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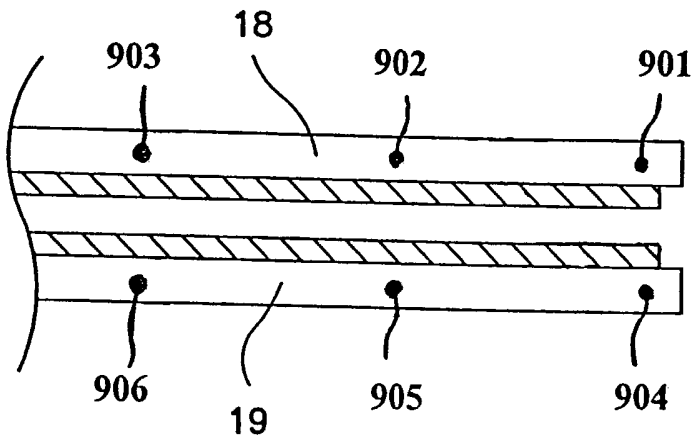
(54) Title: ABLATION SYSTEM AND METHOD OF USE



(57) Abstract: There is disclosed how complete or partial submersion of one or both of the jaws of an ablation device in a fluid may be detected prior, during or following an ablation procedure.Submersion sensors may be incorporated into the jaws of an ablation device and can be used to determine if the electrodes are fully submerged, partially submerged, or are in a state of oscillation etween submersion and non-submersion. There is also disclosed a system and method for creating lesions and assessing their completeness or transmurality. Assessment of transmurality of a lesion is accomplished by monitoring the impedance of the tissue to be ablated.

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ABLATION SYSTEM AND METHOD OF USE

Field of the Invention

The present invention relates to tissue ablation devices generally and relates more particularly to devices adapted to ablate lines of tissue, for example for use in conjunction with an electrosurgical version of the Maze procedure.

Background of the Invention

The Maze procedure is a surgical intervention for patients with chronic atrial fibrillation (AF) that is resistant to other medical treatments. The operation employs incisions in the right and left atria which divide the atria into electrically isolated portions which in turn results in an orderly passage of the depolarization wave front from the sino-atrial node (SA Node) to the atrial-ventricular node (AV Node) while preventing reentrant wave front propagation. Although successful in treating AF, the surgical Maze procedure is quite complex and is currently performed by a limited number of highly skilled cardiac surgeons in conjunction with other open-heart procedures. As a result of the complexities of the surgical procedure, there has been an increased level of interest in procedures employing electrosurgical devices or other types of ablation devices, e.g. thermal ablation, micro-wave ablation, cryo-ablation or the like to ablate tissue along pathways approximating the incisions of the Maze procedure. Electrosurgical systems for performing such procedures are described in U.S. Patent No 5,916,213, issued to Hiassaguerre, et al. U.S. Patent No. 5,957,961, issued to Maguire, et al. and U.S. Patent No. 5,690,661, all incorporated herein by reference in their entireties. Cryo-ablation systems for performing such procedures are described in U.S. Patent No. 5,733,280 issued to Avitall, also incorporated herein by reference in its entirety.

In conjunction with the use of electrosurgical ablation devices, various control mechanisms have been developed to control delivery of ablation energy to achieve the desired result of ablation, i.e. killing of cells at the ablation site while leaving the basic structure of the organ to be ablated intact. Such control systems include measurement of temperature and impedance at or adjacent to the ablation site, as are disclosed in U.S.

Patent No. 5,540,681, issued to Struhl, et al., incorporated herein by reference in its entirety.

Additionally, there has been substantial work done toward assuring that the ablation procedure is complete, i.e. that the ablation extends through the thickness of the tissue to be ablated, before terminating application of ablation energy. This desired result is some times referred to as a "transmural" ablation. For example, detection of a desired drop in electrical impedance at the electrode site as an indicator of transmurality is disclosed in U.S. Patent No. 5,562,721 issued to Marchlinski et al, incorporated herein by reference in its entirety. Alternatively, detection of an impedance rise or an impedance rise following an impedance fall are disclosed in U.S. Patent No. 5,558,671 issued to Yates and U.S. Patent No. 5,540,684 issued to Hassler, respectively, also incorporated herein by reference in their entireties.

Three basic approaches have been employed to create elongated lesions using electrosurgical devices. The first approach is simply to create a series of short lesions using a contact electrode, moving it along the surface of the organ wall to be ablated to create a linear lesion. This can be accomplished either by making a series of lesions, moving the electrode between lesions or by dragging the electrode along the surface of the organ to be ablated and continuously applying ablation energy, as described in U.S. Patent No. 5,897,533 issued to Mulier, et al., incorporated herein by reference in its entirety. The second basic approach to creation of elongated lesions is simply to employ an elongated electrode, and to place the elongated electrode along the desired line of lesion along the tissue. This approach is described in U.S. Patent No. 5,916,213, cited above and. The third basic approach to creation of elongated lesions is to provide a series of electrodes and arrange the series of electrodes along the desired line of lesion. The electrodes may be activated individually or in sequence, as disclosed in U.S. Patent No. 5,957,961, also cited above. In the case of multi-electrode devices, individual feedback regulation of ablated energy applied via the electrodes may also be employed. The present invention is believed useful in conjunction with all three approaches

Summary of the Invention

The present invention is directed toward an improved system for creating lesions and assessing their completeness or transmurality. In particular, the preferred

embodiments of the invention are directed toward an improved system for creating elongated lines of lesion and assessing their completeness or transmurality. In the preferred embodiment as disclosed, the apparatus for producing the lesions is an electrosurgical device, in particular a saline-irrigated bipolar electrosurgical forceps. However, the mechanism for assessing lesion transmurality provided by the present invention is believed useful in other contexts, including unipolar radio-frequency (RF) ablation and RF ablation using catheters or hand-held probes. The mechanism for assessing transmurality may also be of value in the context of other types of ablation systems, particularly those which ablation occurs in conjunction with an induced rise in tissue temperature such as those applying ablation energy in the form of microwave radiation, light (laser ablation) or heat (thermal ablation).

According to the present invention, assessment of transmurality of a lesion is accomplished by monitoring the impedance of the tissue to be ablated. The inventors have determined that, particularly in the case of a saline-irrigated electrosurgical ablation device, tissue impedance first falls and then reaches a stable plateau, during which portion the lesion is completed. Thereafter, the impedance rises. Rather than attempting to detect a desired drop or a desired increase impedance as described in the above cited Yates, Hassler and Marchlinski patents, the present invention detects completeness of a lesion in response to the measured impedance remaining at a stable level for a desired period of time, hereafter referred to as an impedance plateau. In the context of RF ablation, measurement of impedance may be done using the ablation electrodes or may be done using dedicated electrodes adjacent to the ablation electrodes. In the context of the other types of ablation discussed above, impedance measurement would typically be accomplished by means of a dedicated set of impedance measurement electrodes.

In the context of RF ablation, the invention is believed most valuable in the conjunction with an ablation device having multiple, individually activatable electrodes or electrode pairs to be arranged along a desired line of lesion. In this context, the mechanism for determining transmurality of lesions adjacent individual electrodes or pairs may be used to deactivate individual electrodes or electrode pairs, when the lesions in tissue adjacent these individual electrodes or electrode pairs are complete. This allows the creation of an essentially uniform lesion along the line of electrodes or electrode pairs, regardless of differences in tissue thickness adjacent the individual electrodes or electrode

pairs. However, the invention is also believed useful in conjunction with assessment of transmurality of lesions produced by devices having only a single electrode or single electrode pair. Similar considerations apply to the use of the present invention in the contexts of other types of ablation as listed above.

In yet another aspect of the invention, RF power delivery can also be controlled in order to assess lesion transmurality. The ablation will commence at a first power level and will be increased to a second power level as certain conditions are satisfied. The power level can also be increased from the second power level to a third power level as certain conditions are satisfied. The increase in power level can continue in the same stepwise manner, increasing the power level from an N power level to an n+1 power level until a set of conditions are met that indicates that transmurality has been achieved and/or that the power should be turned off. Conditions for an increase in power level can include one or more of: the detection of a plateau in impedance or the achievement of a maximum permitted time for that power level. Conditions indicating that transmurality has been achieved can include one of: the lack of change in detected impedance in response to the change in power level or the detection of a rapid rise in impedance. If transmurality is detected by satisfying one of these conditions, the power is turned off and the ablation is complete. If a condition indicating that transmurality has been achieved is not detected, such as a drop in detected impedance in response to the change to the higher power level, ablation is continued at the higher power level until the conditions are met for again increasing the power level or conditions indicating transmurality are met. This process may be continued in a stepwise fashion until the conditions for detection of transmurality are detected, a predetermined number of plateaus in impedance have been detected or until an overall maximum time for the ablation is achieved.

In yet another aspect of the invention, complete or partial submersion in a fluid of the ablating portion of an ablation device may be detected prior to, during or following an ablation procedure. During an ablation procedure one or more fluids, such as blood, CPB fluids and/or surgical field irrigation fluids, can collect or pool in the atria and/or pericardial sac. When the ablation device is positioned and/or clamped onto tissue, a portion of the device, such as one or more ablating elements of the device, may become fully or partially submerged by these fluids. One or more submersion sensors positioned on the device can be used to detect and monitor the submersion of at least a portion of the

device. Since total submersion, oscillating submersion, or partial submersion of one or more ablating elements, e.g., ablation electrodes, can cause, for example, impedance changes and affect the ablation cycle and lesion quality, different power or ablating energy and transmurality algorithms may be applied for the various degrees of submersion.

Brief Description of the Drawings:

Figure 1 is a plan view of a type of electrosurgical hemostat that may be used in conjunction with the present invention.

Figures 2a and 2b illustrate alternative electrode configurations for a hemostat generally according to Figure 1.

Figure 3 illustrates the fall and plateau of impedance measured across tissue ablated using a bi-polar, saline irrigated electro surgical hemostat.

Figure 4 is a functional block diagram of an RF generator appropriate for use in practicing the present invention, particularly adapted for use in conjunction with an ablation system employing multiple, individually activatable electrodes or multiple electrode pairs.

Figure 5a is a functional flow chart illustrating a first mode of operation of the device illustrated in Figure 4 in practicing the present invention.

Figure 5b illustrates an alternative mode of operation of a device as in Figure 4 in practicing the present invention.

Figure 6 illustrates an additional alternative mode of operation of a device as in Figure 4 in practicing the present invention.

Figure 7 illustrates a first mode of operation of a device as in Figure 4 to activate and deactivate of individual electrodes or electrode pairs.

Figure 8 illustrates a second mode of operation of a device as in Figure 4 to activate and deactivate individual electrodes or electrode pairs.

Figures 9-12 are graphs illustrating modes of operation for a device according to the present invention.

Figure 13 illustrates an alternative configuration for a hemostat generally according to Figure 1.

Detailed Description Preferred Embodiments

Figure 1 is a plan view of a bipolar, saline irrigated electrosurgical hemostat of a type that may be employed in conjunction with the present invention. The hemostat is provided with elongated handles 11 and 12 and a lock mechanism 14, similar to a conventional surgical hemostat. The handles are connected to one another by pivot or hinge 16, and continue distally in the form of elongated jaws 18 and 19. Jaws 18 and 19 carry an elongated electrode or series of electrodes 24, 25, respectively, to which ablation energy, e.g. RF energy is applied by means of conductors 21 and 22. The electrodes are adapted to be irrigated by a saline solution or other conductive fluid along their length, provided via inlet tubes 20 and 23. In operation, tissue to be ablated is compressed between the jaws, and RF energy is applied between the electrode or electrode sets 24 and 25, as generally described in U.S. Patent No.: 6,096,037 issued to Mulier et al incorporated herein by reference in its entirety.

