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(54) Title: ELECTROCAUTERY METHOD AND APPARATUS

(57) Abstract: An electrode structure and a mechanism for automated or user-selected operation or compensation of the electrodes, for example to determine tissue coverage and / or prevent arcing between bottom electrodes during electrocautery is disclosed.



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ELECTROCAUTERY METHOD AND APPARATUS

BACKGROUND OF THE INVENTION

1. Field of the Invention

The invention relates to tissue cauterization. More particularly, the invention concerns an electrocautery system with various electrodes and a mechanism for automated or user-selected operation or compensation of the electrodes.

2. Description of the Related Art

Various physiological conditions call for tissue and organ removal. A major concern in all tissue removal procedures is hemostasis, that is, cessation of bleeding. All blood vessels supplying an organ or a tissue segment to be removed have to be sealed, either by suturing or cauterization, to inhibit bleeding when the tissue is removed. For example, when the uterus is removed in a hysterectomy, bleeding must be inhibited in the cervical neck, which must be resected along the certain vessels that supply blood to the uterus. Similarly, blood vessels within the liver must be individually sealed when a portion of the liver is resected in connection with removal of a tumor or for other purposes. Achieving hemostasis is necessary in open surgical procedures as well as minimally invasive surgical procedures. In minimally invasive surgical procedures, sealing of blood vessels can be especially time consuming and problematic because there is limited access via a cannula and other small passages.

Achieving hemostasis is particularly important in limited access procedures, where the organ or other tissue must be morcellated prior to removal. Most organs are too large to be removed intact through a cannula or other limited access passage, thus

requiring that the tissue be morcellated, e.g. cut, ground, or otherwise broken into smaller pieces, prior to removal.

In addition to the foregoing examples, there exist a variety of other electrosurgical instruments to seal and divide living tissue sheets, such as arteries, veins, lymphatics, nerves, adipose, ligaments, and other soft tissue structures. A number of known systems apply radio frequency (RF) energy to necrose bodily tissue. Indeed, some of these provide significant advances and enjoy widespread use today. Nevertheless, the inventors have sought to identify and correct shortcomings of previous approaches, and to research possible improvements, even when the known approaches are adequate.

In this respect, one problem recognized by the inventors concerns the small size of today's electrode structures. In particular, many electrosurgical instrument manufacturers limit the total length and surface area of electrodes to improve the likelihood of completely covering the electrodes with tissue. This small electrodes strategy results in the surgeon having to seal and divide multiple times to seal and divide long tissue sheets adequately. Such time consuming processes are also detrimental to patients, increasing anesthetic time and potentially increasing the risk of injury to surrounding structures, as the delivery of energy and division of tissue is repeated again and again.

The consequences of partial electrode coverage can be significant. This condition can cause electrical arcing, tissue charring, and inadequate tissue sealing. Mechanical, e.g. blade, or electrosurgical division of tissue is performed immediately following tissue sealing, and the division of inadequately sealed tissue can pose a risk to the patient because unsealed vessels may hemorrhage. Arcing presents its own set of problems. If electrocautery electrodes generate an arc between them, instead of passing RF energy through targeted tissue, the tissue fails to undergo the intended electrocautery. Furthermore, depending upon the path of the arc, this might damage non-targeted tissue. Another problem is that adjacent electrodes in a

multiple electrode system may generate electrical cross-talk or generate excessive thermal effect in the transition zone between two adjacent electrodes that fire sequentially. Previous designs prevented this by imposing a mechanical standoff for the jaws that the electrodes were fastened onto. However, this standoff prevented very thin tissue from making contact with the opposing electrodes, preventing an optimal electrical seal in these regions. These standoffs, if too shallow, can also result in arcing between electrodes.

At typical radiofrequency energy (RF) frequencies in the 300kHz to 10MHz range, tissue impedance is largely resistive. Prior to tissue desiccation, initial impedances can vary greatly depending on the tissue type and location, vascularity, etc. Thus, to ascertain the adequacy of tissue electrode coverage based solely on local impedance is imprecise and impractical. A feasible and dependable methodology for determining electrode coverage by tissue would allow for the development of electrodes of greater length and surface area for use in the safe and rapid sealing and division of tissue sheets during surgical procedures. It would therefore be advantageous to provide a methodology for determining the area of tissue coverage of one or more electrodes.

SUMMARY

An electrode structure and a mechanism for automated or user-selected operation or compensation of the electrodes, for example to determine tissue coverage and / or prevent arcing between bottom electrodes during electrocautery is disclosed.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a block diagram of the components and interconnections of an electrocautery system according to the invention;

FIGURE 2 is a combination block and schematic diagram illustrating an electrocautery device with a first embodiment of compensating circuitry according to the invention;

FIGURE 3 is a combination block and schematic diagram illustrating an electrocautery device with a second embodiment of compensating circuitry according to this invention;

FIGURE 4 is a combination block and schematic diagram illustrating an electrocautery device with a third embodiment of compensating circuitry according to the invention;

FIGURE 5 is a combination block and schematic diagram illustrating an electrocautery device with circuitry for selectively firing electrodes according to the invention; and

FIGURE 6 is a block diagram showing an electrode having a dielectric coating according to the invention.

DETAILED DESCRIPTION

In view of the problems of conventional technology that the inventors have recognized (as discussed above), the inventors have sought to improve the ability of a user to control electrocautery electrodes after said electrode have been inserted into the body. Further areas of their focus include improving the efficiency of transferring power to electrode structures, and improving the accuracy of measurements taken from the electrode structure *in situ*. One benefit of implementing these improvements is the ability to use larger electrode surfaces, with the advantageous consequences discussed above.

FIGURE 1 illustrates one embodiment of electrocautery system 100. The system 100 includes an electrode structure 102 that is electrically driven by a power, electrode selector, and compensator module 108. The module 108 is operated in accordance with user input conveyed via one or more user interfaces 110.

As explained below in greater detail, certain components of the system 100 may be implemented with digital data processing features. These may be implemented in various forms.

Some examples include a general purpose processor, digital signal processor (DSP), application specific integrated circuit (ASIC), field programmable gate array (FPGA) or other programmable logic device, discrete gate or transistor logic, discrete hardware components, or any combination thereof designed to perform the functions described herein. A general purpose processor may be a microprocessor, but in the alternative, the processor may be any conventional processor, controller, microcontroller, or state machine. A processor may also be implemented as a combination of computing devices, e.g. a combination of a DSP and a microprocessor, a plurality of microprocessors, one or more microprocessors in conjunction with a DSP core, or any other such configuration.

As a more specific example, a digital data processing includes a processor, such as a microprocessor, personal computer, workstation, controller, microcontroller, state machine, or other processing machine, coupled to digital data storage. In the present example, the storage includes a fast-access storage, as well as nonvolatile storage. The fast-access storage may be used, for example, to store the programming instructions executed by the processor. Storage may be implemented by various devices. Many alternatives are possible. For instance, one of the components may be eliminated. Furthermore, the storage may be provided on-board the processor, or even provided externally to the apparatus.

The apparatus also includes an input/output, such as a connector, line, bus, cable, buffer, electromagnetic link, antenna, IR port, transducer, network, modem, or other means for the processor to exchange data with other hardware external to the apparatus.

As mentioned above, various instances of digital data storage may be used, for example, to provide storage used by the system 100 (FIGURE 1), to embody the storage, etc. Depending upon its application, this digital data storage may be used for various functions, such as storing data, or to store machine-readable instructions. These instructions may themselves aid in carrying out various processing functions, or they may serve to install a software program upon a computer, where such software program is then executable to perform other functions related to this disclosure.

