



(11) **EP 2 265 196 B9**

(12) **CORRECTED EUROPEAN PATENT SPECIFICATION**

(15) Correction information:
Corrected version no 1 (W1 B1)
Corrections, see
Claims EN 1

(48) Corrigendum issued on:
02.10.2013 Bulletin 2013/40

(45) Date of publication and mention
of the grant of the patent:
14.08.2013 Bulletin 2013/33

(21) Application number: **09728455.8**

(22) Date of filing: **31.03.2009**

(51) Int Cl.:
A61B 5/05 (2006.01) A61B 18/12 (2006.01)
A61B 18/14 (2006.01)

(86) International application number:
PCT/US2009/039046

(87) International publication number:
WO 2009/124097 (08.10.2009 Gazette 2009/41)

(54) **Electrosurgical system with means for measuring permittivity and conductivity of tissue**
Elektrochirurgisches System mit Mitteln zur Messung der Permittivität und der Leitfähigkeit von Gewebe
Système électrochirurgical avec des moyens pour mesurer la permittivité et la conductivité d'un tissu

(84) Designated Contracting States:
**AT BE BG CH CY CZ DE DK EE ES FI FR GB GR
HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL
PT RO SE SI SK TR**

(30) Priority: **31.03.2008 US 41045 P**
31.03.2008 US 40994 P
31.03.2008 US 41012 P
31.03.2008 US 40980 P
31.03.2008 US 40828 P
31.03.2008 US 40890 P
31.03.2008 US 40957 P
18.11.2008 US 115756 P

(43) Date of publication of application:
29.12.2010 Bulletin 2010/52

(60) Divisional application:
10192506.3 / 2 359 762
10192580.8 / 2 364 662
10192593.1 / 2 319 447
10192614.5 / 2 335 631
13174814.7

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DescriptionBackgroundField

[0001] The present application relates generally to an electrosurgical system. More specifically, the present application relates to determination of an electrosurgery endpoint using phase shift monitoring.

Discussion of the Relevant Art

[0002] US Pat. No. 6,053,172 describes an electrosurgical system that includes an electrosurgical handpiece or probe connected to a power supply for providing high frequency voltage to a target site and a fluid source for supplying electrically conducting fluid to the probe. The high frequency voltage is sufficient to vaporize the electrically conductive fluid to form ionized plasma and accelerate charged particles towards tissue to cause the molecular disintegration of several cell layers of tissue.

[0003] Surgical procedures often involve cutting and connecting bodily tissue including organic materials, musculature, connective tissue and vascular conduits. For centuries, sharpened blades and sutures have been mainstays of cutting and reconnecting procedures. As bodily tissue, especially relatively highly vascularized tissue is cut during a surgical procedure, it tends to bleed. Thus, medical practitioners such as surgeons have long sought surgical tools and methods that slow or reduce bleeding during surgical procedures.

[0004] More recently, electrosurgical tools have become available that use electrical energy to perform certain surgical tasks. Typically, electrosurgical tools are hand tools such as graspers, scissors, tweezers, blades, needles, and other hand tools that include one or more electrodes that are configured to be supplied with electrical energy from an electrosurgical generator including a power supply. The electrical energy can be used to coagulate, fuse, or cut tissue to which it is applied. Advantageously, unlike typical mechanical blade procedures, application of electrical energy to tissue tends to stop bleeding of the tissue.

[0005] Electrosurgical tools typically fall within two classifications: monopolar and bipolar. In monopolar tools, electrical energy of a certain polarity is supplied to one or more electrodes on the tool. A separate return electrode is electrically coupled to a patient. Monopolar electrosurgical tools can be useful in certain procedures, but can include a risk of certain types of patient injuries such as electrical burns often at least partially attributable to functioning of the return electrode. In bipolar electrosurgical tools, one or more electrodes is electrically coupled to a source of electrical energy of a first polarity and one or more other electrodes is electrically coupled to a source of electrical energy of a second polarity opposite the first polarity. Thus, bipolar electrosurgical tools, which operate without separate return electrodes, can deliver electrical signals to a focused tissue area with a reduced risk of patient injuries.

[0006] Even with the relatively focused surgical effects of bipolar electrosurgical tools, however, surgical outcomes are often highly dependent on surgeon skill. For example, thermal tissue damage and necrosis can occur in instances where electrical energy is delivered for a relatively long duration or where a relatively high-powered electrical signal is delivered even for a short duration. The rate at which a tissue will achieve the desired coagulation or cutting effect upon the application of electrical energy varies based on the tissue type and can also vary based on pressure applied to the tissue by an electrosurgical tool. However, even for a highly experienced surgeon, it can be difficult for a surgeon to assess how quickly a mass of combined tissue types grasped in an electrosurgical instrument will be fused a desirable amount.

[0007] Attempts have been made to reduce the risk of tissue damage during electrosurgical procedures. For example, previous electrosurgical systems have included generators that monitor an ohmic resistance or tissue temperature during the electrosurgical procedure, and terminate electrical energy once a predetermined point is reached. However, these systems have had shortcomings in that they have not provided consistent results at determining tissue coagulation, fusion, or cutting endpoints for varied tissue types or combined tissue masses. These systems can also fail to provide consistent electrosurgical results among use of different tools having different tool and electrode geometries. Typically, even where the change is a relatively minor upgrade to tool geometry during a product's lifespan, the electrosurgical generator must be recalibrated for each tool type to be used, a costly, time consuming procedure which can undesirably remove an electrosurgical generator from service.

Summary

[0008] In view of at least the foregoing shortcomings of the previous electrosurgical systems, there is a need in the art to improve control of electrosurgical procedures to enhance consistency of electrosurgical results among electrosurgical tools and tissue types. Accordingly, there is a need for an improved electrosurgical system that can accurately

assess an electrical energy application endpoint for a desired electrosurgical procedure. There is also a need for an electrosurgical system that monitors tissue properties during the electrosurgical procedure to assess the energy application endpoint.

[0009] In various embodiments, a system for bloodless dissection of connective and vascular tissue is provided. The system described herein can be used in minimally invasive surgery, particularly laparoscopic surgery.

[0010] An electrosurgical tool may comprise a handle assembly, an elongate shaft, a jaw assembly, and a force regulation mechanism. The handle assembly comprises a stationary handle and an actuation handle movably coupled to the stationary handle. The elongate shaft extends distally from the handle. The elongate shaft has a proximal end and a distal end defining a central longitudinal axis therebetween. The jaw assembly is positioned on the distal end of the elongate shaft. The jaw assembly comprises a first jaw and a second jaw. The first jaw has an inner surface, an outer surface, and at least one electrode disposed on the inner surface. The second jaw has an inner surface, an outer surface, and at least one electrode disposed on the inner surface. The jaw assembly is actuatable by movement of the actuation handle from an open configuration in which the inner surface of the first jaw is spaced apart from the inner surface of the second jaw to a closed configuration in which the inner surface of the first jaw is proximate the inner surface of the second jaw. The force regulation mechanism couples the handle assembly to the jaw assembly. The force regulation assembly is configured such that in the closed configuration, the jaw assembly delivers a gripping force between the first jaw and the second jaw between a predetermined minimum force and a predetermined maximum force.

[0011] An electrosurgical tool is provided comprising a handle assembly, an elongate shaft, and a jaw assembly. The handle assembly comprises a moveable actuation handle. The elongate shaft extends distally from the handle. The elongate shaft has a proximal end and a distal end defining a central longitudinal axis therebetween. The jaw assembly is positioned on the distal end of the elongate shaft. The jaw assembly comprises a first jaw, a second jaw, and a blade. The first jaw has an inner surface, an outer surface, a proximal end and a distal end, and at least one electrode disposed on the inner surface. The second jaw has an inner surface, an outer surface, a proximal end and a distal end and at least one electrode disposed on the inner surface. The blade is advanceable along the inner surface of the first jaw along a cutting path defined between a retracted position adjacent the proximal end and an advanced position between the proximal end and the distal end. The jaw assembly is actuatable from an open configuration to a closed configuration by movement of the actuation handle. The at least one electrode on the first jaw and the at least one electrode on the second jaw define a sealing area enclosing the cutting path of the blade.

[0012] An electrosurgical tool is provided comprising a handle assembly, an elongate shaft, and a jaw assembly. The elongate shaft extends distally from the handle assembly, the shaft having a proximal end and a distal end defining a central longitudinal axis therebetween. The jaw assembly is positioned on the distal end of the elongate shaft. The jaw assembly comprises a first jaw and a second jaw. The first jaw has an inner surface, an outer surface, a proximal end and a distal end, and at least one fusion electrode disposed on the inner surface. The second jaw has an inner surface, an outer surface, a proximal end and a distal end and at least one fusion electrode disposed on the inner surface and a cutting electrode disposed on the outer surface.

[0013] An electrosurgical system for performing surgical procedures on body tissue of a patient comprises an electrosurgical generator and an electrosurgical tool. The electrosurgical tool comprises a memory module storing tool data. The electrosurgical generator is configured to receive the tool data from the memory module and apply an electrosurgical signal profile to the electrosurgical tool based on the tool data.

[0014] An electrosurgical generator for performing surgical procedures on body tissue of a patient comprises a power supply, a signal generation module, and a first tool port. The signal generation module is electrically coupled to the power supply. The signal generation module is configured to generate a radiofrequency signal. The first tool port is configured to interface with an electrosurgical tool having tool data stored therein. The first tool port is adapted to receive the tool data stored on the electrosurgical tool and to supply the radiofrequency signal from the signal generation module to the tool.

[0015] A controller for electrosurgical tools comprises a first actuator, a second actuator and a tool selector. The first actuator is moveable between an on position and an off position for actuating a first electrosurgical action when in the on position. The second actuator is moveable between an on position and an off position for actuating a second electrosurgical action when in the on position. The tool selector has a first state wherein the controller is adapted to be operatively coupled to a first electrosurgical tool and a second state wherein the controller is adapted to be operatively coupled to a second electrosurgical tool.

[0016] A surgical tool can comprise jaw elements having a plurality of electrodes to be used for both electrosurgical coagulation and cutting. The electrodes can be powered in a first configuration to provide coagulation - leading to hemostasis of small vascular vessels and tissue - and powered in a second configuration for electrosurgical cutting of the coagulated tissue. The two powered configurations can be generated by addressing different electrodes on the jaw elements and applying them with voltages appropriate for electrosurgical coagulation and/or cutting. The surgical tool can initially be powered in the first configuration to provide coagulation, and can then be powered in the second configuration for electrosurgical cutting. Alternatively, the electrosurgical tool can be powered only in a coagulating configuration

to achieve tissue hemostasis, only in a cutting configuration to dissect tissue, or in a cutting configuration followed by a coagulation configuration.

[0017] At the same time, the surgical tools described herein can include different electrode configurations. I.e., while in one tool only the lower jaw is utilized to provide both coagulation and cutting functions, another tool can also employ the upper jaw element to be used in the coagulation and/or cutting process. In yet another tool, each jaw element can carry multiple electrode elements, greatly increasing the functionality of the tool. A specific electrode arrangement can allow for tools that are more suitable for particular surgical procedures.

[0018] Another aspect of the surgical tools described herein relates to activation and deactivation of one or multiple electrodes, based on the position of the jaw elements. This position-based actuation allows, for example, activation of the upper jaw electrodes only in a near-closed position of the tool (or, in an opened or near-opened position of the tool). Electrical switches in the jaw element driving mechanism can be positioned in a hand-piece of the surgical tool to selectively activate and deactivate one or multiple electrodes based on a position of the jaw elements. Alternatively, the activation and deactivation can be performed by sliding contacts that are assembled in the hand-piece.

[0019] Yet another aspect of the surgical tools described herein is the automated switching from coagulation to cutting, enabled by use of a multi-electrode generator. Here, a tissue feedback mechanism triggers both switching from one set of coagulation electrodes (applied with voltages appropriate for coagulation) to another set of cutting electrodes (applied with voltages appropriate for cutting). As such, each individual tool electrode can be relayed through a bus bar connection to any polarity of choice of the power supply. In addition, tool position switches in the hand tool can provide with logic switching for the population of different coagulation and/or cutting settings, depending on the specific tool position.

[0020] An electrosurgical tool is provided comprising a first jaw, a second jaw, a first electrode, a second electrode, and a third electrode. The second jaw is pivotable with respect to the first jaw. The first electrode is positioned on the first jaw. The second electrode is positioned on the first jaw. The third electrode is positioned on the first jaw. The electrosurgical tool can be selectively configurable in a coagulation configuration such that at least one of the first, second, and third electrodes is electrically coupled with a source of electrical energy having a first polarity and at least one other of the electrodes is electrically coupled with a source of electrical energy having a second polarity generally opposite the first polarity and in a cutting configuration such that one of the first, second, and third electrodes is electrically coupled with a source of electrical energy having a cutting voltage and at least one other of the electrodes is configured to be a return electrode.

[0021] An electrosurgical tool is provided having a proximal end and a distal end and comprising a distal end-piece, an elongate shaft, a handle assembly and a switching mechanism. The distal end-piece is positioned at the distal end of the tool. The distal end-piece comprises a first jaw element, a second jaw element, and a plurality of electrodes. The first and second jaw elements are movable relative to one another between an open position and a closed position. The plurality of electrodes is disposed on at least one of the first jaw element and the second jaw element. The plurality of electrodes is selectively configurable in one of a coagulation configuration and a cutting configuration. The elongate shaft has a distal end connected to the distal end-piece and a proximal end. The handle assembly is positioned at the proximal end of the tool and connected to the proximal end of the elongate shaft. The handle assembly comprises a hand-piece and a trigger. The trigger is pivotally coupled to the hand-piece and operably coupled to the distal end-piece such that movement of the trigger relative to the hand-piece moves the first and second jaw elements relative to one another. The switching mechanism is electrically coupled to the distal end-piece to selectively configure the plurality of electrodes in one of the coagulation configuration and the cutting configuration.

[0022] A method for substantially bloodless dissection of biological tissue is provided. The method comprises positioning an electrosurgical tool adjacent tissue to be dissected, measuring tissue properties to determine the switching point from coagulation to cutting, applying electrical energy to the electrosurgical tool, assessing the tissue coagulation (phase shift) through a feedback loop, switching a configuration of the electrosurgical tool, and applying electrical energy to the electrosurgical tool in a cutting configuration. The electrosurgical tool comprises a plurality of electrodes configurable in one of a coagulation configuration and a cutting configuration. Applying electrical energy to the electrosurgical tool comprises applying electrical energy to the electrosurgical tool in the coagulation configuration to achieve hemostasis in the tissue. Switching the electrosurgical tool comprises switching the electrosurgical tool to the cutting configuration.

[0023] A method for controlling an output of an electrosurgical generator operatively coupled to a bipolar electrosurgical device is provided. The method comprises measuring a phase angle, determining a target phase angle, measuring the phase angle of a second measurement signal, and ceasing delivery of a treatment signal. Measuring the phase angle comprises measuring a phase angle of a first measurement signal applied to tissue of a patient via at least one electrode of the electrosurgical device. The first measurement signal is applied to the tissue prior to treatment of the tissue by the electrosurgical device. Determining a target phase angle comprises determining a target phase angle using the phase angle of the first measurement signal. Following delivery of a treatment signal comprises following delivery of a treatment signal to the tissue. Measuring the phase angle of a second measurement signal comprises measuring the phase angle of a second measurement signal applied to the tissue. The treatment signal is capable of causing modification of the tissue. Ceasing delivery of the treatment signal comprises ceasing delivery of the treatment signal to the tissue when

the phase angle of the second measurement signal reaches the target phase angle.

[0024] A method for controlling an output of an electrosurgical generator operatively coupled to a bipolar electrosurgical device is provided. The method comprises determining permittivity and conductivity of tissue, determining a threshold phase angle, measuring a phase angle, and ceasing the delivery of the treatment signal. Determining permittivity and conductivity of tissue comprises determining permittivity and conductivity of tissue of a patient using a measurement signal. The measurement signal is applied to tissue of a patient via at least one electrode of the electrosurgical device. The measurement signal is applied to the tissue prior to modification of the tissue by the electrosurgical device. Determining a threshold phase angle comprises determining a threshold phase angle based on the permittivity and the conductivity of the tissue. Measuring a phase angle comprises measuring a phase angle of a signal applied to the tissue. Ceasing the delivery of the treatment signal comprises ceasing the delivery of the treatment signal to the tissue when the phase angle of the signal reaches the threshold phase angle.

[0025] A method of characterizing tissue prior to the delivery of electrosurgical energy to the tissue via a bipolar electrosurgical device is provided. The method comprises measuring a phase angle, determining the product of the relative permittivity and conductivity, and characterizing the tissue. Measuring a phase angle comprises measuring a phase angle of a measurement signal applied to tissue of a patient via at least one electrode of the electrosurgical device. The measurement signal is applied to the tissue at a predetermined frequency prior to modification of the tissue by the electrosurgical device. Determining the product of the relative permittivity and conductivity comprises determining the product of the relative permittivity and conductivity of the tissue using the phase angle measurement and the predetermined frequency. Characterizing the tissue comprises characterizing the tissue based on the product of the relative permittivity and conductivity of the tissue.

[0026] A method of characterizing tissue prior to the delivery of electrosurgical energy to the tissue via a bipolar electrosurgical device is provided. The method comprises generating a measurement signal, determining a treatment endpoint condition, and stopping delivery of a treatment signal. Generating a measurement signal comprises generating a measurement signal applied to tissue of a patient positioned between at least two jaw members of an electrosurgical device. At least one of the jaw members comprises an electrode. The measurement signal is delivered to the tissue via the electrode and applied to modification of the tissue by the electrosurgical device. Determining a treatment endpoint condition comprises determining a treatment endpoint condition using the measurement signal. The treatment endpoint condition is determined substantially independently of the dimensions of the tissue positioned between the at least two jaw members. Stopping delivery of a treatment signal comprises stopping delivery of a treatment signal to the tissue when the treatment endpoint condition is reached. The treatment signal is capable of causing modification of the tissue.

[0027] An electrosurgical system for application of treatment energy to a patient involved in bipolar electrosurgery is provided according to the invention. The system comprises an electrosurgical generator, an electrosurgical control unit; and an electrosurgical tool. The electrosurgical generator is configured to generate and output a treatment energy along with a measurement signal. The electrosurgical control unit is configured to direct the output of treatment energy and a measurement signal. The electrosurgical tool is removably connected to one of the electrosurgical generator and the electrosurgical control unit and arranged to contact tissue and apply the treatment energy and the measurement signal to the tissue. The electrosurgical control unit measures permittivity and conductivity of the tissue through the application of the measurement signal, and is configured to determine an end point to disrupt the application of the treatment energy based on the measured permittivity and conductivity of the tissue.