Figure 2a shows a first embodiment of an electrode arrangement for a hemostat generally as illustrated in Figure 1. Illustrated components correspond to identically numbered components in Figure 1. In this embodiment, electrodes 24 and 25 take the form of elongated coil electrodes 30 and 32, mounted around porous tubes 34 and 36, through which saline or other conductive fluid is delivered. The arrangement of the electrodes may also be reversed, for example placing coils 30 and 32 within elongated porous tubes 34 and 36, to accomplish a similar result. Alternatively, any other arrangement for providing an elongated electrode and delivery of saline solution along the length thereof may be substituted. The particular configuration of the electrode is not critical to the present invention. For example, irrigated electrodes corresponding to those described in U.S. Patent No. 6,096,037 issued to Mulier, et al., U.S. Patent No. 5,876,398 issued to Mulier, et al., U.S. Patent No. 6,017,378 issued to Brucker, et al or U.S. Patent No. 5,913,856 issued to Chia, et al., all incorporated herein by reference in their entireties may also be substituted. It should also be noted that while the electrode system as illustrated in Figure 2a is a bipolar system, the invention may also be employed in conjunction with unipolar electrodes and/or in the form of a probe or a catheter. In some embodiments, irrigation of the electrodes may be omitted.

Figure 2b illustrates an alternative embodiment of an electrode system for a hemostat generally as illustrated in Figure 1. In this case, rather than a single pair of

electrodes, multiple electrode pairs are provided. The electrode pairs comprise coil electrodes 40 and 42, 44 and 46, 48 and 50, 52 and 54, and 56 and 58. However, other pairings of electrodes might also be substituted, for example, pairing electrodes 40 and 44, electrodes 48 and 52 or the like. In this embodiment, the electrode pairs are mounted around porous plastic tubes 60 and 62 through which saline or other electrically conductive fluid is delivered. As in the case with the embodiment of Figure 2a, the arrangement of these electrodes may readily be reversed, placing the electrodes within the lumen of plastic tube 60 or 62 and any other arrangement providing multiple, irrigated electrodes may also be substituted. As in the case of the embodiment of Figure 2a, unipolar electrodes might be substituted for the multiple bipolar pairs as illustrated and/or the invention may be practiced in conjunction with a multi-electrode probe or catheter. While the particular arrangement of electrodes is not believed critical to practicing the present invention, it is believed that the invention may be most beneficially practiced in conjunction with a set of linearly arranged bipolar electrode pairs as illustrated in Figure 2b.

In use, the hemostat is arranged so that the tissue to be ablated is located between the jaws 18 and 19, and pressure is applied in order to compress the tissue slightly between the jaws to ensure good electrical contact. All electrode pairs may be activated individually and may be individually deactivated when the lesions between the individual electrode pairs are completely transmural. Alternatively, electrode pairs could be activated sequentially, with one pair deactivated upon a detection of a complete lesion between the electrode pair, followed by activation of the next sequential electrode pair. Corresponding use of the invention in conjunction with a series of unipolar electrodes, for example corresponding to electrodes along one of the two jaws in conjunction with a remote ground plate or a similar series of individually activatable electrodes on a catheter or probe in conjunction with a ground plate is also possible.

Figure 3 is a graph 64 illustrating measured impedance versus time across tissue located between the electrodes of an irrigated bipolar hemostat 10 as illustrated in Figure 1. Figure 3 illustrates the drop in impedance 66 followed by an impedance plateau 68, ultimately followed by an impedance rise 70. The impedance plateau 68 is the primary indicator of transmurality employed by the present invention. Following the impedance plateau 68, as tissue is desiccated or as steam or microbubbles forms in the tissue, an

impedance rise 70 will generally occur. In some embodiments of the invention, the detection of this rise in impedance 70 is employed as an alternative or mechanism for assessing transmurality and/or as a safety mechanism in order to assure shut off of the ablation electrodes before excessive physical damage to the tissue results.

Figure 4 is a functional block diagram illustrating one embodiment of an RF generator system 799 for use in conjunction with the present invention. In this embodiment, separately controllable RF outputs are provided for individual ablation electrodes or electrode pairs on an associated RF ablation device, for example as in Figure 2B. The RF generator could of course also be used with ablation devices having only a single electrode or electrode pair as in Figure 2A. With the exception of the electrogram amplitude measurement circuits discussed below, the generator 799 corresponds generally to that described in conjunction with Figure 14 of the '961 patent issued to Maguire, et al., cited above. The RF generator disclosed in the '961 patent provides feedback control of RF power based upon either measured power (constant power) or temperature. The present invention is somewhat easier to implement in conjunction with the constant power mode, but may also be adapted to a temperature-regulated mode or to other feedback power regulation mechanism.

Display 804 and controls 802 are connected to a digital microprocessor 800, which permits interface between the user and the remainder of the electrical components of the system. Microprocessor 800 operates under control of stored programming defining its operation including programming controlling its operation according to the present invention, as discussed in more detail below. Microprocessor 800 provides control outputs to and receives input signals from the remaining circuitry via address/data bus 806. In particular, the microprocessor 800 provides for monitoring of power, current, voltage, impedance and temperature. As necessary, the microprocessor will provide this information to the display 804. Additionally, the microprocessor 800 permits the user to select the control mode (either temperature or power) and to input the power set point, temperature set point, and a timer set point to the system. The primary source of power for the radio-frequency generator may be a 12 V battery rated at 7.2 ampere-hours. Alternatively, the device may be AC powered. A back-up battery (not shown) such as a lithium cell may also be provided to provide sufficient power to the microprocessor 800 to maintain desired memory functions when the main power is shut off.

The power supply system as illustrated includes a desired number "M" of individually controllable RF power supplies and receives temperature inputs from a desired number "N" of temperature sensing devices in the ablation device, illustrated schematically at 836 and receives temperature inputs from a desired number "M" of impedance monitoring circuits. Each RF power supply includes a transformer (822, 824, 826), a power control circuit (810, 812, 814) and a power measurement circuit (816, 818, 820). A crystal-locked radio-frequency oscillator 840 generates the switching pulses, which drive both the power transformers (822, 824, 826) and the power controllers (810, 812, 814). Power controllers (810, 812, 814) may be analog controllers which operate by pulse-width modulation by comparing a power set point signal from microprocessor 800 with an actual power signal generated by a power measurement circuit (816, 818, 820), which may, for example, include a torroidal transformer coupled to the power output from the associated transformer (822, 824, 826). The power measurement circuits (816, 818, 820) multiply the output current and voltage and provide the resulting actual power signal to both the power controllers (810, 812, 814) and the microprocessor 800.

The RF power output of the transformers (822, 824, 826) is provided to inter face board 808, and thereby is provided to the ablation electrode or electrodes on the ablation device 838. Separate analog comparator circuits (not illustrated) may also be provided for monitoring the output of the power measurement circuits (816, 818, 820), in order to shut-off current to the output transformers (822, 824, 826) if the power exceeds a limit, typically 55 watts. Power transformers (822, 824, 826) may include center taps, which receive the outputs of the power controllers (810, 812, 814). Secondary windings of the transformers (822, 824, 826) may provide for continuous monitoring of the applied voltage in order to permit the power calculations by power measurement circuits (816, 818, 820).

The illustrated power RF generator system 799 employs software controlled temperature processing, accomplished by microprocessor 800, which receives the "N" temperature input signals from temperature measurement circuits (828, 830, 832), each of which are coupled to a corresponding temperature sensor in ablation device 838 by means of an electrical connector, illustrated schematically at 836 and interface board 808. If programmed to operate in the temperature controlled mode, processor 800 receives the "N" temperature signals and, based upon the indicated temperatures, defines power set points

for each of the power control circuits (810, 812, 814), which in the manner described above control the power levels applied to electrodes on the ablation device through interface 808. Processor 800 may also selectively enable or disable any of the "M" provided RF power supplies, in response to external control signals from controls 802 or in response to detected anomalous temperature conditions.

In addition to the circuitry as described above and disclosed in and disclosed in the Maguire, et al. '961 patent, the apparatus of Figure 4 includes multiple impedance monitoring circuits ZM1, ZM2...ZMM (842, 844 and 846 respectively), which may operate as described in U.S. Patent No. 5,733,281, issued to Nardella, or U.S. Patent No. 5,863,990, issued to Li, also both incorporated herein by reference in their entireties to measure an impedance between electrodes on a RF ablation device. Impedance may be measured between the ablation electrodes or between electrodes located adjacent the ablation electrodes, as described in U.S. Patent No. 5,558,671, incorporated by reference above. Individual impedance measurements made by measurement circuits 842, 844 and 846 are provided to the address/data bus 806 and thence to microprocessor 800 for analysis to determine whether the impedance over time, indicates that the lesion associated with the measured impedance is completely transmural. As discussed in more detail below, a determination of transmurality is made in response to a detection of a series of impedance measurements that are relatively constant, over a desired period of time or over a defined number of successive impedance measurements. In some embodiments, an abrupt rise in impedance may also be employed to terminate delivery of ablation energy.

As an alternative to dedicated impedance monitoring circuits, the microprocessor may employ voltage and current measurements of impedance measurement signals generated by the power transformers (822, 824, 826) to derive impedance and may use such derived impedance values in conjunction with the present invention. For example, measurement of impedance in this fashion is disclosed in US Patent No. 5,540,681, issued to Struhl, et al, cited above or U.S. Patent No. 5, 573,533, issued to Struhl, also incorporated herein by reference in its entirety.

In cases in which an alternative ablation energy generation apparatus is employed, particularly those in which a rise in tissue temperature is induced, e.g. laser, microwave or thermal ablation, the RF generation circuitry of Figure 4 would be replaced with a corresponding alternative ablation energy generation apparatus. The measurement of

tissue impedance and its use according to the present invention, however, may still be useful in conjunction with these alternative ablation energy generation systems.

Figure 5A is a functional flow chart illustrating the operation of a device as in Figure 4, according to the present invention. The flow chart of Figure 5A illustrates operation of the device of Figure 4 to control provision of RF energy to an individual electrode or electrode pair. In the event that multiple electrodes or electrode pairs are employed, the control methodology of Figure 5A would be applied to each electrode or electrode pair individually, as discussed in more detail below in conjunction with Figures 7 and 8.

The flow chart of Figure 5A illustrates a method of assessing transmurality and terminating delivery of ablation energy to an electrode or an electrode pair responsive to detection of a plateau in impedance in conjunction with a detected drop in impedance. Following the detection of a plateau in conjunction with the required impedance drop, the device waits a defined time period and then terminates the application of ablation energy to the associated electrode pair. Measurement of impedance in tissue associated with the electrode pair may be made using the ablation electrodes themselves or electrodes located in proximity to the ablation electrodes, for example as described in the Yates '671 patent, incorporated by reference above.

After initialization at 200, the microprocessor 800 (Fig. 4) initiates delivery of ablation energy at 201 and causes the impedance measurement circuitry associated with the electrode or electrode pair being evaluated or derives impedance based on applied voltage and current as discussed above to acquire a base line or initial impedance Z_i, which may be, for example the maximum impedance during the first three seconds of ablation. At 202 and 204 counts "n" "m" are reset to zero. The microprocessor thereafter acquires a current impedance value Z_n at 206. The value of "n" is incremented at 208 and compared with a predefined value "a" at 210 to determine whether a sufficient number of impedances have been measured in order to calculate the rate of change of impedance (dZ/dt). For example, dZ/dt may be calculated by taking the measured impedance Z_n and comparing it to the preceding measured impedance Z_{n-1}, in which case n would have to be greater or equal to 2 in order for dZ/dt to be calculated. Alternatively, dZ/dt may be calculated by taking the measured impedance Z_n and comparing it to the previously measured impedance Z_{n-2}, in which case n would have to be greater or equal to 3 in order

for dZ/dt to be calculated. If "n" is less than "a" at 210, the microprocessor waits an impedance sampling interval Δt_I which may be, for example, 0.2 seconds, and then triggers an impedance measurement again at 206. This process continues until there are a sufficient number of collected impedance measurements to calculate dZ/dt at 212.