An exemplary storage medium is coupled to a processor so the processor can read information from, and write information to, the storage medium. In the alternative, the storage medium may be integral to the processor. In another example, the processor and the storage medium may reside in an ASIC or other integrated circuit.

In contrast to storage media that contain machine-executable instructions (as described above), a different embodiment uses logic circuitry to implement processing data processing features of the system.

Depending upon the particular requirements of the application in the areas of speed, expense, tooling costs, and the like, this logic may be implemented by constructing an application-specific integrated circuit (ASIC) having thousands of tiny integrated transistors. Such an ASIC may be implemented with CMOS, TTL, VLSI, or another suitable construction. Other alternatives include a digital signal processing chip (DSP), discrete circuitry (such as resistors, capacitors, diodes, inductors, and transistors), field programmable gate array (FPGA), programmable logic array (PLA), programmable logic device (PLD), and the like.

Electrode Structure 102

Referring to FIGURE 1, the electrode structure 102 includes first and second electrode surfaces 103-104. The electrode surface 104 is formed by a group of electrodes, such as individual electrodes 104a, 104b, etc. In one instance, the electrodes may be substantially contiguous. The electrode surface 103, in one instance, includes a single electrode, as illustrated. In another instance, the surface 103 includes multiple electrodes, of the same or different number than the electrodes 104.

In one embodiment the electrode surfaces 103-104 are arranged to provide electrical power to a targeted tissue area using opposed, bipolar electrodes. The use of opposed, bipolar electrodes is advantageous because it concentrates energy flux between the electrodes and limits the effect on adjacent tissue that is not confined within the opposed electrodes.

In one case, the electrode structures 103-104 may have generally similar geometries to contact tissue in a symmetric fashion. Alternatively, the electrode structures 103-104 may have dissimilar geometries. For example, one electrode structure may comprise a probe for insertion into a natural body orifice with the other electrode structure being structured to engage an exterior tissue surface apart from the body orifice. In some instances, more than two electrode structures may be employed, but at least two electrode structures, or separate regions of a single structure, are energized with opposite polarity to apply RF energy to the targeted tissue. In some instances, the electrode structures may be different regions formed as part of a single support structure, *e.g.* a single elastic tube or shell which may be placed over an organ or other tissue mass and which has two or more electrode surfaces formed thereon.

The different electrode surfaces are isolated from each other when high frequency energy of the same or opposite polarity is applied to them. In still other instances, a single electrode structure may have a plurality of electrically conductive or active regions, where the electrically conductive regions may be energized with the same or an opposite polarity.

In some instances, it may be desirable to provide additional structure or components on the electrode structures to enhance or increase the effective electrical contact area between the electrode structure and the tissue. In particular, the electrode structures may include tissue-penetrating elements to enhance electrical contact *i.e.* reduce electrical impedance between the electrode and the tissue and increase the total surface contact area between the electrode and the tissue. Exemplary tissue-penetrating elements include needles, pins, protrusions, channels, or the like. A particular example includes pins having sharpened distal tips so that they can penetrate through the tissue surface and into the underlying tissue mass. The pins may have depths in the range from 1 mm to 5 cm, or from 3 mm to 1 cm. The diameters of the pins range from 0.1 mm to 5 mm, or from 0.5 mm to 3 mm. In one instance, the pins are evenly distributed over the tissue-contact area of an electrode structure, with a pin density in the range from 0.1 pin/cm² to 10 pin/cm², or from 0.5 pin/cm² to 5 pin/cm². When tissue-penetrating elements are used, they may be dispersed in a general uniform matter over the electrically active area of the electrode structure. The pins or other tissue-penetrating elements may be provided in addition to an electrically conductive conformable or rigid electrode surface, but in some instances the pins may provide the total electrically conductive or active area of an electrode structure.

In one example, the electrodes comprise a plurality of different electrically conductive regions, where the regions may be electrically isolated from each other or may be electrically coupled to each other. Single electrode structures may include three, four, five, and as many as ten or more discrete electrically conductive

regions thereon. Such electrically conductive regions may be defined by electrically insulating regions or structure between them.

One example of a multiple-electrode surface 104 is a plurality of electrically conductive strips that are separated by a gap which may be an air gap, a plastic member or other insulator. The gap is preferably less than 0.5mm. In addition, multiple tissue-penetrating pins may be disposed along the length of each electrically conductive strips. The electrically conductive strips may be energized in an alternating polarity configuration. Most simply, opposing strips are connected to opposite polls on a single power supply. Electrical connections may be rearranged, however, to power the strips in virtually any pattern. Moreover, it is also possible to isolate different regions of each strip electrically to permit powering those regions at different polarities; or to set the electrodes to the same polarity but with various sequences of firing pattern that can include firing every electrode, firing specific electrode, or firing multiple electrodes simultaneously.

Although shown as flat plates, the electrode structure 102 may be implemented in a variety of different shapes without departing from the scope of the invention. For instance, the electrode structures 103-104 may be generally curved to facilitate placement over a tubular body structure or tissue mass. In one case, electrode configurations are specifically configured to have a geometry intended to engage a particular organ or tissue geometry. In other cases, the electrode configurations are conformable so that they can be engaged against and conform to widely differing tissue surfaces. In this regard, electrode strips may be constructed from such material as, for example, conformable meshes, permitting the electrode structures to be flattened out or to assume a wide variety of other configurations. Additionally, the insulating structures may also be formed from a flexible or conformable material, permitting further reconfiguration of the electrode structures. The structure 102 may be implemented according in any one, or a combination, of known shapes configurations, which are familiar to the ordinarily skilled artisan. Some exemplary

shapes include opposing jaws, cylinder, probe, flat pads, etc. In this regard, the electrodes may be configured in any manner suitable for engaging a tissue surface.

Thus, the electrodes can be rigid, flexible, elastic, inelastic (non-distensible), planar, non-planar, or the like, and may optionally employ tissue-penetrating elements to enhance electrical contact between the electrode structure and the tissue, as well as to increase the electrode area. Electrode configurations may be conformable so that they can be engaged against and conform to widely differing tissue surfaces, or they are specifically configured to have a geometry intended to engage a particular organ or tissue geometry. In both instances, the electrode structures may further be provided with tissue-penetrating elements.

Optionally, electrode structures may include both a conductive surface and a non-conductive surface. In some embodiments this is accomplished by leaving one surface as an exposed metallic face, while the other surface of the electrode is covered or insulated with, for example, a dielectric material. In the case of rigid electrodes, the insulation can be laminated, coated, or otherwise applied directly to the opposed surface. In the case of flexible and elastic electrodes, the insulating layer is flexible so that it can be expanded and contracted together with the electrode without loss or removal. In some cases, a separate, expandable sheet of material covers the face for which insulation is desired. In some embodiments, all electrode surfaces may be coated with a dielectric material.

In one embodiment, the electrically active regions of the electrode structures have an area ranging from one to fifty cm² or larger. Further details and examples of electrode structures are explained in the U.S. patent applications as identified incorporated herein by reference above.

Power Supply 106

The power supply 106 includes one or multiple power supplies. Basically, the power supply 106 generates high frequency, such as RF, power for application to targeted tissue through one or more electrically active regions of the electrode structure 102. As described below, the duration and magnitude of power cauterizes or necroses tissue between the electrode surfaces 103-104.

Exemplary frequency bands include 100 kHz to 10 MHz or 200 kHz to 750 kHz. Power levels depend on the surface area and volume of tissue being treated, with some examples including a range from 10 W to 500 W, or 25 W to 250 W, or 50 W to 200 W. Power may be applied at a level of from 1 W/cm² to 500 W/cm², or 10 W/cm² to 100 W/cm², for example.