Brief Description of the Drawings

[0028] The present invention may be understood by reference to the following description, taken in connection with the accompanying drawings in which the reference numerals designate like parts throughout the figures thereof.

Figure 1A is a schematic block diagram of an electrosurgical system.

Figure 1B is a schematic block diagram of another electrosurgical system.

Figure 2A is a perspective view of components of an electrosurgical system.

Figure 2B is a perspective view of components of an electrosurgical system.

Figure 2C is a perspective view of components of an electrosurgical system.

Figure 3A is a perspective view of an electrosurgical unit for use in an electrosurgical system.

Figure 3B is a front view of the electrosurgical unit of Figure 3A.

Figure 3C is a rear view of the electrosurgical unit of Figure 3A.

Figure 4A is an exemplary screenshot of a display of the electrosurgical unit of Figure 3A.

Figure 4B is another exemplary screenshot of the display of the electrosurgical unit of Figure 3A.

Figure 5 is a block diagram of various electrosurgical units.

Figure 6 is a front view of a user interface of an electrosurgical unit.

Figure 7 is a front view of a user interface of an electrosurgical unit.

Figure 8 is a front view of a user interface of an electrosurgical unit.

Figure 9 is a block diagram of an electrosurgical unit.

Figure 10 is a block diagram of an electrosurgical unit.

Figure 11 is a graphical representation of a high voltage driving signal at low frequency relative to a low voltage measurement voltage at a high frequency.

Figure 12 is a graphical representation of filtered measurement and current signals for a time near the end of the fusion process.

Figure 13 is a block diagram of an electrosurgical unit.

Figure 14 is a block diagram of an electrosurgical unit.

Figure 15 is a schematic diagram of an external measurement circuitry of an electrosurgical unit.

Figure 16 is a schematic diagram of switch circuitry of an electrosurgical unit.

Figure 17 is a schematic diagram of a phase comparator or detection circuitry of an electrosurgical unit.

Figure 18 is a schematic diagram of a battery power circuitry of an electrosurgical unit.

Figure 19 is a schematic diagram of an input interface of an electrosurgical unit.

Figure 20 is a graphical representation of experimental data for the voltage applied to the tissue during a typical vessel fusion process.

Figure 21 is a graphical representation of experimental data for the voltage applied to the tissue during the measurement cycle.

Figure 22 is a graphical representation of experimental data for the voltage applied to the tissue during the RF measurement cycle to determine the phase shift through the tissue.

Figure 23 is a graphical representation of a sample of experimental data for a typical vessel sealing process, showing a temporal snapshot of applied voltage, electrical current, and dissipated power at 1 second into the fusion.

Figure 24 is a graphical representation of a sample of experimental data for a typical vessel sealing process, showing the peak voltage and peak electrical current as function of fusion time.

Figure 25 is a graphical representation of a sample of experimental data for a typical vessel sealing process, showing the vessel impedance as function of fusion time.

Figure 26 is a graphical representation of a vessel sealing and tissue welding process showing the relative impedances of various tissues as a function of time.

Figure 27 is a graphical representation of a fusion/vessel sealing process showing a temporal snapshot of applied voltage, electrical current, and dissipated power at 4 seconds into the fusion process.

Figure 28 is a graphical representation of a fusion/vessel sealing process showing a temporal snapshot of applied voltage, electrical current, and dissipated power at 7 seconds into the fusion process.

Figure 29 is a graphical representation of bursting pressure as a function of phase shift used in end point determination.

Figure 30 is a table of dielectric constants or permittivity and conductivities for various types of biological tissue, arranged by increasing values of the product of dielectric constants and tissue conductivity.

Figure 31 is a graphical representation of empirically determined phase shifts to adequately fuse and/or weld various types of biological tissue.

Figure 32 is a graphical representation of endpoint phase shifts relative to initial phase shift measurements of various types of biological tissue.

Figure 33 is a graphical representation of a phase diagram of two electrosurgical tools and their associated capacitance and resistance.

Figure 34 is a graphical representation of a phase diagram of an electrosurgical tool in tissue contact and the associated capacitance and resistance.

Figure 35 is a graphical representation of the ohmic resistance of a porcine renal artery during the electrosurgical fusion process.

Figure 36 is a graphical representation of phase shift during the electrosurgical fusion process.

Figure 37 is a graphical representation of the derivative of the phase shift during the electrosurgical fusion process.

Figure 38 is a graphical representation of phase shift during the electrosurgical fusion process.

Figure 39 is a graphical representation of the derivative of the phase shift during the electrosurgical fusion process.

Figure 40 is a block diagram of a fusion or welding process of an electrosurgical unit.

Figure 41A is a perspective view of a laparoscopic sealer/divider.

Figure 41B is a disassembled view of a laparoscopic sealer/divider of Figure 41A.

Figures 42A-42C are views of an actuator of the laparoscopic sealer/divider of Figure 41A.

Figure 43 is a top cross-sectional view of an actuator of the laparoscopic sealer/divider of Figure 41A.

Figures 44A-44D are views of a shaft assembly of the laparoscopic sealer/divider of Figure 41A.

Figures 45A-45C are views of a jaw assembly of the laparoscopic sealer/divider of Figure 41A.

Figures 46A-46G are cross-sectional side views of the laparoscopic sealer/divider of Figure 41A.

Figure 47 is a perspective view of a controller of the laparoscopic sealer/divider of Figure 41A.

Figure 48A is a side view of a jaw assembly of a laparoscopic sealer/divider of Figure 41A.

Figures 48B-48C are graphical representations of exemplary vessel sealing pressures provided by the laparoscopic sealer/divider of Figure 41A.

Figure 49 is a top level view of an electrode configuration of the laparoscopic sealer/divider of Figure 41A.

Figure 50 is a top level view of a jaw assembly of the laparoscopic sealer/divider of Figure 41A.

Figure 51 is a side view of a jaw assembly of the laparoscopic sealer/divider of Figure 41A.

Figure 52 provides views of a jaw assembly of the laparoscopic sealer/divider of Figure 41A.

Figure 53A is a perspective view of a jaw assembly of the laparoscopic sealer/divider of Figure 41A.

Figure 53B is a perspective view of an actuator of the laparoscopic sealer/divider of Figure 41A.

Figure 54 provides views of portions of a shaft assembly of the laparoscopic sealer/divider of Figure 41A.

Figure 55 provides views of a jaw assembly of the laparoscopic sealer/divider of Figure 41A.

Figure 56 is a perspective view of a surgical tool for use in a laparoscopic surgical procedure.

Figure 57 is a perspective drawing of the distal end of an exemplary tissue fusion/cutting device.

Figures 58A-D are schematic drawings of various distal end configurations for an electrosurgical bloodless tissue dissection device.

Figures 59A-C are schematic drawings of active electrode switching circuitries in the hand tool.

Figure 60 is a schematic drawing of the inside of the hand-piece, illustrating an active electrode switching mechanism based on the opening of the jaw elements.

Figure 61 depicts another active electrode switching mechanism, also based on the opening of the jaw elements.

Figure 62 depicts a passive switching mechanism, also based on the opening of the jaw elements.

Figure 63 depicts another passive switching mechanism, based on both the opening and closing of the jaw elements.

Figure 64 depicts a schematic circuitry that connects five electrodes through relays to a bus bar which is relayed to a measurement circuit, or an electrosurgical power plant.

Figure 65 schematically illustrates a method for substantially bloodless dissection of biological tissue.

Detailed Description

[0029] The following description is provided to enable any person skilled in the art to make and use the surgical tools described herein and sets forth the best modes contemplated by the inventors of carrying out their invention.

Electrosurgical System

[0030] Figure 1A illustrates a schematic diagram of an electrosurgical system 2. The electrosurgical system 2 can comprise an electrosurgical unit (ESU) 10 and an electrosurgical tool 40. The electrosurgical tool 40 can be electrically coupled to the electrosurgical unit 10. An electronic coupler 30 such as an electrical wire, wire bundle, or cable can electrically couple the electrosurgical tool 40 to the ESU 10. The electrosurgical system 2 can optionally further comprise an external tool controller 80.

[0031] With continued reference to Figure 1A, the electrosurgical unit 10 can comprise a generator 12 and a feedback circuit 20. The generator 12 can include an actuator 16 such as a power supply and a signal processor configured to generate a radiofrequency (RF) electrosurgical signal. The generator 12 can further comprise a display 14. The display 14 can be configured to indicate the status of the electrosurgical system 2, including, among other information, the status of the actuator 16 and the status of the electrosurgical tool 40 electrically coupled to the electrosurgical unit 10.

[0032] With continued reference to Figure 1A, the feedback circuit 20 of the ESU 10 can comprise a phase discriminator 22, a tissue identifier 24, and an encryption module 26. The phase discriminator 22 can be electrically coupled to the tissue identifier 24. The phase discriminator 22 can be configured to receive information from the electrosurgical tool 40 electrically coupled to the ESU 10.

The information from the electrosurgical tool 40 may comprise information regarding an applied voltage and a supplied current to the electrosurgical tool, and the phase discriminator 22 can be configured to calculate a phase difference between the applied voltage and the supplied current. The encryption module 26 can be configured to transmit and receive data formatted according to an encrypted protocol. The encrypted protocol can be one of several commercially-available encryption protocols, or can be a purpose developed encryption protocol.

[0033] With continued reference to Figure 1A, the feedback circuit 20 can be one or more integrated circuits, printed circuit boards, or other processor collocated with the generator 12 within an integrated ESU 10. As illustrated in Figure 1B, the feedback circuit 20' can be electrically coupled to a stand-alone generator 12' to form an ESU 10'. The tool 40 can be electrically coupled to the feedback circuit 20'. Other aspects of electrosurgical systems having a stand-alone generator 12' and feedback circuit 20' can be substantially similar to systems having an integrated ESU discussed with respect to Figure 1A.

[0034] With continued reference to Figure 1A, the tool 40 can comprise an indicator 42, a tissue selector 50, an actuator 60, and a memory 70. the indicator 40 can comprise an audio indicator 44 such as a speaker, a chime, a clicker device, or another audio generation device. The indicator 40 can comprise a visual indicator 46 such as a lamp, an LED, a display, a counter, or another visual indication device. The visual indicator 46 may comprise a multi-color LED. The tool

40 may comprise both an audio indicator 44 and a visual indicator 46.

[0035] The tissue selector 50 can comprise an electrode assembly 52 and a cutting tool 54. Various electrode assemblies can be configured to perform a desired electrosurgical procedure such as, for example, coagulation, cutting, or fusion, on a particular tissue. The electrode assembly 52 can be configured for use as a vascular sealer. Alternatively, the electrode assembly 52 can be configured for use as a bariatric stapler. In still other cases, the electrode assembly 52 can be configured for use as a tissue cutting device. The cutting tool 54 can be a mechanical element such as a stationary or moveable blade or sharpened edge. Alternatively, the cutting tool 54 can be an electrosurgical element such as an energizable wire or filament.

[0036] With continued reference to Figure 1A, the actuator 60 can be operatively coupled to the tissue selector 50 to selectively select tissue. For example, the tissue selector 50 can include a jaw-based grasper, and the actuator can comprise an actuation mechanism to selectively move the grasper from an open position to a closed position. It is contemplated that other tissue selectors can be used in the electrosurgical system 2. The actuator 60 can also be configured to selectively energize the electrodes. For example, the actuator 60 can comprise a switch or button on the tool.

[0037] With continued reference to Figure 1A, the tool 40 can further comprise a memory 70. The memory 70 can comprise an encryption module 72 and a configuration device module 74. The encryption module 72 can be configured to facilitate an encrypted information exchange with the encryption module 26 on ESU 10. The configuration device module 74 can store operational parameter information about the tool 40. For example, the configuration device module 74 can store information regarding the electrode assembly, the number of uses and total operational time of use of the tool, and other operational parameters.

[0038] With continued reference to Figure 1A, the electrosurgical system 2 can further comprise an external tool controller 80 electrically coupling the ESU 10 to the tool 40. The external tool controller 80 may comprise a tool selector 82 such as a switch. The external tool controller 80 can allow for multiple devices to connect thereto. A tool selector 82 allows selection of one of the multiple devices to be energized. For example the tool selector 82 can comprise a dial, switch, or toggle. The tool actuator 84 can selectively electrically couple the selected tool 40 with the ESU 10.

[0039] With reference to Figure 2A, an exemplary electrosurgical system 102 is illustrated including an ESU 110, and an electrosurgical fusion tool 120. The electrosurgical fusion tool 120 can be electrically coupled to the ESU 110 by an electrical coupler 130 such as with a cabled connection to a tool port 112 on the ESU 110. In the illustrated case, the electrosurgical fusion tool 120 comprises a tissue sealer and divider, as discussed in further detail below with respect to Figures 41A-55. The electrosurgical fusion tool 120 comprises visual indicators 122 such as multi-color LEDs positioned thereon to apprise a user of the status of the tool. Alternatively, the electrosurgical fusion tool 120 can be electrically coupled to a generator or a different electrosurgical unit. A manual controller such as a hand or foot switch can be electrically coupled to the ESU 110 or the electrosurgical fusion tool 122 to allow selective control of the tool.

[0040] With reference to Figure 2B, an exemplary electrosurgical system 202 is illustrated including an ESU 210, and an electrosurgical tool 220. The electrosurgical tool 220 can be electrically coupled to the ESU 210 such as with a cabled connection to a tool port 212 on the ESU 210. In the illustrated case, the electrosurgical tool 220 comprises an electric cutting and coagulation tool, as discussed in further detail below with respect to Figures 56-65. The electrosurgical tool 220 comprises visual indicators 222 such as multi-color LEDs positioned thereon to apprise a user of the status of the tool. In other cases, the electrosurgical tool 220 can be electrically coupled to a generator or a different electrosurgical unit. A manual controller such as a hand or foot switch can be electrically coupled to the ESU 210 or the electrosurgical fusion tool 222 to allow selective control of the tool.

[0041] With reference to Figure 2C, an exemplary electrosurgical system 2302 is illustrated including an ESU 310, and an electrosurgical tool 320. The electrosurgical tool 320 can be electrically coupled to the ESU 310 such as with a cabled connection to a tool port 312 on the ESU 310. The electrosurgical tool 320 comprises visual indicators 322 such as multi-color LEDs positioned thereon to apprise a user of the status of the tool. Alternatively, the electrosurgical tool 320 can be electrically coupled to a generator or a different electrosurgical unit. A manual controller such as a hand or foot switch can be electrically coupled to the ESU 310 or the electrosurgical tool 322 to allow selective control of the tool.

Integrated Electrosurgical Unit

[0042] With reference to Figures 3A-3C, an electrosurgical unit 410 is illustrated in perspective, front, and rear views. The electrosurgical unit 410 can be an integrated ESU as discussed above with respect to Figure 1A, and can comprise a generator and a feedback circuit. The housing or console of the electrosurgical unit 410 can be sized and configured to fit on a standard operating room cart or storage rack. The housing or console of the electrosurgical unit 410 can be configured to be stackable with other surgical electrical equipment.

[0043] With reference to Figures 3A-3B, a perspective view of the electrosurgical unit 410 is illustrated. The electrosurgical unit 410 comprises two dedicated tool ports 412, one bipolar tool port 414, and one electrical power port 416. Electrosurgical units can comprise different numbers of ports. For example, an electrosurgical unit can comprise more or fewer than two dedicated tool ports 412, more or fewer than one bipolar tool port 414, and more or fewer than one power port 416.

[0044] With continued reference to Figures 3A-3B, each dedicated tool port 412 is configured to be coupled to an electrosurgical tool having a memory, as described above with respect to Figure 1A. Thus the dedicated tool ports 412 can be electrically coupled to the feedback circuit of the electrosurgical unit 410 as well as the generator. The dedicated tool ports 412 can comprise multi-pin connectors comprising a plurality of electrical connection pins or pin receptacles. The connectors can comprise more than 10, for example 20 pins or pin receptacles. As discussed above with respect to Figure 1A, and discussed in further detail below, the dedicated tool ports 412 can be configured for encrypted transmission and reception of data from an electrically coupled electrosurgical tool.

[0045] With continued reference to Figures 3A-3B, the bipolar tool port 414 can include a plug configured to receive a conventional bipolar electrosurgical tool. The bipolar tool port 414 can be coupled to the generator of the electrosurgical unit 410. In some cases, the bipolar tool port 414 is not coupled to the feedback circuit of the electrosurgical unit 410. Thus, advantageously, the electrosurgical unit 410 can energize both specialized electrosurgical tools, as described in further detail here and, conventional bipolar electrosurgical tools. Accordingly, the electrosurgical unit 410 can be used in place of a standalone bipolar electrosurgical generator without requiring additional rack or cart space in a surgical workspace.

[0046] With continued reference to Figures 3A-3B, the electrical power port 416 can be coupled to the generator of the electrosurgical unit 410. The electrical power port 416 can be configured to supply direct current. For example, the electrical power port 416 can provide approximately 12 Volts DC. The electrical power port 416 can be configured to power a surgical accessory, such as a respirator, pump, light, or another surgical accessory. Thus, advantageously, in addition to replacing an electrosurgical generator for standard bipolar tools, the electrosurgical unit 410 can also replace a surgical accessory power supply. In some cases, replacing presently-existing generators and power supplies with the electrosurgical unit 410 can reduce the amount of storage space required on storage racks, carts or shelves and the number of mains power cords required in a surgical workspace.

[0047] With continued reference to Figures 3A-3B, the electrosurgical unit 410 can comprise a display 420. The display can comprise a multiline display capable of presenting text and graphical information such as for example an LCD panel display, which, can be illuminated via backlight or sidelight. The display 420 can comprise a multi-color display that can be configured to display information about a particular tool electrically coupled to the electrosurgical unit 410 and a color that corresponds to a standard color associated with a surgical procedure (such as, for example cutting operations displayed in yellow text and graphics, fusion or welding operations displayed in purple, and coagulation displayed in blue, bloodless dissection operations displayed in yellow and blue). The display can be configured to simultaneously indicate status data for a plurality of tools electrically coupled to the electrosurgical unit 410. A user can toggle the display 420 between presenting the status of multiple electrically connected tools and the status of a single electrically connected tool. Further exemplary aspects of the display are discussed generally with respect to Figures 4A and 4B, and more specifically with respect to operation of the system below.

[0048] With continued reference to Figures 3A-3B, the electrosurgical unit can comprise a user interface such as, for example a plurality of buttons 422. The buttons 422 can allow user interaction with the electrosurgical unit such as, for example, requesting an increase or decrease in the electrical energy supplied to one or more tools coupled to the electrosurgical unit 410. Alternatively, the display 420 can be a touch screen display thus integrating data display and user interface functionalities. The electrosurgical unit 410 can comprise an audible indicator, such as a speaker or chime to alert a user of a possible error, the termination of electrical energy supplied, or other conditions. The electrosurgical unit 410 can be configured such that the audible indicator can sound a particular sound during cutting operations, a different sound during fusion or welding operations, and another distinct sound during coagulation operations to provide audible feedback to a user.

