constant temperature heating comprises inserting into a patient's body a chamber containing electrically conductive fluid preselected for resistive heating, there being a plurality of spaced electrical

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contacts enclosed within the chamber and a corresponding plurality of conductors for connecting the electrical contacts to a power supply for applying a radio frequency electrical potential to the contacts, the contacts being
5 exposed to the fluid-containing space of the chamber so that the radio frequency electrical potential can cause current to flow through fluid between the contacts, the chamber and the contacts being cooperatively constructed and arranged to cause the current to be substantially confined to the fluid
10 within the chamber, applying radio frequency potential to the electrical contacts, and monitoring temperature at a point influenced by the temperature of the liquid and, in response thereto, controlling the radio frequency energy applied to the electrical contacts to maintain the
15 temperature constant, whereby, on the basis of I^2R losses of the controlled radio frequency electric current flowing between the electrical contacts, the fluid is heated and the fluid in turn heats the surrounding tissue by thermal conduction through a wall of the chamber.

20 Preferred embodiments of this aspect of the invention may include one or more of the following features.

The chamber comprises a balloon on a catheter introduced into a lumen or cavity of the body. The temperature at a point in the body adjacent the chamber is monitored and used
25 to control the application of energy to the electrodes to maintain temperature at the point constant for a selected duration, on the basis of thermal transfer from liquid heated in the balloon to the point. The temperature of the liquid in the chamber is monitored and used to control the
30 application of energy to the electrodes to maintain temperature of the fluid constant at a set point whereby it

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is assured that tissue in the vicinity of the chamber is not heated above the set point.

These and other features and advantages will be seen from the following description of a presently preferred embodiment, and from the claims.

Description of a Presently Preferred Embodiment

We first briefly describe the drawings.

Fig. 1 shows a balloon catheter according to the invention;

Fig. 2 is a detailed drawing of the balloon portion of the balloon catheter of Fig. 1, according to an embodiment of the invention in which a temperature sensing device is mounted inside the balloon;

Fig. 3 is a transverse cross-section of the catheter shaft of the balloon catheter of Fig. 2;

Fig. 4 is a block diagram of the RF power supply and temperature control circuitry according to an embodiment of the invention of Fig. 2;

Fig. 5 is a block diagram of the RF power supply and temperature control circuitry according to an embodiment of the invention in which a temperature sensor is placed in direct contact with the tissue surrounding the balloon;

Fig. 6 is a block diagram of the RF power supply and temperature control circuitry according to an aspect of the invention in which a pressure transducer inside the balloon is used as a means for indirectly measuring the amount of heating of surrounding tissue; and

Fig. 7 is a detailed block diagram of the temperature control circuit of Figs. 4, 5 and 6.

Referring now to Fig. 1, a balloon catheter 34 of the invention includes a polyethylene terephthalate (PET) balloon 8 mounted on nylon catheter shaft 10. The fully

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extended diameter of balloon 8, when inflated, ranges from about 2 millimeters for coronary vascular procedures to about 20 to 35 millimeters for hyperthermia treatment of the prostate, esophagus or colon. The volume of the balloon ranges from about 1/8 cc for the smallest balloon to about 100 cc for the largest balloon. The wall thickness of balloon 8 is about 0.001 inch. Guidewire 46, which can extend past the distal end of the catheter, may be used to guide the catheter through the vascular system or luminal structure of a patient's body. Balloon may be filled with an electrically conductive fluid 36 such as normal saline (0.9 percent NaCl in water), a conductive radiopaque fluid, or a mixture of saline solution and a radiopaque fluid. The exterior of the balloon is coated with a non-stick coating having a low coefficient of friction, such as silicone or polysiloxane.

Annular electrical contacts 22 and 24 inside balloon 8 have internal diameters matching the 10a of the catheter shaft 10 about which they are fastened, and the contacts are bonded directly to the catheter shaft. The contacts are positioned in a manner to heat the balloon evenly, e.g. the spacing between contacts is approximately one-half the length of the balloon, and the spacing of each contact from its respective end of the balloon is approximately one-fourth the length of the balloon. While the dimensions of the contacts vary according to the nature of the medical procedure to be performed, in the embodiment described the contacts are in the form of annular thin-wall bands having axial length and diameter about equal. For the range of uses contemplated for this embodiment, the inner diameter of the smallest contact is about 0.050 inch, and the inner diameter of the largest contact is about 0.120 inch. The contacts present a low profile, having a radial thickness of

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approximately 0.002 inch. The contacts may be formed of any conductive material that is compatible with the conductive solution and the conditions of use, but are preferably of a radiopaque metal such as platinum or tantalum, so that they
5 may serve as radiopaque markers during placement of the catheter. Contacts 22, 24 are joined to 34-gauge multi-filament, nickel wires 20, 18, respectively, by welding. These wires, which are TEFLON-insulated, and have outer diameters of 0.012 inch, connect contacts 22, 24,
10 respectively, to opposite poles of current-controlled (constant current) radio-frequency (RF) power supply 50. Wires 20, 18 are enclosed within catheter shaft 10 along its length, and exit catheter shaft 10 through lumen 40, which is located inside balloon 8.

15 RF power supply 50 preferably operates at 650 kilohertz, but can be at any frequency within the range of about 100 kHz to 100 MHz. Radio frequency power is preferred over direct or low frequency current, or microwave power, because the risk of a physiological response or
20 electrocution response is reduced at RF frequencies above 100 kHz as compared with direct current (d.c.) or low frequencies, and because microwave power would lead to radiative losses in wires 18, 20, which could result, e.g., in unwanted heating of catheter shaft 10. The fluid
25 36, while selected to have resistive losses, has an electrical impedance low enough to cause it to conduct the current supplied by RF power supply 50 at voltages of about 100 volts or lower, so there will be no arcing across insulated wires 18, 20. For example, if the current is set
30 at 1 amp, and the impedance R between the electrodes, through the fluid, is 100 ohms, the voltage V will be 100 volts according to $V = IR$, and the power P dissipated into

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the fluid will be 100 watts, according to $P = I^2R$. In general, where two electrodes are employed, the impedance between the electrodes will be less than 1000 ohms, preferably in the range of 50 to 500 ohms, and, in the present embodiment, most preferably at about 100 ohms.

