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# DESCRIPTION

## CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit of U.S. Provisional Patent Application 62/286,534, filed January 25, 2016.

## FIELD OF THE INVENTION

[0002] The present invention relates generally to surgery, and specifically to surgery using radiofrequency ablation.

## BACKGROUND OF THE INVENTION

[0003] Radiofrequency (RF) ablation is a treatment modality that kills unwanted tissue by heat. Starting with cardiac arrhythmia treatment in the 1980s, RF ablation has found clinical application in a number of diseases, and is now the treatment of choice for certain types of cardiac arrhythmia, and certain cancers. During RF ablation, an electrode is inserted into proximity with the target region under medical imaging guidance. Tissue surrounding the electrode in the target region is destroyed by heating via RF electric current.

[0004] RF ablation is typically performed at continuous power levels of the order of 20 - 50 watts, with a contact force of approximately 10 g, and under irrigation. The time of ablation, depending on the size of the lesion to be achieved, is typically approximately 1 minute. In general, higher power levels reduce the time needed for forming a specific lesion. However, in prior art systems large values of continuous power cannot be used because of the danger of steam pops being formed.

[0005] US Patent Application 2010/0057072, to Roman et al., describes an ablation catheter for performing tissue ablation. The disclosure states that RF energy may be safely delivered potentially at wattages up to 100 W.

[0006] US Patent 7,207,989, to Pike Jr. et al., describes a method for ablating tissue in or around the heart to create an enhanced lesion. The distal end of a needle electrode is introduced into the tissue. An electrically-conductive fluid is infused through the needle electrode and into the tissue. The tissue is ablated after and/or during introduction of the fluid into the tissue.

[0007] US Patent Application 2015/0272655, to Condie et al., describes a system for preventing unintended tissue damage from the delivery of unintended bipolar radiofrequency

energy. The disclosure states that if 100 watts of RF energy is being delivered but only 10 watts is required to produce a desired electrode temperature, an electrode may be activated for 10% of a given period of time and deactivated for 90% of that duration of time.

**[0008]** US Patent 8,641,705, to Leo et al., describes an apparatus for controlling lesion size in catheter-based ablation treatment. The apparatus measures the force exerted by a contact ablation probe on a target tissue and integrates the force over an energization time of the ablation probe. The force-time integral can be calculated and utilized to provide an estimated lesion size (depth, volume and/or area) in real time.

**[0009]** US Patent 8,882,761, to Desai, describes a catheter for ablation. The disclosure refers to commonly practiced ablation procedure, and states that in such a procedure 35 to 50 watts of power is delivered at 40 to 50 degree Celsius through a temperature controlled Radiofrequency Generator, and that the saline irrigation fluid rate during the ablation is 30 ml/min.

**[0010]** US Patent Application 2011/0009857, to Subramaniam et al., describes an open-irrigated catheter with turbulent flow. Pressurized fluid is delivered from a fluid lumen of a catheter body into an ablation electrode. Fluid flow in the fluid lumen is generally laminar. The generally laminar fluid flow is transformed from the fluid lumen into a turbulent fluid flow within the ablation electrode.

**[0011]** In an article by Topp et al., entitled "Saline-linked surface radiofrequency ablation: Factors affecting steam popping and depth of injury in the pig liver," Ann. Surg., vol. 239, no. 4, pp. 518-27 (2004), the authors claim to have determined parameters that predict steam popping, and depth of tissue destruction under nonpopping conditions.

**[0012]** US2002/0151884A1 describes an apparatus and method for creating, maintaining and controlling a virtual electrode used for the ablation of tissue. An apparatus in accord with the present invention includes a supply of a conductive or electrolytic fluid to be provided to the patient, an alternating current generator, and a processor for creating, maintaining and controlling the ablation process. A method as disclosed in the present application includes delivering a conductive fluid to a predetermined tissue ablation site for a predetermined time period, applying a predetermined power level of radio frequency current to the tissue, monitoring at least one of several parameters, and adjusting either the applied power and/or the fluid flow in response to the measured parameters.

## **SUMMARY OF THE INVENTION**

**[0013]** The invention is defined by the apparatus of independent claim 1. Preferred embodiments are defined by the dependent claims. Any disclosed methods are merely exemplary and do not fall within the scope of the present invention. Any example or embodiment which does not fall under the scope of the claims is not part of the invention.

Disclosed is a method, including:

selecting a maximum radiofrequency (RF) power to be delivered by an electrode within a range of 70W - 100W;

selecting an allowable force on the electrode within a range of 5g - 50g;

selecting a maximum allowable temperature, of tissue to be ablated, within a range of 55°C - 65°C;

selecting an irrigation rate for providing irrigation fluid to the electrode within a range of 8 - 45 ml/min; and

performing an ablation of the tissue using the selected values.

**[0014]** In a disclosed embodiment the selected values are: maximum RF power 90W, allowable force between 10g and 20g, maximum allowable temperature 60°C, and irrigation rate 15 ml/min, and the power is delivered for 3s so as to provide a lesion having a depth between 1 mm and 3 mm.

**[0015]** In a further disclosed embodiment the selected values are: maximum RF power 90W, allowable force between 10g and 20g, maximum allowable temperature 60°C, and irrigation rate 15 ml/min, and the power is delivered for 3s, and is then reduced to 50W so as to provide a lesion having a depth between 4 mm and 5 mm.

**[0016]** In a yet further disclosed embodiment the method includes measuring an impedance to an RF power delivered by the electrode during the ablation, and, when a change in the impedance exceeds a preset value, halting the ablation of the tissue. Typically, the change is at least 7Ω.

**[0017]** In an alternative embodiment the method includes measuring at respective times a temperature of the tissue, and, when the temperature exceeds the selected maximum allowable temperature, reducing a level of an RF power delivered by the electrode. Typically, the temperature is measured at a frequency of at least 30 Hz.