The power supply 106 may be implemented using various conventional general purpose electrosurgical power supplies. The power supply 106 may employ sinusoidal or non-sinusoidal wave forms and may operate with fixed or controlled power levels. Suitable power supplies are available from commercial suppliers.

In one embodiment, the power supply provides a constant output power, with variable voltage and current, where power output varies based upon load. Thus, if the system sees a very high impedance load, the voltage is maintained at a reasonable level to avoid arcing. With tissue electrocautery, impedance ranges from two ohms to 1000 ohms, for example. By applying constant power, the power supply 106 can provide significant current at low impedance to achieve initial desiccation when the tissue is first being cauterized and, as cauterization proceeds, to apply higher voltage to complete the tissue sealing process. Thus, the power supply 106 can provide larger current and smaller voltage at the beginning of the cauterization process and a higher voltage and lower current at the sealing phase of the process. Control of such power generator is based, at least in part, on the system 100 monitoring power.

In one embodiment, the power supply 106 includes a mechanism for setting the desired power. This setting may occur by real-time control, pre-set selection by a user, default settings, selection of predetermined profile, etc. In one embodiment, pulse width modulation is used in connection with a flyback transformer. The system charges a primary of the flyback transformer and produces a regulated output. The secondary may be regulated, for example, to 15 volts at a desired number of amperes to produce the desired power output. Based upon the period, as determined by the width of the pulse which charges the primary, the power curve is determined. Thus, the invention establishes a certain level of power in the primary of the flyback transformer and the same level of power is provided by the secondary without regard to impedance of the load, *i.e.* the tissue.

The power supply 106 may include digital data processing equipment, such as mentioned above. This optional equipment, if implemented, is used to establish and control features and operation of the power supply 106.

As illustrated, the power supply 106 is a source of power for multiple electrodes of the structure 102. Accordingly, the power supply 106, or the module 108, provides multiple output channels, each of which is independently adjustable. In this embodiment, the system 100 includes a conductive supply path of multiple conductors 108c to provide power to the electrodes, and a return path 108b for providing a ground path and/or feedback to the power supply or *vice versa*, depending on the direction of current flow.

In a more particular embodiment, the module 108 has multiple outputs 108c routed to the individual electrodes by a digital data processor of the module 108. These multiple outputs are independently operated by the processor and readily modulated and assignable. Thus, the processor may assign an output to any one or more of the electrode elements at a certain point in operation of a cauterization cycle, and dynamically reassign them other points of time. For example, if the power source were a four channel power source and the electro-surgical device had sixteen

electrodes, then each channel may support four electrodes in electro-surgical device. However, this arrangement may be varied so that some channels support more electrodes than others.

User Interface 110

The user interface 110 comprises one or more devices for a human to exchange information with the module 108, including the power supply 106. There may be a common user interface, or separate user interfaces for each component 106, 108. The user interface may be implemented in various ways, with the following serving as some examples. As for human-to-machine flow, some examples of the interface 110 include buttons, dials, switches, keyboards, remote control console, or other mechanical devices. Other examples include pointing devices such as a mouse, trackball, etc. Still other examples include digitizing pads, touch screens, voice input, or any other example suitable for the purposes described herein. As for the machine-to-human exchange, the interface 110 may employ a video monitor, display screen, LEDs, mechanical indicators, audio system, or other example suitable for the purposes described herein.

User input is conveyed from the interface to the module 108 via the link 108a.

Sensors

The system 100 may also include various sensors attached to various components of the system 100. The sensors, which are not shown in FIGURE 1 to avoid cluttering the diagram, may be attached to components such as the electrodes 103-104, subparts of the module 108, equipment of the power supply 106, and the like. Examples of these sensors include devices for sensing voltage, current, impedance, phase angle between applied voltage and current, temperature, energy, frequency, etc. More particular, some of these devices include voltmeters, analog-to-digital converters, thermistors, transducers, ammeters, etc.

Module 108

As shown above, the module 108 includes one or more power supplies 106. Aside from this function, module 108 may be implemented to perform some or all of automated or user-selected operation or compensation of the electrodes in the manner shown below. According to one aspect, the module 108 may be used to target a specific region of tissue, or the control firing order of electrodes, by selectively limiting power application to electrodes whose selection is predetermined, machine-selected, or user-selected. According to another aspect, the module 108 may introduce impedance into the electrode circuitry to provide a predetermined, machine-selected, or user-selected impedance matching or compensation.

According to one optional aspect of the module 108, the module 108 may target a specific region of tissue by selectively limiting power application to electrodes whose selection is predetermined, machine-selected, or user-selected. In this regard, the module 108 has a variety of outputs 108b-108c individually coupled to each of the electrodes 103-104. As one example, the outputs 108b-108c may comprise wires, cables, busses, or other electrical conductors. In the illustrated example, there are multiple conductors 108c leading to the multiple electrodes 104a, 104b, etc.

The module 108 applies voltage from the power supply 106 across the first and second electrode surfaces 103-104, such that the voltage is applied exclusively to selected ones of the electrodes. These electrodes may be selected according to user input from the interface 110, selected by a machine-implemented analysis, and/or selected by a default state. In this regard, the module 108 may include a switching network of electrical and/or mechanical switches, relays, or other mechanism to provide power to selected ones of the electrodes. As shown, the power supply 106 is integrated into the module 108, and computer control selectively activates selected output conductors.

Whether by independent switching network or computer regulated activation of output conductors, the module 108 activates electrodes according to input from user interface 110, or input from a machine such as a digital data processing device as discussed above. Depending upon the nature of the application, such controlled application of power to electrodes may be performed in accordance with a machine-selected criteria or analysis, default state, or user input.

FIGURE 5 illustrates a typical application of one example of a processor-controlled switching network, shown in context of two power supplies, electrode structures, and a targeted tissue region. In this example, the electrode surfaces are configured as follows. The electrode surfaces are substantially parallel during performance of electrocautery, each electrode of one surface is aligned with its counterpart in the other electrode surface. In this example, there are two electrodes from the upper surface corresponding to each electrode of the lower surface.

Significantly, the module 108 selectively limits power application to certain electrodes, to target a specific region of tissue. Electrodes may be selected for a different end, as well. Namely, the module 108 may monitor or control the selection of electrodes to prevent firing of adjacent electrodes of the same electrode surface concurrently or sequentially. Ensuring that electrode firing occurs in this spaced-apart fashion prevents unintentional arcing between electrodes and improves the effectiveness of electrocautery. In one embodiment, the controlled firing order is implemented by computer control, and particularly, by a digital data processing component of the module 108. As an alternative to computer control, mechanical means may be used, such as an electromechanical distributor or other device.

In another embodiment, the module 108 may introduce impedance into the electrode circuitry to provide predetermined, machine-selected, fixed, or user-selected impedance matching or compensation. In other words, the module 108 contains a mechanism to electrically introduce impedance into a circuit containing the power supply, the outputs 108b-108c, and the electrodes 103-104.

More particularly, the module 108 includes capacitors, inductors, and/or other impedance elements that can be adjusted or selectively introduced to control the amount of impedance in the circuit containing the power supply and electrodes 103-104. These impedance elements may comprise discrete elements, integrated circuit features, or other constructs suitable for the purposes described herein. The module 108 establishes this impedance matching or compensation according to directions from a user, machine-implemented analysis, and/or default setting.