In all events, the shape of the balloon and the construction and spacing of the electrical contacts are preselected so that the electrical current is substantially confined to the interior of the balloon.

Catheter 34 plugs into RF power supply and temperature control circuitry 38 by means of a plug 39, which is keyed with respect to the particular size of its associated balloon catheter, to cause the power supply to operate at a maximum current of 1/10, 1/4, 1/2 or 1 amp. Plug 39 has seven pins, three of which are needed to operate the catheter. During manufacture, a jumper connection is made within plug 39 between a selected two of the remaining four pins. The jumper connection indicates how much current, at maximum, the RF power supply 50 should produce, depending upon which pins are connected. Thus, the user need only select the appropriate catheter 34, and need not be concerned about selecting the appropriate maximum current.

Referring to Fig. 2, in one embodiment of the invention, a bead thermistor 26, 0.014 inch in diameter and 0.020 inch long, is mounted directly upon catheter shaft 10 between electrodes 22, 24. Stainless steel thermistor lead 28 connects thermistor 26 with electrode 22. A 34 gauge, multi-filament, TEFLON coated, nickel wire 30, outer diameter 0.012 inch, which is welded to the other stainless steel thermistor lead 32, connects thermistor lead 32 with RF power supply and temperature control circuitry 38 via one

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of the pins of the plug. Thermistor 26 fits snugly on top of an opening 48 in the wall of catheter shaft 10 midway between electrodes 22, 24. Wire 30 and thermistor lead 32 are enclosed within catheter shaft 10, and thermistor lead 5 32 connects with thermistor 26 through opening 48. An insulating coating of epoxy or urethane seals thermistor 26 on top of opening 48, and secures thermistor lead 28 to catheter shaft 10. Alternatively, thermistor lead 28 may be electrically connected to RF power supply and temperature 10 control circuitry 28 in the same manner as thermistor lead 32, rather than being connected to electrode 22.

Referring to Fig. 3, catheter shaft 10 has three lumens 12, 14, 16. Lumen 12 extends from the proximal end of catheter shaft 10 to the distal end, and provides a 15 conduit for guidewire 46. Lumen 14 extends from the proximal end of catheter shaft 10 to an outlet inside balloon 8, and provides a conduit for fluid 36 as balloon 8 is inflated and deflated. Lumen 16 extends from the proximal end of catheter shaft 10 to the inside of balloon 20 8, and provides a conduit for wires 18, 20, which exit lumen 16 through opening 40 in the wall of catheter shaft 10, and also provides a conduit for wire 30 and thermistor lead 32 through opening 48 in catheter shaft 10 that is located directly below thermistor 26, as mentioned above.

25 Referring to Fig. 4, RF power supply and temperature control circuitry 38 consists of RF power supply 50, temperature control circuit 52, and solid state switch 54. Wire 18 connects electrode 24 with RF power supply 50, and wire 30 connects thermistor 26 with temperature control 30 circuit 52. Timing circuit 56 of temperature control circuit 52 toggles hold/NOT sample line 58 so that solid state switch 54 toggles back and forth, whereby wire 20 functions alternately as a lead connecting RF power supply

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50 with electrode 22 and as a lead connecting temperature control circuit 52 with thermistor 26. (Recall that electrode 22 and thermistor 26 are connected by wire 28.) The temperature sensing period is 1 percent of the 60 hertz cycle. When solid state switch 54 connects wire 20 with temperature control circuit 52, temperature control circuit 52 determines how much power, at maximum, RF power supply 50 should supply when solid state switch 54 next connects wire 20 with RF power supply 50. By thus multiplexing between temperature sensing and application of current to the electrodes, the temperature control circuitry eliminates the possibility that thermistor 26 will pick up RF noise from the electrodes 22, 24.

Referring to Fig. 5, another embodiment of the invention is shown in which temperature sensor 26 is placed in direct contact with tissue 44, outside of balloon catheter 34. Wires 60, 62 connect temperature sensor 26 with temperature control circuit 52, and wires 20, 18 connect electrodes 22, 24 respectively with RF power supply 50. Temperature control circuit 52 regulates RF power supply 50 in response to the input from temperature sensor 26.

Referring to Fig. 6, another embodiment of the invention is shown in which the temperature sensor consists of a pressure transducer 64 in conjunction with pressure sensing circuit 66 and pressure-to-temperature conversion circuit 68. In this embodiment, the electrodes 22, 24 are sufficiently small so that the electric current density in the immediate vicinity of the electrodes can induce localized boiling, which aids in convection of heat from the electrodes to the surrounding tissue 44. The balloon material is heat-set at a temperature in excess of 100° Celsius, so that the balloon material remains dimensionally

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stable when the fluid 36 within the balloon 8 boils at about 100° Celsius. A flexible tube 70 provides a conduit for fluid into lumen 14 of catheter shaft 10. Inflator 72 is used to inject fluid into flexible tube 70 until a desired
5 pressure is obtained, as indicated by pressure gauge 74. When RF power supply 50 is activated, the high electric field density in the immediate vicinity of each of the electrodes 22, 24 can induce localized boiling of fluid 36. As the fluid 36 heats up, the boiling increases in
10 intensity. The boiling causes the pressure inside balloon 8 to increase. The increase in pressure is measured by pressure transducer 64, as an indirect indication of the amount of heating of the fluid 36, according to phase change pressure/temperature relationships. Temperature control
15 circuit 52 regulates RF power supply 50 in response to the input obtained from pressure-to-temperature conversion circuit 68. Temperature display circuit 76 displays the temperature obtained from pressure-to-temperature conversion circuit 68. Impedance stability sensor 78 detects the
20 initiation of boiling by sensing the instability of catheter impedance due to the formation of vapor at the surfaces of electrodes 22, 24.

Referring to Fig. 7, in temperature control circuit 52, linearization network 80 linearizes the input signal
25 from temperature sensor 26 and delivers the linearized signal to sample and hold register 82. The signal is delivered to amplifier buffer 84 having low-temperature reference 86. Actual temperature display circuit 88 displays the output of amplifier buffer 84. Control
30 amplifier 90 compares the output of amplifier buffer 84 with a temperature set voltage 92 set by the user. The maximum RF power control circuit 94 receives the output of control amplifier 90 and determines the maximum level of RF power

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that the RF power supply 50 should produce. The signal from the maximum RF power control circuit 94 is received by isolation network 96, which interfaces with RF power supply 50. The temperature set voltage 92 is received by buffer amplifier 98 and displayed by set temperature display 100.