**[0018]** There is further disclosed a method, including:

selecting a first maximum radiofrequency (RF) power to be delivered by an electrode within a range of 70W - 100W;

selecting a second maximum RF power to be delivered by the electrode within a range of 20W - 60W;

selecting an allowable force on the electrode within a range of 5g - 50g;

selecting a maximum allowable temperature, of tissue to be ablated, within a range of 55°C - 65°C;

selecting an irrigation rate for providing irrigation fluid to the electrode within a range of 8 - 45 ml/min; and

performing an ablation of tissue using the selected values by initially using the first power, switching to the second power after a predefined time between 3s and 6s, and terminating the ablation after a total time for the ablation between 10s and 20s.

**[0019]** In a disclosed embodiment the method includes measuring an impedance to an RF power delivered by the electrode during the ablation, and, when a change in the impedance exceeds a preset value, halting the ablation of the tissue. Typically, the change is at least 7Ω.

**[0020]** In a further disclosed embodiment the method includes measuring at respective times a temperature of the tissue, and, when the temperature exceeds the selected maximum allowable temperature, reducing a level of an RF power delivered by the electrode. Typically the temperature is measured at a frequency of at least 30 Hz.

**[0021]** There is further disclosed a method, including:

performing an ablation procedure on biological tissue using radiofrequency (RF) power;

measuring an impedance to the RF power during the procedure; and

when a change in the impedance exceeds a preset value, halting supply of the RF power to the tissue. Typically, the change is at least 7Ω.

**[0022]** There is further provided, according to an embodiment of the present invention, a method, including:

performing an ablation procedure on biological tissue using radiofrequency (RF) power;

measuring at respective times a temperature of the tissue; and

when the temperature exceeds a preset maximum allowable temperature, reducing a level of the RF power supplied to the tissue. Typically, the temperature of the tissue is measured at a frequency of at least 30 Hz.

**[0023]** There is further provided, according to an embodiment of the present invention, apparatus, including:

an electrode;

a power control module configured to select a maximum radiofrequency (RF) power to be delivered by the electrode within a range of 70W - 100W; and

a processor coupled to the power control module and configured to:

select an allowable force on the electrode within a range of 5g - 50g;

select a maximum allowable temperature, of tissue to be ablated, within a range of 55°C - 65°C;

select an irrigation rate for providing irrigation fluid to the electrode within a range of 8 - 45 ml/min; and

perform an ablation of the tissue using the selected values.

**[0024]** There is further provided, according to an embodiment of the present invention, apparatus, including:

an electrode;

a power control module configured to select a first maximum radiofrequency (RF) power to be delivered by the electrode within a range of 70W - 100W and to select a second maximum RF power to be delivered by the electrode within a range of 20W - 60W; and

a processor coupled to the power control module and configured to:

select an allowable force on the electrode within a range of 5g - 50g;

select a maximum allowable temperature, of tissue to be ablated, within a range of 55°C - 65°C;

select an irrigation rate for providing irrigation fluid to the electrode within a range of 8 - 45 ml/min; and

perform an ablation of tissue using the selected values by initially using the first power, switching to the second power after a predefined time between 3s and 6s, and terminating the ablation after a total time for the ablation between 10s and 20s.

**[0025]** There is further provided, according to an embodiment of the present invention, apparatus, including:

a power control module configured to perform an ablation procedure on biological tissue using radiofrequency (RF) power; and

a processor configured to:

measure an impedance to the RF power during the procedure; and

when a change in the impedance exceeds a preset value, halt supply of the RF power to the tissue.

**[0026]** There is further provided, according to an embodiment of the present invention, apparatus, including:

a power control module configured to perform an ablation procedure on biological tissue using radiofrequency (RF) power; and

a processor configured to:

measure at respective times a temperature of the tissue; and

when the temperature exceeds a preset maximum allowable temperature, reduce a level of the RF power supplied to the tissue.

**[0027]** The present disclosure will be more fully understood from the following detailed description of the embodiments thereof, taken together with the drawings, in which:

#### **BRIEF DESCRIPTION OF THE DRAWINGS**

**[0028]**

Fig. 1 is a schematic illustration of an ablation system, according to an embodiment of the present invention;

Figs. 2A, 2B, 2C, and 2D schematically illustrate a distal end of a probe used in the system, according to an embodiment of the present invention; and

Fig. 3 is a flowchart of steps performed during an ablation session using the system.

#### **DETAILED DESCRIPTION OF EMBODIMENTS OVERVIEW**

**[0029]** Radiofrequency (RF) ablation in prior art systems is typically performed at continuous power levels of the order of 20 - 50 watts, with a contact force of approximately 10 g, and

under irrigation. The time of ablation, depending on the size of the lesion to be achieved, is typically approximately 1 minute. In general, higher power levels reduce the time needed for forming a specific lesion. However, in prior art systems large values of continuous power, of approximately 100 watts, cannot be used because of the danger of steam pops being formed.

**[0030]** The inventors have found that there is a range of values of contact force and irrigation rate that allows continuous power of approximately 100 watts to be applied, and that within this range of values, a "sweet spot," no steam pops are formed. Application of this higher continuous power reduces the time required to form a given lesion.

**[0031]** For example, in a disclosed embodiment, a first RF power to be delivered to an electrode performing an ablation is selected to be in a range of 70W - 100W, and a second RF power for the electrode is selected to be in a range of 20W - 60W. An allowable contact force on the electrode is selected to be in a range of 5g - 50g, a maximum allowable temperature of tissue to be ablated is selected to be in a range of 55°C - 65°C, and an irrigation rate for providing irrigation fluid to the electrode is selected within a range of 8 - 45 ml/min.