One example of an adjustable impedance is an adjustable inductor that may comprise any known inductance, such as a coil of conducting material wrapped around an adjustable ferromagnetic core or discrete inductors. In this example, the overall inductance is selectively increased by closing a switch that may be activated manually, mechanically, electrically, or by any means suitable to the purposes of this disclosure, for example, via the user interface 110.

FIGURE 2 illustrates an electrode arrangement having an inductance in series with each electrode of an upper electrode surface (as illustrated). FIGURE 3 shows a different example, including an inductance in series with each electrode of the lower electrode surface (as illustrated). In a different example still, FIGURE 4 contains "T" type network where a capacitor is placed in series with each electrode of the upper electrode surface. Additionally, a different inductor is placed in parallel with each pair of electrodes that are designed to be activated together. The examples of FIGURES 2-4 may employ impedance elements that are fixed, adjustable, or a combination of fixed and adjustable. Furthermore, in connection with the electrodes having a dielectric coating on their surface, a nearly limitless number of additional circuitry configurations for impedance matching and/or compensation will be apparent to ordinarily skilled artisans having the benefit of this disclosure.

In addition to the arrangement for introducing impedance into the electrode circuits, another consideration is the value of such impedance elements. In one example,

the impedance is selected to achieve maximum power transfer and to make accurate power measurements. In this regard, the impedance is chosen to maintain an impedance match between the RF generator, namely, the power supply 106, and the tissue. Impedance matching is achieved when the phase-angle between applied voltage and current is zero. Namely, additional inductance is increased to compensate for the increased capacitive reactance. In one example, this is carried out with a continuously variable inductor, with a finite range and nearly infinite resolution. Such an inductor can be adjusted to a near zero phase. In a different example, impedance matching is carried out by using discrete inductive elements in an appropriate arrangement, such as shown in FIGURES 2-4, to find the least possible phase angle, though this may not be exactly zero.

Having described the structural features of the invention, the operational aspects of the invention will be described. The steps of any method, process, or algorithm described in connection with the embodiments disclosed herein may be embodied directly in hardware, in a software module executed by hardware, human-performed steps, or a combination of these.

A sequence for performing an electrocautery procedure uses an electrocautery system that includes an electrode structure and a mechanism for automated or user-selected operation or compensation of the electrodes. For ease of explanation, but without any intended limitation, this example is described in the specific context of the system 100 of FIGURE 1.

In a first step, different parameters for operating the system 100 are selected. In one example, one or more human users select these parameters and convey them to the system 100 via the user interface 110. In a different example, the parameters for operating the system 100 are selected by digital data processing equipment aboard the module 108. In this case, the parameters are set according to user input, default values, measurements gathered by the various sensors installed in the system 102, programming of the module 108, etc.

Without any intended limitation, the following are some non-exclusive examples of parameters that may be selected in the first step:

- (1) Identity of individual electrodes to be activated *e.g.*, FIGURE 5 in order to focus energy of the electrodes 103-104 on a specific region of tissue.
- (2) Firing order of electrodes.
- (3) Assessment or measurement of magnitude of impedance, *e.g.* FIGURES 2-4, to be used in compensating and/or impedance matching between the power supply 106 and electrodes 103-104.
- (4) Parameters of electrical power to be applied in electrocautery, such as magnitude, frequency, phase, or other characteristics of voltage, current, power, etc.
- (5) Any other parameter by which the operation of the system 100 can be varied.

In a next step appropriately trained personnel apply the electrodes 103-104 to a targeted tissue region to be electrocauterized. The manner of applying the electrodes 103-104, varies according to the construction of the electrodes 103-104, the nature of the targeted body part, the procedure to be performed, and other such factors. There may be circumstances where both electrode structures 103-104 are used within the body, and other embodiments where one electrode is inserted into the body and the other electrode used externally, *i.e.* bipolar or monopolar applications, as is known in the art.

In a specific example of this next step, there are multiple electrodes of one surface, such as 104, corresponding to one electrode of the other surface, such as 103. Optionally, personnel arrange the first and second electrode surfaces 103-104 so that the electrode surfaces are substantially parallel, and each one of the second electrodes is aligned with its corresponding first electrodes, although alignment is preferably obtained during manufacture of the device. FIGURES 2-5 show examples of the final arrangement.

In a further step, directions are given to begin electrocautery. This occurs by user input submitted via the interface 110. For example, a user may press a start button, utter a start command, press a foot pedal, trip a lever, or perform other action. In a different example, electronically occurs upon expiration of a user-initiated timer.

In a still further step, the system 100 responds to the start command and electrocautery is conducted. Here, the system 100 directs bipolar RF power at target tissue regions defined by spaced-apart placement of the electrode structures 103-104. The use of opposed, bipolar electrodes concentrates energy between the electrodes and limits the effect on adjacent tissue that is not confined within the opposed electrodes. In practice, power may be applied for a time sufficient to raise the tissue temperature in the tissue mass being treated to above a threshold level required for cauterization or necrosis, such as 60-80° C, or even higher.

More specifically, electrocautery is conducted according to the configuration set. For instance, the power supply 106 operates according to the power settings established. Moreover, the module 108 acts to invoke individual ones of the electrodes according to the electrode combination selected. In other words, the module 108 applies voltage from the power supply 106 across the first and second electrode surfaces 103-104, such that voltage is applied exclusively to the electrodes selected in. In the case of computer control, this is achieved by the module 108 selectively applying power to the selected electrodes.

As a further enhancement to the use of selected electrodes, the electrodes may be activated using a selected firing order. In this example, the module 108 applies voltage from the power supply 106 across the first and second electrode surfaces 103-104, such that voltage is applied to one or more of the first electrodes 102 and one or more of the second electrodes 103 at any one time, and the module 108 prevents firing of adjacent electrodes of the same electrode surface concurrently or

sequentially. The module 108 may further implement a predetermined or user-selected firing order.

For example, one way of preventing interaction, either thermal or electrical, between two or more multiple electrodes in an RF device with multiple electrodes is to alter the firing sequence of electrodes so that adjacent electrodes are never sequentially charged. For example, instead of sequential firing a four electrode system, where the electrodes are sequentially numbered 1,2,3,4, the invention fires them in an order such as 3,1,4,2, 4,2, 4,1,3,1,3, etc. so that adjacent electrodes are not fired sequentially. Firing times may be different for each electrode to balance the energy delivered in such a sequence where some electrodes fire more frequently than others. This prevents cross-talk during the transmission from one electrode to another as well as cumulative effects of sequential heat build-up in the transition area between the two electrodes. Additionally, rounded electrodes can minimize the edge effect that occurs between electrodes and at any transition surface.

Additionally, if one electrode surface or both opposing surface of conductive, typically metal, electrodes are coated with dielectric, non-conductive materials, RF energy may still be transmitted through tissue between them via capacitive coupling. FIGURE 6 is a block diagram showing an electrode having a dielectric coating according to the invention. However, due to the non-conductive nature of the surface coating the electrode surfaces does not create a short circuit if brought into close proximity or contact. In this way, if a portion of an electrode pair only partially captures tissue, *i.e.* there is a small, 5mm air gap between a portion of the electrodes, the RF energy still passes through the tissue, as opposed to going around the tissue and flowing directly between the close proximity electrodes. This is especially important late in the sealing cycle as the tissue impedance rises. When the tissue impedance is high the energy seeks alternate pathways of lower resistance, such as between exposed electrode sections. These dielectric layers can be thin coats of polymers, such as Teflon, metal oxides, such as titanium, tungsten,

or tantalum or ceramics. To obtain adequate capacitance these layers may be in the micron range of thickness.