Timing circuit 56 toggles hold/NOT sample line 58 at 60 hertz, so that hold/NOT sample line 58 is low during 1 percent of the cycle and high during the other 99 percent of the cycle. Hold/NOT sample line 58 is low when signals from temperature sensor 26 are being sampled and high when signals from temperature sensor 26 are not being sampled. Hold/NOT sample line 58 is received by RF output enable gate 102. The output of sample and hold register 82 is processed by open and shorted sensor detector 104 to determine whether a sensor malfunction, such as a shorted or open sensor, has occurred. The output of open and shorted sensor detector 104 is received by RF output enable gate 102. RF output enable gate 102 delivers a signal to isolation network 96, which turns off RF power supply 50 when there has been a sensor malfunction or when signals from temperature sensor 26 are being sampled.

Divider 106 receives hold/NOT sample line 58 and delivers its output to time elapsed display 108. Time set display 110 displays the time indicated by time set switches 112, which are set by the user. Time compare network 114 compares the elapsed time with the time set by the user, and delivers an output signal to output disable circuit 116. The output of output disable circuit 116, which is active only when the elapsed time is less than the time set by the user, is delivered to RF output enable register 118. RF output enable register 118 in turn delivers the signal to the enable input to time elapsed display 108, and also to RF output enable gate 102, so that RF power supply 50 may be

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turned off when the time set by the user has elapsed. Switch debounce circuits 120 are provided for time set switches 112.

The user must depress foot switch 122 in order for
5 RF power supply 50 to operate. While foot switch 122 is
activated, and while the elapsed time is less than the time
set by the user, output disable circuit 116 delivers a
signal to RF output enable register 118, which in turn
delivers the signal to the enable input of time elapsed
10 display 108, and also to RF output enable gate 102 so that
RF power supply 50 may be turned on. Deactivation of foot
switch 122 causes a signal to pass through elapsed time
reset register 124, in order to reset time elapsed display
108 and in order to reset RF output enable register 118.
15 The resetting of RF output enable register 118 causes RF
output enable gate 102 to turn off RF power supply 50.
Debounce circuit 126 is provided for foot switch 122.

Referring to Fig. 1, balloon catheter 34 may be used
as a heat source during or after angioplasty to seal the
20 splitting of the intimal layers of the wall of blood vessel
42 that occurs during angioplasty, and to mold the vessel
wall. The blood vessel may be a coronary artery, or a
peripheral artery such as an iliac, femoral, renal, carotid,
or popliteal artery. The user first preselects the desired
25 therapeutic temperature (temperature set voltage 92, Fig.
7), and sets the length of time for which balloon 8 is to be
heated (time set switches 112, Fig. 6). A percutaneous
insertion is made with a needle, and guide wire 46 is
introduced into the blood vessel 42. Balloon catheter 34
30 follows the wire. If balloon 8 contains conductive
radiopaque fluid, the location of balloon 8 can be monitored
by means of fluoroscopy. Balloon 8 is inflated through

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lumen 14 with either saline, a conductive radiopaque fluid, or a mixture of saline and a radiopaque fluid, to a pressure of 4 to 17 atmospheres, in order to expand the wall of blood vessel 42. The balloon remains inflated for about 20
5 seconds or longer, depending upon the particular blood vessel in which the angioplasty is being performed. Either during or after the plastic deformation of the vessel wall, with balloon 8 inflated to at least a low level of pressure, the user depresses foot switch 122 (Fig. 7) to initiate the
10 bipolar heating between the electrodes 22, 24. Heat is dissipated into the fluid according to the formula $P=I^2R$, where P is the power that is dissipated into the fluid, I is the current that is passed through the electrodes, and R is the resistance of the fluid. The heat from the fluid is
15 conducted across the balloon wall into the surrounding tissue 44. For angioplasty procedures, RF power supply 50 supplies a maximum current of 1/4 amp, and the power dissipated into fluid 36 is about 10 to 25 watts. The fluid will heat to the temperature set by the user, which may be
20 in the range of 45° to 80° Celsius. Heating will continue until the time set by the user has elapsed, or until the user deactivates foot switch 122.

The balloon catheter may also be used to perform glazing or smoothing of the vessel wall, whereby the balloon
25 8 is inflated to make light contact with the wall of blood vessel 42, foot switch 122 is activated by the user to initiate heating of the balloon, and the catheter 34 is guided through blood vessel 42 to glaze or smooth the plaque on the vessel wall. The balloon catheter may also be used
30 to dehydrate, compress, and mold plaque to improve patency.

Catheters according to the invention can be used in nonvascular applications such as hyperthermia treatment of

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benign or malignant tumors, or enlargement of the prostate gland. Hyperthermic effects begin at about 44° Celsius. Heat from balloon 8 destroys the undesired cells, which are eventually absorbed into the patient's body. When a
5 catheter according to the invention is used in such nonvascular applications, the balloon 8 may be sufficiently large so that no temperature sensing device is needed, and the fluid 36 can be left to boil at the electrodes without the buildup of excessive pressure within the balloon. The
10 fluid will begin to boil locally in about 5 seconds if the balloon has a diameter of 4 millimeters.

Other embodiments are within the following claims. For example, wires 18, 20 may be copper, and contacts 22, 24 may be coated with tin so the wires may be joined to the
15 contacts by soldering with tin solder. Wire 30 may also be formed of copper and attached by soldering.

What is claimed is:

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1 1. Device for heating tissue, comprising
2 a chamber constructed for insertion into a patient's
3 body,
4 an electrically conductive fluid preselected for
5 resistive heating for filling the chamber,
6 a plurality of spaced electrical contacts enclosed
7 within the chamber and a corresponding plurality of
8 conductors for connecting the electrical contacts to a power
9 supply for applying a radio frequency electrical potential
10 to the contacts, said contacts being exposed to the fluid-
11 containing space of said chamber so that said radio
12 frequency electrical potential can cause current to flow
13 through fluid between the contacts, said chamber and said
14 contacts being cooperatively constructed and arranged to
15 cause said current to be substantially confined to said
16 fluid within the chamber,
17 whereby, on the basis of I^2R losses of said radio
18 frequency electric current flowing between the electrical
19 contacts, the fluid can be heated and the fluid in turn can
20 heat the surrounding tissue by thermal conduction through a
21 wall of the chamber.