**[0032]** A lesion may be formed in the tissue using the selected values by initially using the first power, switching to the second power after a predefined time between 3s and 6s, and terminating the ablation after a total time for the ablation between 10s and 20s.

**[0033]** In embodiments of the present disclosure, during an ablation procedure the temperature of the tissue being ablated is carefully monitored and recorded at an extremely high rate. If the monitored temperature exceeds a preset maximum temperature limit, the RF power supplied to the tissue is reduced.

**[0034]** The impedance to the RF energy supplied to the tissue being ablated is also monitored. If the impedance increases by more than a preset value, the RF energy supply is halted.

**[0035]** The monitoring of the temperature and of the impedance allows embodiments of the present invention to perform tissue ablations at powers up to 100W without adverse effects on the tissue during the ablation session. The high powers enable the ablation session to be shortened to times typically of no more than 10s.

## **DETAILED DESCRIPTION**

**[0036]** Reference is now made to Fig. 1, which is a schematic illustration of an invasive medical procedure using an ablation apparatus 12, according to an embodiment of the present invention. The procedure is performed by a physician 14, and, by way of example, the procedure in the description herein below is assumed to comprise ablation of a portion of a myocardium 16 of the heart of a human patient 18. However, it will be understood that embodiments of the present invention are not just applicable to this specific procedure, and may include substantially any ablation procedure on biological tissue.

**[0037]** In order to perform the ablation, physician 14 inserts a probe 20 into a lumen of the patient, so that a distal end 22 of the probe enters the heart of the patient. Distal end 22 comprises one or more electrodes 24 mounted on the outside of the distal end, the electrodes contacting respective locations of the myocardium. Probe 20 has a proximal end 28. Distal end 22 of the probe is described in more detail below with reference to Figs. 2A, 2B, 2C and 2D.

**[0038]** Apparatus 12 is controlled by a system processor 46, which is located in an operating console 48 of the apparatus. Console 48 comprises controls 49 which are used by physician 14 to communicate with the processor. During the procedure, processor 46 typically tracks a location and an orientation of distal end 22 of the probe, using any method known in the art. For example, processor 46 may use a magnetic tracking method, wherein magnetic transmitters external to patient 18 generate signals in coils positioned in the distal end. The Carto® system produced by Biosense Webster, of Diamond Bar, CA, uses such a tracking method.

**[0039]** The software for processor 46 may be downloaded to the processor in electronic form, over a network, for example. Alternatively or additionally, the software may be provided on non-transitory tangible media, such as optical, magnetic, or electronic storage media. The track of distal end 22 is typically displayed on a three-dimensional representation 60 of the heart of patient 18 on a screen 62. The progress of the ablation performed with apparatus 12 is typically also displayed on screen 62, as a graphic 64 and/or alphanumeric data 66.

**[0040]** In order to operate apparatus 12, processor 46 communicates with a memory 50, which has a number of modules used by the processor to operate the apparatus. Thus, memory 50 comprises a temperature module 52, a power control module 54, a force module 56, and an irrigation module 58, the functions of which are described below. The modules may comprise hardware as well as software elements.

**[0041]** Figs. 2A, 2B, 2C, and 2D schematically illustrate distal end 22 of probe 20, according to an embodiment of the present invention. Fig. 2A is a sectional view along the length of the probe, Fig. 2B is a cross-sectional view along a cut IIB-IIB that is marked in Fig. 2A, Fig. 2C is a perspective view of a section of the distal end and Fig. 2D is a schematic cross-sectional view of a force sensor 90 incorporated into a proximal portion 92 of the distal end. An insertion tube 70 extends along the length of the probe and is connected at the termination of its distal end to a conductive cap electrode 24A, which is used for ablation. Conductive cap electrode 24A is herein also termed the ablation electrode. Cap electrode 24A has an approximately plane conducting surface 84 at its distal end and a substantially circular edge 86 at its proximal end. Proximal to ablation electrode 24A there are typically other electrodes such as an electrode 24B. Typically, insertion tube 70 comprises a flexible, biocompatible polymer, while electrodes 24A, 24B comprise a biocompatible metal, such as gold or platinum, for example. Ablation electrode 24A is typically perforated by an array of irrigation apertures 72. In one embodiment there are 36 apertures 72, distributed evenly over electrode 24A.

**[0042]** An electrical conductor 74 conveys radio-frequency (RF) electrical energy from ablation module 54 (Fig. 1), through insertion tube 70, to electrode 24A, and thus energizes the electrode to ablate myocardial tissue with which the electrode is in contact. As described below, module 54 controls the level of RF power dissipated via electrode 24A. During the ablation procedure, irrigation fluid flowing out through apertures 72 irrigates the tissue under treatment, and the rate of flow of fluid is controlled by irrigation module 58. The irrigation fluid is delivered to electrode 24A by a tube (not shown in the diagram) within insertion tube 70.

**[0043]** Temperature sensors 78 are mounted within conductive cap electrode 24A at locations that are arrayed around the distal tip of the probe, both axially and circumferentially. In a disclosed embodiment considered herein, cap 24A contains six sensors, with one group of three sensors in a distal location, close to the tip, and another group of three sensors in a slightly more proximal location. This distribution is shown only by way of example, however, and greater or smaller numbers of sensors may be mounted in any suitable locations within the cap. Sensors 78 may comprise thermocouples, thermistors, or any other suitable type of miniature temperature sensor. Sensors 78 are connected by leads (not shown in the diagram) running through the length of insertion tube 70 to provide temperature signals to temperature module 52.