In an alternative embodiment, a variety of different tissue cauterization patterns can be achieved with the system 100 by selectively energizing different ones of the electrode surfaces or regions. By selectively energizing two adjacent electrodes, while leaving all other electrodes non-energized, a limited tissue region is cauterized. In contrast, by energizing other multiple electrode surfaces, a larger region is cauterized. Slightly different patterns are achieved depending on the precise pattern of electrode surface polarity. In other embodiments, the electrode surfaces can be energized in an alternating pattern of polarity to produce a tissue cauterization pattern. Different patterns may also be used to produce somewhat different patterns of cauterized tissue.

A different approach for selected firing is employed to prevent local areas of high impedance from impacting the overall system impedance along the entire electrode, and thus potentially reducing the power output of the entire system as voltage reaches its maximal capacity. Here, electrodes are activated to prevent one area that has already been well sealed and has thus reached high impedance value from affecting other regions in which the tissue is not yet sealed, and is thus at a lower impedance. Optionally, the module 108 may employ unique power and energy delivery profiles for each electrode or electrode pair, based on the properties of the tissue in a specific electrode location/position.

The performance of electrocautery employs the selected impedance compensation and/or matching selected. As a result, power delivered from the power supply 106 is delivered to the targeted tissue region with less electrical loss.

The system 100 may further sense and automatically adjust conjugate matching impedance. In response, the module 108 adjusts the impedance applied to the conductive path containing the electrode surfaces 103-104 and power supply 106.

Alternatively, the sensors may provide raw data to the module 108, which analyzes whether and how to adjust impedance. In a different instance, the module 108 may adjust impedance responsive to direction or data from the sensors. This can be carried out by changing the frequency of RF energy delivered by the power supply 106. For example, in one embodiment the module 108 senses whether or not tissue is present at each electrode at the beginning of a cauterization cycle by measuring any of impedance, pressure, or any combination of these and/or other parameters. If tissue is not present at any electrode, then such electrode pair is idle; the module 108 deactivates firing of this electrode, and/or provides a warning to an operator via the user interface 110. The module 108 may also provide a status indicator for each electrode pair that indicates whether the sealing cycle is active or completed with regard to each electrode pair. In this embodiment, each electrode pair may include a mode status indicator, such as an LED for example, that indicates any of an idle, active, or complete condition, once a cauterization cycle is commenced.

The invention also addresses the problem of determining the area of tissue coverage of one or more electrodes through the use of dielectric coated electrode surfaces (See FIGURE 6). With a suitable RF generator and with electrode surfaces coated with a dielectric coating, determination of tissue coverage may be obtained by measuring phase-angle of RF voltage and current. Because a dielectric coating essentially forms a capacitive coupling to tissue, for a given dielectric material thickness, the capacitance is a function of the area of coverage.

The basic formula for a capacitor is:

$$C = \epsilon_0 \epsilon_r A/d$$

Expressed in Farads, where ϵ_0 is the permittivity of free-space ($8.854\text{E-}12$), ϵ_r , is the relative permittivity of the dielectric, A/d is the ratio of the area and the dielectric thickness.

At a given frequency, the reactance is expressed as

$$X_c = 1/\omega C$$

where ω is $2\pi \times \text{Frequency}$.

A suitable RF generator is required to insert a conjugate impedance inductance in this case to cancel out the capacitive reactance with a fully covered electrode and to measure the phase-angle of RF voltage and current. When an electrode is only partially covered, the capacitance changes *i.e.* becomes smaller, because the effective area is smaller. As a result, the reactance and, ultimately, the phase-angle of RF voltage and current change. While the magnitude of change is affected in part by the tissue resistance, it is believed that this methodology allows the greatest degree of determination of electrode coverage by tissue.

A further advantage of such a methodology may signal the RF generator's control algorithm to change frequency, *e.g.* increase, with smaller surface areas, thus maintaining maximum power transfer while minimizing chances for electrical arcing and tissue charring. Potential electrical arcing and tissue charring conditions may be detected rapidly by rapid changes in phase and/or impedance and by appreciating that electrodes which are only partially covered by tissue may be used to signal the RF generator control algorithm to shorten or change treatment parameters.

To achieve maximum power transfer and to make accurate power measurements, it is desirable to maintain an impedance match between the RF generator and the tissue. Impedance matching is achieved when the phase-angle is zero. Several methodologies may be used to attain near-zero phase. One such methodology uses additional reactive elements *e.g.* greater inductance, to compensate for the increased capacitive reactance. This approach can be achieved in two different ways:

- (1) Via the insertion of a continuously variable inductor with a finite range and nearly infinite resolution, such an inductor can be adjusted to a near zero phase; or

- (2) Via the insertion of discrete elements, e.g. inductors to find the lowest phase, though this may not be near-zero phase.

In both cases, electro-mechanical devices are required within the RF generator.

Another methodology of achieving maximum power-transfer, e.g. zero phase, is by changing the RF frequency. Given that the reactance is frequency dependent, this methodology allows the RF generator to compensate for phase discrepancy by electronically changing frequency. This may not require any mechanical devices such as relays, servos, etc. Further, the RF generator can change frequency during operation rather than first interrupting RF power to change elements. Thus, this may be the most desirable methodology.

Although the invention is described herein with reference to the preferred embodiment, one skilled in the art will readily appreciate that other applications may be substituted for those set forth herein without departing from the spirit and scope of the present invention. Accordingly, the invention should only be limited by the Claims included below.

CLAIMS

1. An electrocautery apparatus, comprising:
 - a plurality of adjacent first electrodes forming a first electrode array;
 - at least one second electrode;
 - a power supply having outputs electrically coupled to the first electrodes and said at least one second electrode;
 - means for selectively applying a voltage from the power supply between two or more electrodes among any of the electrodes in the first electrode array and said at least one second electrode; and
 - means for determining the area of tissue coverage of at least one of any of said first electrodes and said at least one second electrode.
2. The apparatus of claim 1, wherein said at least one second electrode comprises at least one return electrode.
3. The apparatus of Claim 1, at least one of said first electrodes and said second electrode having rounded edges to minimize an edge effect that occurs both between electrodes and at any transition surface.
4. The apparatus of Claim 1, at least one of said first electrodes and said at least one second electrode further comprising:
 - an electrode surface coated with a dielectric or non-conductive material that allows RF energy to be transmitted between said electrodes via capacitive coupling.
5. The apparatus of Claim 4, at least of portion of said first electrodes and said at least one second electrode having a spaced relation defining an insulating gap of less than 0.5mm.
6. The apparatus of Claim 4, said electrode surface coating comprising a polymer.

7. The apparatus of Claim 6, said polymer comprising any of:
Teflon®, metal oxides of any of titanium, tungsten, and tantalum, or a ceramic material.
8. The apparatus of Claim 4, said surface coating comprising:
at least one coating layer.
9. The apparatus of Claim 1, said means for selectively applying a voltage from the power supply further comprising:
means for activating said electrodes in a selected firing order that prevents firing of adjacent electrodes concurrently or sequentially.
10. The apparatus of Claim 4, said means for determining the area of tissue coverage comprising:
means for measuring a phase-angle of RF voltage and current;
wherein said dielectric coating forms a capacitive coupling to tissue; and
wherein for a given dielectric coating thickness, capacitance is a function of the area of coverage.
11. The apparatus of Claim 1, said power supply comprising:
an RF generator selectively operable by said means for selectively applying a voltage from the power supply to insert a conjugate impedance in the form of an inductance to cancel out capacitive reactance with a fully covered electrode and to permit measurement of phase-angle of RF voltage and current;
wherein when an electrode is only partially covered, capacitance changes;
and
wherein, as a result, reactance and phase-angle of RF voltage and current change.
12. The apparatus of Claim 11, said means for selectively applying a voltage from the power supply further comprising:

an RF generator control algorithm for changing RF generator frequency upon detection of smaller electrode surface areas to maintain maximum power transfer while minimizing electrical arcing and suboptimal and/or excessive energy delivery.