1 2. The device of claim 1 wherein said chamber is
2 defined by an expandable wall, said chamber being adapted to
3 be empty and the expandable wall collapsed at the time of
4 introduction into the patient and wherein a conduit is
5 adapted to fill said chamber with said fluid after
6 introduction of said chamber into a patient's body.

1 3. The device of claim 1 in the form of a catheter,
2 said device further comprising

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3 a catheter shaft constructed for insertion into a
4 patient's body,

5 said chamber being defined by a wall which at least
6 in part is expandable, and

7 said chamber being associated with a lumen for fluid
8 flow between said chamber and a fluid source outside of said
9 body, said chamber being fillable after placement in the
10 body with an electrical conductive fluid preselected to
11 produce resistive heating.

1 4. The device of claim 1, 2 or 3 wherein the
2 chamber is defined by an inflatable balloon.

1 5. The device of claim 3 wherein the spaced
2 contacts are mounted directly upon the catheter shaft within
3 the chamber.

1 6. The device of claim 3 wherein the conductors are
2 enclosed within the shaft along its length.

1 7. The device of claim 3 wherein said chamber has
2 the form of an inflatable balloon mounted upon said shaft.

1 8. The device of claim 1, 3, 5 or 7 wherein said
2 electrical contacts are radiopaque and serve as radiopaque
3 markers.

1 9. The device of claim 1, 3 or 7 wherein the
2 impedance between a pair of said electrodes, when said
3 chamber is filled with said preselected fluid, is less than
4 1000 ohms.

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1 10. The device of claim 9 wherein said impedance is
2 in the range of 50 to 500 ohms.

1 11. The device of claim 1, 3 or 7 including a power
2 supply constructed to operate at a frequency between 100 kHz
3 and 100 MHz.

1 12. The device of claim 11 wherein the electrical
2 potential applied across the contacts by the power source is
3 about 100 volts or less.

1 13. The device of claim 11 further comprising
2 a temperature sensor, and
3 a temperature control circuit for controlling the
4 output of the power supply in response to information
5 received from the temperature sensor.

1 14. The device of claim 1, 3 or 7 wherein a
2 temperature sensor constructed to sense the temperature of
3 said fluid for controlling the application of said
4 electrical potential to said contacts is located within the
5 chamber.

1 15. The device of claim 1, 3 or 7 associated with
2 an temperature sensor located outside the chamber in contact
3 with tissue surrounding the chamber for controlling the
4 application of said electrical potential to said contacts is
5 located within the chamber.

1 16. The device of claim 1, 3 or 7 wherein said
2 chamber is filled with a saline solution.

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1 17. The device of claim 1, 3 or 7 wherein said
2 chamber is filled with a fluid that is radiopaque.

1 18. The device of claim 1, 3 or 7 sized and
2 constructed for insertion into a blood vessel.

1 19. The device of claim 1, 3 or 7 sized and
2 constructed for insertion into the body to apply heat to the
3 prostate gland.

1 20. The device of claim 1, 3 or 7 wherein said
2 chamber is coated with a coating that prevents said chamber
3 from sticking to said tissue.

1 21. The device of claim 1, 3 or 7 including a power
2 supply adapted to apply said current at a level sufficient
3 to cause localized boiling of said fluid at said electrical
4 contacts, to cause mixing of the fluid in said chamber and
5 produce uniform heating of the chamber wall.

1 22. The device of claim 21 including a pressure
2 transducer exposed to sense fluid pressure in said chamber
3 and means constructed and arranged to control the energy
4 applied to said electrical contacts in response to
5 information received from the pressure transducer.

1 23. The device of claim 1, 3 or 7 associated with a
2 power supply controlled by a thermistor sensor, and a
3 control constructed and arranged to operate alternately in a
4 power application mode in which RF potential is applied to
5 said contacts and a sensing mode during which application of
6 RF potential to said contacts is disrupted.

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1 24. The device of claim 1, 3 or 7 including a
2 thermistor exposed to fluid in said chamber, said thermistor
3 connected to one of said electrical contacts, said device
4 adapted to be used with a power supply controlled to
5 alternately apply potential to said electrical contacts and
6 to sense the temperature of the fluid in the absence of RF
7 potential on the contacts.

1 25. A method for heating tissue, comprising
2 inserting into a patient's body a chamber containing
3 electrically conductive fluid preselected for resistive
4 heating, there being a plurality of spaced electrical
5 contacts enclosed within the chamber and a corresponding
6 plurality of conductors for connecting the electrical
7 contacts to a power supply for applying a radio frequency
8 electrical potential to the contacts, said contacts being
9 exposed to the fluid-containing space of said chamber so
10 that said radio frequency electrical potential can cause
11 current to flow through fluid between the contacts,
12 said chamber and said contacts being cooperatively
13 constructed and arranged to cause said current to be
14 substantially confined to said fluid within the chamber, and
15 applying radio frequency potential to said
16 electrical contacts,
17 whereby, on the basis of I^2R losses of said radio
18 frequency electric current flowing between the electrical
19 contacts, the fluid is heated and the fluid in turn heats
20 the surrounding tissue by thermal conduction through a wall
21 of the chamber.

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1 26. The method of claim 25 wherein said radio
2 frequency potential applied across said contacts is at
3 frequency in the range between about 100 kHz and 100 MHz.

1 27. The method of claim 25, including controlling
2 the electrical current between the electrical contacts to
3 induce localized boiling at the contacts.

1 28. A method for constant temperature heating,
2 comprising inserting into a patient's body a chamber
3 containing electrically conductive fluid preselected for
4 resistive heating, there being a plurality of spaced
5 electrical contacts enclosed within the chamber and a
6 corresponding plurality of conductors for connecting the
7 electrical contacts to a power supply for applying a radio
8 frequency electrical potential to the contacts, said
9 contacts being exposed to the fluid-containing space of said
10 chamber so that said radio frequency electrical potential
11 can cause current to flow through fluid between the
12 contacts,

13 said chamber and said contacts being cooperatively
14 constructed and arranged to cause said current to be
15 substantially confined to said fluid within the chamber,
16 applying radio frequency potential to said
17 electrical contacts, and

18 monitoring temperature at a point influenced by the
19 temperature of said liquid and, in response thereto,
20 controlling the radio frequency energy applied to said
21 electrical contacts to maintain said temperature constant,
22 whereby, on the basis of I^2R losses of said
23 controlled radio frequency electric current flowing between
24 the electrical contacts, the fluid is heated and the fluid

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25 in turn heats the surrounding tissue by thermal conduction
26 through a wall of the chamber.