[0049] With reference to Figure 3C, a rear view of the electrosurgical unit 410 is illustrated. The rear of the electrosurgical unit 410 includes a rear panel 430. The rear panel 430 can include various ports, such as a controller port 432 configured to be electrically coupled to an external controller such as a foot pedal controller, as described above with respect to Figure 1A. The rear panel 430 can also include a grounding lug. Alternatively, one or more controller ports and/or the grounding lug can be located on another face of the electrosurgical unit 410, for example on the front face or a side face. The rear face of the electrosurgical unit 410 can include a power module 440 including a mains power port configured to be plugged into an AC power mains such as a wall socket and a master power switch for powering the electrosurgical unit 410 on and off. Alternatively, the master power switch can be positioned on another face of the electrosurgical unit 410, for example on the front face or a side face. The rear face of the electrosurgical unit 410 can also include a heat exchange feature, such as, for example slots, a grill, or a plurality of louvers 450. Alternatively, the heat exchange feature can be positioned on another face of the electrosurgical unit 410, for example on the front face or a side face. The heat

exchange feature can enhance air or other fluid cooling of the generator, the feedback circuit, and other electrical components housed within the electrosurgical unit 410 console.

[0050] With reference to Figure 4A, an exemplary screen shot of the display is illustrated. The display 420 can be portioned to display status information for a DC tool 460, a bipolar tool 470, a first radiofrequency electrosurgical tool 480, and a second radiofrequency electrosurgical tool 490, corresponding to the four ports on the front panel of the electrosurgical unit 410 discussed above with respect to Figures 3A, 3B. In the illustrated screenshot, a first section 462 displays information regarding the DC tool 460. A second section 472 displays information regarding the bipolar electrosurgical tool 470. A visual indicator such as a status bar graph 474 can be used to illustrate a proportion of total available electrical energy to be applied to the bipolar electrosurgical tool 470 when actuated. As discussed above, the visual indicator can be color-coded to indicate a surgical procedure to be performed. A third section 482 can display information regarding a first radiofrequency electrosurgical tool 480 with a visible indicator such as a status bar graph 484. A fourth section 492 can display information regarding a second radiofrequency electrosurgical tool 490 with separate visual indicators or bar graphs 494, 496, 498 for each type of surgical operation that can be performed for that tool. For example an electrosurgical tool operable to cut, coagulate, or fuse tissue could have three color-coded bar graphs. The display 420 can also include a controller icon, such as a foot pedal icon 476 positioned in a section corresponding to a tool to which a foot pedal is electrically coupled.

[0051] With reference to Figure 4B, another exemplary screen shot of the display 420 is illustrated. The display has been configured to maximize the information presentation of the section 492 corresponding to the second electrosurgical tool. As discussed above, the electrosurgical unit can be configurable display status information regarding a single tool electrically coupled thereto. In some cases, the electrosurgical unit can allow user manipulation of energy levels applied to electrosurgical tool. In one configuration, energy levels for an electrosurgical tool can be adjusted proportionally for each type of electrosurgical procedure to be performed by the tool. For example, a user can increase or decrease a master energy level which correspondingly increases or decreases the energy levels supplied to the electrosurgical operation performed by the tool, which can be reflected in the bar graphs 494, 496, 498 on the display 420. In another configuration, energy levels for an electrosurgical tool can be manipulated in a procedure-specific manner. For example, a user can increase or decrease an energy level corresponding to one of the electrosurgical procedures performed by a specific electrosurgical tool while leaving energy levels for other electrosurgical procedures unchanged. This change can be reflected in one of the bar graphs on the display 420, for example, the cut bar graph 494.

Electrosurgical System Phase Angle Operation

Electrosurgical Unit

[0052] Generally, an electrosurgical unit is provided that includes an electrosurgical generator, an electrosurgical controller and one or more electrosurgical tools. The controller can be incorporated in or attached to the generator with the tool attached to the controller.

[0053] In one case, a controller is attachable to various electrosurgical generators. The generator attached to the controller provides the supply of RF energy as directed by the controller. The controller provides feedback control and preprogrammed settings for the various attachable generators. This is largely enabled by using an internal measurement signal that is independent from the attached generator. In other words, regardless of the driving frequency of the drive signal the generator generates (which has an impact on the end point measurement, e.g., the phase shift), the measurement signal and hence the final phase shift remain the same.

[0054] Referring to Figure 5, an electrosurgical generator includes an RF amplifier, pulse width modulator (PWM) and relays. The electrosurgical generator is coupled to a 120Hz Voltage main input. The main input is isolated with a low leakage isolation transformer of a power supply 631. The power supply provides operational voltages for the control processor 637 and the RF amplifier 633. Additionally, the power supply includes two 50VDC output modules connected in series to provide a total output of 100VDC and 8 Amps. RF power is generated by the RF amplifier, e.g., a switched mode low impedance RF generator that produces the RF output voltage. A 600 peak cut voltage for cutting and 10 A current for coagulation/fusing can be generated.

[0055] Fusing tissue involves applying RF current to a relatively large piece of tissue. Because of the potentially large tool contact area tissue, impedance is very low. Accordingly, to deliver an effective amount of RF power, the current capability of the RF amplifier is large. As such, where a typical generator might be capable of 2 to 3 amps of current, the RF amplifier of the generator can supply more than 5 A RMS into low impedance loads. This results in rapid tissue fusion with minimal damage to adjacent tissue.

[0056] The RF amplifier circuitry has redundant voltage and current monitoring. One set of voltage and current sensors is connected to the PWM circuitry and used for servo control. The voltage and current can also be read by the processor 637 using an analog to digital converter (ADC) located on the PWM circuitry. The PWM circuitry also has an analog multiplier, which calculates power by computing the product of the voltage and current. The PWM circuitry uses the

average value of voltage and current and does not include a phase angle and thus is actually calculating Volt Amps Reactive (VAR) rather than actual power. A second set of voltage and current sensors is also connected to the Telemetry circuitry 642. The signals are connected to an ADC for redundant monitoring of the voltage and current. The processor multiplies the voltage and current readings to verify that the power output does not exceed 400 W. The Telemetry circuitry has monitoring circuits that are completely independent of the PWM circuitry. This includes the ADC, which has an independent voltage reference.

[0057] The RF amplifier is a switching class D push pull circuitry. As such, the amplifier can generate large RF voltages into a high tissue impedance, as well as large RF currents into low tissue impedance. The output level of the RF amplifier is controlled by Pulse Width Modulation (PWM). This high voltage PWM output signal is turned into a sine wave by a low pass filter on the RF amplifier. The output of the filter is the coagulation output of the RF amplifier. The output is also stepped up in voltage by an output transformer resulting in the cut output of the RF amplifier. Only one output is connected to the control servo on the PWM circuitry at a time and only one output is selected for use at a time.

[0058] Coupled to the RF amplifier is the PWM circuitry 634. The PWM 634 receives voltage and current set points, which are input by the user through a user interface, to set the output level of the RF amplifier. The user set points are translated into the operating levels by digital to analog converters of the PWM. The set points include a maximum voltage output, maximum current output, maximum power output, and a phase stop. The servo circuit of the PWM circuitry controls the RF output based on three set points. The servo circuit as such controls the output voltage of the RF amplifier so that the voltage, current, and power set points are not exceeded. For example, the output of the ESG is restricted to be less than 400 W. The individual voltage and current set point can be set to exceed 400 W depending on the tissue impedance. The power servo however limits the power output to less than 400 W.

[0059] The RF output voltage and current are regulated by a feedback control system. The output voltage and current are compared to set point values and the output voltage is adjusted to maintain the commanded output. The RF output is limited to 400 Watts. Two tool connections are supported by using relays 635 to multiplex the RF output and control signals. The EMI line filter 636 limits the RF leakage current by the use of an RF isolation transformer and coupling capacitors.

[0060] The cut and coagulation output voltages of the RF amplifier are connected to the relay circuitry 635. The relay circuitry contains a relay matrix, which steers the RF amplifiers output to one of the three output ports of the electrosurgical unit. The relay matrix also selects the configuration of the tool electrodes. The RF output is always switched off before relays are switched to prevent damage to the relay contacts. To mitigate against stuck relays steering RF to an idle output port each output port has a leakage current sensor. The sensor looks for unbalanced RF currents, such as a current leaving one tool port and returning through another tool port. The current sensors are located on the Relay PCB, and the detectors and ADC are on the Telemetry PCB. The CPU monitors the ADC for leakage currents. Any fault detected results in an alarm condition that turns off RF power.

[0061] The relay circuitry also contains a low voltage network analyzer circuit used to measure tool impedance before RF power is turned on. The circuit measures impedance and tissue phase angle. The processor 637 uses the impedance measurement to see if the tool is short-circuited. If a Tool A or B output is shorted the system warns the user and will not turn on RF power. The RF amplifier is fully protected against short circuits. Depending on the servo settings the system can operate normally into a short circuit, and not cause a fault condition.

[0062] Voltage and current feedback is provided using isolation transformers to ensure low leakage current. The control processor 637 computes the power output of the RF amplifier and compares it to the power set point, which may be input by the user. The processor also monitors the phase lag or difference between current and voltage. Additionally, the processor matches the different phase settings, which depend on tissue types to the monitored phase difference. The processor as such measures a phase shift of tissue prior to any application of RF energy. As will be described in greater detail below, the phase measurement is proportional to tissue permeability and conductivity that uniquely identifies the tissue type. Once the tissue type is identified, the phase angle associated with an end point determination of that tissue type can be determined. The generator may have three RF output ports (Tool A, Tool B and generic bipolar). The tool A and B ports 639 are used to connect smart tools, while the generic bipolar port 640 supports standard electrosurgical tools. Audible tones are produced when the RF output is active or an alarm condition exists.

[0063] The hand and foot controls are also isolated to limit leakage current. The control processor checks the inputs for valid selections before enabling the RF output. When two control inputs from the switches are simultaneously activated the RF output is turned off and an alarm is generated. Digital to analog converters are used to translate control outputs into signals useable by the Analog Servo Control. The control set points are output voltage and current. The analog to digital converter is used to process the analog phase angle measurement. Voltage RMS, current RMS, and power RMS information from the controller is also converted into a form usable for presentation to the user. The digital I/O bus interface 638 provides digital communication between the user, controller and hand/foot switches. Isolation circuitry is used to eliminate a possible leakage path from the electrosurgical generator. It also provides communication between the user and the generator through a data channel protocol.

[0064] There are four tool Interface circuits in the unit. These circuits are used to electrically isolate the user input

switches from mains power inside the system. The four tool interface circuits are identical and have an on board micro-processor to read the user switch inputs as well as the tool crypto memory and script memories. The switch closure resistance is measured with an ADC to avoid a contaminated switch contact being read as a closure. Switch closures below 300 Ohms are valid, while any reading above 1000 Ohms is open. Readings between 300 and 1000 Ohms are considered to be faulty inputs.

[0065] The four tool interface circuits communicate with the processor using an RS485 network. Each tool interface circuit has jumpers to select its address and location in the unit. The RS485 interface is isolated to eliminate any potential leakage current paths. One tool interface circuit is connected to each of the Tool A and B ports. A third tool interface circuit is connected to the DC output port, and the fourth circuit is connected to the rear panel foot switch inputs. The processor is the network master and each of the four circuits is a network slave. The processor polls each circuit for input. The tool interface circuitry can only reply to commands. This makes the network deterministic and prevents any kind of dead lock. Each Tool Interface circuit is connected to a System OK logic signal. If a system error is detected by a Tool Interface circuit, this signal is asserted. The processor monitors this signal and indicates a fault. This signal also has a hardware connection to the PWM circuit and will disable the RF amplifier when asserted. A system error could be two input switches activated at the same time, or a loss of communication with the processor. The Tool A & B ports as well as the DC port have a micro switch that detects when a tool is plugged into the receptacle. Until this switch is depressed the Tool Interface circuit front panel connections are configured off to prevent any leakage current flowing from front panel connections. Once the switch is depressed the Tool Interface allows the processor to initiate reads and writes to the tool crypto memory and script memory. Once a tool is detected a window opens in the user interface display showing the type of tool connected and status. The generic bipolar port supports legacy tools, which do not have any configuration memory. The tissue measurement circuitry is used to monitor the bipolar connection contacts. When a bipolar tool is connected the tool capacitance is detected and the processor opens the bipolar tool window on the user interface display and shows status for the bipolar tool. The DC port is used to interface with 12 Volt DC powered custom surgical tools. When a tool is plugged into this port a window opens in the user interface display showing the type of tool connected and status. When the DC tool script commands power on, the processor closes a relay on the Power Control and Isolation circuitry 643 turning on the isolated 12 Volt tool power.

[0066] The power control and isolation circuitry 643 has two other features. It controls the 100 Volt power supply that drives the RF amplifier. This power supply is turned on by a relay controlled from the PWM circuitry. The processor commands this power supply on via the PWM circuitry. If the PWM circuitry is reset or detects a fault condition, the relay will not operate leaving the 100 Volt power supply off. Also located on the power control and isolation circuitry is a RS485 isolation circuit that adds an extra layer of isolation.

[0067] The front panel interface circuitry 641 is used to connect the front panel control switches and LCD display to the processor. The front panel interface circuitry also contains a microprocessor, which is powered by an isolated standby power supply, which is on whenever the main power switch is on. When the front panel power switch is pressed, the microprocessor uses a relay on the Power Control and Isolation circuitry to turn on the main logic power supply. When the button is pressed to turn power off, the microprocessor signals a power off request to the processor. When the processor is ready for power to be turned off it signals the microprocessor to turn off power. The power control relay is then opened, turning off the main power supply.

[0068] In one case, the generator accepts only single switch input commands. With no RF active, e.g., RF energy applied, multiple switch closures, either from a footswitch, tool, or a combination of footswitch and tool are ignored. With RF active, dual closures shall cause an alarm and RF shall be terminated. The footswitch in one case includes momentary switches providing activation of the application of RF energy. The switches for example when manipulated initiates activation of the RF energy for coagulation, for cutting and/or sequenced coagulation or cutting. A two-position pushbutton on the foot pedal switch allows toggling between different tools. The active port is indicated on the display of the generator and an LED on the hand tool.

[0069] In one case, all RF activation results in a RF ON Tone. Activation tone volume is adjustable, between 40dB (minimum) and 65dB (maximum) with a rear panel mounted control knob. The volume control however does not affect audio volume for alarms. Also, in one case, a universal input power supply is coupled to the generator and operates over the input voltage and frequency range without the use of switches or settings. A programming port in one case is used to download code to the generator and is used to upload operational data.

[0070] The generator may provide 12V DC at 3 A. Examples of such tools that use DC power are, but are not limited to, a suction/irrigation pump, stapler, and a morcellator (tool for dividing into small pieces and removing, a tumor). The DC connector has an intuitive one-way connection. Similar to the other tool receptacles, a non-sterile electronic chip module is imparted into the connector of the appropriate DC-powered hand tool by a one-time, one-way locking mechanism. Tool-specific engravings on both the connector and chip module ensure that the chip module fits only to the type of tool for which it has been programmed. The chip connector allows tool recognition and the storage of data on tool utilization. The DC connector is also configured to prevent improper insertion. The generator is also configured to recognize the attached DC-powered tool. The generator reads configuration data from the tool connector, allowing tool

recognition and the storage of tool utilization data.

[0071] The controller may recognize the tool upon the tool being attached to the controller. Based on the recognized tool, the generator accesses and initiates specific operations and setting parameters utilized to configure the controller to properly apply RF energy as desired by the tool. For example, parameters set may include an automatic preset of the output voltage, activation of specific output pins (connected to the tool) or determination of the feedback cycle.

[0072] In one case, the controller supplies control signals and/or power to a connected tool to indicate activity via a LED and/or a distinctive audio tone. The controller is also arranged to display when and/or which specific tool is active. The controller also prevents the tool from being reused after certain expiration of the tool shelf life, or a specific time period after the first tool activation.

[0073] In one case, a phase measurement is a relative measurement between two sinusoidal signals. One signal is used as a reference, and the phase shift is measured relative to that reference. Since the signals are time varying, the measurement cannot be done instantaneously. The signals must be monitored long enough so that a difference between them can be determined. Typically the time difference between two known points (sine wave cross through zero) is measured to determine the phase angle. In the case of the phase controller, the device makes the output sine wave with a precise crystal controlled clock. That exact same clock is used to read the input samples with the analog to digital converter. In this way the output of the phased controller is exactly in phase with the input of the phase controller. The phase controller may compare the input sine wave signal to a reference sine wave to determine the amount of phase shift.

[0074] The phase controller does this comparison using a mathematical process known as a Discrete Fourier Transform (DFT). In this particular case 1024 samples of the input signal are correlated point by point with both a sine function, and a cosine function. By convention the cosine part is called real, and the sine part is called imaginary. If the input signal has no phase shift the result of the DFT is 100% real. If the input signal has a 90-degree phase shift the result of the DFT is 100% imaginary. If the result of the DFT has both a real and imaginary component, the phase angle can be calculated as the arctangent of the ratio of the imaginary and real values.

[0075] It should be appreciated that the phase angle calculation is independent of the units of the real and imaginary numbers. Only the ratio matters. The phase results of the phase controller are also independent of gain and no calculation of impedance is made in the process of calculating the phase angle. By performing a DFT, the phase controller encodes the phase measurement as a pair of numbers.

[0076] A user interacts with the electrosurgical unit via a graphical panel display and associated switches 641. The front panel switches allow interaction with LCD display menus generated on the graphical panel display. The menus allow language selection, and modification of tool set points. In one case, parameters can be changed for a tool, only when the tool is plugged in and detected by the unit.

[0077] The electrosurgical unit as described above includes one or more receptacles in which electrosurgical tools connect to the unit. Through this connection, a tool and unit communicate with each other. Connecting the tool also causes the controller to update the display of the system to show tool information and current intensity.

[0078] An example of a display or user interface 641 is shown in Figure 6. The user interface provides tool information such as tool status for each connected tool and allows a user to modify set points, e.g., the application or intensity of the RF energy. The user interface may also show the tool settings for functions for each connected tool. In the illustrated case, three tools are connected to the generator. Accordingly, a suction/irrigation pump display 621, a Kii fusion tool display 622 and a spatula tool display 623 are shown. Associated operations or actions available for each tool are also provided in which the suction/irrigation pump has an on/off setting 624; the Kii fusion tool has relative power settings for cut 625, coagulation 626 and fuse 627; and the spatula tool has relative power settings for cut 628 and coagulation 629.