13. The apparatus of Claim 12, said means for selectively applying a voltage from the power supply further comprising:

means for detecting electrical arcing and preventing suboptimal and/or excessive energy delivery by determining rapid changes in phase and/or impedance.

14. The apparatus of Claim 13, means for detecting electrical arcing and preventing suboptimal and/or excessive energy delivery further comprising:

means for using electrodes which are only partially covered by tissue to signal said RF generator control algorithm to shorten or change treatment parameters.

15. The apparatus of Claim 11, said means for selectively applying a voltage from the power supply further comprising:

means for maintaining an impedance match between said RF generator and tissue;

wherein impedance matching is achieved when a phase-angle is about zero.

16. The apparatus of Claim 15, said means for maintaining an impedance match between said RF generator and tissue further comprising:

one or more reactive elements which compensate for increased capacitive reactance.

17. The apparatus of Claim 16, said means for maintaining an impedance match between said RF generator and tissue further comprising any of:

means for insertion of a continuously variable inductor with a finite range and nearly infinite resolution, wherein said inductor adjustable to a near zero phase;

means for insertion of discrete elements to find a lowest phase; and

means for changing the frequency of said RF generator, wherein said RF generator compensates for phase discrepancy by electronically changing frequency.

18. An electrocautery method, comprising the steps of:

providing a plurality of adjacent first electrodes forming a first electrode array;

providing at least one second electrode;

providing a power supply having outputs electrically coupled to the first electrodes and said at least one second electrode;

selectively applying a voltage from the power supply between two or more electrodes among any of the electrodes in the first electrode array and said at least one second electrode; and

determining the area of tissue coverage of at least one of any of said first electrodes and said at least one second electrode.

19. The method of Claim 18, wherein said at least one second electrode comprises at least one return electrode.

20. The method of Claim 18, said steps of providing a plurality of adjacent first electrodes forming a first electrode array and providing at least one second electrode further comprising the step of:

providing at least one electrode surface coated with a dielectric or non-conductive material that allows RF energy to be transmitted between said electrodes via capacitive coupling.

21. The method of Claim 19, further comprising the step of:

activating said electrodes in a selected firing order that prevents firing of adjacent electrodes concurrently or sequentially.

22. The method of Claim 19, further comprising the step of:

measuring a phase-angle of RF voltage and current;

wherein said dielectric coating forms a capacitive coupling to tissue; and

wherein for a given dielectric coating thickness, capacitance is a function of the area of coverage.

23. The method of Claim 19, further comprising the step of:

providing an RF generator selectively operable to insert a conjugate impedance in the form of an inductance to cancel out capacitive reactance with a fully covered electrode and to permit measurement of phase-angle of RF voltage and current;

wherein when an electrode is only partially covered, capacitance changes; and

wherein, as a result, reactance and phase-angle of RF voltage and current change.

24. The method of Claim 22, further comprising the step of:

providing an RF generator control algorithm for changing RF generator frequency upon detection of smaller electrode surface areas to maintain maximum power transfer while minimizing electrical arcing and suboptimal and/or excessive energy delivery.

25. The method of Claim 19, further comprising the step of:

detecting electrical arcing and suboptimal and/or excessive energy delivery by determining rapid changes in phase and/or impedance.

26. The method of Claim 19, further comprising the step of:

using electrodes which are only partially covered by tissue to signal said RF generator control algorithm to shorten or change treatment parameters.

27. The method of Claim 19, further comprising the step of:

maintaining an impedance match between said RF generator and tissue; wherein impedance matching is achieved when a phase-angle is about zero.

28. The method of Claim 19, further comprising the step of:

providing one or more reactive elements which compensate for increased capacitive reactance.

29. The method of Claim 28, further comprising any of the steps of:

inserting a continuously variable inductor with a finite range and nearly infinite resolution, wherein said inductor adjustable to a near zero phase;

inserting discrete elements to find a lowest phase; and

changing the frequency of said RF generator, wherein said RF generator compensates for phase discrepancy by electronically changing frequency.

30. An electrocautery apparatus, comprising:

a plurality of adjacent first electrodes forming a first electrode array;

at least one second electrode;

a power supply having outputs electrically coupled to the first electrodes and said at least one second electrode;

means for selectively applying a voltage from the power supply between two or more electrodes among any of the electrodes in the first electrode array and said at least one second electrode; and

means for determining the area of tissue coverage of at least one of any of said first electrodes and said at least one second electrode;

at least one of said first electrodes and said at least one second electrode further comprising:

an electrode surface coated with a dielectric or non-conductive material that allows RF energy to be transmitted between said electrodes via capacitive coupling.

31. An electrocautery method, comprising the steps of:

providing a plurality of adjacent first electrodes forming a first electrode array;

providing at least one second electrode;

providing a power supply having outputs electrically coupled to the first electrodes and said at least one second electrode;

selectively applying a voltage from the power supply between two or more electrodes among any of the electrodes in the first electrode array and said at least one second electrode; and

determining the area of tissue coverage of at least one of any of said first electrodes and said at least one second electrode;

said steps of providing a plurality of adjacent first electrodes forming a first electrode array and providing at least one second electrode further comprising the step of:

providing at least one electrode surface coated with dielectric or nonconductive material that allows RF energy to be transmitted between said electrodes via capacitive coupling.