1 29. The method of claim 28 wherein said chamber
2 comprises a balloon on a catheter introduced into a lumen or
3 cavity of the body.

1 30. The method of claim 28 or 29 wherein
2 temperature at a point in the body adjacent said chamber is
3 monitored and used to control the application of energy to
4 said electrodes to maintain temperature at said point
5 constant for a selected duration, on the basis of thermal
6 transfer from liquid heated in said balloon to said point.

1 31. The method of claim 28 or 29 wherein
2 temperature of the liquid in said chamber is monitored and
3 used to control the application of energy to said electrodes
4 to maintain temperature of said fluid constant at a set
5 point whereby it is assured that tissue in the vicinity of
6 said chamber is not heated above said set point.

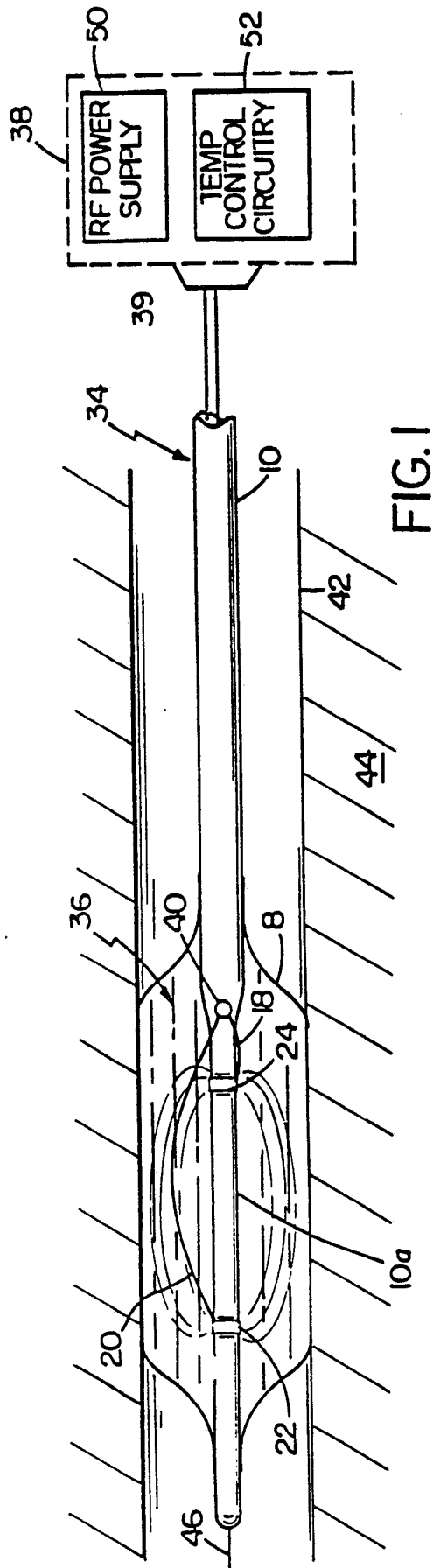
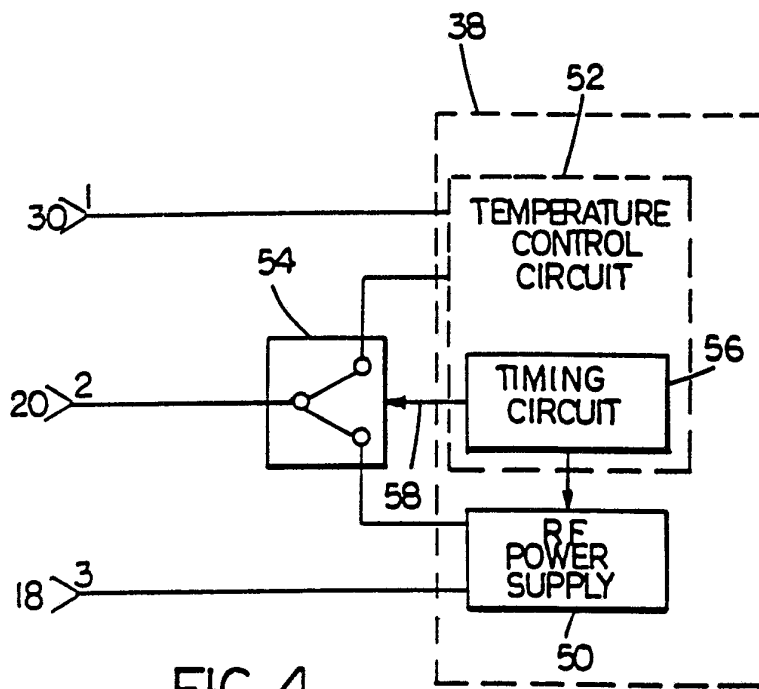
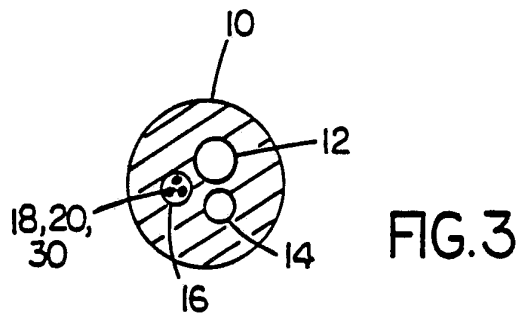
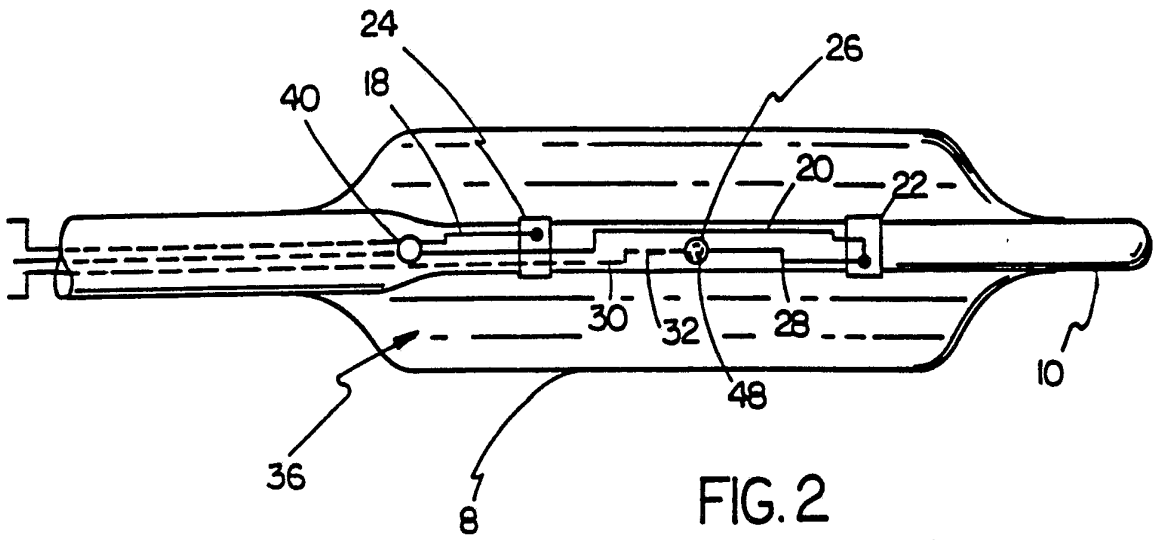