[0079] In one case, the user interface allows a simultaneous change to all settings for a selected tool (indicated by the highlighted rim 631) by pushing single button from the navigation buttons 632. For example, as shown in Figure 7, pushing the up button 633 will simultaneously change the cut, coagulation and fuse relative power settings for the connected Kii fusion tool. Additionally, the settings can be changed individually by navigating into a sub menu, as shown in Figure 8. In the illustrated case, the coagulation level of the Kii fusion tool is changed without changing the cut and/or fuse relative power setting. By selecting the default button 634, the settings for all tool functions of the selected tool are returned to the default setting. Also, as warranted by the context, an associated button operation and corresponding label can vary as shown in button 635 being a menu button in Figure 7 and a back button in Figure 8.

[0080] A block diagram illustrating a controller is shown in Figure 9. As shown, the output of a generator is fed into circuitry that determines the frequency of the driving signal and circuitry to measure the phase shift between voltage and current applied to the tissue. The voltage applied by the generator is sent through a buffer/level shifter 541 that reduces the amplitude of the output voltage. The signal is processed to deliver the frequency of the generator output via frequency measurement 542 and fed into a microcontroller 543. The frequency of the driving signal can directly impact the phase shift. Similarly, the generator output is sent through a signal conditioning circuitry 544 to reduce high-frequency noise, and then conditioned via voltage and current conditioning 545a-b and filtered by multi-pole low pass filter 546a-b to deliver signals to represent applied voltage and current. Both signals representing voltage and current are measured for phase shift using a phase comparator 547. The output of the phase comparator is fed into the micro-

controller 543. Depending on the frequency of the electrosurgical unit used, which can determine the final phase shift to be reached, the microcontroller compares the output of the phase comparator with the trigger level determined by the driving frequency of the generator. When such a trigger level is achieved, i.e., the tissue fusion or welding is completed, the microcontroller 543 causes the tissue to be disconnected from the generator and indicates that state by acoustical or visual indicators 548 (buzzer, display or lights). An over-voltage detector 549 is also provided to which the generator output is supplied for detection of excessive voltage, the condition of which is supplied to the microcontroller 543.

[0081] Figure 10 shows a block diagram of a controller of an electrosurgical unit utilizing the phase shift between voltage and current to determine the end-point of the fusion process. A microcontroller 553 delivers a low-voltage square-wave signal 551 at 5MHz, which is converted by a 4-pole low pass filter 550 into a low-voltage sin-wave signal 552 at 5 MHz. The low-voltage 5MHz signal is superimposed to the output of the generator, which is typically in the 100 to 200V range at frequencies of 300 to 500 kHz. As an example, the superimposed voltage signal of a 200V driving voltage at 500kHz and a 5V measurement voltage at 5 MHz is shown in Figure 11.

[0082] The combined voltages are then applied to the tissue and, just as in the previous example, also conditioned through a buffer/level shifter circuitry for processing. Similarly, the current through the tissue is measured and also conditioned for processing. The processed voltage (and current) signal containing the high voltage (and high current) signal at 300 to 500kHz from the ESU, as well as low voltage (low current) signal at 5MHz are sent through a multi-pole band pass filter centering at 5MHz. The filter discriminates the signal from the ESU, leaving only the two signals at 5MHz for measuring the phase shift in a phase comparator. The filtered signals for both the voltage and current at 5MHz are illustrated in Figure 12 at a time near the end of the fusion process.

[0083] The measured phase shift is fed into a microcontroller, which compares the reading with a pre-determined level indicative to the completion of the fusion process at 5MHz frequency. Again, when such a trigger level is achieved, i.e., the tissue fusion or welding is completed, the microcontroller 553 will cause the tissue to be disconnected from the generator and with indicate that state by acoustical or visual indicator 548 (buzzer, display, or lights).

[0084] Figure 13 shows a schematic block diagram of one aspect of a controller. As shown, a microprocessor 561 times the switching of the tissue between the output of a generator and an internal measurement circuit. As a result, the tissue is periodically assessed for the status of the fusion process by measuring the phase shift of a low-voltage and low-current measurement signal. Depending on the value of the obtained phase shift, the tissue is either switched back to the high-voltage output of the generator for further fusion, or permanently disconnected from the generator. As such, the internal circuit comprises a microprocessor 561 generating a low-voltage square wave signal 562 at 500kHz that is transferred into a low-voltage sinusoidal wave 563 at 500kHz. This signal is applied to the tissue, and analyzed by a phase comparator 564 only during it electrically disconnection from the generator during regular measurement intervals.

[0085] In one case, the phase shift is derived directly from the driving signal, i.e., the voltage and current supplied by the electrosurgical generator to the tissue. In one case, an electrical circuit modifies the driving voltage having one (sinusoidal) frequency by superimposing a measurement signal at a vastly different frequency. As a result, electrical energy for the fusion process is provided at one frequency, while simultaneously applying a second signal at a second frequency for measurement. Separation of the two different signals by using band pass filters in the measurement circuit allows continuous measurement of the phase shift during the electrosurgical fusion or welding process. In one case, the controller periodically interrupts the supply of electrosurgical energy to assess the status of the fusion or welding process by applying a low-voltage measurement signal. Depending on the phase shift obtained during the measurement cycle, the controller switches the driving signal from the generator back to the tissue or isolates the tissue. In one case, the controller interrupts the tissue fusion or welding process at a pre-determined level of phase shift by terminating the supply of RF energy from the generator to the tissue.

[0086] Figure 14 depicts a controller or control unit for the controlled fusion or welding of biological tissue. As shown, the control unit is connecting the bipolar power outlet of a generator 507 to the tool 508 that is arranged to compress vessels or tissue. The tool also houses a switch 509 that activates the fusion process. If the generator is equipped with an input for hand activation (rather than using a foot pedal 511 or other intermediary device), a third connection 512 from the control unit to the generator allows activation of the generator with the same hand switch.

[0087] The controller may include a processor 513 that controls the switching of the tissue between the direct output of the generator and an internal measurement circuit, e.g., switch 515. It is powered with an internal battery power module 514. The timed switching causes the tissue to be fused in intervals while periodically measuring the status of the tissue. As such, the measurement signal is a 500kHz sinusoidal low voltage signal, generated by a signal generator 518 when fed with a 500kHz square wave from the microprocessor 513. When the low-voltage sinusoidal measurement signal is applied to the tissue, a phase comparator 516 measures the phase shift between the applied measurement voltage and the current caused by application of the measurement voltage. Depending on the result analyzed or processed by the processor, the tissue will be either be switched back to the generator, or disconnected from the generator accompanied by an acoustical and/or visual indication via LEDs/buzzers 517.

[0088] Figure 15 shows an external measurement circuit that generates the low-voltage sinusoidal signal used to measure the phase shift. It is generated by passing a 500kHz square wave through a 4-pole low-pass active filter 531.

The 4-pole low pass filter removes higher harmonic components and passes the sinusoidal fundamental frequency. The 500KHz square wave is generated via the PWM peripheral 522 in the microcontroller 524.

[0089] Figure 16 illustrates switch 515 configured to switch between the application of the drive signal and the measurement signal, e.g., the 500 kHz, 5 Volt peak-to-peak sine wave reference signal, from the generator. Although the use of a solid-state switch to implement the switching offers a long operational life and inherent current surge control, it can be difficult to block the relatively high voltage (-200VAC) and high frequency (-500KHz) signal generated by a typical generator in a bipolar coagulation mode. As such, two double pole, double-throw mechanical relays 527,528 are used. The first relay 527 switches between the generator and the reference signal. The second relay 528 limits the current surge, which can damage the relay and create an electromagnetic interference (EMI) pulse that can disrupt the low-voltage circuitry. Additionally, this protects the tissue against complications or issues caused by electrical arcing. Since most generators are constant power devices, the highest voltages occur during conditions of no load. By first switching in the generator through a series resistor, the output voltage of the generator is shared across the resistor, limiting the voltage imparted to the tissue. Furthermore, the resistor serves as an energy limiter, enabling high conductive channels in the tissue to fuse before the full power of the generator is applied.

[0090] In one case, switching takes place in the following sequence. When switching from the low voltage measurement or reference signal to the generator, the first relay 528 switches out both ends of the reference and switches in one generator lead directly and one through a 100 Ohm resistor. The 100 Ohm resistor limits the surge current to two A for a 200 Volt source. If a shorted output occurs, 400 W are dissipated in the 3 W resistor, which would quickly burn up. However, approximately 50 milliseconds after the first relay 528 switches in the generator, a second relay 527 switches out the 100 Ohm resistor, keeping it from burning up and allowing the full power of the generator to be delivered to the tissue. When the device switches the other way (from the ESU to the reference signal), it first switches in the 100 Ohm resistor, reducing the current, and then switches out the generator entirely. This sequence reduces inductive kickback and EMI generation.

[0091] The relays 527,528 may be of a latching type. Most mechanical relays draw a fair amount of power in their non-default state (an electrical current is needed to fight the force of the returning spring). Since the controller is equipped with a battery of limited power capacity, two latching type relays are used. These relays only use current to transition between two stable states and can operate at a much lower power level.

[0092] The phase detection circuitry 530 is shown in Figure 17, which measures the phase shift between the two above-mentioned sine waves. The first part of the circuit level-shifts the sine wave to the same DC value as a reference voltage. The level-shifted signal is then sent to the negative input of a comparator 531. The positive input is connected directly to the DC reference voltage. A small amount of hysteresis is used to reduce switching noise. The output of the comparator is a square wave with the same phase as the input sine wave. These two signals are sent to an exclusive OR gate 532. The output of the gate is high when one of the two inputs is high, and low otherwise. The duty cycle of the output is therefore linearly related to the phase of the two input square waves. The duty cycle is converted to a DC voltage through a low pass filter, which is measured by the analog to digital converter peripheral of the microcontroller.

[0093] Figure 18 shows the battery power circuit that is powering the control circuit by two low-capacity coin cells. The battery provides a life of 500 fusing cycles over a 5-hour time span. When a specific number of seals, or a specific time limit have been reached, the controller issues a warning and ceases operating. The controller manages its power demand around the power characteristics of the specific batteries used. The controller includes management controls that prevent specific operations from occurring simultaneously that may exceed the power capacity of the batteries, power down selected portions of the circuit between fusing cycles, and slow the microcontroller oscillator down from 4 MHz to 32kHz between fusing cycles.

[0094] Figure 19 shows an input port 534 adapted for connecting to a tool. With engagement of a switch on the tool, the controller takes initial measurements on the tissue (shorting,) and based on the initial measurements activates the generator to supply electrosurgical power that is passed and controlled by the controller.

[0095] As many generators can exclusively (but also alternatively, with the surgeon's preference) be activated with a foot-pedal, the controller accommodates such a scenario. For example, if the generator is activated with a foot switch while subsequent activation of the hand switch on the tool occurs, the controller allows switching-in of the output of the generator.

[0096] The result of using the control circuit described above is shown in Figure 20, showing the effective voltage applied to the biological tissue as a function of time. As shown in this specific example of porcine renal arteries, the tissue is being exposed to 6 high-power fusion intervals of about 850ms time duration, interrupted by 5 measurement cycles of about 300ms.

[0097] In one case, the fusion process starts with depressing a switch on the tool, which starts an initial measurement sequence. This point in time is marked start (switch on) 535. The tool in one case checks the resistance between the two electrodes and whether the phase shift is within an acceptable range. Verifying the phase shift prevents an attempt to re-fuse already fused tissue. Based on the results of the initial check, the controller switches-in the activated output of the generator to the tissue. This starts the application of RF energy to the compressed tissue. After about 850ms, the

controller disconnects the tissue from the generator and switches back to the first tissue assessment phase. Depending on the result, the tissue gets heated further, or remains disconnected from the generator to remain on the measurement circuit. The latter case is marked power stop (switch on) 536. In this case, an acoustical and/or visual signal is given, indicating that the tissue is sealed (or that shorting of the electrodes has occurred). The supply of the measurement signal to the tissue is ended when the switch on the tool is released, marked manual stop (switch off) 537. At this point, all supply of energy to the tissue is terminated.

[0098] A more detailed analysis of the measurement cycle 538 is shown in Figures 21 and 22, showing that additional measurements (other than the phase shift) can be included in that measurement period. Such measurements, for example, could prevent attempting to fuse already fused tissue, or powering of electrically shorted electrodes.

[0099] Figure 22 shows a more detailed analysis of the measurement plateau 539 of 2V in Figure 21. A detailed view is shown of the low-voltage measurement signal 540 at 500kHz used to determine the phase shift through the tissue during the RF measurement cycle.

Electrosurgical Systems and Processes

[0100] Electrosurgical systems and processes apply monopolar or bipolar high-frequency electrical energy to a patient during surgery. Such systems and processes are particularly adapted for laparoscopic and endoscopic surgeries, where spatially limited access and visibility call for simple handling, and are used to fuse blood vessels and weld other biological tissue and in one aspect to cut, dissect and separate tissue/vessels. The systems and processes include the application of RF energy to mechanically compressed tissue to (a) desiccate the tissue, and (b) to denature collagens (type I-III) and other proteins, which are abundant in most biological tissue. As heating of collagens to an appropriate temperature causes them to unfold, shrink or denature, the system enables the sealing of capillaries and blood vessels during surgery for permanent occlusion of the vessels. As described in greater detail below, as an example, arteries up to seven millimeters can be occluded and dissected by radio frequency (RF) energy and mechanical pressure.

[0101] When concurrently applying controlled high-frequency electrical energy to the compressed tissue, the tissue is compressed with a relatively high pressure (about 1000KPa - 2000 KPa), and the tissue is supplied with sufficient electrical energy to denature proteins and remove sufficient water in the tissue. During this process, the applied voltages are sufficiently reduced to avoid electrical arcing (typically < 200V RMS).

[0102] When applying electrical energy in the described manner stated above, the tissue quickly moves through the following fusion/welding process. Starting at body temperature the tissue (a) heats quickly, leading to (b) cell rupture, expelling of juices (mainly water and salt ions), (c) unraveling and activation of collagens and elastin in the blood vessels at about 60-650° C, and (d) desiccation of the vessel. Here, the desiccation process can be seen by the release of water in form of steam where the vessel temperature has reached about 1000°C. The reduction of water in presence of unraveled collagen and elastin strands leads to formation of bonds between collagen strands, leading to a strong and elastic seal of the tissue. As confirmed by measurements, the strongest (highest burst pressure) vessel fusions are obtained when the vessels have been heated to at least 70° C, pressurized with about 1000 KPa - 2000 KPa, and then desiccated by about 40-50% of their original water content.

[0103] Electrically, the tissue can be characterized during the fusion process by its impedance, which is typically starting at 10- 100 Ohms purely ohmic resistance. During the fusion process, the purely ohmic resistance is reduced by 20- 50% before it increases by two orders of magnitude. As the resistance approaches a final value, the impedance of the tissue gradually increases in capacitive behavior with a phase shift of about 20 degrees. The tissue will exhibit a pronounced capacitive behavior at the end of the fusion process with a phase shift of about 40 degrees, even though the ohmic component will remain nearly unchanged during this phase.

[0104] Referring now to Figure 23, a graphical representation exemplifying experimental data for the sealing of a four-millimeter diameter porcine renal artery is shown. The fusion process is performed by compressing the artery with 0.75 millimeter wide electrodes with a compression load of 10 N, and by energizing it with a voltage-stabilized electrosurgical power supply using 200V at 60W maximum power setting. Voltage 501, current 502 and electrical power 503 in the beginning of the fusion process (1 second) are shown. As can be seen, the sinusoidal voltage and current are substantially in-phase, e.g., the phase difference or angle equals zero. At this time, the impedance of the artery is purely ohmic with a value of about 100 Ohms.

[0105] The temporal progression of the applied peak voltage and peak current for the same-sized artery is provided in Figure 24. The applied voltage quickly stabilizes to a constant value, which is an artifact of the voltage-stabilized power supply. Regardless of the applied load, voltage-stabilized electrosurgical power supplies regulate the output voltage to a pre-set value since the voltage has a dominant impact on the electrosurgical effect. In contrast to the voltage, the current driven through the artery increases from an initial 1A to 1.5A at 0.5s, and then gradually reduces over the next three seconds to about 0.2A. For the remaining 4 seconds of the fusion time the peak value of the current remains nearly unchanged.

[0106] Another way to depict the information from Figure 24 is shown in Figure 25, showing the impedance 506 of the

artery as function of fusion time. The initial impedance of the harvested artery is 75 Ohms. With application of high frequency electrical energy the artery heats quickly, leading to shrinkage of collagens, rupture of cell membranes, and the ultimate expelling of trapped liquid (mainly water and ions). As a result, the impedance is reduced to about 54 Ohms. Further supply of electrical energy starts to desiccate the artery, resulting in an impedance increase. At about 4 seconds into the fusion process the impedance of the artery starts to stabilize, with a slow increase of the impedance from about 800 Ohms to about 1,200 Ohms.

[0107] The fusion process could be terminated (a) at a fixed and absolute resistance (for example 2k Ohms), which would neglect both the size and type of tissue, (b) at a specific multiple of the time where the ohmic resistance is minimal, (c) at a specific multiple of the time where the ohmic resistance is the same as the initial one, or (d) at a specific multiple of the time where the ohmic resistance is a certain factor of the minimal one. However, considering burst pressure of fused arteries and thermal spread, the termination of the fusion process is determined to be in the flattened part of the impedance curve. As can be seen in Figure 25, however, this region is also an inexact range for impedance measurements. Similarly, each succession of (a) to (d) becomes better in determining the end-point of the fusion time (resulting in the highest desired bursting pressure with the least desired thermal spread). Utilizing the ohmic resistance only as termination criterion can lead to incomplete results. This can be more pronounced when fusing differently sized tissues (even of the same nature), also exemplified in Figure 26 showing the relative resistance (relative to the initial resistance) of various-sized arteries and other tissue as a function of fusion time.

[0108] Termination of the fusion process for same-material tissue (i.e., arteries) cannot be controlled with the desired precision by specifying one relative ohmic load (e.g., when the resistance reaches 3 times the initial resistance). Instead, the relative change in resistance depends on the size of the vessel, i.e., < 2 mm arteries seal in fractions of a second (where the resistance about doubles compared to the initial resistance), about 3 mm arteries seal in about 2 seconds (where the resistance about triples), and 15 mm arteries/veins seal in about 7 seconds (where the resistance increases by a factor of 5). At the same time, some arteries may not follow that characterization (e.g., a 3-4mm artery would not reach more than 2.5 times the initial resistance). Instead, the fusion process should end within the flat region in Figure 25. As previously described, precision is difficult in the flat region with the function of time at different fusion times.

Phase Based Monitoring

[0109] In one aspect, the determination of the end-point of the fusion process is given by monitoring the phase shift of voltage and current during the fusion process. Unlike impedance, the phase shift changes in a much more pronounced way at times where the artery desiccates and the fusion completes, and hence offers a more sensitive control value than the impedance. This can be seen when monitoring the voltage and current as functions of time at different fusion times, as is shown in Figure 23 for the beginning of the fusion process.