At 212, the microprocessor 800 employs the stored impedance measurements to calculate dZ/dt, which may, for example, be calculated as equal to $(1/(2\Delta t_I))\ (Z_n - Z_{n-2})$. The absolute value of dZ/dt, i.e., $|dZ/dt|_n$ is employed to assess whether or not an impedance plateau has been reached at 214. The microprocessor checks at 214 to determine whether $|dZ/dt|_n$ is less than a defined constant b, indicative of a minimal rate of change of impedance. In the case of an elongated, fluid irrigated ablation electrode similar to that illustrated in Figure 2A, for example using an electrode of approximately 5 centimeters in length operated in a constant power mode with a power of less than 27 watts, an appropriate value of "b" might be 1.3. For other electrode configurations and other power levels, the value of "b" may have to be adjusted. Other power control modes, e.g. temperature controlled would similarly require adjustment of this parameter. The value of "b" and other parameters employed to determine transmurality using the present invention can be determined empirically in the laboratory by applying the specific electrode set and RF generation system in question to test specimens, reading impedances at defined sample intervals and using the results to optimize the various parameters.

In the event that $|dZ/dt|_n$ is sufficiently small in value at 214, the count "m" is incremented at 216 and m is compared to a third constant "c" which sets forth the defined number of low value $|dZ/dt|_n$ measurements required to detect an impedance plateau. For example, in a system as described herein, "c" may be 6 – 12. Alternatively, rather than requiring an entire series of measured $|dZ/dt|_n$ values to be less than "b", a requirement that a defined proportion of the $|dZ/dt|_n$ values must be less than "b" may be substituted, e.g. 8 of 12, or the like.

If the number of low values of $|dZ/dt|_n$ is less than "c" at 218, the microprocessor waits the impedance sampling interval Δt_I at 220 and continues to acquire successive impedance measurements until sufficient number of sequential low values of $|dZ/dt|_n$ have occurred at 218. At that point, the microprocessor then compares the current impedance value Z_n with the initial impedance value Z_i to determine whether a sufficient impedance

drop "d" has occurred. If not, the microprocessor waits for the next impedance sampling interval at 220 and continues to collect impedance measurements and make calculations of $|dZ/dt|_n$ until such time as an impedance plateau is recognized at 218 and a sufficient impedance drop is recognized at 220. When both of these criteria have been met at 220, the microprocessor than waits for an additional time interval Δ_{t2} to assure completeness of the lesion at 222 and thereafter terminates the provision of ablation energy to the specific electrode pair being regulated at 224 and the ablation process with regard to that electrode or electrode pair is terminated at 226.

Figure 5B illustrates an additional set of operations for implementing a transmurality measurement method generally as in Figure 5A. The operations of Figure 5B may either be substituted for step 222 of Figure 5A or alternatively may be performed before or after step 222. In the additional operations illustrated in Figure 5B, the microprocessor increases the power to the electrodes under consideration slightly at 228 and sets a timer at 230. The microprocessor then causes the impedance measurement apparatus associated with the electrodes under consideration to measure current impedance at 234 and calculate $|dZ/dt|_n$ at 236, in the same fashion as discussed above. In the event that the value of $|dZ/dt|_n$ is greater then a defined constant "e" at 240, the microprocessor returns to 204 and resets the value of "m" to zero, essentially reinitializing the search for an impedance plateau. The value of "e" may be equal to "b" or may be different. If the value of $|dZ/dt|_n$ is sufficiently small at 240, the microprocessor checks at 242 to determine whether the timer has expired. If not, the microprocessor waits the impedance sampling interval Δt_1 at 238 and continues to collect impedance values and calculate $|dZ/dt|_n$ values until expiration of the timer at 242, at which point it either terminates ablation at 224 or initiates the waiting period Δt_2 at 222.

Figure 6 illustrates a second basic approach to assessment of transmurality and control of delivery of ablation energy to an electrode pair. In the same fashion as for Figures 5a and 5b, the procedure defined by the flow chart of Figure 6 should be understood to be employed in conjunction with an impedance measurement circuit with a single electrode pair, which procedure would be repeated for other electrodes or electrode pairs, if present. After initiation at 300, the value of "n" is set to zero at 302 and a timer is initiated at 304, used to determine that a sufficient amount of time has passed prior to termination of ablation. For example, in the context of a bipolar irrigated hemostat similar

to Figure 1 and 2a as described above, having electrode lengths of 2 to 5 centimeters and receiving RF energy at a level of 27 watts or less, ten seconds may be an appropriate time interval for the timer initiated at 304.

The microprocessor than measures the current impedance Z_n at 306, increments the value of "n" at 310 and checks at 314 to determine whether an adequate number of impedance measurements have been accumulated to make a calculation of dZ/dt at 314, in the same fashion as discussed above in conjunction with Figures 5a and 5b. If an inadequate number of samples have been collected, the microprocessor waits the impedance sampling interval Δt at 308 and continues to collect impedance measurements until an adequate number "a" of measurements have been collected. In the specific example presented, "a" may be set equal to 5 and Δt may be 0.2 seconds. After an adequate number of impedance measurements have been collected at 314, the microprocessor calculates the value of dZ/dt_n and $|dZ/dt|_n$ at 316. In conjunction with the specific mechanism of plateau detection illustrated in Figure 6, filtered or average impedance values Z_a may be employed to calculate dZ/dt and $|dZ/dt|_n$.

For example, at 316, the microprocessor may calculate the value of dZ/dt according to the following method. The microprocessor may employ a 5 point moving average filter to produce an average impedance value Z_a, which is equal to $(Z_n + Z_{n-1} + Z_{n-2} + Z_{n-3} + Z_{n-4})/5$. The value of dZ/dt_n and $|dZ/dt|_n$ may be calculated in the same fashion as in conjunction with the flow charts of Figure 5A and 5B discussed above, substituting the averaged impedance values Z_a for the individual impedance values Z_n as employed in the previous flow charts. In this case, dZ/dt_n would be $(1/(2\Delta t))(Z_n - Z_{n-2})$ and $|dZ/dt|_n$ would be the absolute value of dZ/dt_n.

At 318, microprocessor 800 may attempt to determine whether an impedance plateau has been reached employing the following method. The microprocessor reviews the preceding 15 measurements of dZ/dt_n, and $|dZ/dt|_n$ and applies three criteria to those values, all three of which must be met in order for an impedance plateau to be detected. For a fluid irrigated hemostat as described, the rules may be as follows: for n = 1 to 15; $|dZ/dt|_n$ must be less than or equal to 1 for all 15; and for n = 1 to 15 the value of dZ/dt_n must be less than or equal to 0.75, for 13 of the 15; and for n = 1 to 15, $|dZ/dt|_n$ must be less than or equal to 0.5, for 10 of the 15. If all of these criteria are met at 318, the microprocessor checks at 319 to determine whether an adequate period of time has elapsed

since ablation was initiated, if not, the microprocessor waits for the impedance sampling interval Δt at 312 and continues to measure impedances and calculate values of dZ/dt according to the above described method until both a plateau is present and the defined time period "b" has elapsed at 319. After the required time period at "b" at 319 has elapsed, delivery of ablation energy to the associated electrode or electrode pair is terminated at 322 and the ablation process ceases at 324 as to that electrode pair.

In this embodiment, in the event that an impedance plateau fails to manifest itself, the microprocessor may nonetheless safely terminate provision of ablation energy to the electrode pair under consideration in response to a detected rapid rise in impedance, which normally follows the impedance plateau. In the event that a plateau is not detected at 318, the microprocessor checks the preceding stored values of dZ/dt_n to look for a rapid rise in impedance. For example, a rapid rise in impedance may be detected using the following rule: for n = 1 to 10, dZ/dt_n must be greater than or equal to 1.0 for all 10. If this rapid rise criteria is met at 320, the processor checks to see whether the required minimal time period has elapsed at 319, and if so, terminates ablation at 322 as discussed above. If the minimal time interval "b" has not elapsed, the microprocessor continues to acquire measurements of impedance and continues to calculate values of dZ/dt_n and $|dZ/dt|_n$ until either an impedance plateau is detected at 318 or a rapid rise in impedance is detected at 320 and the minimum time interval has expired at 319.

Figure 7 is a function flow chart illustrating the over-all operation of the device in conjunction with a multi electrode or multi electrode pair ablation apparatus. In the flow chart of Figure 7, all the electrodes are activated simultaneously and individual electrodes or electrode pairs are deactivated in response to impedance measurements associated with the electrode pair indicating that the lesion formed between that electrode pair is completely transmural. In this circumstance, the ablation system works as follows.

After initialization at 400, all electrodes 1-x are activated at 402, meaning that ablation energy is provided to all electrodes and electrode pairs. The microprocessor then checks the value of dZ/dt and/or |dZ/dt| at the first of the electrode pairs at 404, using any of the mechanisms discussed above in conjunction with Figures 5a, 5b and 6. At 408, the microprocessor checks using any of the mechanisms described above to determine whether an impedance plateau has been reached or, in the event that additional criteria for shut off of ablation energy are provided, to see whether any of these additional criteria are reached.

If so, the electrode being examined is deactivated at 410 by ceasing the delivery of ablation energy to the electrode or electrode pair. If not, the microprocessor checks the value of dZ/dt and/or |dZ/dt| for the next electrode at 406. This process continues until all electrodes are deactivated at 412, after which the procedure is deemed complete at 414 and the ablation process is terminated at 416.

Figure 8 illustrates a functional flow chart of overall operation of a device in which a multi-electrode or multi-electrode pair ablation apparatus is employed, as in Figure 7. In this embodiment, however, electrodes or electrode pairs are activated initially and sequentially. After initialization at 500, the microprocessor activates delivery of ablation energy to the first electrode at 502, checks dZ/dt and/or |dZ/dt| at 504 and, in the same manner as described for Figure 7 above, checks to determine whether the impedance plateau criteria and/or other criteria as described above have been met. If so, the electrode is deactivated at 510. If not, application of ablation energy continues until the plateau criterion or other criteria are met as described above. After deactivation of an electrode at 510, the microprocessor checks to determine whether all electrodes have been activated and deactivated at 512, if not, the microprocessor then activates the next electrode at 506 and initiates delivery of ablation energy to that electrode. This process continues until the last electrode has been deactivated at 512, following which the microprocessor determines that the ablation process is complete at 514 and the ablation process is stopped at 516.

The overall operational methodology of Figure 7 is believed to be desirable in that it allows for a more rapid completion of an ablation procedure. However, the overall operational method is described in Figure 8 has the advantage that it may allow the use of a somewhat simplified generator because that multiple, separate impedance measurement circuits, power control circuits, and the like need not be provided for each electrode or electrode pair. A simple switching mechanism may be used in conjunction with only a single RF generator and impedance measurement circuit to successively apply energy to each electrode and to monitor impedance according to the invention.

Figures 9-12 show yet another aspect of the invention in which RF power delivery can also be controlled in order to assist in the assessment of lesion transmurality. The ablation commences at a first power level 600 and is then increased to a second power level 602 as certain conditions are satisfied. The power level can also be increased from the second power level to a third power level 604 and in the same stepwise manner,

increasing the power level from an N power level to an n+1 power level until a set of conditions are met that indicates that transmurality has been achieved and/or that the power should be turned off. For example, an initial power level P_0 can be selected in the range of about 10 to 25 watts. The power level can then be rapidly increased to a second power level P_1 in an increment in the range of about 3 to 10 watts at a rate of at least about 0.5 watts/second. Subsequent power levels P_2, P_3, etc. can be similarly achieved. A maximum permitted power in the range of about 25-50 watts can also be selected to ensure that the power level is not raised beyond safe limits. Typical power levels could be an initial power level P_0 of about 25 watts and a second power level P_1 of about 30 watts. Power levels P2, P3, etc. could be increased in similar increments until a maximum power level of about 40 watts was achieved.