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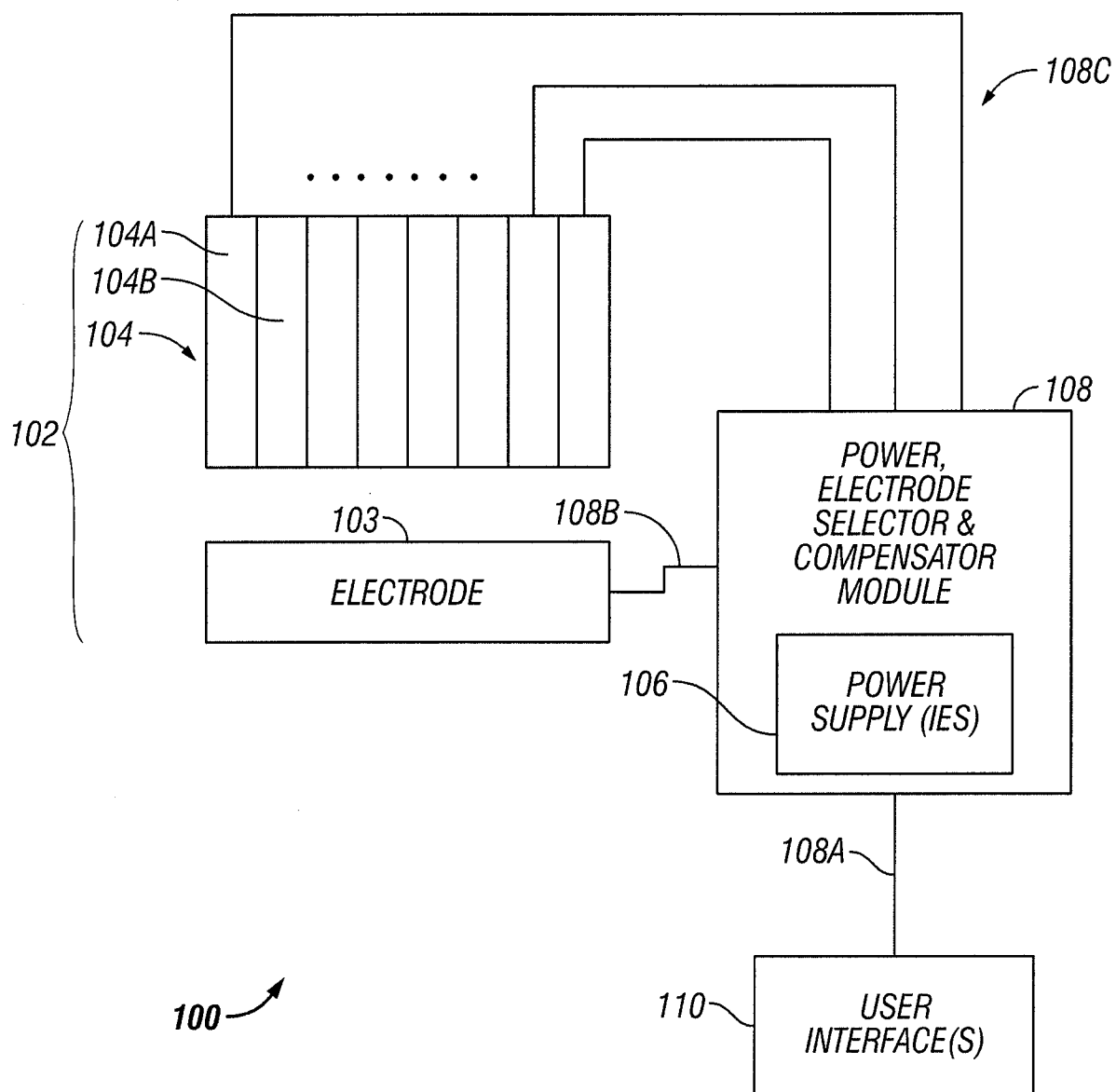