[0110] In Figure 23, the beginning of the fusion shows that the applied voltage and current are almost in phase (with a shift of about -3 degrees), revealing that the artery behaves dominantly like an ohmic load of about 75 ohms. Further supply of energy leads to heating of the artery, an initial reduction in impedance (caused by shrinking of collagens, cell membrane rupture and expelling of mainly water and dissolved ions), and a subsequent increase in impedance. During this period of vessel fusion, the phase difference between voltage and current remains small with minimal changes, indicating that the artery is purely ohmic.

[0111] The artery is not fully desiccated, and thus the seal is not complete. Referring to Figure 27, at 4 seconds into the fusion process, the phase difference slowly increases to -10 degrees (current leads). While further supply of electrical energy does not significantly change the value of the resistance (see Figure 24), it does cause a pronounced increase in the phase difference between voltage and current. This can be seen in Figure 28 at 7 seconds into the fusion process, showing a phase difference of about 25 degrees. The vessel fusion process continues and yields the desired burst pressures at the least desired thermal spread when the phase difference or angle reaches about 35-40 degrees as shown in Figure 29. Also, as shown the phase angle reaches about 20 to 40 degrees. Similarly, the phase difference or angle necessary to result in welding of other tissue reaches about 45-50 degrees for lung tissue, and 60 to 65 degrees for small intestine. However, for all types of tissue, reaching a high end of the phase range can lead to excessively long sealing times. Accordingly, as will be described in greater detail below, the application of RF energy, i.e., a drive signal, via an electrosurgical generator and the measuring or monitoring of phase shift, i.e., a measurement signal, via an electrosurgical controller are adapted to fuse or weld vessels and tissue.

Endpoint Determination based on Tissue Properties

[0112] Using the phase difference between voltage and current as a control value in the fusion or welding process, instead of the impedance, can be further shown when characterizing the tissue electrically. When considering vessels and tissue to be a time-dependant ohmic resistor R and capacitor C in parallel (both of which depend on the tissue size and type) the phase difference can be obtained with

$R = \frac{\rho \cdot d}{A}$, where R is the ohmic resistance, ρ the specific resistance, A the area, and d the thickness of the fused

tissue, $X_C = \frac{1}{\omega \cdot C}$, where X_C is the capacitive impedance, ω the frequency, and C the capacity of the tissue, and

$C = \frac{\epsilon \cdot \epsilon_0 \cdot A}{d}$, where ϵ and ϵ_0 are the relative and absolute permittivity.

[0113] The phase difference φ can then be expressed as

$$\varphi = \arctan\left(\frac{X_C}{R}\right) = \arctan\left[(\omega \cdot \epsilon \cdot \epsilon_0 \cdot \rho)^{-1}\right]$$

[0114] As such, the difference between monitoring the phase difference φ as opposed to the (ohmic) resistance R is that φ depends on the applied frequency ω and material properties only (namely, the dielectric constant ϵ and the conductivity p), but not on tissue dimensions (namely the compressed tissue area A and tissue thickness d). Furthermore, the relative change in phase difference is much larger at the end of the fusion process than the change in tissue resistance, allowing for easier and more precise measurement.

[0115] In addition, with measurement of the initial dielectric properties of the tissue (dielectric constant ϵ and conductivity p) at a certain frequency, the type of tissue can be determined. The dielectric properties for various types of biological tissue, arranged by increasing values of the product of dielectric constant ϵ and conductivity p are given in Figure 30 at a frequency of 350kHz (which is in the frequency range of a typical electrosurgical generator). By measurement of the product of the dielectric constant ϵ and the conductivity p of the tissue (which are material characteristics and independent of tissue dimensions) before the actual tissue fusion or welding process, the phase shift required to adequately fuse or seal the specific biological tissue can be determined from Figure 30. The phase shift required to reliably fuse or seal the respective type of tissue is measured as a function of the product of the dielectric constant ϵ and the conductivity p of the tissue (at 350kHz). In Figure 31, the endpoint determination is shown as a function of an initial phase reading and in Figure 32, end point determination is shown as a function of tissue properties (conductivity times relative permittivity). The function of tissue properties can also be expressed as $\phi_{\text{end}} = 38 + 29 [1 - \exp(-0.0091 \rho \epsilon)]$.

[0116] As a result, (a) measurement of the dielectric properties of the tissue and (b) control and feedback of the phase difference allows for a precise control and feedback mechanism for various tissue types, regardless of the tissue size and allows employing standard electrosurgical power supplies (which individually run in a very close range of frequencies). It should be noted however that the specific frequency at which the tissue properties measurement is performed can be the same or different from the specific frequency of the phase. If the tissue measurement is based on the driving frequency of the generator, and various generators are used (all of which run in a close range of frequencies) though, the end points will be different. Hence, for such a case, it can be desirable to (a) use an external measurement signal (which is at the same frequency), or (b) utilize a stand-alone generator.

[0117] As such, the controller is configured to determine the product of the dielectric constant and the conductivity, as well as the phase difference between the applied voltage and current to monitor and control the tissue fusion or welding process. In particular, the control and feedback circuitry of the controller determines when the phase difference reaches the phase shift value determined by the result of the dielectric and conductivity measurements. When this threshold is reached, the fusion or welding process is terminated. An indicator, e.g., visual or audible, is provided to signal the termination and in one aspect the controller restricts (completely, nearly completely or to a predetermined minimum) further delivery of electrical energy through the electrodes. As such, the tool generating the seal, weld or connection of the tissue provides atraumatic contact to the connecting tissue and provides enough burst pressure, tensile strength, or breaking strength within the tissue.

Capacitive Load Compensation of Connected Tools

[0118] In one embodiment, measuring and accounting for the tool capacitance and tool resistance are provided for consistent initial tissue assessment (conductivity and permittivity) which provides the tissue-specific endpoint of the process (i.e., coag, fuse, or weld). In another aspect of the invention, measuring and accounting for the tool capacitance and tool resistance are provided for consistent tissue feedback measurements (phase shift) which ensures consistent

tissue modification results (i.e., coag, fuse or weld).

[0119] Figure 33 shows phase diagrams of two electrosurgical tools. As can be seen, both tools are electrically represented as resistive or ohmic loads originating mainly from the wire harness 1500 connecting the hand tool to the generator, as well as the connections within the hand tools, as well as capacitive loads (originating mainly from the tool jaws, as well as the wire harness 1500 connecting the hand tool to the generator). In a phase diagram, the tool can be characterized by a phase angle.

[0120] The values of the ohmic and capacitive impedances found in typical arrangements of tools are in the range of 1-10 Ohms for the ohmic load and 1 - 100 kOhms for capacitive resistances (several ten to several hundred pF capacitance at several 100kHz). Even for two equal tools, variations in the tool characteristics (such as wire connections, harness length) can lead to different phase angles for the same tool. As will be shown in the following, these variations can lead to different tissue measurement results, both before and during tissue assessment.

[0121] As shown in Figure 34, the phase diagram of an electrosurgical tool that is in contact with tissue is composed of the resistive and capacitive component of the tool (dotted arrows) which add to the ohmic and capacitive component of the tissue (solid arrows) to present a total load to the electrosurgical generator (dashed line). For tissue measurement techniques that rely on the phase shift of voltage and current, the presence of the tool significantly alters the results of the intended tissue measurement by the apparent phase.

[0122] In this context, the presence of the tool (impedance) does not pose an actual problem if the tissue measurement before powering (to determine an end point of fuse/weld), or during powering (to determine the end point of the fuse/weld) has been defined with the very same tool (i.e., tool impedance). However, variances of the tool impedances lead to different results in both the initial tissue assessment (pointing to an inaccurate endpoint) and in the tissue feedback measurement (determining the end point of the fuse/weld).

[0123] As such, the controller used to measure the phase shift during the tissue modification process can be used to initially determine the initial tool impedance (e.g., during plug-in of the tool connector to the electrosurgical generator), where tolerances/changes in the tool characteristics are then accounted for in the tissue measurement algorithm. This will allow for tissue measurement values which are independent of the ohmic and capacitive values and/or tolerances of the specific electrosurgical tool.

[0124] Accordingly, generally speaking, when tool capacitance increases, the endpoint phase shift decreases. In particular, when the tool capacitance increases, the capacitive impedance decreases ($X=1/\omega C$). Decreased capacitive impedance leads to a smaller or decreased end point phase shift. Similarly, when tool resistance increases, the end point phase shift decreases.

[0125] Also, from an initial tissue determination perspective, generally speaking, when tool capacitance increases, the apparent initial phase shift decreases compared to the ideal value, the ideal value being a tool having zero or near zero capacitance. Similarly, when tool resistance increases, the apparent initial phase shift decreases compared to the ideal value. As such, when the tool capacitance ($C=\epsilon\epsilon_0 A/d$) and/or the tool resistance ($R=\rho d/A$) increase, there is an increase in permittivity and/or conductivity which reflects a decrease in $\tan \phi$, i.e., a decrease in phase. In one example, an electrosurgical tool having a capacitance of 160 pF had an initial phase shift of 9- 59 degrees versus a tool having a capacitance of 230 pF having an initial phase shift of 6- 23 degrees. Additionally, with tissue permittivity and conductivity product values being inversely proportional with the initial phase shift, when tool capacitance and/or resistance increases, the apparent tissue permittivity and conductivity product value increases compared to the ideal value.

[0126] Figure 35 shows the ohmic resistance of a porcine renal artery during the electrosurgical fusion process. As was shown previously, the fusion process of blood vessels and/or welding of tissue can be better controlled when the phase difference or angle between applied voltage and incurred current is measured and used to interrupt the fusion/sealing process. Depending on the type of tissue, the end point has been found to be ideal at about 40 degrees (blood vessels) or 60 degrees (intestines), respectively.

[0127] Instead of the tissue quickly reaching a pre-determined phase (ranging from 40 to 60 degrees, depending on the type of tissue), the measured phase shift approaches the cut-off threshold asymptotically. This is shown in Figure 36 for the same seal as given in Figure 35. As can be seen, the phase shift quickly increases during the initial fusion process, but then increases slowly for the remainder of the seal. The asymptotic approach can require a significant amount of time to reach the final phase threshold (e.g., 40 degrees). As such, instead of depending on the phase value to reach a definite value alone, additionally the derivative of the phase can be used to avoid asymptotic approaches to a finalized phase value. The derivative of the phase value of the same seal is shown in Figure 37. As shown, the phase changes (increases) strongly during the first 0.5s into the seal and changes little for the remainder of the seal. After about 1.5s sealing time, the derivative of the phase $d\phi/dt$ reaches a pre-determined value of 0.1 degrees / second to terminate the seal (independent of the actual phase reading).

[0128] Additionally, the determined phase value can be overshoot without being detected, for example, when the phase trip level is reached during the read out time of the processor controlling the power supply. In such cases, the processor may not recognize that the final phase stop has been reached. This is shown in Figure 38 for welding of porcine intestines. As can be seen, the phase shift overshoots a pre-determined phase threshold of 60 degrees, but instead reaches an

asymptotic steady- state level of 50 degrees. Instead of relying on the phase value to reach a definite value alone, the derivative of the phase is also used to ensure the seal to end.

[0129] The derivative of the phase value of the same seal is shown in Figure 39. As shown, the phase changes (increases) strongly during the first 0.25s into the weld and changes only little for the remainder of the seal. At about 1.5s into the weld, the derivative of the phase $d\phi/dt$ reaches a pre-determined value of 0.1 degrees / second and terminates the weld (independent of the actual phase reading). The derivative of the phase in one embodiment is set to 0.02 degrees per second. A range of phase derivative from 0.2 to 0.01 degrees per second has also been found to be acceptable. In the latter case, the derivative of the phase angle reading provides a safety feature for terminating a seal/ weld.

[0130] As previously described and described throughout the application, the electrosurgical generator ultimately supplies RF energy to a connected electrosurgical tool. The electrosurgical generator ensures that the supplied RF energy does not exceed specified parameters and detects faults or error conditions. An electrosurgical tool provides the commands or logic used to appropriately apply RF energy for a surgical procedure. An electrosurgical tool includes memory having commands and parameters that dictate the operation of the tool in conjunction with the electrosurgical generator. For example, in a simple case, the generator can supply the RF energy but the connected tool decides how much energy is applied. The generator however does not allow the supply of RF energy to exceed a set threshold even if directed to do so by the connected tool, thereby providing a check or assurance against a faulty tool command.

[0131] Each tool may come with an integrated circuit that provides tool authentication, configuration, expiration, and logging. Connection of tools into the receptacles or ports initiates a tool verification and identification process. Tool authentication may be provided via a challenge-response scheme and/or a stored secret key also shared by the controller. Other parameters have hash keys for integrity checks. Usages are logged to the controller and/or to the tool integrated circuit. Errors can result in unlogged usage. The log record is set in binary and interpreted with offline tools or via the controller.

[0132] Connection of a standard bipolar tool into the standard bipolar outlet may possibly not actively check the tool. However, the controller recognizes a connection so that the information on the bipolar outlet can be displayed on the monitor or user interface of the unit. The display reserves a field for the bipolar outlet before the outlet is activated. The controller may use time measurement components to monitor a tool's expiration. Such components utilize polling oscillators, timer or real-time calendar clocks and are configured at boot time. Timer interrupts are handled by the controller and can be used by scripts for timeouts. Logging also utilizes timers or counters to timestamp logged events.

[0133] The tool may have memory integrated with or removable from the tool. A tool algorithm or script within the tool's memory is loaded into a script interpreter of the generator. The script provides commands and parameters readying the tool for use when connected to the generator. Upon activation of a switch coupled to the tool, the controller detects the switch closure, and authenticates the tool, checks the tool's expiration status, and initializes internal data structures representing the receptacle's tool. A subsequent activation of the tool switch initiates an event that causes the script to direct the generator to supply RF energy. The controller logs the usage to both the tool and the generator. When the tool is disconnected from the receptacle of the generator, the controller resets the information associated with the receptacle. The controller constantly monitors the generator for proper operation. Unrecoverable errors and faults are announced and further operation of the system is prevented. All faults are stored in the controller's memory and/or the tool's memory.

[0134] Data from a specific procedure (e.g., from power-up to power-down) is stored on each tool. The tool additionally holds the data from a procedure, i.e., the number of tool uses, the power setting and faults. Each tool may hold the information from all other tools as well. Tool memory includes but is not limited to the following parameters: serial number of generator, time stamp, tissue assessment and endpoint setting for each tool use, cut, coagulation, weld, power setting, duration of RF and endpoint (auto stop, fault, manual stop).

[0135] The generator logs usage details in an internal log that is down loadable. The generator has memory for storage of code and machine performance. The generator has reprogrammable memory that contains instructions for specific tool performance. The memory for example retains a serial number and tool use parameters. The generator stores information on the type of tools connected. Such information includes a tool identifier, e.g., a serial number of a connected tool, along with a time stamp, number of uses or duration of use of the connected tool, power setting of each and changes made to the default setting. The memory may hold data for about two months or about 10,000 tool uses and is configured to overwrite itself as needed.

[0136] The controlled include may include a state machine interpreter module that parses tool scripts. Tool scripts represent a tool process for a specific or given tool. The tool scripts are stored on memory connected to or integrated with a tool, the controller or a combination thereof. The state machine interpreter module responds to specific events, such as a switch activation/de-activation, tool positions or exceeding measurement thresholds. The module upon response controls the output of RF energy and/or electrode activation. An interpreter module may be provided for each tool input receptacle. The controller detects tool events and forwards the detected event to the appropriate interpreter module. The module in turn requests actions of the controller based on the detected event which provides output to the

connected tool associated with the appropriate tool input receptacle and also the appropriate interpreter module.

[0137] The controller may have a specific or predetermined fixed tool script for a specific input receptacle. As such, only this tool script is used for the tool connected to the particular input receptacle. The interpreter module includes an event detector and a script parser. The event detector receives and identifies tool events, such as a switch activation/de-activation event or a measurement event (e.g., phase threshold exceeded). The event detector formulates requests to the controller to control RF output, output selection and/or selection of outputs, changes to the display and audio tones. Other events detected include detecting hand and foot switches, jaw switches, phase over and phase under-after-over events, shorts and opens and tool script states. The script parser interprets the tool scripts. Keywords in the scripts assist the script parser to extract operational commands and data for tool operation based on a detected event identified by the event detector. In addition to the voltage and current set points, a tool script specifies the RF source as from the CUT or the COAG source. The script also specifies which electrodes get connected to RF+, RF- or are allowed to float. Because the script controls the electrode configuration, and can set thresholds that trigger events, a script can completely reconfigure a tool during its use.

[0138] The script controls the voltage and current output settings as well as sequences of voltage and current settings. For example the permittivity and conductivity of blood vessels are the same independent of size. A small blood vessel will fuse very rapidly while a large vessel may take several seconds. Applying a large amount of current to a small vessel may cause excess tissue damage, while using a small amount of current will make it take an unacceptably long time to perform the fusion function. So to modify tool performance the script can initially command a small amount of RF current, and if the fusion endpoint is not reached in less than one second, a high current is commanded to speed up the fusion of a large vessel. Another script usage to modify tool performance to switch from one operation (coagulation) to another operation (cut) is to reconfigure the tool electrodes and the ESG output to simplify a multistep process such as fuse and cut. When the clinician starts the process the script will first setup the unit for the fusion and measure the tissue phase angle that indicates the fusion endpoint. RF power is then turned on until the fusion endpoint is reached. The unit will then turn off RF power and beep to indicate that fusion is complete. The unit then switches the electrodes to the cut configuration, sets the RF output for cut, and restarts the RF output. The cut operation is stopped by the clinician when the cut is completed.

[0139] Referring to Figure 40, an overview of tool operations is provided. A tool connected to the electrosurgical generator is verified at 601. The endpoint is determined at 602. The tool applies energy at 603, e.g., RF energy, and continues until an endpoint is reached or an error condition is detected. Upon determination of an endpoint being reached or exceeded 604, the tool is deactivated (e.g., application of energy is stopped) the process is thus ended.

[0140] Based on the tool algorithm for the connected tool, the tool verification and determination of an end point can vary. In particular, a tool short is determined by measuring resistance at a tissue contacting surface of the tool. If the resistance is less than ten (10) Ohms, a tool short condition is recognized. In accordance with various embodiments, the product of measured tissue permittivity and conductivity or an initial phase shift is utilized to determine the end point for a connected tool.

[0141] In accordance with various embodiments, phase shift and/or a phase rate of change is measured throughout the process to determine if an endpoint is reached or exceeded. Also, timeout parameters, e.g., a timer or counter reaching or exceeding a set time limit, or a fault condition stops or interrupts the process even if the determined end point is not reached or exceeded.