In each of the figures 9-12, an initial selected power level P_0 is either maintained or increased to a second power level in response to changes in the detected impedance occurring during the ablation. In each case, the initial detected impedance Z_0 drops initially as ablation proceeds. However, each of Figures 9-12 shows exemplary alternative responses of a system according to the invention as differing impedance conditions are detected. In Figure 9, the power level remains the same during the entire ablation procedure because a detected rapid rise in impedance dZ/dt_{rise} is detected without first detecting a plateau. One condition indicating that transmurality has been achieved is a rapid rise in impedance 70 such as that shown in Figure 9. Upon detecting a rapid rise in impedance 70, the power is turned off and the ablation for the lesion is completed. Conditions for an increase in power level can include one or more of: the detection of a plateau 68 in impedance or a slow rise in impedance or the achievement of a maximum permitted time for that power level. Conditions indicating that transmurality has been achieved can include one of: the lack of change in detected impedance in response to the change in power level or the detection of a rapid rise in impedance. Figure 10 shows the detection of a plateau 68 in the impedance curve at dZ/dt_1, which triggers a rapid increase in power level from P_0 to P_1. The increase in power level causes a drop in impedance and therefore the ablation is continued at the second power level P_1 until the detected impedance indicates a rapid rise dZ/dt_{rise}. Upon detection of the rapid impedance rise, the power is turned off and the ablation for the lesion is completed. In the event that neither a plateau 68 or a rapid rise 70 is detected, ablation at the power level P_0 may be continued

for a maximum pre-selected period of time followed by an increase in power level to power level P_1. For example, a time in the range of about 3 to 20 seconds, or more preferably about 8 seconds could be selected as the maximum duration for ablation at a particular power level. Figure 11 shows the detection of a plateau 68 in impedance at dZ/dt_1 which triggers an increase in power level from P_0 to P_1. Because the impedance drops in response to the increased power level, ablation continues at the second power level P_1 until a second plateau 68 in impedance is detected at dZ/dt_2. The detection of the second impedance plateau triggers a second increase in power level, from P_1 to P_2. Because the impedance drops in response to the increase in power level, ablation is continued at the third power level P_2 until a rapid rise in impedance is detected at dZ/dt_{rise}. Upon detection of the rapid impedance rise, the power is turned off and the ablation for the lesion is completed. Figure 12 shows the detection of a plateau in impedance at dZ/dt_1, which triggers an increase in power level from P_0 to P_1. Because the impedance drops in response to the increased power level, ablation continues at the second power level P_1 until a second plateau is detected at dZ/dt_2. The detection of the second plateau triggers a second increase in the power level from P_1 to P_2. Because the impedance does not drop in response to the increase in power level from P_1 to P_2, the continued plateau is verified by impedance measurement at dZ/dt_3 and the ablation is immediately terminated. Each of Figures 9-12 illustrates successful termination of ablation by detecting impedance that is characteristic of achievement of transmurality. If the detection of impedance does not indicate the achievement of transmurality, the ablation can still be terminated if the total time for the ablation exceeds a predetermined limit. For example, a total limit on ablation to form the lesion could take about 30 to 60 seconds, and preferably about 40 seconds. Alternatively, ablation could also be stopped upon reaching a maximum power level or after the completion of a predetermined number of power level increases.

Figure 13 shows yet another aspect of the invention in which complete or partial submersion of one or both of the jaws of the device in a fluid may be detected prior, during or following an ablation procedure. During the medical procedure, blood, cardiopulmonary bypass (CPB) fluids, such as cardioplegia fluids, and/or surgical field irrigation fluids can collect or pool in the atria and/or pericardial sac, for example. When the ablation device is positioned and/or clamped onto tissue, one or more electrodes of the device may become fully or partially submerged by one or more fluids. In addition, during the ablation

procedure, the state of fluid contact with the electrodes may change. These changes in fluid contact with the electrodes may be caused by fluid levels changing or repositioning the tissue to be ablated. For example, the surgeon may reposition the heart or the ablation device during the ablation procedure, thereby changing the degree of submersion in fluid. In vitro and in vivo experiments have shown that total submersion, oscillating submersion, or partial submersion of one or more electrodes can cause impedance changes and affect the ablation cycle and lesion quality. For example, a low impedance shunt may be established between submerged electrodes. Impedance changes can make the implementation and reliability of a transmurality algorithm very challenging.

As shown in Figure 13, submersion sensors 901, 902, 903, 904, 905, 906 may be incorporated into jaws 18 and 19 of ablation device 10, for example. Sensors 901, 902, 903, 904, 905, 906 can be used to determine if the electrodes are fully submerged, partially submerged, or are in a state of oscillation between submersion and non-submersion. Each sensor may be connected to an RF generator, for example to generator 799, by means of individually insulated conductors (not shown). The conductors can be routed through the ablation device similar to the RF conductors 21 and 22. Through quantitative testing the optimum number and position or location of submersion sensors can be determined for individual ablation devices. For example, different ablation device designs may require a different number of sensors located at different positions.

One embodiment of the present invention includes an ablation system comprising a RF generator, for example generator 799, having a sensor interrogation program and an ablation device, for example as shown in Figure 13, having submersion sensors. A signal can be sent from one sensor of a sensor pair and read at the other sensor of the sensor pair. For example, a signal may be sent from sensor 901 and the interrogation program determines if a signal is received at sensor 902. If a signal is received at sensor 902, sensors 901 and 902 would be determined to be submerged in fluid. The interrogation program then determines if a signal from sensor 901 is received at 903. If a signal is received at 903, then sensor 903 is also submerged in fluid. The interrogation program may continue to sample different sensor pairs to determine if the sensor pairs are submerged or not. Various signal vectors between the individual sensors may be randomly sampled throughout an ablation cycle. If no signal is detected between any sensor pair, the program would assume a non-submerged condition and the standard power and

transmurality algorithm would be employed. If a signal is detected between any sensor pair, the program would interrogate the sensors and determine if the device is fully submerged, partially submerged or in an oscillating condition. Different power and transmurality algorithms, as discussed above, could be applied for the various degrees of submersion.

The signal transmitted from the submersion sensors needs to be physiologically compatible. It has been demonstrated that human and animal cells are affected or stimulated by frequencies below 10,000Hz. For this reason, it is particularly important for cardiac ablation procedures on a beating heart to maintain frequencies above the 10,000Hz, for example RF frequencies of about 100KHz to about 100MHz may be deployed. Signals transmitted from submersion sensors need to be discernable and/or isolated from the RF ablation current. Using different frequencies, modulation methods, or vector analysis of the signals can allow for simultaneous ablation and sensor monitoring. For example, a first reading of the sensor circuit could be accomplished when the ablation cycle is initiated. A built in delay in RF generator operation could allow for sampling of the sensor circuit prior to delivery of RF power to the ablation electrodes. Alternatively, pulsed RF may be used to perform the ablation procedure. Pulsed RF has been thought to provide benefits in creating ablation lesions. One benefit appears to be the avoidance of over ablating the surfaces closest to the ablation electrode. Pulsed RF has a pulse train of RF energy, wherein the RF energy is oscillated between being off and being on. During the off periods the sensor circuit could be sampled.

During an ablation process, submersion sensors may be in contact with various fluids and tissues having various differences in conductance, impedance, and capacitance. The sensor interrogation program would take into account these various differences. The sensor interrogation program may analyze the various vectors and resulting phase angle between the sensors. For example, it is known that current leads voltage in a capacitive circuit and lags voltage in a reactive circuit; (P=E*I*CosQ; where P=power, E=voltage, I=amperage, and CosQ=phase angle).

In one embodiment, the submersion sensors may be thermocouples thereby allowing for simultaneous temperature and submersion monitoring. Thermocouples generally would require filtering of RF noise. Thermocouples may sense a temperature

gradient along the length of an ablation jaw. For example, a thermocouple in a fluid may be at a different temperature than a thermocouple in air or contacting tissue.

In one embodiment, the submersion sensors may be fiber optic sensors that would sample the light refraction between the various sensor locations. For example, air and water have different refraction indices, i.e., air=1.0003 vs. water=1.33. Depending on the light refraction each sensor senses or measures, it can be determined if the sensor is in air, fluid or placed against a tissue surface. Knowing the position of the sensors relative to the device determines what portion of the device is in air or a fluid, for example. A light refraction method has the advantage of being electrically isolated from the ablation current, thereby allowing simultaneous monitoring of submersion conditions while ablating tissue with RF energy. In one embodiment, the submersion sensors may employ ultrasound technology. As with the use of light refraction for monitoring changes in submersion, mechanical wave propagation in various materials could be monitored.

In one embodiment, segmented electrodes that are electrically isolated from each other may also serve as submersion sensors. For example, multiple electrodes of an ablation device, for example, as shown in Figure 2b, could be used as submersion sensors as well as ablation elements. For example, electrode 56 on jaw 18 could transmit a signal that would be sensed or measured at electrode 58 on jaw 19. The sensor interrogation program could continue to evaluate all of the possible electrode combinations. The program could then determine if the portion of the device having the submersion sensors is fully submerged, partially submerged or in an oscillating condition. Different power and transmurality algorithms, as discussed above, could then be applied for the various degrees of submersion. The submersion sensors could also be used to determine if the jaws are fully clamped onto tissue or if they are only partially clamped onto tissue, i.e. a partial bite of tissue.

It will be appreciated by those skilled in the art that while the invention has been described above in connection with particular embodiments and examples, the invention is not necessarily so limited, and that numerous other embodiments, examples, uses, modifications and departures from the embodiments, examples and uses are intended to be encompassed by the claims attached hereto. The entire disclosure of each patent and publication cited herein is incorporated by reference, as if each such patent or publication were individually incorporated by reference herein.

We Claim:

1. A method of ablating tissue, comprising:

applying ablation energy from an ablation device to a first tissue site;

monitoring submersion of at least a portion of the ablation device at the first tissue site; and

responsive to the degree of submersion of the ablation device at the first tissue site, changing the application of ablating energy to the first tissue site.

2. The method of claim 1 wherein the applying of ablation energy to the first tissue site comprises applying RF energy.

3. The method of claim 1 wherein the step of monitoring submersion of at least a portion of the ablation device at the first tissue site comprises monitoring submersion using one or more submersion sensors.

4. The method of claim 3 wherein the submersion sensors comprise an electrode.

5. The method of claim 3 wherein the submersion sensors comprise a fiber optic sensor.

6. The method of claim 3 wherein the submersion sensors comprise a thermocouple.

7. The method of claim 1 wherein the applying of ablation energy to the first tissue site comprises applying RF energy using an irrigated RF electrode.

8. The method of claim 1 wherein the application of ablating energy to the first tissue site is increased in response to the degree of submersion of the ablation device at the first tissue site.

9. The method of claim 1 wherein the application of ablating energy to the first tissue site is decreased in response to the degree of submersion of the ablation device at the first tissue site.

10. The method of claim 1, further comprising:

applying ablation energy from the ablation device to a second tissue site;

monitoring submersion of at least a portion of the ablation device at the second tissue site; and

responsive to the degree of submersion of the ablation device at the second tissue site, changing the application of ablating energy to the second tissue site.

11. The method of claim 10 wherein the applying of ablation energy to the second tissue site comprises applying RF energy.

12. The method of claim 10 wherein the step of monitoring submersion of at least a portion of the ablation device at the second tissue site comprises monitoring submersion using one or more submersion sensors.

13. The method of claim 12 wherein the submersion sensors comprise an electrode.

14. The method of claim 12 wherein the submersion sensors comprise a fiber optic sensor.

15. The method of claim 12 wherein the submersion sensors comprise a thermocouple.

16. The method of claim 10 wherein the applying of ablation energy to the second tissue site comprises applying RF energy using an irrigated RF electrode.

17. The method of claim 10 wherein the application of ablating energy to the second tissue site is increased in response to the degree of submersion of the ablation device at the second tissue site.

18. The method of claim 10 wherein the application of ablating energy to the second tissue site is decreased in response to the degree of submersion of the ablation device at the second tissue site.