FIG. 1

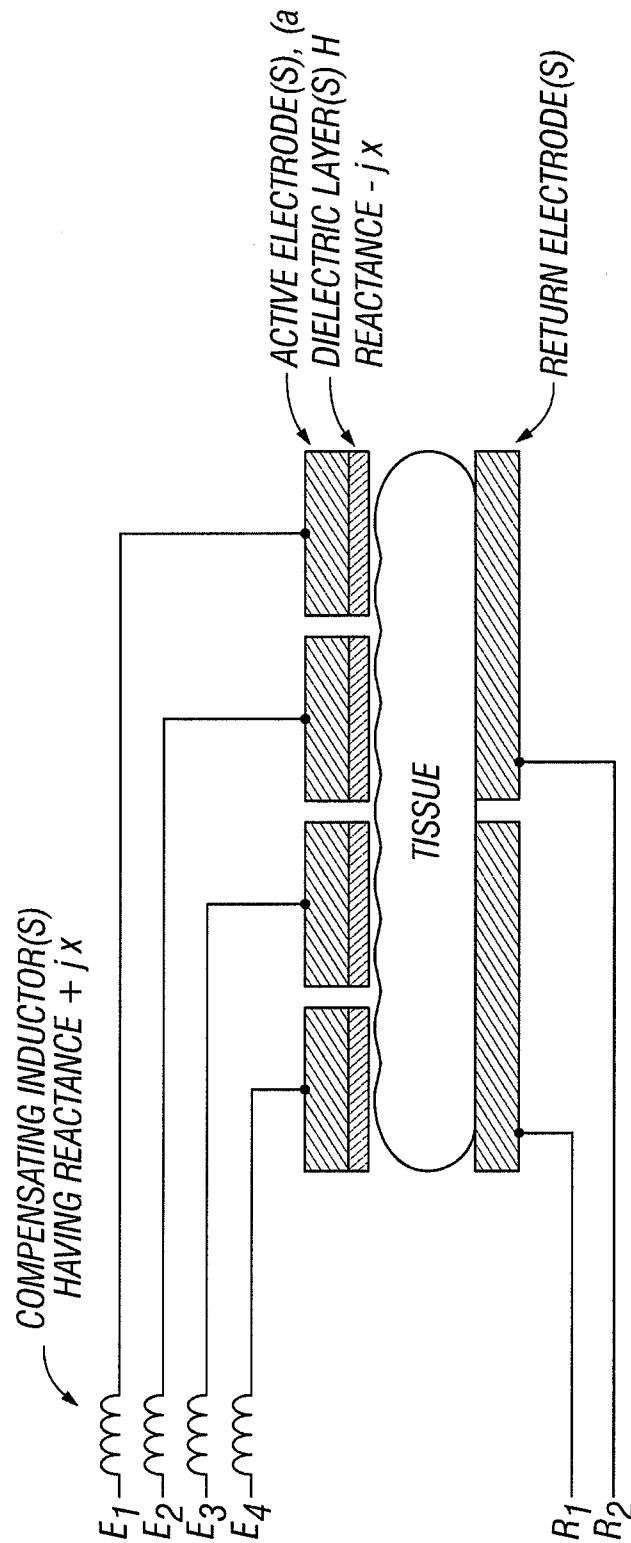


FIG. 2

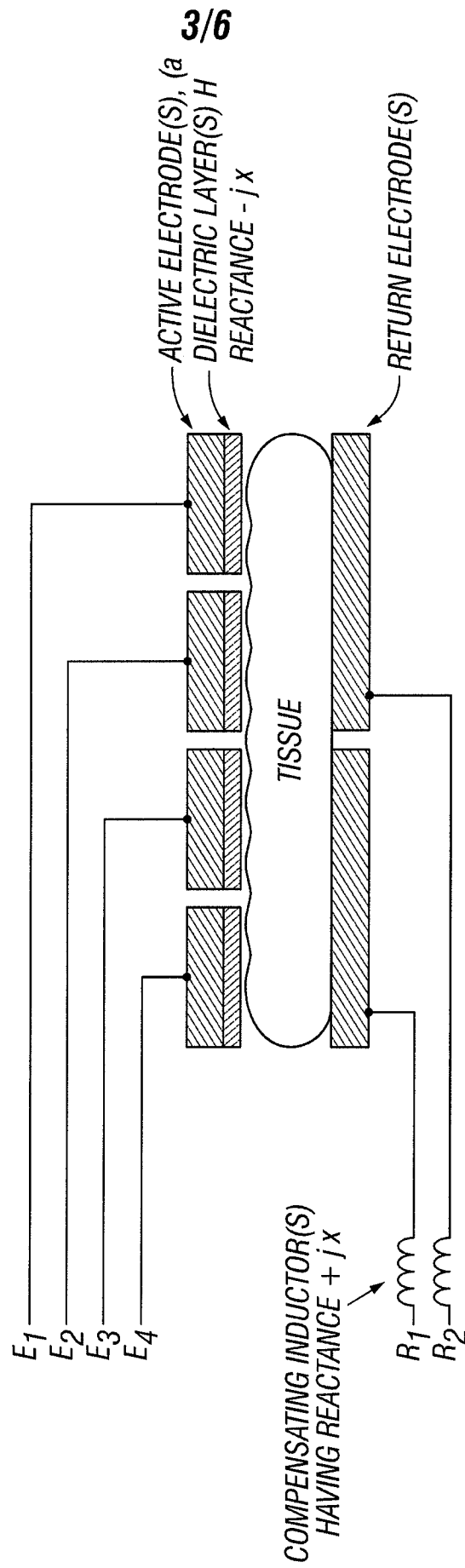


FIG. 3

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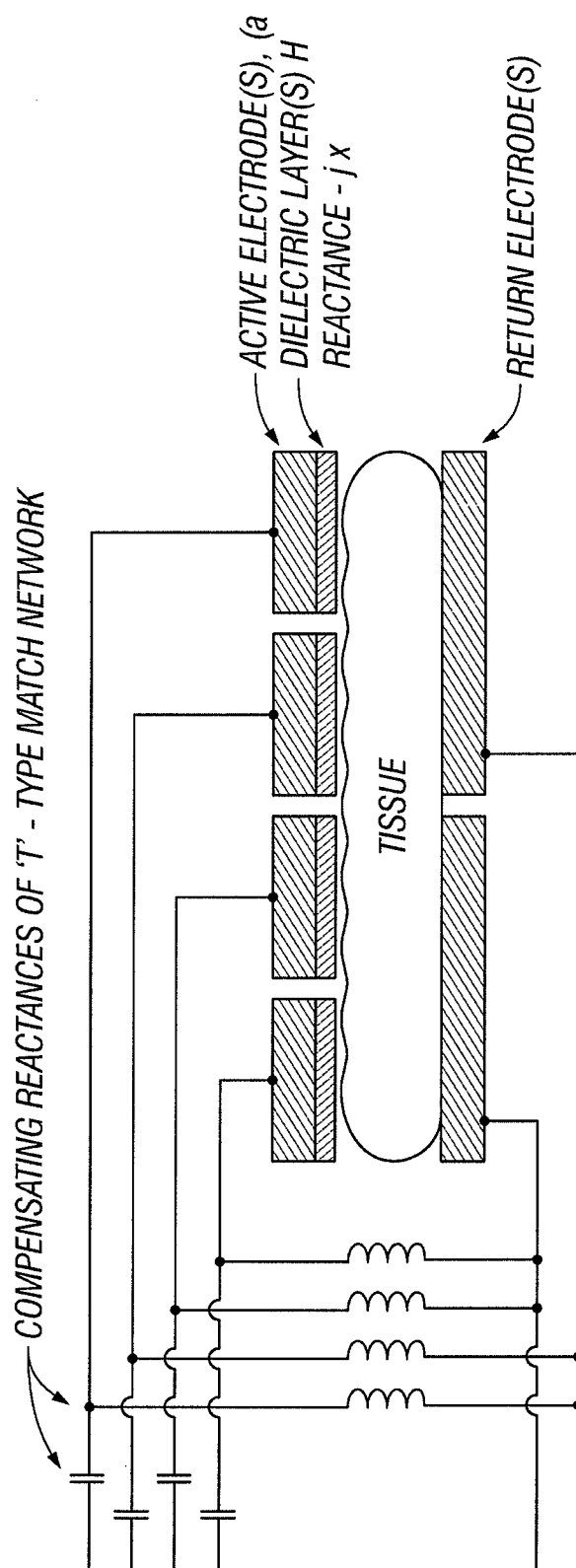


FIG. 4

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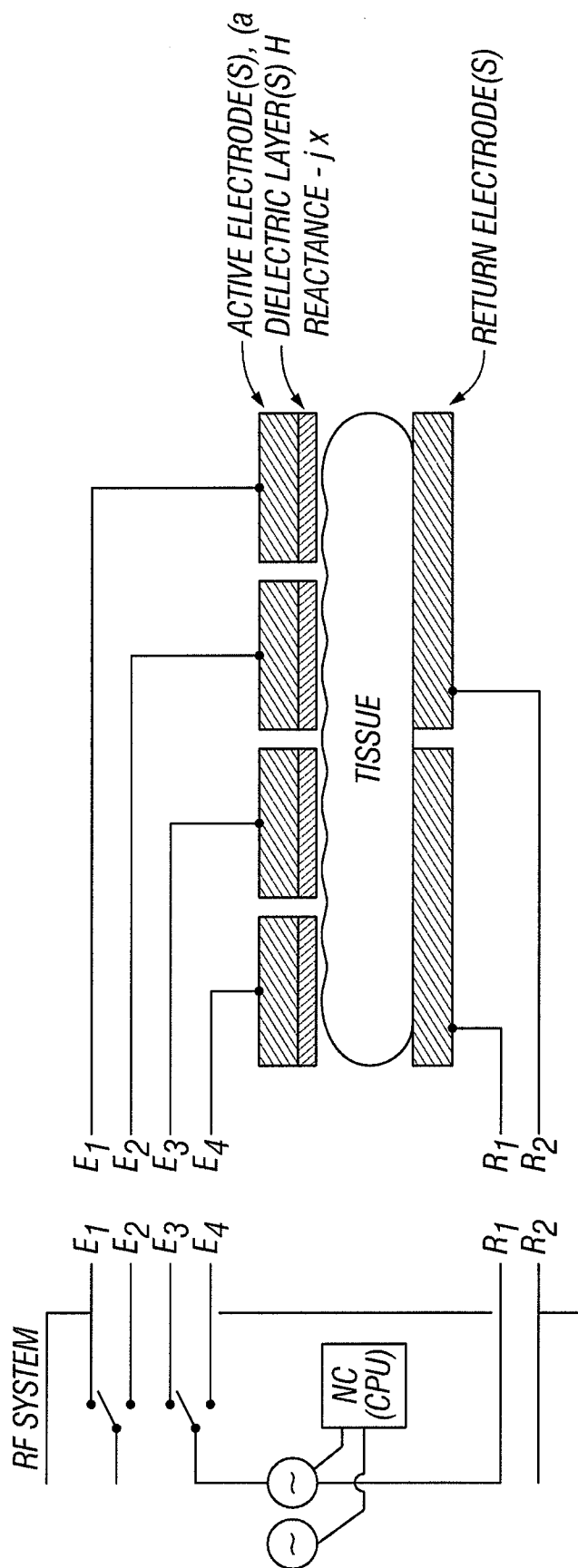


FIG. 5

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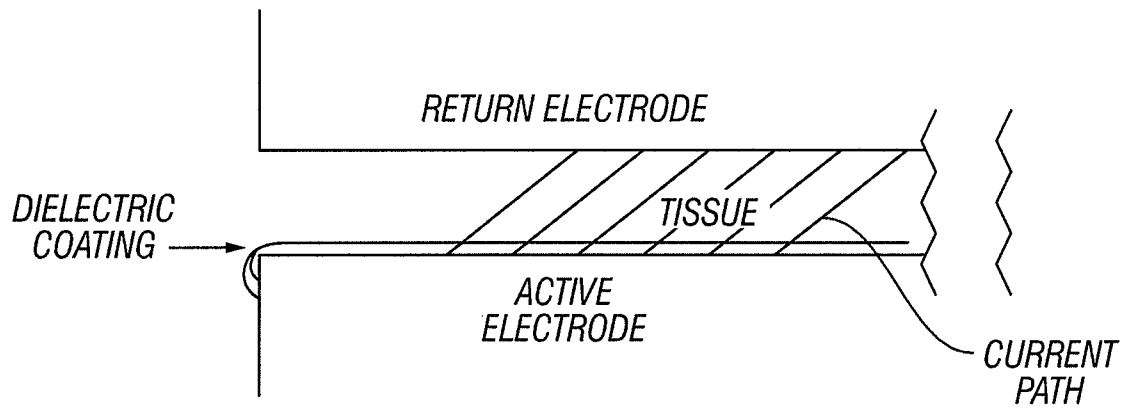


FIG. 6