**[0044]** In a disclosed embodiment cap 24A comprises a side wall 73 that is relatively thick, on the order of 0.5 mm thick, in order to provide the desired thermal insulation between temperature sensors 78 and the irrigation fluid inside a central cavity 75 of the tip. The irrigation fluid exits cavity 75 through apertures 72. Sensors 78 are mounted on rods 77, which are fitted into longitudinal bores 79 in side wall 73. Rods 77 may comprise a suitable plastic material, such as polyimide, and may be held in place at their distal ends by a suitable glue 81, such as epoxy. U.S. Patent Application 2014/0171821 describes a catheter having temperature sensors mounted in a similar configuration to that described above. The arrangement described above provides an array of six sensors 78, but other arrangements, and other numbers of sensors, will be apparent to those having ordinary skill in the art, and all such arrangements and numbers are included within the scope of the present invention.

**[0045]** In the description herein, distal end 22 is assumed to define a set of xyz orthogonal axes, where an axis 94 of the distal end corresponds to the z axis of the set. For simplicity and by way of example, the y axis is assumed to be in the plane of the paper, the xy plane is herein assumed to correspond to the plane defined by circle 86, and the origin of the xyz axes is assumed to be the center of the circle.

**[0046]** Fig. 2D is a schematic, sectional view of force sensor 90, according to an embodiment of the present invention. Sensor 90 comprises a spring 94, herein assumed to comprise a plurality of helices 96, connecting cap 24A to proximal end 92. A position sensor 98 is fixed to the distal side of spring 94, and is herein assumed to comprise one or more coils coupled by conductors 100 to force module 56.

**[0047]** An RF transmitter 102, typically a coil, is fixed to the proximal side of spring 94, and the

RF energy for the transmitter is provided from force module 56 via conductors 104. The RF energy from the transmitter traverses sensor 98, generating a corresponding signal in conductors 100 of the sensor.

**[0048]** In operation, as force is exerted on cap 24A sensor 98 moves relative to transmitter 102, and the movement causes a change in the signals of the sensor. Force module 56 uses the change in signal of the sensor to provide a metric of the force on cap 24A. The metric typically provides the force in magnitude and direction.

**[0049]** A more detailed description of a sensor similar to sensor 90 is provided in US Patent Application 2011/0130648, which is incorporated herein by reference.

**[0050]** Returning to Fig. 1, temperature module 52 receives signals from the six sensors 78 within cap 24A, and uses the signals to determine a maximum value of the six measured temperatures. The temperature module is configured to calculate the maximum temperature at a fixed rate, herein assumed to be every 33 ms, but other embodiments may calculate the maximum temperature at higher or lower rates. In some embodiments the maximum temperature is determined at a frequency of at least 30 Hz. The calculated maximum temperature is herein also termed the measured temperature, and the measured temperature registers the temperature of the tissue being ablated. The temperature module passes the measured temperature value to power control module 54.

**[0051]** Power control module 54 provides RF power to cap 24A in a range of 1W to 100W. In embodiments of the present invention the module can be configured to provide a maximum RF power to cap 24A that can be set within a range of 70W - 100W. In some embodiments, the module can be configured to provide a further RF power to cap 24A in a different range from the maximum. In one embodiment the further power range is 20W - 60W, and the further power is typically provided after the maximum power. The maximum RF power and the further RF power are also termed herein the first power and the second power.

**[0052]** The power control module also measures an impedance of cap 24A. The impedance is measured at a predefined rate, herein assumed to be every 500 ms, but other embodiments may measure the impedance at a lower or higher rate.

**[0053]** The maximum power, and the time period for which the power is delivered, is selected by physician 14. The physician may also select values of the power less than 70W, and corresponding time periods for delivery of this reduced power. The actual power delivered is determined by the measured temperature received from temperature module 52, as described below.

**[0054]** Typically, during an ablation session, the impedance of cap 24A decreases. Embodiments of the present invention also check if the impedance increases from a previous impedance measurement by more than a pre-set value, herein assumed to be 7 $\Omega$ , although other embodiments may use larger or smaller values of impedance increase for the pre-set

value. An increase of impedance typically occurs if there is an unwanted change in the tissue being ablated, such as charring or steam popping. If the impedance increases by more than the pre-set value, the power control module is configured to stop the RF delivery to cap 24A.

**[0055]** Notwithstanding the powers selected by the physician, the power control module is configured to reduce the power delivered, typically by between approximately 5% and approximately 95%, if the measured temperature received from the temperature module reaches or exceeds a maximum allowable temperature that is set by physician 14.

**[0056]** In one embodiment, power that has been originally set to 90W is reduced to 50W after 4s, regardless of the readings from sensors 78. In an embodiment of the present invention, the maximum allowable temperature may be set within a range 60°C - 65°C. Typically, exceeding the maximum allowable temperature causes undesirable effects such as charring, coagulation on cap 24A, and/or steam pops in the tissue being ablated.

**[0057]** As explained above, force module 56 is able to measure the force on cap 24A. In an embodiment, the allowable force for an ablation is in the range of 5g - 35g.

**[0058]** Irrigation module 58 governs the rate at which irrigation fluid is delivered to the catheter tip. In some embodiments of the present invention it may be set within the range of 8 - 45 ml/min.

**[0059]** Fig. 3 is a flowchart of steps performed in operation of apparatus 12 during an ablation session, according to an embodiment of the present invention. In an embodiment of the present invention, an ablation session comprises two time periods: a first time period during which a first target power applies, followed by a second time period during which a second target power applies. In some ablation sessions only the first time period is used, and in this case there is only one target power set. The target powers within each time period are maximum RF powers which may be delivered by power control module 54.

**[0060]** In a range setting step 200, ranges for each of the variable parameters referred to above are set. In one embodiment the ranges are set as shown in Table I. Typically, for the target powers, an operator of the system only sets the first target power, while the second power is automatically set by the system.