19. A method of ablation, comprising:

applying ablation energy from an ablation device to a tissue site;

monitoring submersion of at least a portion of the ablation device; and

responsive to the amount of submersion of the ablation device, modifying the application of ablating energy to the tissue site.

20. The method of claim 19 wherein the applying of ablation energy to the tissue site comprises applying RF energy.

21. The method of claim 19 wherein the step of monitoring submersion of at least a portion of the ablation device at the tissue site comprises monitoring submersion using at least one submersion sensor.

22. The method of claim 21 wherein at least one submersion sensor comprises an electrode.

23. The method of claim 21 wherein at least one submersion sensor comprises a fiber optic sensor.

24. The method of claim 21 wherein at least one submersion sensor comprises a thermocouple.

25. The method of claim 19 wherein the applying of ablation energy to the tissue site comprises applying RF energy using an irrigated RF electrode.

26. The method of claim 19 wherein the application of ablating energy to the tissue site is increased in response to the amount of submersion of the ablation device at the tissue site.

27. The method of claim 19 wherein the application of ablating energy to the tissue site is decreased in response to the amount of submersion of the ablation device at the tissue site.

28. An ablation device comprising at least one submersion sensor for monitoring submersion of at least a portion of the ablation device in a fluid.

29. The device of claim 28 wherein at least one submersion sensor comprises an electrode.

30. The device of claim 28 wherein at least one submersion sensor comprises a fiber optic sensor.

31. The device of claim 28 wherein at least one submersion sensor comprises a thermocouple.

32. The device of claim 28 wherein the fluid is a biological fluid.

33. The device of claim 28 wherein the fluid is saline.

34. The device of claim 28 wherein the fluid is a CPB fluid.

35. The device of claim 28 wherein the fluid is blood.

36. The device of claim 28 wherein the fluid is a surgical field irrigation fluid.

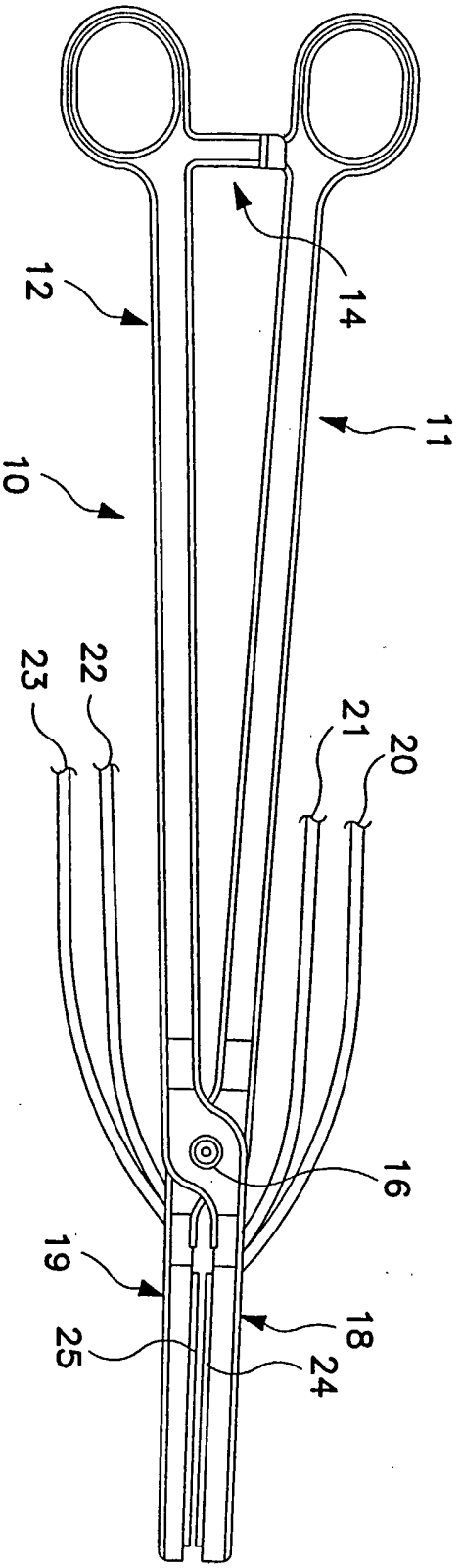


FIG. 1

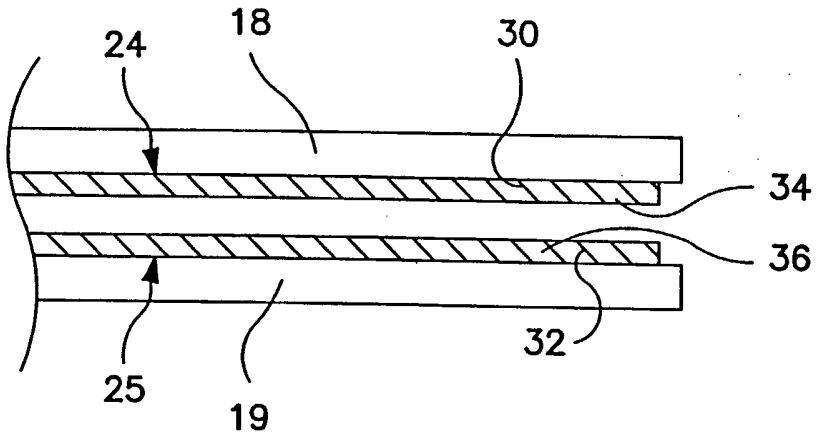


FIG. 2A

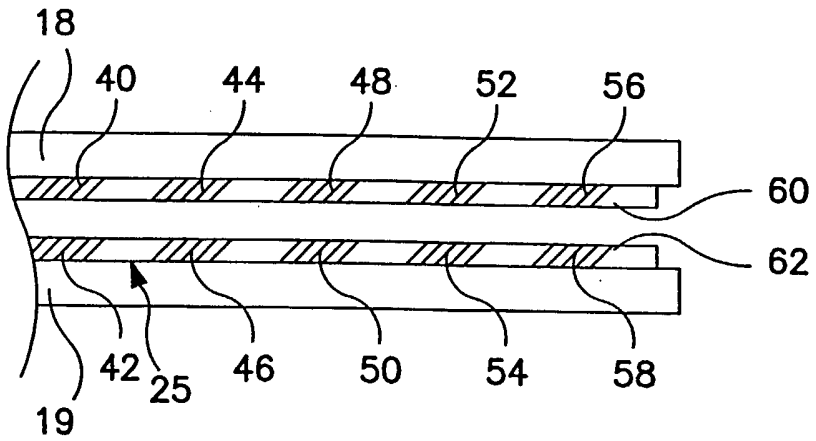


FIG. 2B

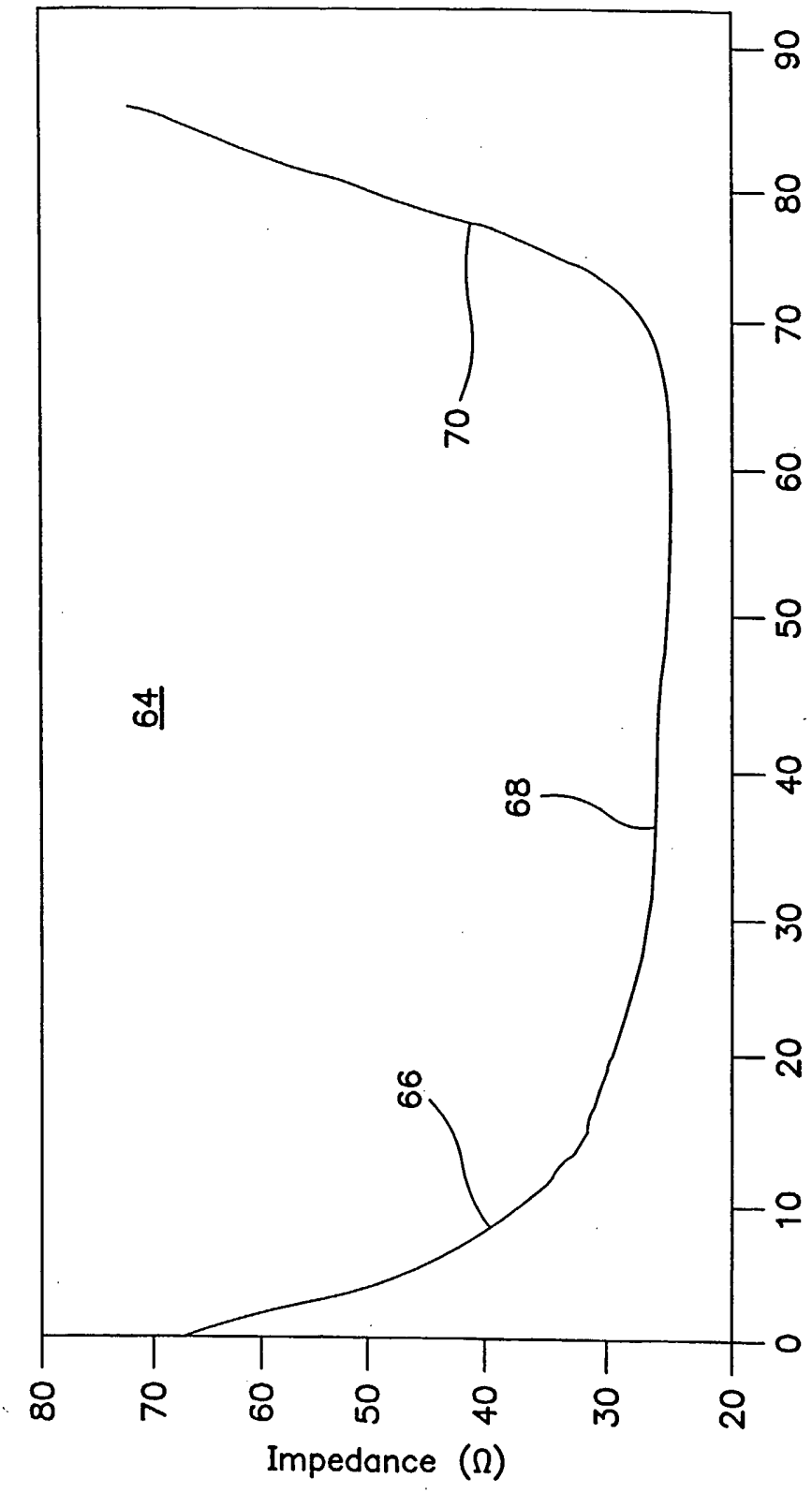
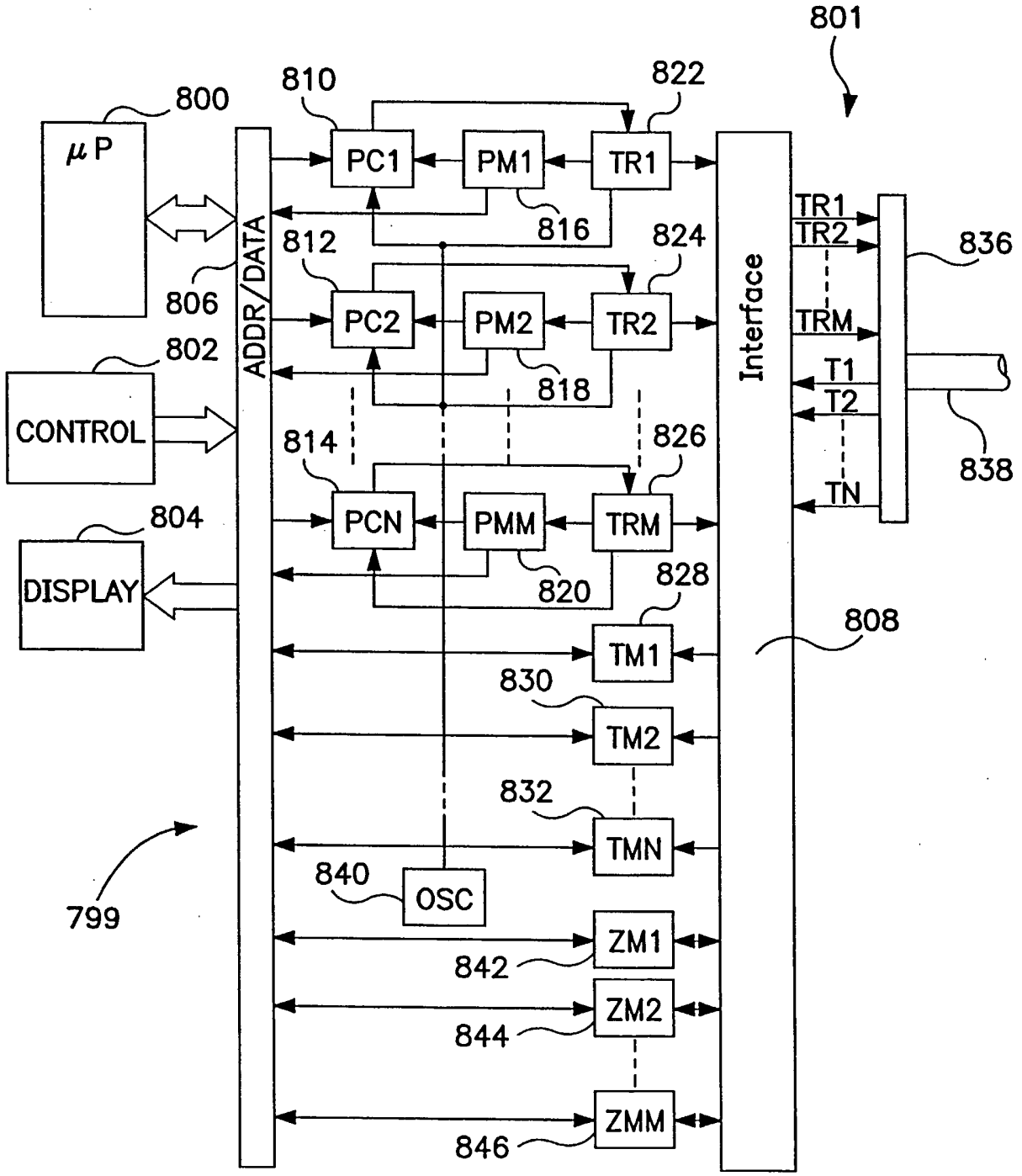