Handheld Electrosurgical Tools

[0142] As described generally above and described in further detail below, various handheld electrosurgical tools can be used in the electrosurgical systems described herein. For example, electrosurgical graspers, scissors, tweezers, probes, needles, and other instruments incorporating one, some, or all of the aspects discussed herein can provide various advantages in an electrosurgical system. Various electrosurgical tools are discussed below. It is contemplated that one, some, or all of the features discussed generally below can be included in any of the tools discussed below. For example, it can be desirable that each of the tools described below include a memory for interaction with a feedback circuit as described above. However, in other cases, the tools described below can be configured to interact with a standard bipolar power source without interaction of a tool memory. Certain aspects of these electrosurgical tools are discussed generally herein, and in more detail below.

[0143] As discussed above with respect to Figures 1A and 1B, an electrosurgical tool can desirably include a memory. The memory can include an encryption module and a configuration device module. The configuration device module can store certain types of tool data. For example the configuration device module can store operational parameters for the tool, including software to be transferred to an electrosurgical unit upon successful electrical connection to the electrosurgical unit. These operational parameters can include data regarding various electrosurgical procedures to be performed by the tool and corresponding energy level ranges and durations for these operations, data regarding an electrode configuration of a tool, and data regarding switching between electrodes to perform different electrosurgical

procedures with the tool. Advantageously, changes to tool profiles and periodic tool updates can be rapidly made without downtime to electrosurgical generators, as the software for tool operation can reside in the electrosurgical tool itself, rather than the generator. Accordingly, updates can be made during tool production.

[0144] The configuration device module can further store a data log comprising, for example, a record of information of each previous tool use. For example, the data log can contain timestamp data including an electrosurgical unit identifier, a log of electrosurgical procedures performed by the tool, and a log of durations and of energies applied to the tool. It can be desirable that use of a particular tool is limited to a maximum usage period or number of procedures, especially where the electrosurgical tool has not been configured for sterilization and reuse. Accordingly, the configuration device module can be configured to prevent operation of a tool after a predetermined usage or number of procedures. A tool can comprise a mechanical lockout in addition to or in place of the data log, such as a breakaway single-use connector to reduce the possibility of unintended reuse.

[0145] It may be desirable that the tool communicate with the electrosurgical unit through an encrypted protocol. Accordingly, the memory can further store an encryption module, or encryption key to facilitate this encrypted communication.

[0146] As discussed above, it can be desirable that an electrosurgical tool for use in the electrosurgical system include one or more audio and/or visual indicators. The electrosurgical tool can include an array of LEDs, or a multi-color LED assembly such as a three-color LED assembly capable of generating many combined colors. The visual indicator can be configured to illuminate with a color corresponding to the type of electrosurgical procedure performed by the tool. Where a tool is configured to perform multiple different types of electrosurgical procedures, desirably the visual indicator updates to reflect the currently-selected electrosurgical procedure. Thus, advantageously, a user can tell, while watching the surgical field, what type of electrosurgical procedure the tool is configured to perform.

Electrosurgical Fusion Tool

[0147] With reference to Figures. 41A-41B, a hand held laparoscopic sealer/divider or fusion tool 1100 is provided. The sealer/divider comprises a handle assembly 1110, an elongate shaft 1120 extending from the handle assembly 1110, and a jaw assembly 1130 positioned on the elongate shaft 1120 opposite the handle assembly 1110. The elongate shaft 1120 has a proximal end and a distal end defining a central longitudinal axis therebetween. The handle assembly 1110 comprises a pistol-grip like handle. The elongate shaft 1120 and the jaw assembly 1130, may be sized and shaped to fit through a 5 mm diameter trocar cannula or access port. In other cases, the elongate shaft and jaw assembly can be sized and configured to fit through trocar cannulae or access ports having other standard, or non-standard sizes. In Figure 41A, the handle assembly 1110 is shown in a first or initial position in which the jaws are open.

[0148] With reference to Figures. 41A-42B, the handle assembly 1110 comprises a stationary handle 1112 and an actuation handle 1114 movably coupled to the stationary handle. The stationary handle 1112 comprises a housing formed of right 1112R and left handle 1112L frames. Alternatively, the stationary handle 1112 can be a single component, or can be a housing formed of more than two pieces. In the illustrated case, the actuation handle 1114 is slidably and pivotally coupled to the stationary housing, as discussed in further detail below. In operation, the actuation handle 1114 can be manipulated by a user, e.g., a surgeon to actuate the jaw assembly, for example, selectively opening and closing the jaws.

[0149] With continued reference to Figures 42A-42B, the actuation handle 1114 is coupled to the stationary handle 1112 to form a force regulation mechanism 1200 coupling the handle assembly 1110 to the jaw assembly 1130. Desirably, the force regulation mechanism 1200 can be configured such that in a closed configuration, the jaw assembly 1130 delivers a gripping force between the first jaw 1132 and the second jaw 1134 between a predetermined minimum force and a predetermined maximum force.

[0150] With continued reference to Figures 42A-42B, in the illustrated case, the actuation handle 1114 is coupled to the stationary handle 1112 at two sliding pivot locations 1202, 1204 to form the force regulation mechanism 1200. The actuation handle 1114 has a first end 1116 including a gripping surface formed thereon, and a second end 1118 opposite the first end 1116. In the illustrated case, the actuation handle 1114 is coupled to a pin 1206 adjacent the second end 1118. The actuation handle 1114 can be integrally formed with a protrusion extending therefrom defining a pin surface, while in other cases, a pin can be press-fit into an aperture in the actuation handle. The 1206 pin can be contained within slots in the stationary handle 1112, such as corresponding slots formed in the right and left handle frames 1112R, 1112L of the stationary handle housing. These slots can allow the sliding pin 1206 to move over a predetermined range. In some cases, the slots can be configured to define a desired actuation handle path as the actuation handle is moved from the first position corresponding to open jaws to a second position corresponding to closed jaws. For example, the illustrated case includes generally linear slots formed in the stationary handle 1112 at an angle from the central longitudinal axis of the elongate shaft 1120. In other cases, the slots can be formed generally parallel to the central longitudinal axis. Alternatively, the slots can be curvilinear.

[0151] The force regulation mechanism 1200 includes a biasing member such as a trigger spring 1208 that biases

the pin in a proximal direction towards the rear of the pin slots in the right and left handle frames (see, for example, Figure 42B). The trigger spring 1208 and the actuation handle 1114 can pivot freely or unhindered at their attachment point 1202. The biasing member 1208 can be preloaded to a predetermined force. In operation, as a predetermined force is exerted on the actuation handle 1114, a biasing force exerted by the trigger spring 1208 is overcome, and the second end 1118 of the actuation handle 1114 can translate generally distally, guided by the pin in the slots.

[0152] While the illustrated case includes a pin-in-slot arrangement coupling one pivot point of the actuation handle to the stationary handle, in other cases, it is contemplated that other connections can be formed. For example, a slot can be formed in the actuation handle and a mating projection can be formed in the stationary handle. Furthermore, while the illustrated case includes a tension coil spring forming the biasing member, in other cases, other biasing members are contemplated. For example, the biasing member can comprise a compression spring, a torsion spring, an elastomeric band, a fluid-filled shock absorbing unit, or another suitable biasing device.

[0153] With continued reference to Figures 42A-42B, the actuation handle 1114 is slidably and pivotably coupled to the stationary handle 1112 at a location between the first and second ends 1116, 1118 of the actuation handle. An actuation member such as a pull block 1250 can be coupled to the actuation handle. In the illustrated case, an actuation path of the pull block 1250 is defined by rails formed in the right and left handle frames 1112L, 1112R. When the actuation handle 1114 is moved proximally, the pull block 1250 also moves, effectively closing the jaws thereby clamping any tissue between the jaws. In the illustrated case, the rails guide the pull block 1250 to slide proximally and distally while limiting movement in other directions. Alternatively, various other guide members such as a pin-in-slot arrangement can define the actuation path of the actuation member.

[0154] As illustrated, the pull block 1250 comprises a generally rectangular prismatic structure having a generally open top and bottom faces and a substantially closed proximal end. The actuation handle 1114 can extend through the top and bottom faces of the pull block 1250. An edge of the actuation handle 1114 can bear on the proximal end of the pull block 1250 such that movement of the actuation handle 1114 relative to the stationary handle can move the pull block 1250 generally longitudinally along the actuation path defined by the rails. A distal end of the pull block 1250 can be coupled with an actuation shaft such as an actuation tube, bar, or rod, which can extend longitudinally along the elongate shaft of the sealer/divider. Thus, in operation, movement of the actuation handle 1114 from the first position to the second position translates the pull block 1250 longitudinally within the stationary housing, which correspondingly translates the actuation rod generally linearly along the longitudinal axis with respect to the elongate shaft. Movement of this actuation tube can control relative movement of the jaws in the jaw assembly.

[0155] With continued reference to Figures 42A and 42B, the sealer/divider can include a latch mechanism 1260 to maintain the actuation handle 1114 in the second position with respect to the stationary handle. The actuation trigger comprises an extended latch arm 1262 which can engage a matching latch 1264 contained within actuation handle 1112 for holding the actuation trigger at a second or closed position. Alternatively, it is contemplated that the one portion of the latch mechanism can be formed on a portion of the actuation handle 1114 adjacent the second end of the actuation handle 1114, and a mating portion of the latch mechanism can be formed on the actuation handle 1112. It is also contemplated that a portion of the latch mechanism can be formed on the pull block 1250 and a mating portion of the latch mechanism can be formed on the stationary housing.

[0156] The jaw assembly 1130 of the sealer/divider may comprise an advanceable cutting blade 1400 (Figure 44B) that can be coupled to a blade actuator such as a blade trigger 1402 positioned on the handle assembly 1110. A blade actuation mechanism 1404 can operatively couple the blade trigger to the cutting blade. The blade trigger 1402 is positioned on a proximal surface of the handle assembly such that it can be easily operated in a pistol-grip fashion. As illustrated, the blade actuation mechanism 1404 comprises a pivoting blade advancement link that transfers and reverses the proximal motion of the blade trigger 1402 to a blade actuation shaft assembly coupled to the cutting blade. Alternatively, the blade trigger 1402 can be positioned elsewhere on the actuation handle 1112 such as on a distal surface of the actuation handle 1112 such that distal movement of the blade trigger 1402 can advance the cutting blade distally without transfer of advancement directions via a linkage. In operation, a user can move the blade trigger 1402 proximally to advance the cutting blade 1400 from a retracted position to an extended position. The blade actuation mechanism 1404 can include a biasing member such as a blade return spring 1406 to bias the blade advancement lever distally within the actuator and thereby bias the cutting blade 1400 into the retracted position.

[0157] With reference to Figure 42C, the handle assembly also comprises a wire harness 1500. The wire harness 1500, may comprise six insulated individual electrical wires or leads contained within a single sheath. As illustrated, the wire harness 1500 can exit the housing of the actuation handle 1112 at a lower surface thereof and can run generally upwards along the interior of the actuation handle 1112. Other wire routings can also be made. For example, the wire harness 1500 can exit a lower portion of the proximal surface of the actuation handle 1112. The wires within the harness can provide electrical communication between the sealer/divider and an electrosurgical generator and/or accessories thereof, as discussed above.

[0158] Inside the actuation handle 1112, two of the leads may be attached to rotational coupling clips 1502 configured to allow infinite rotation of the jaw assembly 1130; two of the other leads are attached to a visible indicator 1504, such

as a multi-colored LED, and the remaining two leads are attached to a switch 1506. The switch 1506 may be connected to a user manipulated activation button and may be activated when the activation button is depressed. In one aspect, once activated, the switch 1506 completes a circuit by electrically coupling the two leads together. As such, an electrical path is then established from an electrosurgical generator to the actuator to supply radio frequency power to one of the two leads attached to the rotational coupling clips 1502.

[0159] Referring now to Figure 43, the handle assembly is coupled to a rotational shaft assembly 1600. Coupling of the handle assembly to the rotational shaft assembly 1600 may be configured to allow infinite 360 degree rotation of the jaw assembly 1130 with respect to the handle assembly. In the illustrated case, the handle assembly 1110 connects to the shaft 1120 at five locations or connections providing a continuous 360 degree rotation of the entire shaft while simultaneously allowing complete actuation of the actuation handle 1114, e.g., for sealing and/or dividing of the vessel. As illustrated, the first two connections are rotational coupling clips 1502 which make contact with the rotational shaft assembly at the actuation tube and conductive sleeve. The next area of engagement or the third connection is a rotational hub assembly 1602 which is located between the two rotational coupling clips 1502.

[0160] With continued reference to Figure 43, the rotational shaft assembly 1600 is desirably contained within the right and left handle frames such that proximal and distal movement of the jaw assembly 1130 with respect to the handle assembly 1110 is prevented while allowing for rotational movement. For example, inwardly-extending flanges can be formed on the actuation handle 1112 that interfere with proximal and distal movement of the rotational hub assembly 1602, rotational coupling clips 1502, or other components of the rotational shaft assembly 1600. The fourth connection is at a plurality of threaded nuts 1604 and the pull block 1250. The fifth connection is between the blade lever 1608 and a rear blade shaft 1606. The rotation shaft assembly 1600 can also comprise a rotation knob 1610 which is fixed to the outer cover tube. The rotation knob 1610 allows the surgeon to rotate the shaft of the device while gripping the handle. While the rotational shaft assembly 1600 is illustrated as having five connection locations with the actuation handle 1112, in some cases, a rotational shaft assembly can have fewer connection locations, such as for example, 1, 2, 3, or 4 connection locations. In still other cases, it can be desirable that a rotational shaft assembly have more than 5 connection locations, such as, for example 6, 7, 8, or more than 8 connection locations.

[0161] Desirably, the rotational shaft assembly 1600 provides the vessel sealer/divider with continuous 360 degree rotation throughout operation of the electrosurgical instrument. By using rotational coupling clips 1502 for the electrical connections to the shaft, the shaft can operate, e.g., deliver RF energy, at any orientation or rotation of the jaw assembly 1130 relative to the handle assembly. Thus, advantageously, the surgeon is provided more surgical options for the placement and activation of the sealer/divider. Advantageously, with a rotational shaft assembly 1600, the wires and electrical and mechanical connections, as such, do not interfere with the continuous, infinite rotation of the shaft. To maintain a bipolar connection through the rotational shaft assembly 1600, one of the electrical connections is electrically isolated from other conductive portions of the shaft.

[0162] As discussed in further detail below, in some cases, the sealer/divider can be configured to grasp with a gripping force within a predetermined range. An overall tolerance stack-up over the length of the shaft can be controlled so that the force applied to the jaw assembly 1130 from the handle assembly can be maintained accurately within the predetermined range. The overall length of the shaft 1120 can be controlled by using threaded nuts 1604 and a threaded coupling. The threaded nuts 1604 can be adjusted to tightly control the length of the elongate shaft 1120. The length is controlled by maintaining the location of the threaded nuts 1604 in relation to the hub portions of the shaft. In the illustrated case, attached to the distal end of the actuation tube is a threaded coupling. Attached to the threaded coupling are two threaded nuts, which are configured to engage with the pull block 1250. The pull block 1250 engages with the threaded nuts 1604 which are attached to the rear of the actuation tube, causing the actuation tube to move proximally. The described interaction can also be reversed so that the threaded nuts 1604 and coupling are attached to an outer cover tube rather than the actuation tube. In other cases, other length adjustment mechanisms can be used to control the overall tolerance stack-up such as a lock screw to selectively secure the position of the pull block 1250 at a desired location relative to the actuation tube or toothed ratchet interfaces defining set distance relationships between the pull block and the actuation tube. In other cases, a length adjustment mechanism can be positioned at the distal end of the elongate shaft, e.g., where the elongate shaft interfaces with the jaw assembly 1130.

[0163] Referring to Figures 44A-44D, the elongate shaft 1120 can comprise a plurality of actuation members extending therethrough. In the illustrated case, the elongate shaft comprises an actuation tube 1122 coupling the jaw assembly 1130 with the handle assembly 1110 and a blade actuation shaft assembly 1124 coupling the blade trigger 1402 with the cutting blade. In some cases, the blade actuation shaft assembly 1124 comprises a two-piece shaft having a proximal portion and a distal portion. The proximal portion of the blade shaft assembly can terminate at a proximal end at an interface node 1126. In the illustrated case, the interface node 1126 comprises a generally spherical protrusion portion which is adapted to engage the blade advancing lever. In other cases, the interface node can comprise other geometries such as cubic or rectangular prismatic protrusions. In the illustrated case, the proximal portion of the blade shaft is operatively coupled to the distal portion of the blade shaft assembly 1124. The distal portion of the blade shaft can comprise a mount at its distal end for attachment of the cutting blade. In the illustrated case, the mount comprises at

least one heat stake post. In certain embodiments, both the proximal and distal portions of the blade shaft are at least partially positioned within a generally tubular section of the actuation tube 1122. (see, e.g., Figure 44C).

[0164] As discussed above with respect to length adjustment of the elongate shaft 1120, in the illustrated case attached to the distal end of the actuation tube 1122 is a threaded coupling 1150 (Figure 44D). As illustrated, attached to the threaded coupling 1150 are two thread nuts 1604, which are configured to engage with the pull block 1250. In the illustrated case, the actuation tube 1122 is housed within an outer cover tube. While the actuation tube 1122 is illustrated as a generally tubular member that can be nested within the outer cover tube 1126, and that can have a blade actuation shaft 1124 nested within it, in other cases, a non-tubular actuation member can be used, for example, a shaft, a rigid band, or a link, which, in certain cases can be positioned generally parallel to the blade actuation shaft within the outer cover tube.

[0165] With continued reference to Figure 44A, in the illustrated case, attached to the distal end of the outer cover tube 1126 is the rotational shaft assembly 1600. The rotational shaft assembly 1600 comprises two mating hubs 1602 and a conductive sleeve 1610. In the illustrated case, the hubs 1602 snap together, engaging with the outer cover tube. Alternatively, the hubs can be of a monolithic construction and configured to interface with mating features on the outer cover tube. The conductive sleeve 1610 can be attached to the proximal portion of the assembled hubs after they are attached to the outer cover tube. When the conductive sleeve 1610 is attached to the rear of the assembled hubs 1602, the sleeve 1610 traps the exposed end of an isolated wire 1612 (see Figure 44D). In the illustrated case, the isolated wire 1612 extends from its entrapment point under the conductive sleeve through a slot in the actuation tube 1122 and then inside a protective sleeve 1614. The protective sleeve 1614 and isolated wire 1612 extend distally inside the actuation tube 1122, towards the jaw assembly 1130. In other cases, the isolated wire can be formed integrally with a protective sheath and no separate protective sleeve is present in the actuation tube.