Table I

<b>Parameter</b>	<b>Range</b>
First Target Power	70W - 100W
Second Target Power	20W - 60W
Allowable Force	5g - 50g
Maximum allowable temperature	55°C - 65°C
Irrigation rate	8 - 45 ml/min
First Time Period (during which First Target Power is operative)	1s to 6s

Parameter	Range
Second Time Period (during which Second Target Power is operative)	Up to 14s
Overall Time Period for Power Delivery (Sum of First and Second Time Periods)	1s - 20s

[0061] Range setting step 200 is implemented before physician 14 performs an ablation.

[0062] At the beginning of an ablation session, in a probe introduction step 202, physician 14 inserts probe 20 into a desired location in myocardium 16, using the tracking system incorporated into apparatus 12.

[0063] In a select value step 204, prior to performing the ablation procedure, physician 14 selects values of the parameters listed in Table I that are to be used in the procedure, and uses controls 49 to provide the values to the system. Alternatively, the physician selects a predetermined set of the values of the parameters listed in Table I, typically by choosing a "recipe," comprising the values, from a group of such recipes. The selected values typically depend on the depth of lesion it is desired to form by the procedure. For lesions of 1 - 3 mm depth the inventors have found that the values of the parameters given by Table II give good results. For lesions of 4 - 5 mm depth the inventors have found that the values of the parameters given by Table III give good results.

Table II

Lesions of 1 - 3 mm Depth	
Parameter	Value
First Target Power	90W
Second Target Power	Not set
Allowable Force	10g - 20g
Maximum allowable temperature	60°C
Irrigation rate	15 ml/min
First Time Period	3s
Second Time Period	Not set

Table III

Lesions of 4 - 5 mm Depth	
Parameter	Value
First Target Power	90W
Second Target Power	50W
Allowable Force	10g - 20g
Maximum allowable temperature	60°C
Irrigation rate	15 ml/min

Lesions of 4 - 5 mm Depth	
Parameter	Value
First Time Period	3s
Second Time Period	7s

**[0064]** Those having ordinary skill in the art will be able to determine, for other lesion depths, required values of the parameters within the ranges given by Table I, without undue experimentation.

**[0065]** In a begin RF delivery step 206, the first time period of the ablation session begins, by physician 14 initiating operation of apparatus 12. The ablation session uses the parameter values selected in step 204, in order to perform the ablation. Typically, during the ablation session, screen 62 displays values of the parameters listed in Table I to the physician. Screen 62 may also be configured to display to the physician, by methods which are known in the art, the progress of the RF delivery. The display of the progress may be graphical, such as a simulation of the dimensions of the lesion as it is produced by the ablation, and/or alphanumeric.

**[0066]** The remaining steps of the flowchart apply for both the first time period, and, if operative, for the second time period.

**[0067]** During the RF delivery procedure the system uses the power control module to perform a number of checks on the progress of the procedure, as shown in the flowchart by decision steps 208, 210, and 214.

**[0068]** In step 208, the power control module checks if the impedance to the delivered RF power of cap 24A has increased by more than the pre-set impedance value. If it has, the system halts the procedure in a termination step 216. If step 208 returns a negative value, control of the flowchart continues to decision step 210.

**[0069]** In step 210, the power control module checks if the measured temperature exceeds or reaches the pre-set maximum allowable temperature selected in step 204. If decision step 210 returns a positive value, the power control module, in a power reduction step 218, reduces the power to cap 24A.

**[0070]** The power reduction in step 218 is a function of a number of parameters:

A difference in temperature between the maximum allowable temperature  $T$  (set in step 204) and the measured temperature  $T_t$  at a time  $t$ ,

A change of measured temperatures between sequential temperature measurements, i.e.,  $T_{t-1} - T_t$ ,

A target power  $P$ , where if the flowchart is functioning in the first time period,  $P$  is the first target power, and if the flowchart is functioning in the second time period,  $P$  is the second target power, and

A power  $P_t$  measured at time  $t$ .

**[0071]** In one embodiment the following equations applies for the power reduction:

$$\Delta P(T) = \frac{a(T_{t-1} - T_t)}{T} + \frac{b(T - T_t)}{T} \quad (1)$$

where  $\Delta P(T)$  is a fractional change in power as a function of temperature, and  $a$  and  $b$  are numerical constants. In a disclosed embodiment  $a = 10$  and  $b = 1$ .

$$\Delta P(p) = \frac{(P - P_t)}{P} \quad (2)$$

where  $\Delta P(p)$  is a fractional change in power as a function of power.

$$\Delta P = \min(\Delta P(T), \Delta P(p)) \quad (3)$$

where  $\min(\Delta P(T), \Delta P(p))$  is the minimum of  $\Delta P(T)$  and  $\Delta P(p)$ , and  $\Delta P$  is the fractional change in power applied in step 218.

**[0072]** Typically, power reduction step 218 is performed reiteratively with decision step 210, until the measured temperature is below the preset maximum temperature.

**[0073]** If step 210 returns a negative value, control continues to decision step 214.

**[0074]** In decision step 214, the system checks if the overall time period for the ablation session, set in step 204, has been reached. If it has, then the flowchart ends. In decision step 214, the system also checks if the end of the first time period has been reached, and if it has, the system enters the second time period.

**[0075]** If the overall time period has not been reached, control passes to a continuing ablation step 222, where the system continues the ablation, and returns to decision steps 208, 210, and 214. Decision steps 208, 210, and 214 have been presented sequentially in the flowchart for simplicity and clarity. Typically, however, the system uses the power control module to perform the steps in parallel.

**[0076]** It will be appreciated that the embodiments described above are cited by way of example, and that the present invention is not limited to what has been particularly shown and described hereinabove. Rather, the scope of the present invention includes both combinations and subcombinations of the various features described hereinabove, as well as variations and modifications thereof which would occur to persons skilled in the art upon reading the foregoing description and which are not disclosed in the prior art.