64
66
68
70
Impedance (Ω)
80
70
60
50
40
30
20
Time (S)
0
10
20
30
40
50
60
70
80
90

FIG. 3


801
800
μP
810
822
PC1
PM1
TR1
816
812
824
PC2
PM2
TR2
818
806
ADDR/DATA
802
CONTROL
814
826
PCN
PMM
TRM
820
804
DISPLAY
828
TM1
808
830
TM2
832
TMN
840
OSC
799
ZM1
842
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844
ZMM
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Interface
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TR2
TRM
T1
T2
TN
836
838

FIG. 4

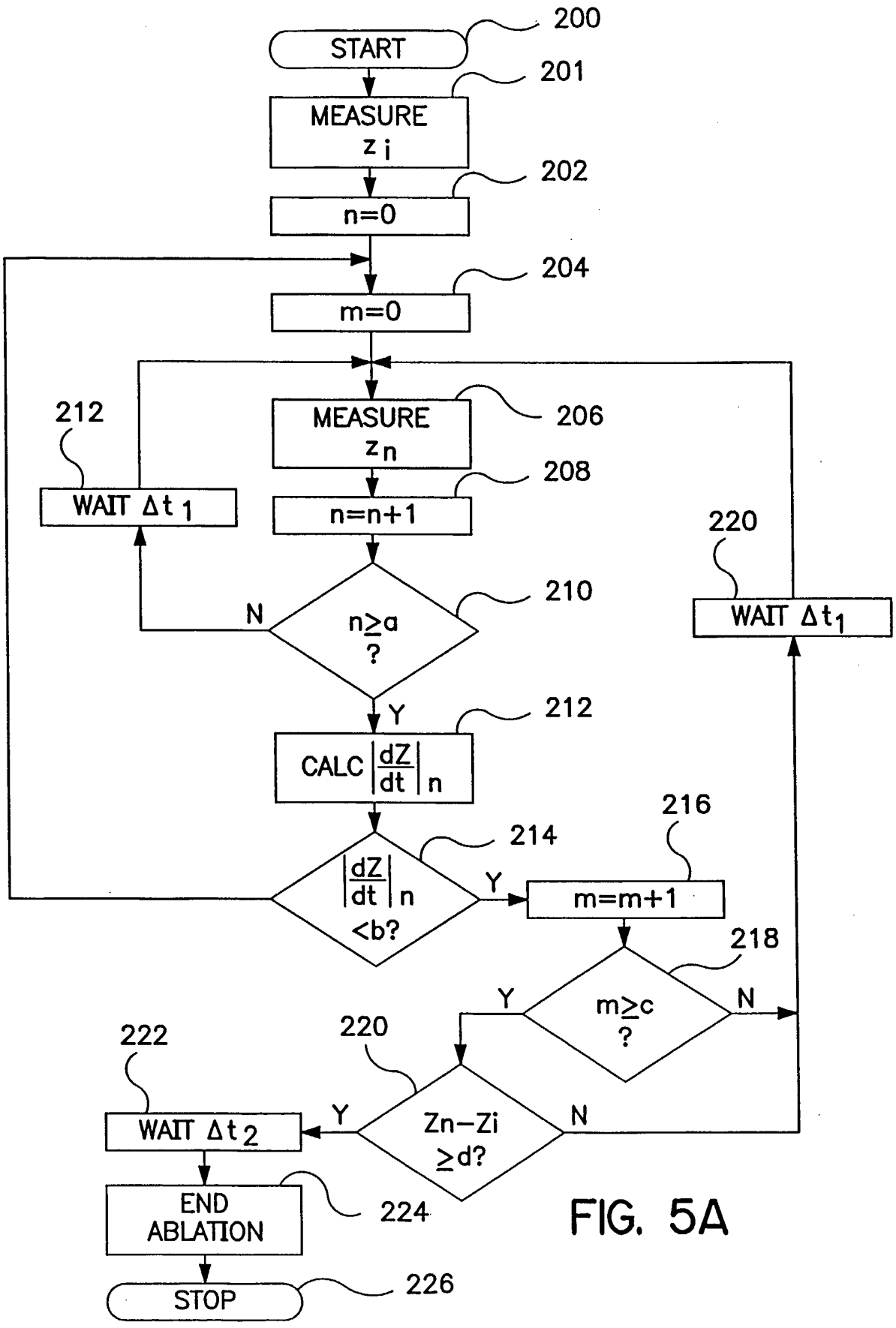
START
200
MEASURE z i
201
n=0
202
m=0
204
MEASURE z n
206
n=n+1
208
n≥a ?
210
N
Y
WAIT Δt 1
212
CALC |dZ/dt| n
212
|dZ/dt| n <b?
214
Y
m=m+1
216
m≥c ?
218
Y
N
Zn−Zi ≥d?
220
Y
N
WAIT Δt 2
222
END ABLATION
224
STOP
226
WAIT Δt1
220

FIG. 5A

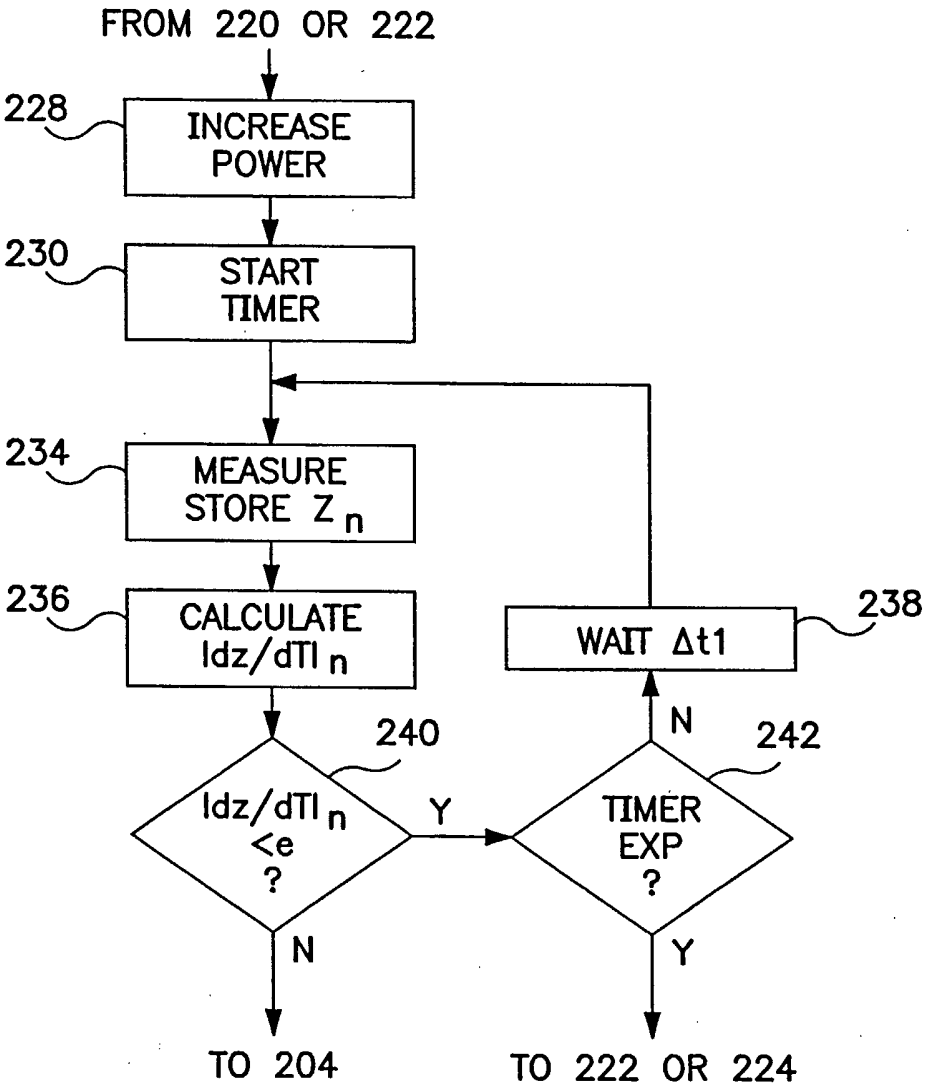
FROM 220 OR 222
228
INCREASE POWER
230
START TIMER
234
MEASURE STORE Z n
236
CALCULATE Idz/dTI n
240
Idz/dTI n <e ?
Y
N
TO 204
238
WAIT Δt1
N
242
TIMER EXP ?
Y
TO 222 OR 224