[0166] With reference to Figures. 45A-45C, attached to the distal end of the elongate shaft 1120 is the jaw assembly 1130. In certain cases, the jaw assembly 1130 comprises a lower jaw 1134, upper jaw 1132, upper conductive assembly 1142, lower nonconductive spacer 1144, and jaw pivot pin 1146. The jaw pivot pin 1146 pivotally couples the upper and lower jaws 1132, 1134 and allows the upper jaw 1132 to pivot relative to the lower jaw 1134. Other pivotal couplings are possible. As illustrated, the proximal portion of the upper jaw 1132 extends through the lower jaw 1134 and into a hole in the actuation tube 1122.

[0167] One jaw can be fixed with respect to the elongate shaft 1120 such that the opposing jaw pivots with respect to the fixed jaw between an open and a closed position. For example, in the illustrated case, the proximal portion of the lower jaw 1134 extends inside the cover tube 1126 and is crimped in place, fixing the jaw assembly 1130 to the rotation shaft assembly 1600. Thus, the upper jaw 1132 is moveable with respect to a fixed lower jaw 1134. In other cases, both jaws can be pivotally coupled to the elongate shaft such that both jaws can pivot with respect to each other.

[0168] Attached to the upper jaw 1132 is the upper conductive assembly 1142, which comprises a nonconductive portion 1702 and a conductive pad 1704 (see Figure 45B). The nonconductive portion 1702 isolates the conductive pad 1704 from the upper jaw 1132, likewise isolating it from the rest of the shaft assembly 1120. The isolated wire 1612 can be routed to electrically couple the conductive pad 1704 on the upper jaw 1132 to the wiring harness 1500 in the handle assembly 1110. The isolated wire 1612 extends from the distal end of the protective sleeve which is housed at the proximal end of the lower jaw and extends into the upper jaw 1132. The upper jaw 1132 can have a slot positioned to receive the isolated wire. The isolated wire 1612 then extends through a hole in the upper jaw 1132 and drops into a slot in the nonconductive portion. The isolated wire then extends to the distal end of the nonconductive portion and drops through to the conductive pad (see Figure 44D).

[0169] The jaw assembly 1130 can include one or more nonconductive space maintaining members such as spacers 1144 to reduce the risk that electrodes on the upper jaw 1132 and lower jaw 1134 can come into direct contact and create a short. In the illustrated case, the lower nonconductive spacer 1144 is housed inside the u-groove portion of the lower jaw and contains space maintaining protrusions which prevent the conductive pad from contacting the lower jaw (see Figure 45C).

[0170] Turning now to some of the operational aspects of the electrosurgical instruments described herein, once a vessel 1030 or tissue bundle has been identified for sealing, the upper and lower jaws are placed around the tissue (see Figure 46A). The actuation handle 1114 is squeezed moving the actuation handle 1114 proximally with respect to the actuation handle 1112 (see Figure 46B). As the actuation handle 1114 moves proximally it pushes the pull block 1250 along the rails in the right and left handle frames. The pull block 1250 engages with the threaded nuts 1604 which are attached to the rear of the actuation tube 1122, causing the actuation tube 1122 to move proximally. Proximal movement of the actuation tube pivots the upper jaw 1132, coupled to the pull tube, towards the lower jaw, effectively clamping the tissue (see Figure 46C). The force applied to the tissue by the upper jaw is translated through the pull tube and pull block 1250 to the actuation handle 1114. Once the preloaded force has been overcome, the actuation handle 1114 will begin to move the sliding pin 1206 distally (see Figure 46D). When the preload on the trigger spring has been overcome, the actuation handle 1114 pivot point shifts from the sliding pin 1206 to the rear portion of the pull block 1250 where it contacts the actuation trigger. The sliding pin 1206 can advance distally because the preloaded force on the trigger

spring 1208 has been overcome.

[0171] The continued manipulation of the actuation handle 1114 pivots the actuation handle 1114 to a location where the actuation handle 1114 engages with the latch mechanism 1260 in the right and left handle frames that maintains the trigger in the engaged position and prevents the trigger from returning to an opened position. When the engaged position is reached and nothing is present between the upper and lower jaws 1132, 1134, the trigger spring is extended to a distance that ensures that the force applied to the electrodes of the jaw assembly 1130 is near the lower end of the force range required for optimal vessel sealing. When a large, e.g., maximum, amount of tissue is placed in the jaws, the actuation handle 1114 extends the trigger spring 1208 a greater distance. However, the trigger spring 1208 ensures that the maximum amount of force applied does not exceed the maximum end of the force range used for optimal vessel sealing. From the engaged position, sealing radio frequency energy is applied to the tissue by depressing the power activation button. Once the tissue has been sealed, the actuation trigger can be reopened by continuing proximal advancement to a position that allows the actuation trigger's finger portion to disengage from the latch portions of the left and right handle frames. (See Figures. 46A-46F))

[0172] The floating dual pivoting mechanism including a sliding pin 1206 and a pull block 1250 described above desirably provides a minimum force, optimal for sealing vessels and tissue, and maintained regardless of the amount of substance contained between the upper and lower jaws. This mechanism also reduces the risk that an extremely large amount of force is applied to the tissue. If too much force is applied to a vessel or tissue bundle, potential damage could occur. Thus, if a very small vessel or thin tissue bundle is clamped within the jaw, the instrument applies the minimum amount of force required to obtain a good tissue weld. The same is true with a very large vessel or tissue bundle. Since the travel of the jaw can vary greatly depending on tissue thickness, the force applied by the jaw is adjustable. It is desired that the instrument be self-adjusting and automatic (no action from the user). The floating dual pivot mechanism described provides the self-adjustment, applying a specific range of force along the length of the electrode.

[0173] Once the actuation handle 1114 has been depressed to a predetermined force range for optimal vessel sealing, it will engage the matching latch of the right and left handle frames, locking the actuation trigger from moving further distally (See Figure 46E). At this point the user can depress the activation button, applying the appropriate energy to the tissue for proper sealing.

[0174] Once the tissue has been sealed, the user can actuate the blade trigger 1402. When the blade trigger 1402 is moved proximally, the blade lever pivots, forcing the front and rear blade shafts and cutting blade 1400 to move distally. The cutting blade advances forward and divides the sealed portion of the tissue (see Figure 46F). When the user releases the blade trigger 1402, the blade spring resets the cutting blade to its original position. When the blade trigger 1402 has been returned to its original or initial position the user can continue to squeeze the actuation handle 1114 to open the upper jaw. Continued proximal movement of the actuation handle 1114 will disengage the actuation handle 1114 from the latch mechanism 1260 of the right and left handle frames by biasing the extended arm portion 1262 of the actuation trigger upwards, over the end of the latch, to a position where the trigger can be released (see Figure 46G).

[0175] The electrosurgical instrument is connectable to an electrosurgical generator specifically configured to apply the proper amount of energy to the tissue when the activation button is depressed, such as the electrosurgical generator described above. With reference to Figure 47, the instrument is also connectable to an intermediate control unit 1800 in conjunction with an electrosurgical generator. The intermediate control unit 1800 can monitor the tissue sealing and ensure that the proper amount of sealing energy is applied to the tissue. The control unit 1800 in one aspect can have a set of cables configured to plug into most typical electrosurgical generators. The control unit also has a port for connecting the wiring harness 1500 plug from the instrument (see Figure 47).

[0176] With continued reference to Figure 47, the non-sterile power controller interfaces with the sterile vessel sealer/divider through a cord extending from the sealer/divider beyond the sterile field and plugged into the controller. In one aspect, the controller regulates and/or distributes power from a non-sterile reusable power supply to which the controller is attached or integrated. The controller can be configured for a single use to maintain sterility of the surgical environment. In order to prevent reuse of the non-reusable controller, the cord of the electrosurgical tool, once plugged into the non-sterile controller cannot be removed. This connection permanently couples the sterile and non-sterile portions, preventing the user from being able to disconnect the controller for reuse in unintended surgical procedures or purposes. (see Figure 47)

[0177] In grasping jaw assemblies such as the jaw assembly 1130 of the electrosurgical tool, the gripping force generated between the jaws can vary along the length of the jaws from a relative maximum F_{max} near the proximal end to a relative minimum F_{min} near the distal end. In some cases, the electrosurgical tool can be configured such that the forces are optimized along the length of the active electrode portions of the jaws, a predetermined force range for vessel sealing being maintained. A predetermined maximum amount of force utilized to obtain a proper vessel seal is desirably not exceeded at the proximal end of the active electrodes (closest to the pivot). In addition a gripping force at the distal most ends of the active electrodes is desirably greater than a predetermined minimum amount of force for optimal vessel sealing. Desirably, the gripping force generated at every point along the jaw assembly 1130 is within the range defined

by the predetermined maximum force and the predetermined minimum force to achieve optimal sealing. (See Figure 48A).

[0178] In some cases, the electrode width to form vessel seals is between about 0.25 mm and about 1.5 mm. In other cases, the electrode width is desirably between about 0.4 mm and about 1 mm. In other cases, the electrode width is preferably between about 0.6 mm and 0.8 mm. In some cases, the electrode width is approximately 0.75 mm. With an electrode of 0.75 mm, the sufficient force for this type of electrode to achieve a vessel seal is approximately 10 N (3 pounds) (see Figures. 48B and 48C). However it can be seen from Figure 48C that a force range of approximately 2 N to 23 N (0.4 pound to 2.3 kg) on a 0.75 mm electrode can maintain burst pressures greater than 100 kPa (15 psi). In some cases, the jaw and electrode arrangement desirably can maintain a pressure of between 300 kPa and 3800 kPa (3 and 39 kg/cm²), more desirably 1000 kPa - 3000 kPa (10-30 kg/cm²) and preferably approximately 2300 kPa (23 kg/cm²). Tools having different electrode widths can have different force ranges. In order to maximize sealing surface area while still maintaining the electrode configuration described above, in some cases, multiple rows of 0.75 mm electrodes may be provided (see Figure 48D).

[0179] In some cases, electrode geometry on the conductive pads of the jaw assembly 1130 ensures that the sealing area completely encloses the distal portion of the blade cutting path. Single linear electrodes could cause vessel leakage when only a portion of a vessel is sealed. In one case, the electrodes positioned on the jaw assembly 1130 comprise a single u-shaped electrode 1902 surface on each of the upper and lower jaws. Each u-shaped electrode can comprise generally parallel linear legs 1910 extending from a proximal end of the conductive pad of the jaw towards the distal end and a curved connector 1912 at the distal end extending from one leg to the opposite leg. Desirably, the u-shaped electrodes can completely encompass the distal end of the blade cutting path. In other cases, to provide a greater sealing area, two or more spaced u-shaped electrode surfaces on both the upper and lower jaws can be provided (see Figure 49). In some cases, the electrodes 1904 can be connected at the distal ends to create a completely enclosed seal (see Figure 49). In certain cases one or multiple bridge members 1908 between the u-shaped electrode 1906 surfaces can further ensure that the sealing area completely encloses the distal portion of the blade cutting path.

[0180] In some cases, for some surgical procedures the outer shape of the jaws 1130' can be curved such that the distal ends of the jaws are offset with respect to the longitudinal axis from the proximal ends of the jaws to improve visibility for a user such as a surgeon. In tools with curved jaws, the u-shaped electrodes can also be provided in a curved fashion while still maintaining proper electrode width and spacing (see Figure 50).

[0181] With reference to Figure 51, in certain cases, the electrosurgical device can include a tissue dissector formed on the jaw assembly 1130". Advantageously, this integrated tissue dissector can facilitate dissection of non-vascular tissue either bluntly or electro-surgically, without having to exchange the vessel sealer/divider with another instrument. Thus, this multiple tool functionality can advantageously facilitate quicker surgical procedures. The reduced number of tool exchanges can be especially advantageous in laparoscopic procedures or procedures with relatively limited access as tool exchanges can be time consuming in these surgical environments.

[0182] With continued reference to Figure 51, in some cases, one of the jaws of the jaw assembly 1130" can have an extended distal end distally beyond the distal end of the other jaw (see Figure 51). In the illustrated case, the lower jaw 1134" can have an extended distal end. Advantageously, in tools where the lower jaw 1134" is pivotally fixed to the elongate shaft, this extended arrangement can facilitate stability of the lower jaw during dissection. In other tools, the upper jaw 1132 can have an extended distal end, allowing the tissue dissector to be pivoted during the dissection operation by movement of the actuation handle 1114. In some tools, the extended distal end can be tapered in shape such that the distal end is relatively short and narrow compared to relatively more proximal portions of the jaw. Advantageously, this tapered shape allows the distal end to access tissue positioned in relatively confined environments while reducing the risk that adjacent tissue is contacted.

[0183] With reference to Figures 52A, 52B, both jaws of the jaw assembly 1130"" may be tapered laterally and/or in height along the length of the jaw's electrode portions, or at least part of the electrode portions. In these cases, the jaw assembly 1130"" has a low-profile distal end which can be used for tissue dissection. Advantageously, the low-profile distal end can also enhance access of the jaw assembly 1130"" to relatively confined surgical environments.

[0184] With reference to Figures 53A, 53B, a cutting/coagulating electrode can be disposed on an exterior surface of the jaw assembly 1130 to provide tissue dissection. The cut/coagulation electrode is located on the jaw at, for example, the distal end on the outer surface of either the upper or lower jaw (see Figure 53A). Desirably, the electrode 1920 can be electrically isolated or insulated from other components of the jaw assembly 1130, providing an active electrode for the bi-polar instrument. As such, an isolated wire can extend from the cut/coagulation electrode 1920 to the proximal end of the elongate shaft 1120 (similar to the isolated wire extending from the conductive pad on the upper jaw) to electrically couple the cut/coagulation electrode to the wiring harness 1500 of the electrosurgical tool in the handle assembly. In some cases, the isolated wire can extend within a protective sleeve within the outer cover tube of the elongate shaft. In other cases, the isolated wire can be integrally formed with a protective sheath. The isolated wire also in one aspect is coupled to a rotational connection, e.g., a rotational clip, similar to the isolated wire extending for the conductive pad.

[0185] With reference to Figure 53B, the cut/coagulation electrode in one aspect can be selectively activated by at

least one actuation button 1922, 1924 or switch on the handle assembly 1110. In some cases, the handle assembly can comprise a cut button 1922 to actuate the electrode with a tissue cutting electrosurgical signal and a coagulation button 1924 to actuate the electrode with a tissue coagulating electrosurgical signal. For example, in Figure 53B, separate cut and coagulation buttons are illustrated on the actuator adjacent a tissue sealing button to actuate the electrodes on inner surfaces of the jaws. In other cases, a single, multifunction switch or button can actuate the cut/coagulation electrode in the desired configuration. In still other cases, the cut/coagulation electrode can be configured to receive only a cutting or only a coagulation electrosurgical signal, and a single corresponding actuation button or switch can be used to selectively actuate the electrode.

[0186] The vessel sealer/divider can use thin metallic tubes and small diameter machined rods for the internal elongated components used to actuate jaws such as the actuation tube and the blade actuation shaft. However, such components can be costly and in some cases, manufacturing and materials costs can be desirably reduced through the use of elongate injection molded plastic components. As discussed above with respect to the blade actuation shaft 1124, costs and manufacturing difficulties can be reduced further through the use of an elongated shaft formed of two mating polymer shaft sections 124a, 1124b such as a proximal or rear shaft portion and a distal or front shaft portion. In some cases, the two shaft portions 1124a, 1124b can be connected by interlocks 1960, e.g., projections on one shaft section or component mating with corresponding slots on the other shaft section, to maintain concentricity and prevent unnecessary movement in their axial direction (see Figure 54A-C). In other cases, other mating structures can be formed on the two mating shaft portions. For example, one of the shaft portions can be formed with one or more barbs thereon and the other shaft portion can be formed with a recess configured to receive and retain the barbs. In still other cases, the two mating shaft portions can be adhered with a chemical adhesive or epoxy, either in addition to, or in place of interlocks formed on the shaft portions.

[0187] With reference to Figures 55A and 55B, the elongate shaft 1120 of the electrosurgical tool can be configured such that the outer surface thereof does not translate proximally and distally during actuation of the jaw assembly 1130 by the actuation handle 1114. Alternatively, moving the outer shaft component can be used to open and close the jaws and provide a proper clamping force without manipulating the handle assembly. However, moving the outer shaft component can also cause the vessel sealer/divider to move in relation to a trocar seal and thus potentially complicating a gas seal between the sealer/divider and the insufflated body cavity. As such, it can be desirable that the outermost shaft components remain stationary throughout a surgical procedure. As such, in certain cases, the elongate shaft maintains the moving components (e.g., the pull tube and the blade actuation shaft) on the inside of a stationary outer cover tube (which may also have a dielectric coating or insulating sleeve). With continued reference to Figures 55A and 55B, as illustrated, the stationary outer cover tube is connected to the stationary portion of the jaws, while the pull tube is connected to the moving portion of the jaws (e.g., the upper jaw). Thus, as the jaw assembly 1130 is actuated from an open position (Figure 55A) to a closed position (Figure 55B), the pull tube translates longitudinally proximally while the outer cover sleeve remains stationary.

[0188] As discussed above with respect to the electrosurgical system, in certain cases the electrosurgical tool can comprise a memory such as a tool ID chip mounted on a small PCB. The PCB can be disposed on or in the actuation handle 1112. Alternatively, the PCB and chip can be integrated in the plug of the wiring harness. The PCB and chip can be molded with a tool-specific pattern. The tool ID chip and PCB can be electrically connected into the wiring harness and plug of the electrosurgical tool. A 'spacer' between the plug and the tool ID chip can allow the use of the same connector for all tools. In some cases, the spacer can have the same shape for all tools on the plug side, and a tool-specific pattern on the chip side such that during assembly there is a reduced risk that a PCB for one type of electrosurgical tool can be assembled into a different type of electrosurgical tool.

[0189] As discussed above with respect to the electrosurgical system, when the plug is inserted into the generator, the encrypted tool information stored in the memory is verified. General information (serial number of tool and generator) is exchanged, and the tool-specific software is uploaded into the generator. With completion of each tool use, tool-specific information (connections to generator, individual tool uses, errors) can be communicated, if needed, and stored in the memory of the generator, the tool chip or both. The generator's memory can be sized to hold data for about two months while the tool chip's memory can hold data for one surgical procedure.

[0190] As discussed above with respect to the electrosurgical system, in some embodiments, the electrosurgical fusion tool can be used in a system which monitors various operational parameters and determines a radiofrequency endpoint based on phase angle.

[0191] It is to be understood that the present system may be practiced otherwise than specifically described, including various changes in the size, shape and materials.