FIG. 1

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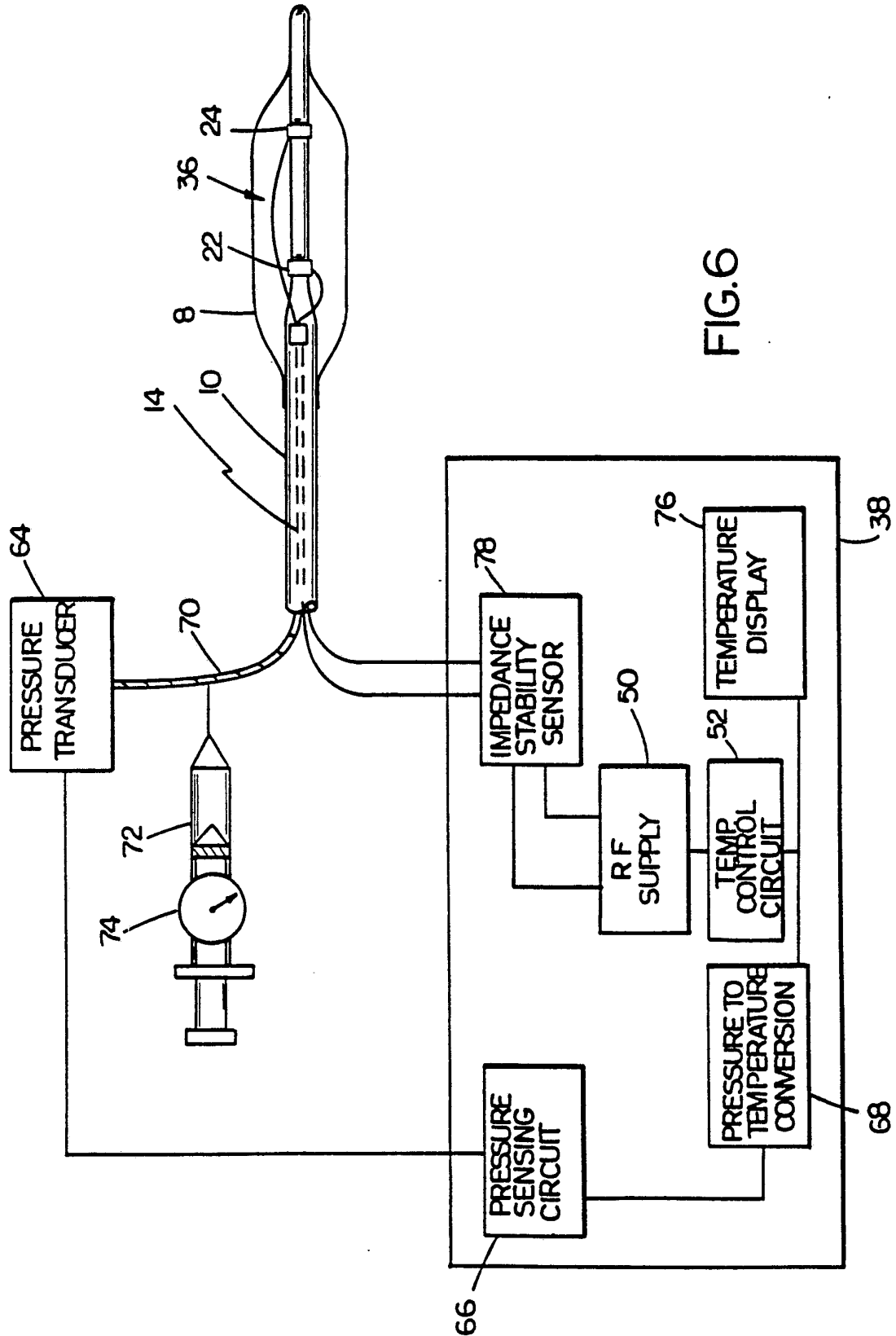