## REFERENCES CITED IN THE DESCRIPTION

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**Patent documents cited in the description**

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- [US20100057072A](#) [0005]
- [US7207989B](#) [0006]
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- [US20110130648A](#) [0049]

**Non-patent literature cited in the description**

- **TOPP et al.** Saline-linked surface radiofrequency ablation: Factors affecting steam popping and depth of injury in the pig liver *Ann. Surg.*, 2004, vol. 239, 4518-27 [0011]

**Patentkrav****1.** Apparat, omfattende:

en elektrode (24A);

5 et effektstyringsmodul (54) konfigureret til at vælge en første maksimal radiofrekvens (RF) effekt der skal leveres af elektroden (24A) indenfor et område på 70W - 100W og til at vælge en anden maksimal RF effekt der skal leveres af elektroden (24A) indenfor et område på 20W - 60W; og

en processor (46) koblet til effektstyringsmodulet (54) og konfigureret til at:

10 vælge en tilladelig kraft på elektroden (24A) indenfor et område på 5g – 50g;

vælge en maksimalt tilladelig temperatur for væv, der skal ablateres, indenfor et område på 55°C - 65°C;

15 vælge en skylningshastighed for at tilvejebringe en skylningsvæske til elektroden (24A) indenfor et område på 8 - 45 ml/min; og

udføre en ablation af væv under anvendelse af de valgte værdier ved initielt at anvende den første effekt, skifte til den anden effekt efter en forudbestemt tid mellem 3s og 6s, og afslutte ablationen efter en total tid for ablationen mellem 10s og 20s.

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**2.** Apparatet ifølge krav 1, hvor processoren (46) er konfigureret til at måle en impedans til en RF-effekt leveret af elektroden (24A) under ablationen, og, når en ændring i impedansen overstiger en forudsat værdi, standser ablationen af vævet.

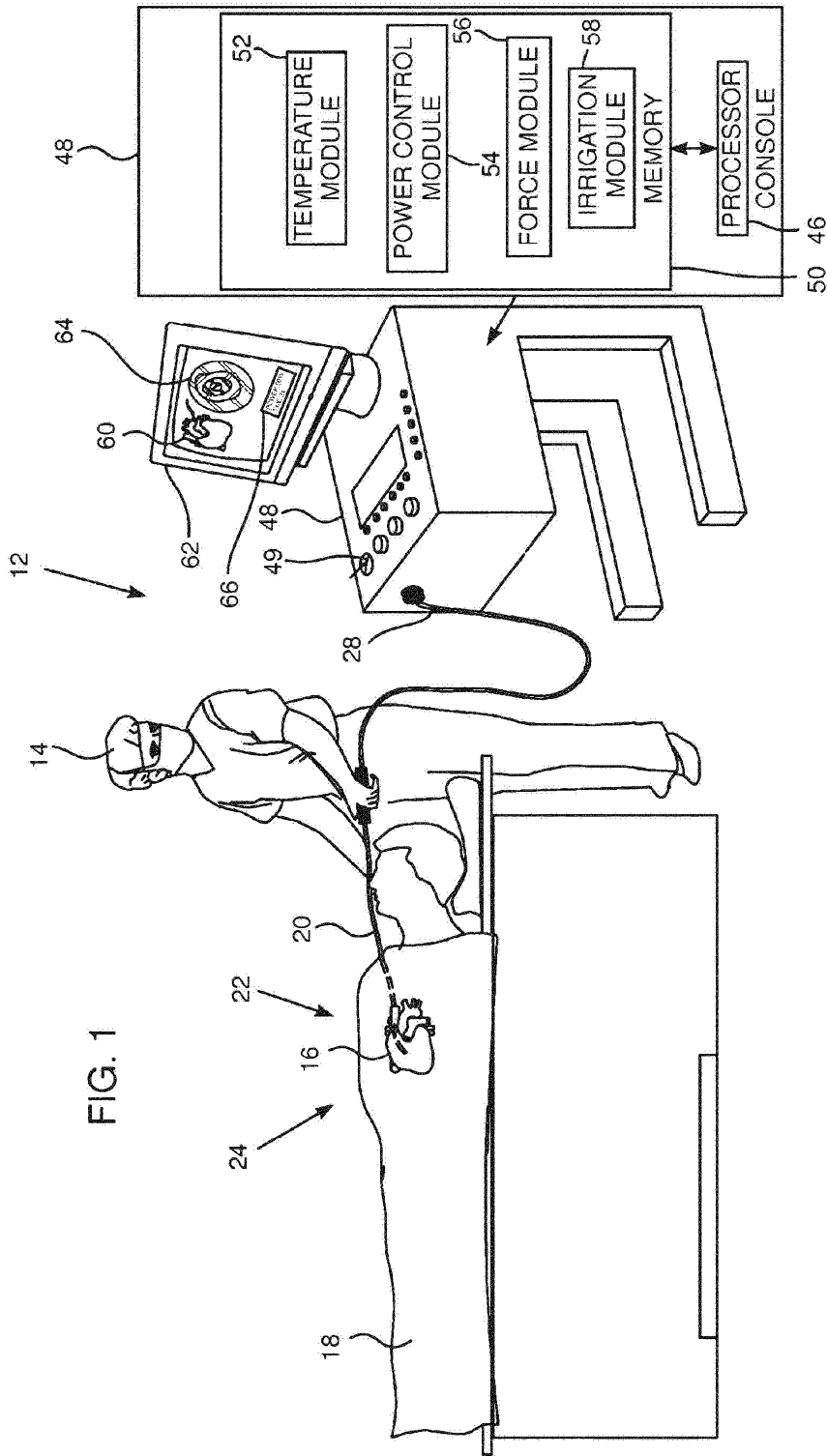
25 **3.** Apparatet ifølge krav 2, hvor ændringen er mindst 7Ω.