FIG. 5B

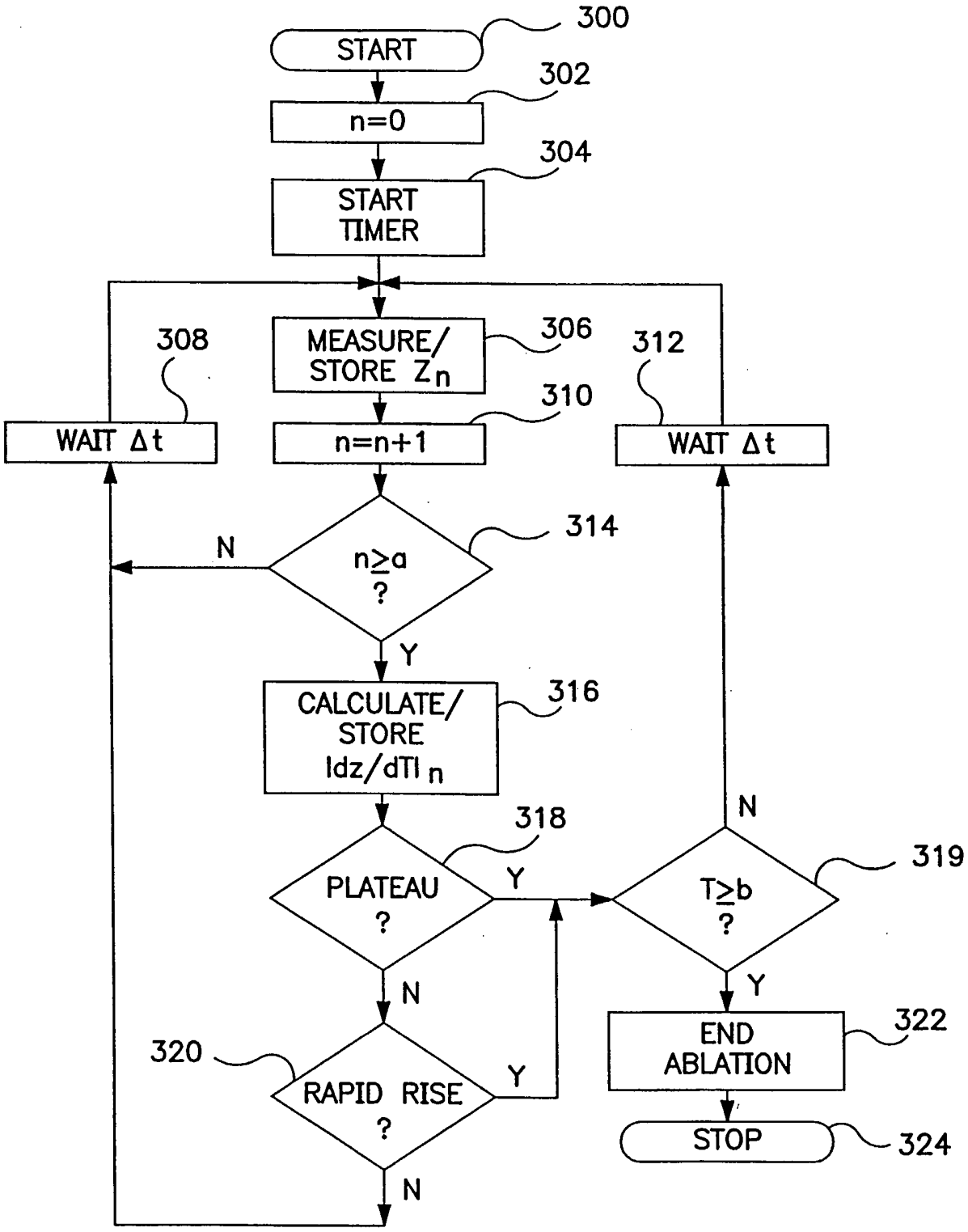
300
START
302
n=0
304
START TIMER
306
MEASURE/ STORE Z_n
308
WAIT Δt
310
n=n+1
312
WAIT Δt
314
n≥a ?
N
Y
316
CALCULATE/ STORE $|dz/dTI|_n$
318
PLATEAU ?
Y
N
319
T≥b ?
N
Y
320
RAPID RISE ?
Y
N
322
END ABLATION
324
STOP

FIG. 6

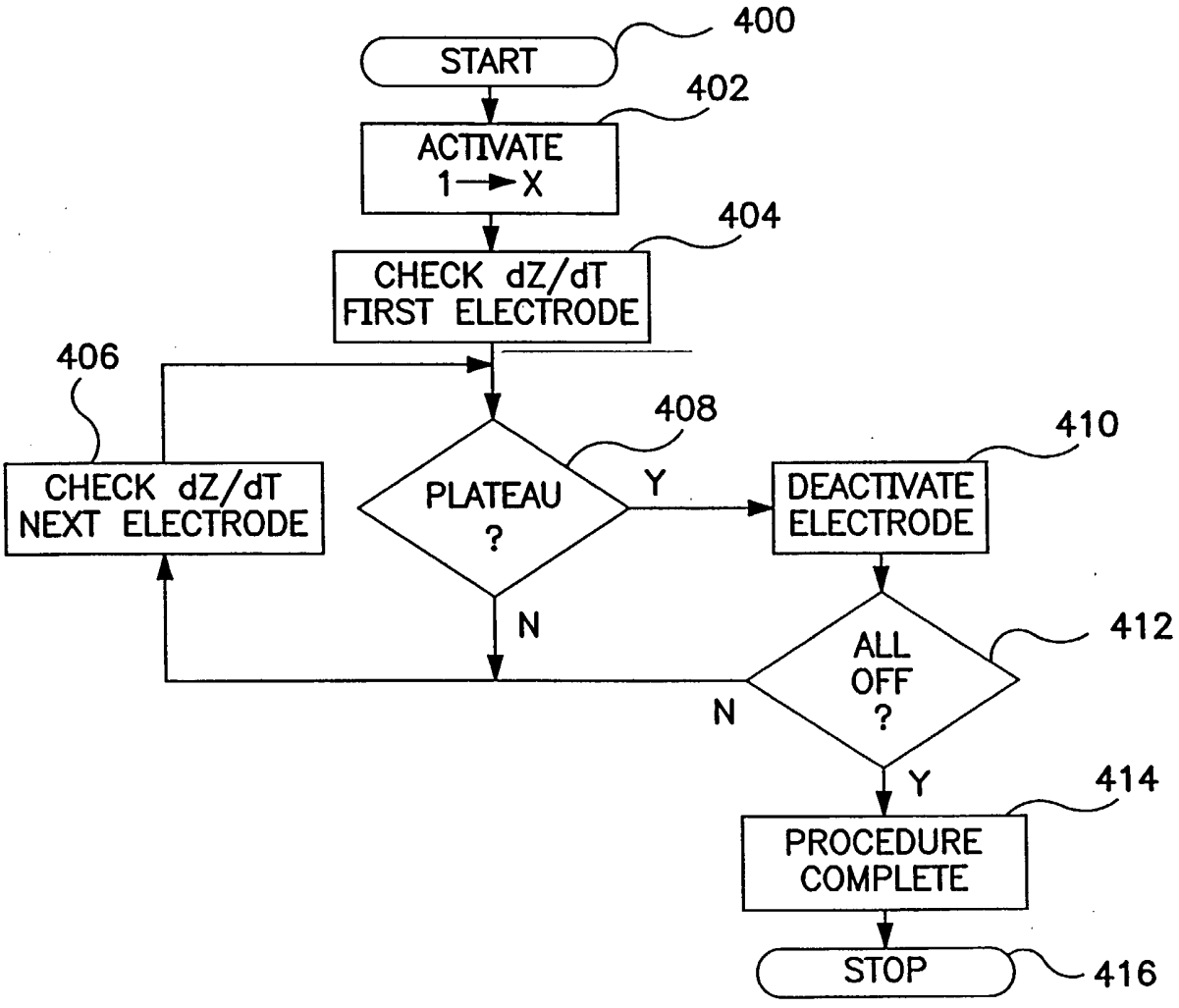
400
START
402
ACTIVATE
1→X
404
CHECK dZ/dT
FIRST ELECTRODE
406
CHECK dZ/dT
NEXT ELECTRODE
408
PLATEAU
?
Y
N
410
DEACTIVATE
ELECTRODE
412
ALL
OFF
?
N
Y
414
PROCEDURE
COMPLETE
STOP
416

FIG. 7

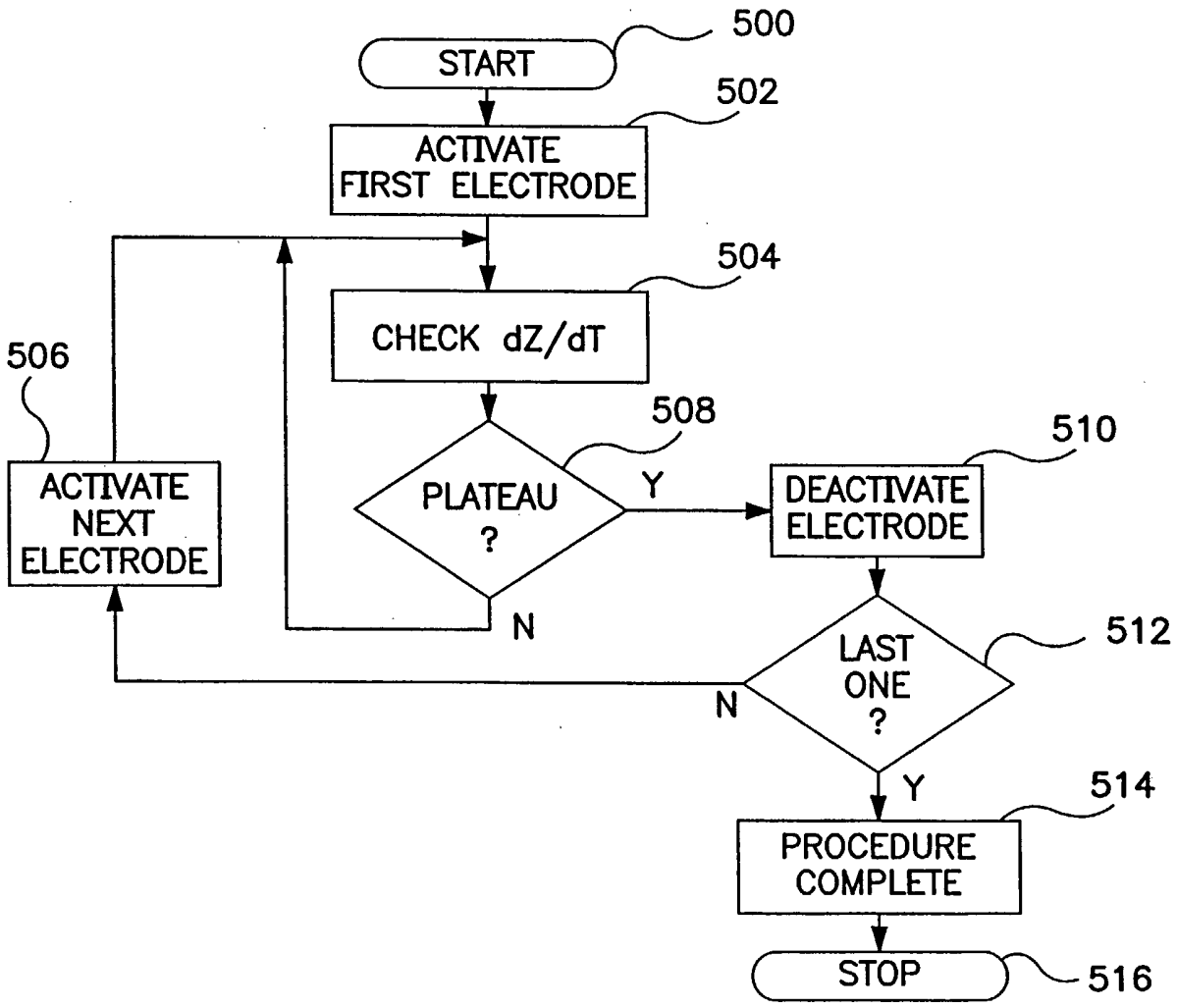
500
START
502
ACTIVATE FIRST ELECTRODE
504
CHECK dZ/dT
506
ACTIVATE NEXT ELECTRODE
508
PLATEAU ?
Y
N
510
DEACTIVATE ELECTRODE
512
LAST ONE ?
N
Y
514
PROCEDURE COMPLETE
STOP
516