FIG. 6

FIG. 7-1

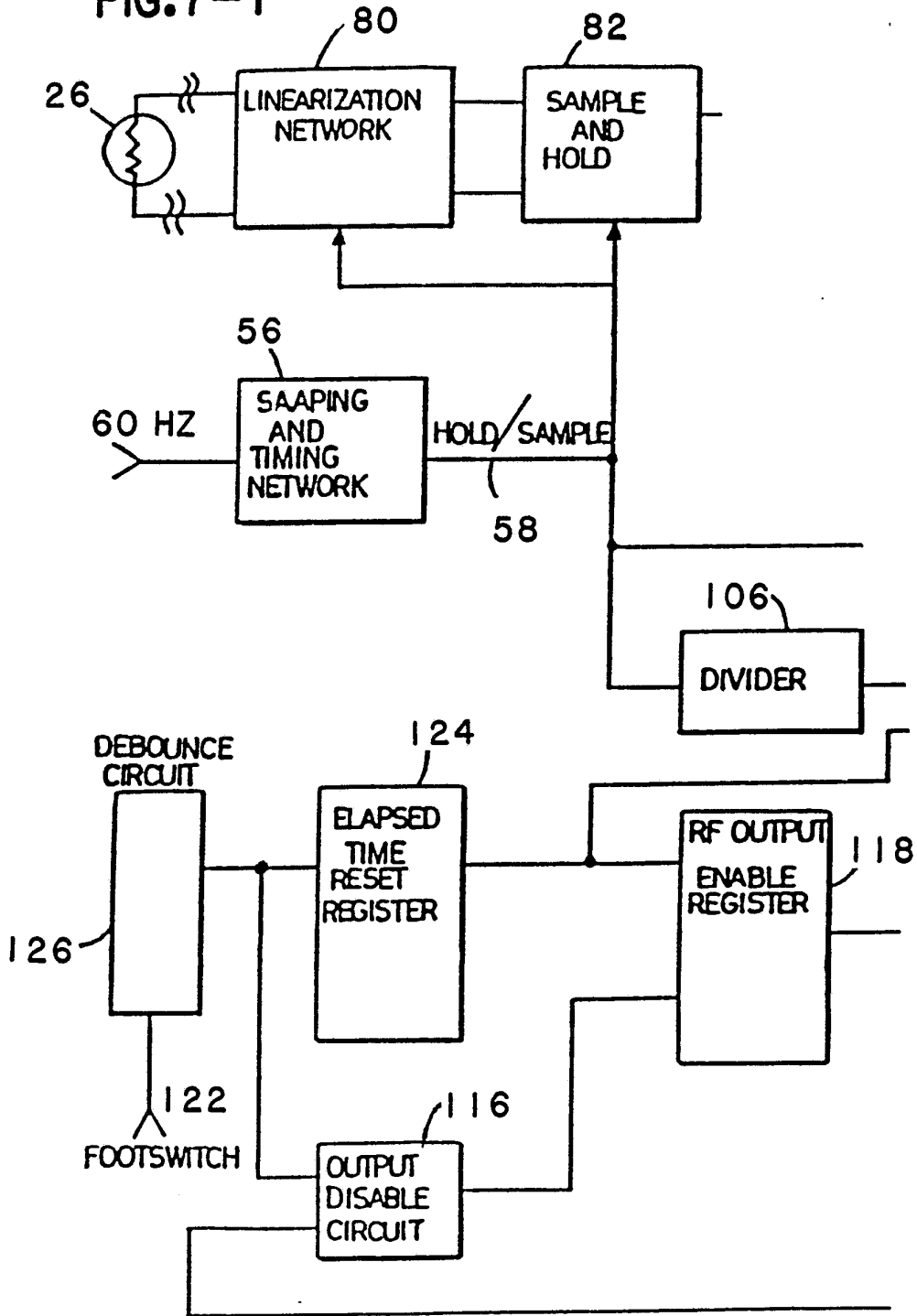
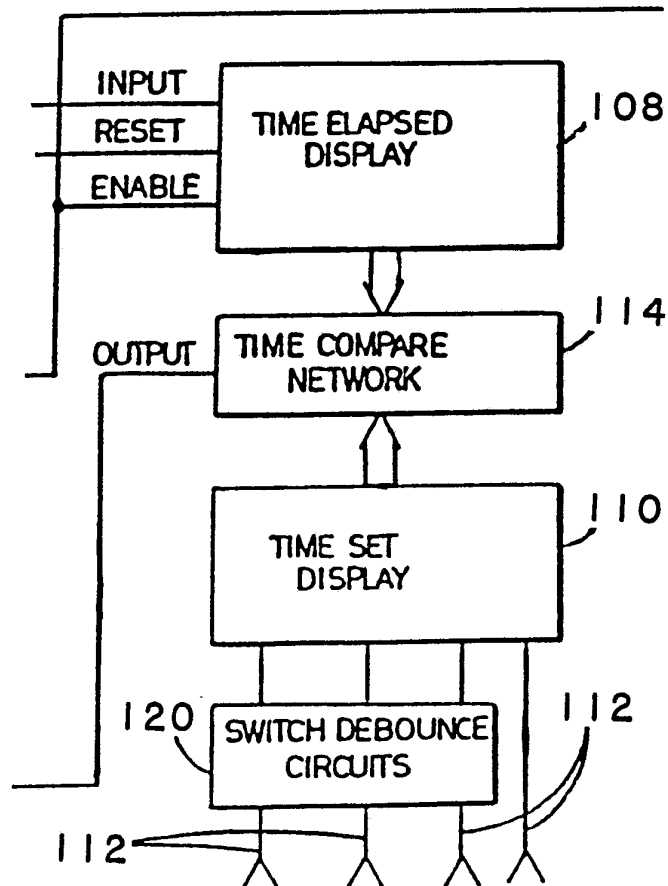
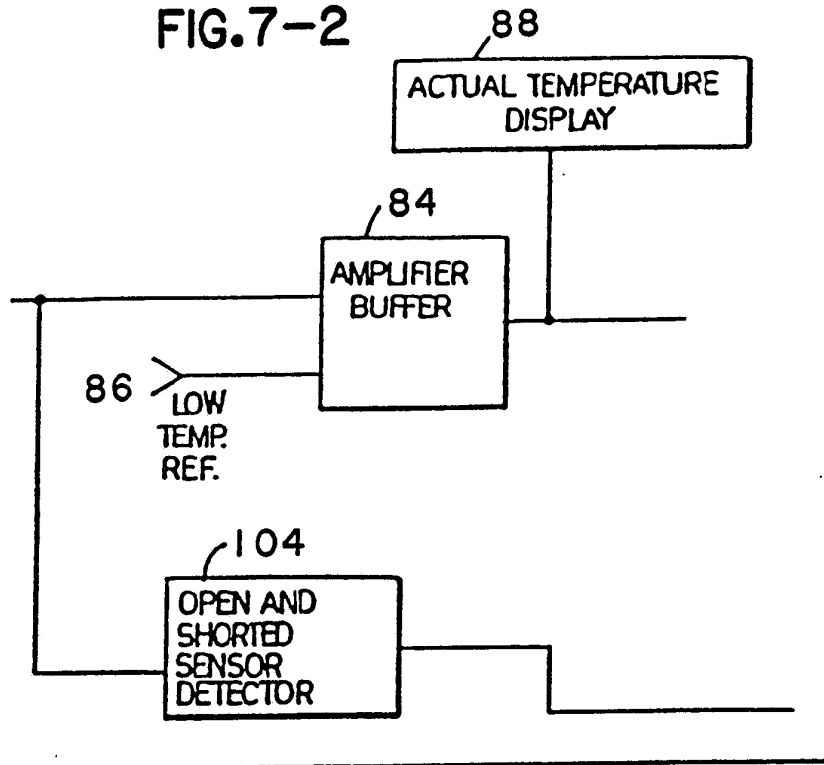
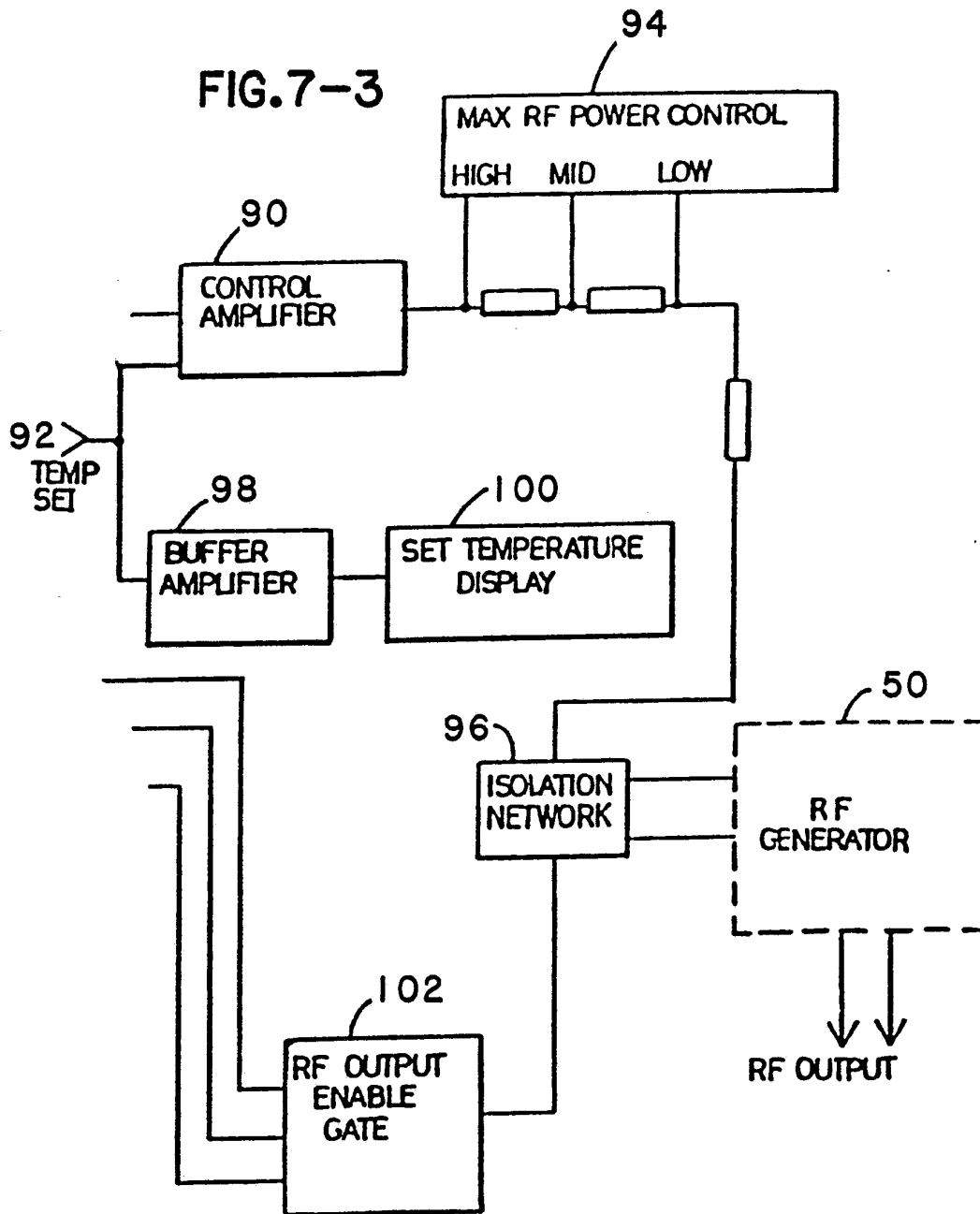