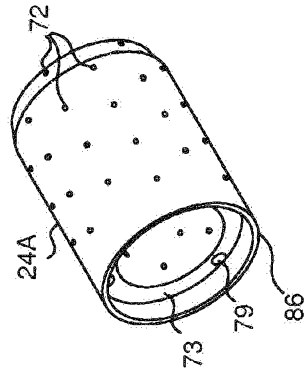
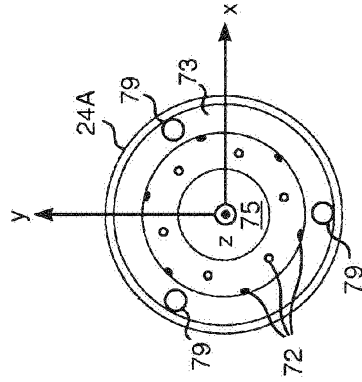
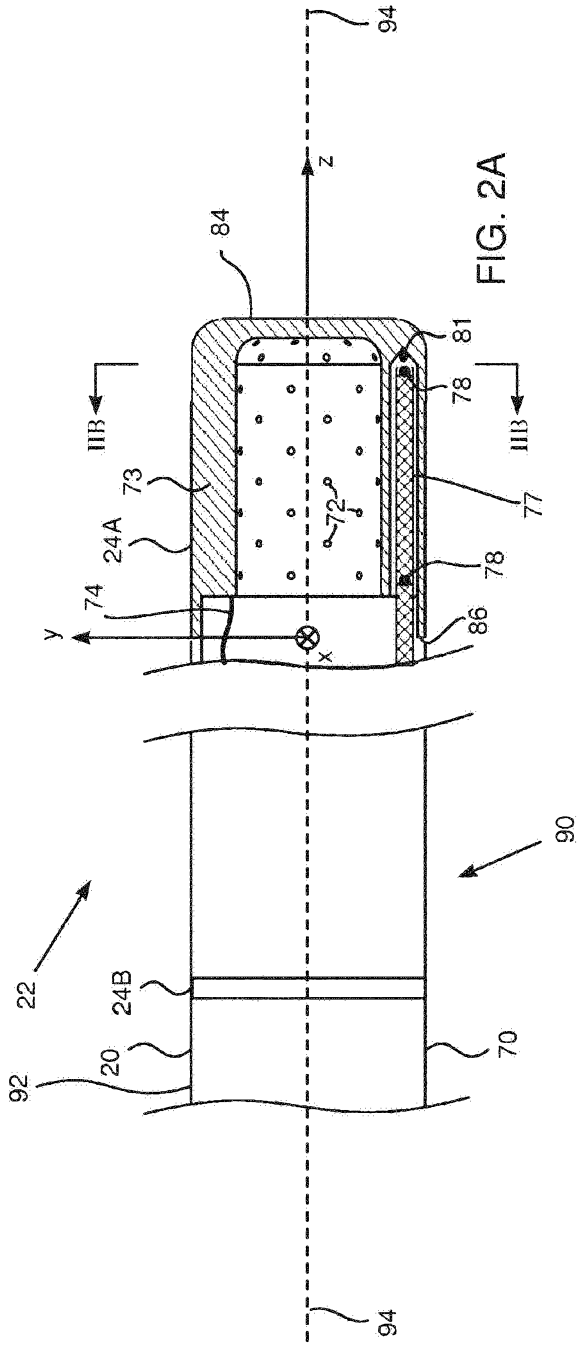
**4.** Apparatet ifølge krav 1, hvor processoren (46) er konfigureret til at måle ved respektive tidspunkter en temperatur af vævet, og, når temperaturen overstiger

den valgte maksimalt tilladelige temperatur, for at reducere et niveau af en RF-effekt leveret af elektroden (24A).