FIG. 8

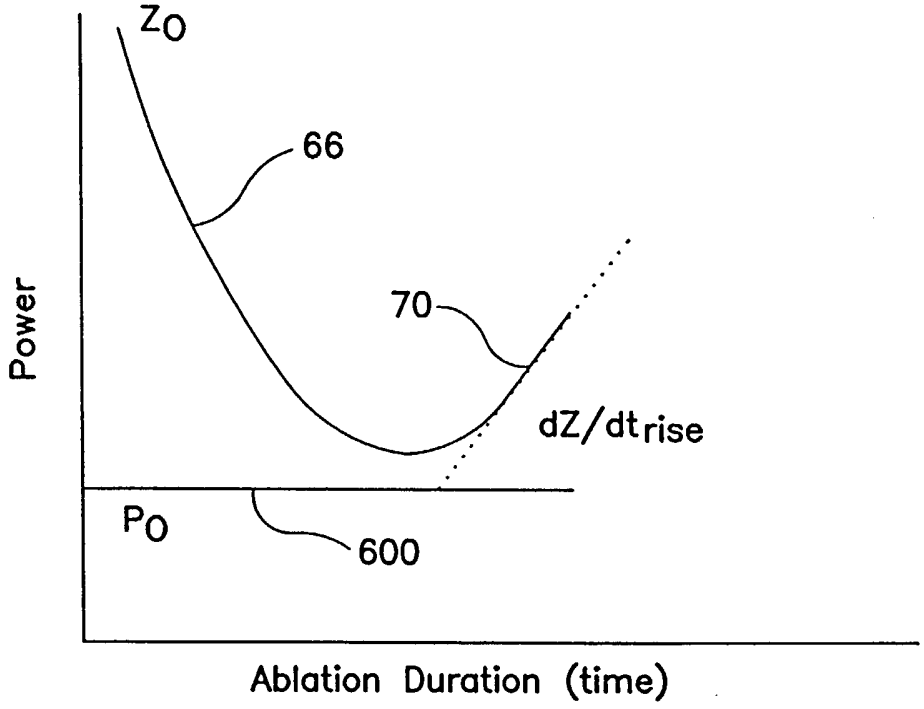
Z0
66
70
dZ/dtrise
Power
P0
600
Ablation Duration (time)

FIG. 9

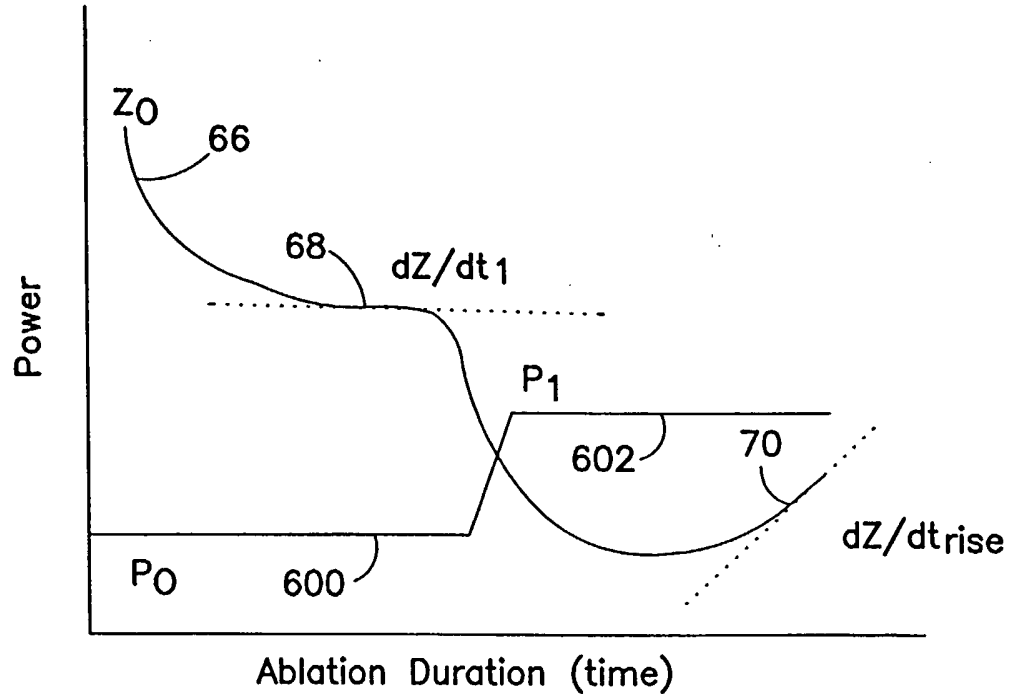
Z0
66
68
dZ/dt1
P1
602
70
dZ/dtrise
Power
P0
600
Ablation Duration (time)

FIG. 10

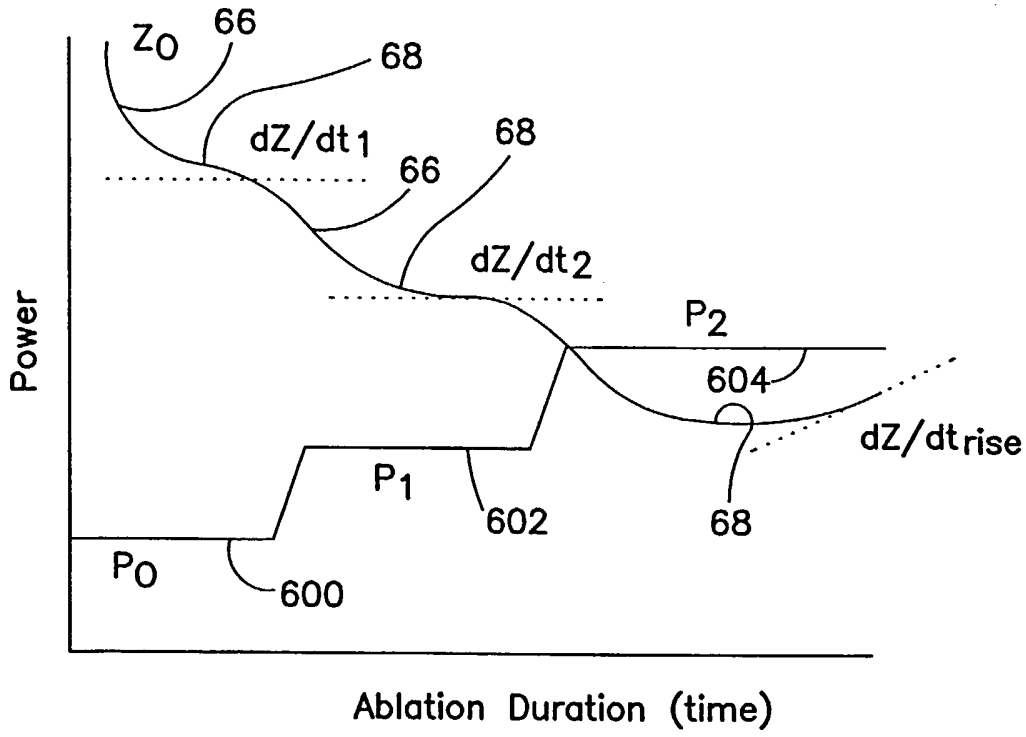
Z0
66
68
dZ/dt1
66
68
dZ/dt2
P2
604
dZ/dtrise
P1
602
68
P0
600
Power
Ablation Duration (time)

FIG. 11

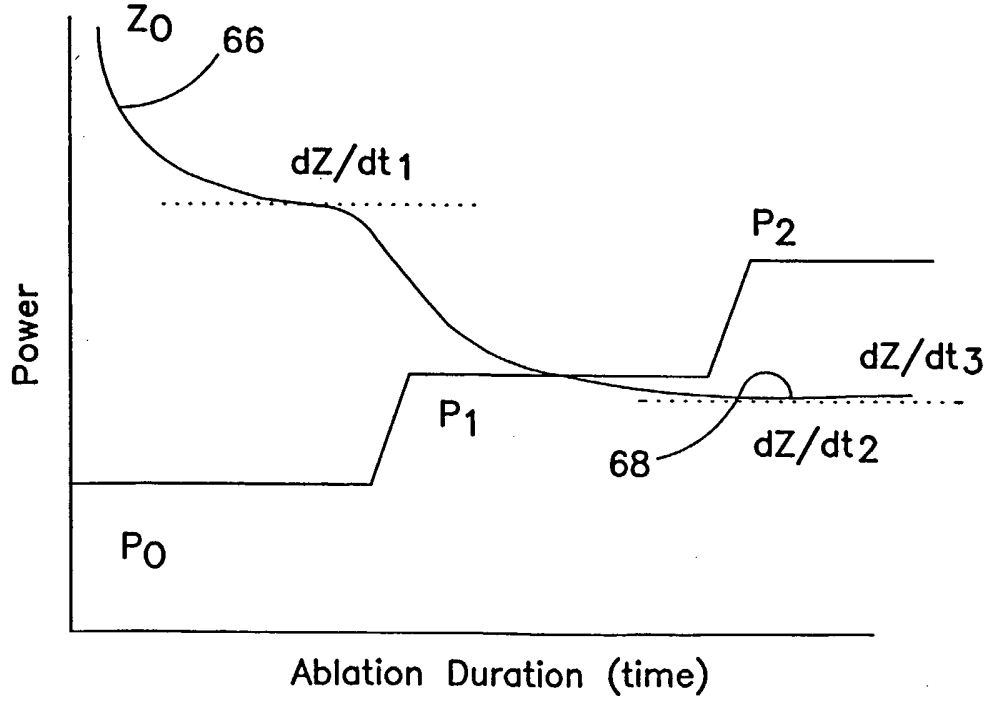
Z0
66
dZ/dt1
P2
dZ/dt3
P1
68
dZ/dt2
P0
Power
Ablation Duration (time)

FIG. 12

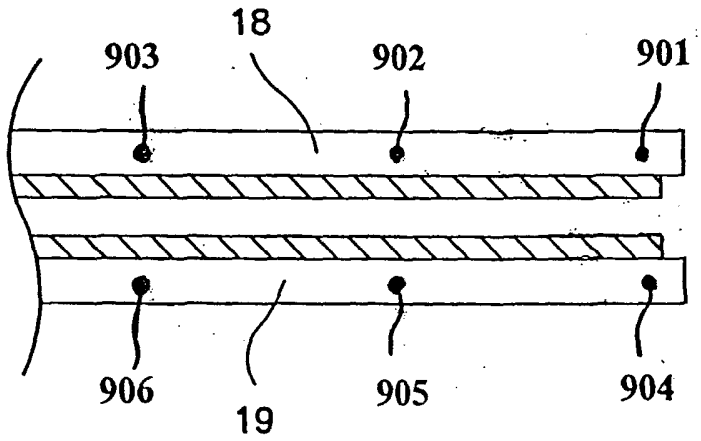

FIG. 13

INTERNATIONAL SEARCH REPORT

Inte onal Application No
PCT/US2005/027422

A. CLASSIFICATION OF SUBJECT MATTER
A61B18/14 A61B17/00

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)
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)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2003/208193 A1 (VAN WYK ROBERT A) 6 November 2003 (2003-11-06) paragraphs '0016! - '0018!, '0029! - '0031!, '0039!, '0040!; figures 1,10	28,31-36
X	US 2001/039419 A1 (FRANCISCHELLI DAVID E ET AL) 8 November 2001 (2001-11-08) paragraphs '0081! - '0090!	28-36
A	US 2003/014047 A1 (WOLOSZKO JEAN ET AL) 16 January 2003 (2003-01-16) paragraph '0122!	32-36
A	US 6 648 883 B2 (FRANCISCHELLI ET AL) 18 November 2003 (2003-11-18) abstract; figures 1,2,4 column 6, lines 14-31	28

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

☒ 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
24 November 2005	05/12/2005

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	Jonsson, P.O.

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Form PCT/ISA/210 (second sheet) (January 2004)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2005/027422

Box II Observations where certain claims were found unsearchable (Continuation of item 2 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.: 1-27
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 surgeryRule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

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 III Observations where unity of invention is lacking (Continuation of item 3 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

International Application No
PCT/US2005/027422

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2003208193 A1	06-11-2003	NONE	
US 2001039419 A1	08-11-2001	AU 5365401 A	12-11-2001
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		DE 60111517 D1	21-07-2005
		EP 1278471 A1	29-01-2003
		WO 0182812 A1	08-11-2001
		WO 0180757 A2	01-11-2001
US 2003014047 A1	16-01-2003	NONE	
US 6648883 B2	18-11-2003	US 2003004507 A1	02-01-2003
		US 2003171745 A1	11-09-2003
		US 2004049179 A1	11-03-2004