FIG.7-2





INTERNATIONAL SEARCH REPORT

International Application No. PCT/US89/04764

| | | |
|---|--|---|
| I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶ | | |
| According to International Patent Classification (IPC) or to both National Classification and IPC | | |
| IPC(5) A61B 17/36 | | |
| US CL. 606/28 | | |
| II. FIELDS SEARCHED | | |
| Minimum Documentation Searched ⁷ | | |
| Classification System | Classification Symbols | |
| U.S | 128/399-402 606/27-31 784-786 804 | |
| Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸ | | |
| III. DOCUMENTS CONSIDERED TO BE RELEVANT ⁹ | | |
| Category ⁹ | Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹² | Relevant to Claim No. ¹³ |
| Y | US,A, 4,709,698 (JOHNSTON et al) 01 December 1987 (See entire reference). | 1-31 |
| Y | US,A, 2,043,083 (WAPPLER) 02 June 1936 (See entire reference). | 1-12, 16-18, 25-27 |
| Y | US,A, 4,397,314 (VAGUINE) 09 August 1983 (See fig. 1). | 13-15,21,23, 24,28-31 |
| Y | US,A, 4,227,535 (CONNOR) 14 October 1980 (See col. 2). | 20 |
| Y | US,A, 4,160,455 (LAW) 10 July 1979 (See col. 3). | 22 |
| <p>⁹ Special categories of cited documents: ¹⁰</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"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)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"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</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"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.</p> <p>"&" document member of the same patent family</p> | | |
| IV. CERTIFICATION | | |
| Date of the Actual Completion of the International Search | | Date of Mailing of this International Search Report |
| 11 December 1989 | | 06 FEB 1990 |
| International Searching Authority | | Signature of Authorized Officer |
| ISA/US | | <i>Max Hindenburg</i> Max Hindenburg |