**5.** Apparatet ifølge krav 4, hvor temperaturen af vævet er målt ved en frekvens på mindst 30 Hz.

# DRAWINGS





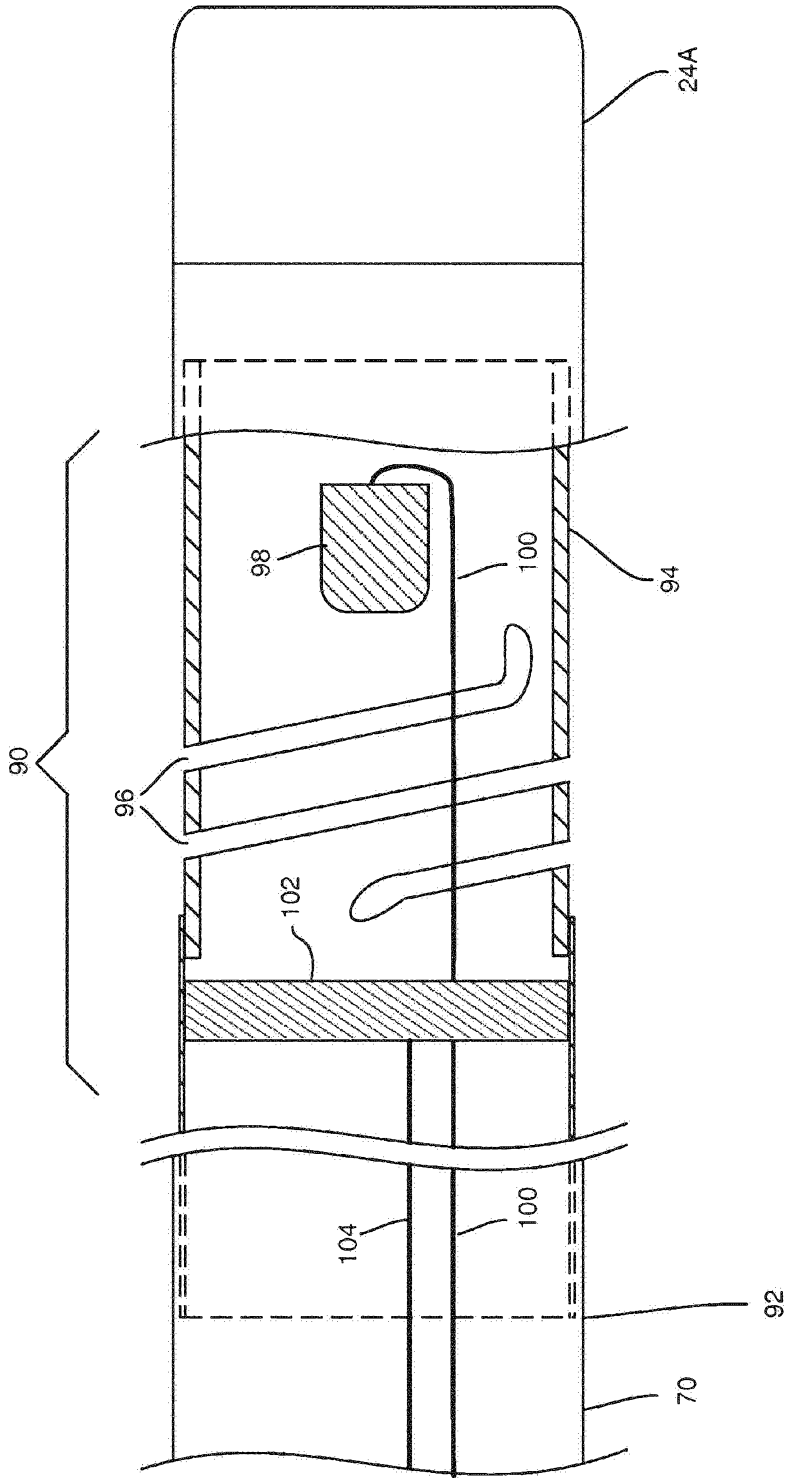


FIG. 2D

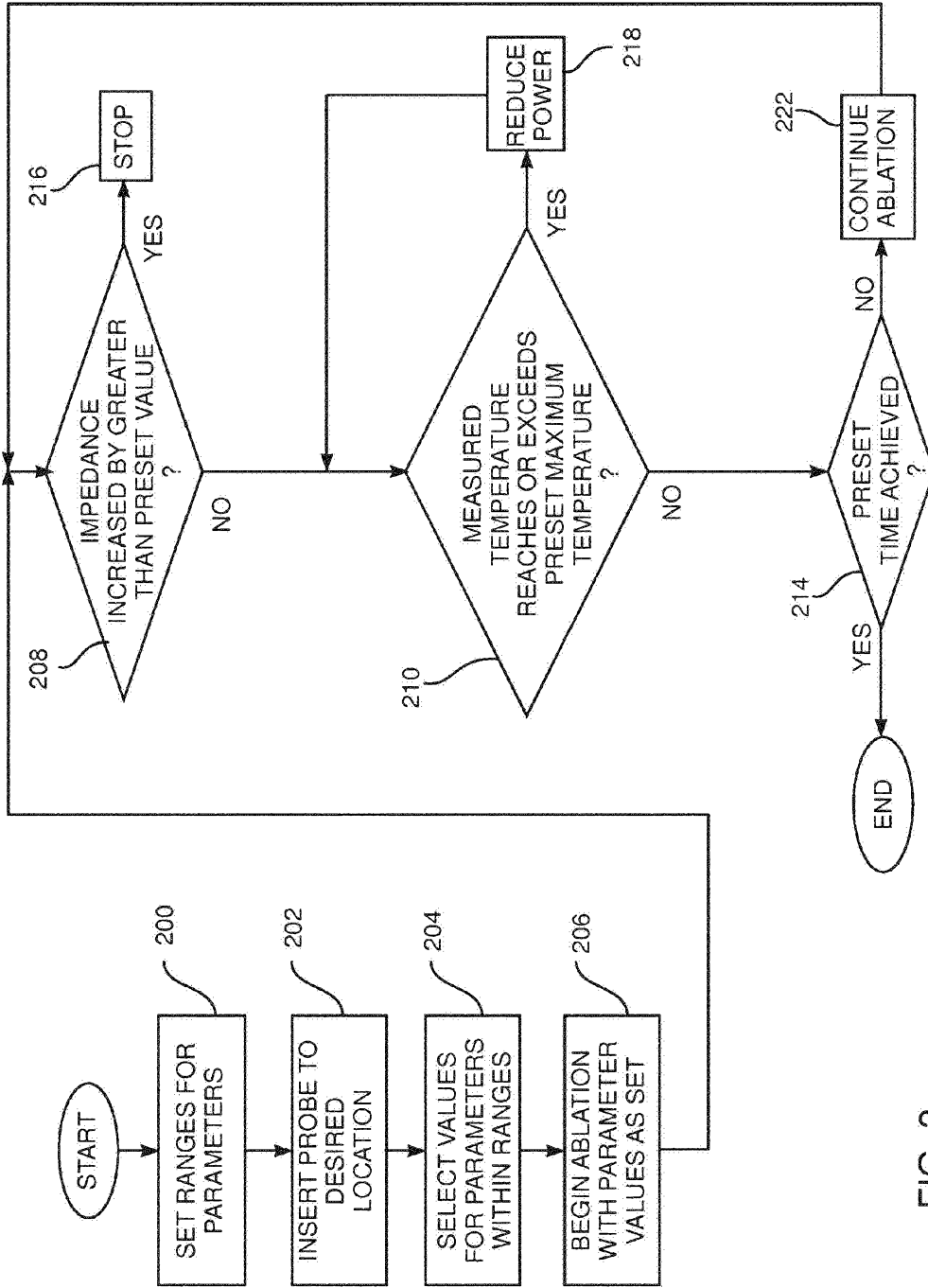


FIG. 3