Electrosurgical Dissection Tool

[0192] Laparoscopic surgical procedures typically require the dissection of connective or vascular tissue. Depending on factors such as tissue type, size, location and condition of the specific tissue, different tools and techniques can be

used to perform a specific procedure. The choice of an individual tool can be based on functionality combined with a desire that the selected tool provide relatively little traumatic damage to the surrounding tissue. As an example, the dissection of connective tissue is usually performed by mechanical or electrosurgical cutting, whereas the dissection of vascular tissue typically relies on ligating techniques employing clips or staplers followed by a mechanical cut. Consequently, a typical laparoscopic procedure including dissection of both connective tissue and vascular tissue calls for multiple tools being consecutively exchanged through trocar access ports to the surgical site. This tool exchange increases both the cost and time of the surgical procedure. It is hence desirable to provide multi-functional tools that can greatly reduce the number of tool exchanges during laparoscopic procedures.

[0193] Referring now to Figure 56, a bloodless tissue-dissecting tool 2101 comprises a proximal hand-piece 2102 that connects through a shaft 2103 to a distal end-piece 2104. Activation of the trigger 2105 on the hand-piece 2102 allows closing and opening of the jaw elements 2106, 2107 on the distal end-piece 2104 so that tissue can be clamped between the upper 2106 and lower 2107 jaw elements.

[0194] With continued reference to Figure 56, the tool 2101 can be configured to be electrically coupled to an electrosurgical generator. For example, the tool 2101 can include an integrated power cord, or a socket or other connector adapted to receive a power cord. At least a portion of the tool can be selectively energized through actuation of a control or switch on the electrosurgical generator. For example, the tool can be energized with a handswitch or a footswitch on or coupled to the electrosurgical generator.

[0195] With reference to Figure 57, an exemplary electrosurgical device is illustrated. Electrosurgical tissue sealing devices that include a mechanical cutter can be used to first electrosurgically coagulate and then mechanically cut through a variety of tissue types. Certain harmonic tissue dividers can also be used to coagulate and/or to dissect a variety of tissue, ranging from connective to highly vascular tissue, such as organs.

[0196] As schematically depicted in Figure 57, electrosurgical tissue dissectors include a lower jaw forming a first electrode 2201 and an upper jaw forming a second electrode 2202. In such devices, the two jaw elements - or electrodes 2201, 2202 - supply a relatively large amount of pressure to the tissue. High pressure with simultaneous application of electrical energy to the compressed tissue can be used to permanently occlude very large blood vessels by electrosurgical vessel fusion. After the electrical fusion process has been completed, the tissue can be separated by advancing a mechanical blade 2203.

[0197] In contrast to such electrosurgical devices, with reference to Figure 58a, an electrosurgical tool that can be configured in either an electrosurgical coagulation state or an electrosurgical cutting state is shown. In the illustrated tool, a lower jaw element 2301 comprises a first coagulating electrode 2302, a second coagulating electrode 2303, and an electrosurgical cutting electrode 2304. Each of the electrodes can be electrically isolated from each other by insulating members 2305. The upper jaw 2306 is not energized in this case, but is merely used to press tissue against the lower jaw element 2301.

[0198] With the electrode arrangement illustrated in Figure 58a, tissue that is in contact with the lower jaw element 2301 can be coagulated by electrically coupling each of the two coagulation electrodes 2302, 2303 with the corresponding outlet of a bipolar electrosurgical unit. Here, the two coagulation electrodes 2302 and 2303 can be supplied with electrical energy having opposite polarities. It can be desirable that the supplied electrical energy have a potential difference of no more than 200V to reduce the risk of arcing and that electrode 2302 and 2303 have the same contact area with the tissue. The latter ensures the same electrosurgical effect for both electrodes.

[0199] With continued reference to Figure 58a, after the two coagulation electrodes 2302, 2303 have achieved substantial hemostasis within the coagulated tissue volume, the tissue can be electrosurgically cut by applying energy to an electrosurgical cutting electrode 2304. During the electrosurgical cutting operation, the two coagulation electrodes 2302, 2303 can be electrically coupled to a corresponding outlet or outlets of a bipolar electrosurgical unit to function as return electrodes. Here, the potential difference between the cutting electrode 2304 and the two return electrodes 2302 and 2303 can desirably be between approximately 300-500V, while the two return electrodes can desirably be substantially equipotential.

[0200] With continued reference to Figure 58a, it can be desirable that the relative contact area of the electrodes with the tissue is much smaller for the cutting electrode 2304 than for the return electrodes 2302, 2303. For example, desirably the cutting electrode can have a contact area that is between approximately 1% and 20% as large as a contact area of one of the return electrodes 2302, 2303. More desirably, the cutting electrode can have a contact area that is between about 5% and 10% as large as a contact area of one of the return electrodes 2302, 2303. The cutting electrode can have a contact area that is approximately 10% as large as a contact area of one of the return electrodes 2302, 2303. This relative proportion between cutting area sizes leads to a relatively high current density (and hence high power density) in tissue close to the cutting electrode, which facilitates localized vaporization, or electrosurgical cutting of the tissue.

[0201] With continued reference to Figure 58a, an additional aspect of the illustrated electrode arrangement is that the lower jaw 2301 can be used for both coagulation and cutting, regardless of whether the jaws are in an opened or closed position. This multiple functionality is advantageous when using the tool to spot-coagulate tissue, or to dissect

tissue by configuring the tool in a cutting state and brushing the tool against the tissue.

[0202] Another electrode arrangement for a surgical tool is illustrated in Figure 58b. The upper jaw 2306' is not only used to press tissue against the lower jaw element 2301, but it also includes an upper electrode 2307 disposed thereon which can be supplied with electrical energy. Tissue can be coagulated by supplying the two lower coagulation electrodes 2302, 2303 with a first electrical polarity, and the upper electrode 2307 with a second, opposing polarity from a bipolar electrosurgical unit. Again, it is desirable that when configured for coagulation, the potential difference between the upper electrode 2307 and the two lower electrodes 2302, 2303 does not exceed 200V to reduce the risk of arcing to the tissue and that electrode 2307 has the same contact area with the tissue as the combined surface area of electrodes 2302 and 2303. The latter ensures the same electrosurgical effect for both electrode sides.

[0203] With continued reference to Figure 58b, after hemostasis of the tissue between the upper electrode 2306' and the two lower electrodes 2302, 2303 has been substantially achieved, the tissue can be electrosurgically cut by supplying the electrosurgical cutting electrode 2304 with electrical energy. The upper coagulation electrode 2307 on the upper jaw 2306' can be configured as a return electrode by electrically coupling it with the corresponding outlet of a bipolar electrosurgical unit.

[0204] With continued reference to Figure 58b, when the surgical tool is configured as a electrosurgical cutting device, desirably the potential difference between the cutting electrode 2304 and the return electrode 2307 is between approximately 300-500V. It can be desirable that the contact area of the electrodes with the tissue is much smaller for the cutting electrode 2304 than with the return electrode 2307 on the upper jaw 2306'. For example, desirably the cutting electrode can have a contact area that is between approximately 1% and 20% as large as a contact area of the return electrode 2307. More desirably, the cutting electrode can have a contact area that is between about 5% and 10% as large as a contact area of the return electrode 2307. The cutting electrode can have a contact area that is approximately 10% as large as a contact area of the return electrode 2307. This relative sizing can lead to relatively high current density (and hence high power density) in the tissue close to the cutting electrode 2304, which facilitates localized vaporization, or electrosurgical cutting of the tissue. With the surgical tool distal end of Figure 58b having electrodes 2302, 2303, 2304, 2307 as described above, only tissue between the two jaw elements can be coagulated and/or cut. Thus, unlike the tool illustrated in Figure 58a, the tool illustrated in Figure 58b is not configured to be used by employing the lower electrode only.

[0205] Another electrode arrangement for a surgical tool is illustrated in Figure 58c. The upper jaw 2306" includes an upper electrode 2307', but also shows two cutting electrodes 2304 and 2309 that are sandwiched between two coagulation electrodes 2302 and 2303. In difference to the tool shown in Figure 58b, both coagulation and cutting are distinguished for cases where the hand tool (and hence the jaw members) are fully opened or not fully opened. With a fully opened tool, tissue can be coagulated by applying the two lower coagulation electrodes 2302 and 2303 with opposing polarities, and will be cut by applying cutting electrode 2304 with the first and both electrodes 2302 and 2303 with the second polarity. In difference, a not fully opened tool will coagulate tissue by applying both lower coagulation electrodes 2302 and 2303 with one polarity and electrode 2307' with the opposing one, while cutting occurs between electrode 309 and return electrode 2307'. Again, it is desirable that when configured for coagulation, the potential difference between the two lower electrodes 2302 and 2303 (tool fully open) or the upper electrode 2307' and the two lower electrodes 2302, 2303 (tool not fully open) does not exceed 200V to reduce the risk of arcing to the tissue.

[0206] The separation of cutting electrodes 2304 and 309 facilitates cutting of tissue that is positioned within the upper and lower jaw elements (not fully opened), or cutting of tissue in contact with the bottom side of the tool. The separation prevents inadvertent cutting of tissue.

[0207] Another electrode arrangement for a surgical tool is illustrated in Figure 58d where the upper jaw 2306''' includes two separate electrodes 2307'' and 2308. In this configuration, the upper jaw element 2306''' can be used to press tissue against the lower jaw element 2301, but can also supply electrical energy.

[0208] With continued reference to Figure 58d, the electrodes 2302, 2303, 2307'', 2308 can be selectively configured to a coagulation state. By supplying the coagulation electrodes 2302, 2303 on the lower jaw 2301 and the two coagulation electrodes 2307'', 2308 on the upper jaw 2306''' with alternating polarities, tissue within the jaws can be coagulated. For example, in one possible coagulation state configuration, one coagulation electrode 2302 on the lower jaw 2301, and one coagulation electrode 2308 on the upper jaw 2306''' can be electrically coupled to a source of electrical energy having a first polarity. The other coagulation electrode 2303 on the lower jaw 2301, and the other coagulation electrode 2307'' on the upper jaw 2306''' can be electrically coupled to a source of electrical energy having a second polarity generally opposite the first polarity. While this is an example, other combinations of connections of the electrodes 2302, 2303, 2307'', 2308 with electrical energy sources are possible to configure the tool in a coagulation state. It can be desirable that the contact area of the opposing coagulation electrode(s) are the same to provide the same electrosurgical effect for both electrode sides.

[0209] With continued reference to Figure 58d, after hemostasis of the tissue between the upper electrodes 2307'', 2308 and the two lower electrodes 2302, 2303 by application of electrical energy with the electrodes in the coagulation state, the tissue can be electrosurgically cut. The distal end of the surgical tool can be configured into a cutting state by

supplying the electrosurgical cutting electrode 2304 with electrical energy. One, some, or all of the other electrodes 2302, 2303, 2307", 2308 can be configured to function as return electrodes when the tool is in a cutting state by electrically coupling them with the corresponding outlet of a bipolar electrosurgical unit.

[0210] With continued reference to Figure 58d, when the tool is configured in a cutting state, the potential difference between the cutting electrode and the return electrode is desirably between approximately 300-500V. Further, it can be desirable that the relative contact area of the electrodes with the tissue is much smaller for the cutting electrode 2304 than for any of the return electrodes 2302, 2303, 2307", 2308 or combinations thereof. For example, desirably the cutting electrode 2304 can have a contact area that is between approximately 1 % and 20% as large as a contact area of one of the return electrodes. More desirably, the cutting electrode can have a contact area that is between about 5% and 10% as large as a contact area of one of the return electrodes. The cutting electrode can have a contact area that is approximately 10% as large as a contact area of one of the return electrodes. Just as with the case illustrated and described with respect to Figure 58a, the electrode arrangement illustrated in Figure 58d can be used to spot-coagulate tissue, or to dissect the tissue when "brushing" the tool against it in a cutting mode.

[0211] The practicality of the tool configurations of Figures 58a through 58d can be further enhanced by selective activation and/or deactivation of the selected electrodes. This selective activation and deactivation can be performed by operator-depressed electrical switches such as wired or wireless hand or foot operated switches, or switches positioned on the hand-piece. The electrosurgical unit will then address specific electrodes, depending on how far the jaws are opened and closed.

[0212] Figure 59a illustrates a schematic circuit diagram for an electrode arrangement as given in Figure 58a. Here, activation of a single-pole electrical switch 401 connects the outer coagulating electrodes 2302, 2303 to opposing polarities, while the center cutting electrode 2304 remains disengaged. This setting configures the electrodes in a coagulation state. Alternately, activation of a double-pole electrical switch 402 supplies the center cutting electrode 2304 with electrical energy having a first polarity, and the outer return electrodes 2302, 2303 with electrical energy having a second polarity generally opposing the first polarity. This setting configures the electrodes in a cutting state. As a result, the tool can be used for electrosurgical coagulation and/or cutting, and hence can perform the bloodless dissection of tissue.

[0213] Figure 59b illustrates a schematic power supply circuit that can be used for the electrode arrangement shown in Figure 58b. Here, activation of a double-pole electrical switch 2403 connects the two outer coagulating electrodes 2302, 2303 on the lower jaw to a supply of electrical energy of a first polarity, and the coagulating electrode 2307 on the upper jaw to a supply of electrical energy of a second polarity substantially opposite the first polarity. With the switch 2403 in this position, the cutting electrode 2304 remains disengaged. This setting configures the electrodes of the surgical tool in a coagulation state. Alternately, activation of a single-pole electrical switch 2404 allows the lower jaw electrodes 2302, 2303 to be used for coagulation. The electrode on the upper jaw 2307 and the cutting electrode 2304 remain disengaged in this alternate coagulation configuration. To dissect tissue after it has been coagulated, a separate electrode outlet 2405 on an electrosurgical generator is used to address the cutting electrode 2304. Desirably, the cutting electrode is supplied with voltages of 300-500V with respect to the two return electrodes 2302, 2303 on the lower jaw.

[0214] Figure 59c illustrates a schematic power supply circuit that can be used to address the electrode arrangement of Figure 58d. Here, activation of a double-pole electrical switch 2406 connects the two coagulating electrodes 2302, 2303, 2307", 2308 on both the lower and upper jaw to sources of electrical energy having opposing polarities. The cutting electrode 2304 remains disengaged. This setting can be used to configure the electrodes of a surgical tool in a coagulation state to coagulate tissue that is clamped between the upper and lower jaw element. Alternately, a second coagulation double-pole switch 2407 can be implemented to separate the activation of the upper and lower jaws such that one or both jaws can be selectively actuated during a coagulation state. To utilize the lower jaw of the tool for electrosurgical cutting of coagulated tissue, activation of the cutting double-pole switch 2408 connects the cutting electrode 2304 to a source of electrical energy having a first polarity and the two return electrodes 2302, 2303 to a source of electrical energy having a second polarity substantially opposite the first polarity. The voltage supplied by the generator for this setting is desirably between approximately 300-500V to facilitate electrosurgical cutting. Here, the electrodes 2307", 2308 on the upper jaw element remain unaddressed during electrosurgical cutting.

[0215] As discussed in more detail above, the activation (or deactivation) of specific electrodes can configure the tool in a coagulation state or a cutting state. The selective activation and deactivation of specific electrodes can be facilitated by push-buttons, switches, or other electrical switching devices mounted on the hand-piece of the laparoscopic tool, or wired or wireless switches. Alternatively, the selective activation and deactivation of specific electrodes can be facilitated by switches or other electrical switching devices that are incorporated into the handle mechanism of the hand-piece to switch at various positions of the jaw elements.

[0216] Regarding the circuit shown in Figure 59a, referring to the tool shown in Figure 58a, switching devices mounted on the hand-piece can be used to allow a user to selectively configure the electrodes on the tool. Switch 2401 can be a hand-activated switching device mounted on the hand-piece that can be selectively activated to configure the electrodes of the tool in a coagulation state. Switch 2402 can be a hand-activated switching device mounted on the hand-piece

that can be selectively activated to configure the electrodes of the tool in a cutting state. Alternatively, switches 2401, 2402 can be incorporated into the handle mechanism to such that the tool is automatically switched from a coagulation state to a cutting state at a predetermined position of the clamping members.

[0217] One benefit of switching the electrodes from a coagulation state to a cutting state at different positions of the jaw elements (e.g., open and nearly closed jaws) can be seen with respect to the circuit of Figure 59b. Switches 2403 and 2404 can be incorporated within the handle of the surgical tool for self-switching based on the position of the trigger mechanism, rather than on the outside of the hand tool for hand-activation. Switch 2403 can be disengaged and switch 2404 engaged in a fully open jaw element position. Thus, with the jaw elements fully opened, the switches 2403, 2404 can be configured such that only the lower jaw element can be used for spot coagulation. In this case when the trigger of the hand-piece is actuated to move the jaw elements closed from the fully opened jaw position, switch 2404 is disengaged and 2403 simultaneously engaged. Thus, with the jaw elements moved into a partially-closed configuration, the tool can be used to coagulate or cut tissue that is clamped between the upper and lower jaw element.

[0218] In the described tool, the electrode switches are automatically actuated as the jaw elements are closed. Although the described tool includes a switch point between a coagulation state and a cutting state upon commencement of closure from the jaws fully opened position, other tools can have different switching positions. For example, with this automatic switching, the switches 2403, 2404 can be configured such that the electrodes are activated and deactivated at any position in an opening or closing cycle. Alternatively, a surgical tool can include the electrode configuration of Figure 58b and the switching circuit of Figure 59b with the switches 2403, 2404 configured for manual actuation, such as by positioning on the tool hand-piece.

[0219] Similarly, a surgical tool having the electrode configuration of Figure 58d with the switching circuit of Figure 59c can have the switches 2406, 2408 incorporated into the trigger mechanism for automatic switching between a coagulation state and a cutting state at certain jaw element positions. In certain cases, it can also be desirable to incorporate the second coagulation switch 2407 into the trigger mechanism of the hand-piece, disengaging the electrodes on the upper jaw element in a predetermined jaw position such as a fully opened jaw position. This switching arrangement of the second coagulation switch 2407 allows for example to spot-coagulate tissue using the lower jaw element without inadvertently touching tissue with the electrodes on the upper jaw element. In other cases, it can be desirable for the second coagulation switch 2407 to be positioned on the hand-piece to be manually actuated by a user, allowing a user to selectively engage and disengage the electrodes on the upper jaw element. Alternatively, all of the switches 2406, 2407, 2408 of the switching circuit of Figure 59c can be positioned on the hand-piece of the surgical tool to be manually actuated by the user.

[0220] With reference to Figure 60, one configuration of tool switching is illustrated. In the illustrated case, electrical contacts are incorporated both into the hand-piece 2501 and the trigger 2502. For example, as illustrated, the hand-piece 2501 includes a first electrical contact 2504, a second electrical contact 2506, and a third electrical contact 2507 positioned therein. In the illustrated case, the trigger 2502 includes a first electrical contact 2503 and a second electrical contact 2505. All of the electrical contacts 2503, 2504, 2505, 2506, 2507 are positioned to engage and disengage one another at predetermined relative positions of the trigger 2502 and the hand-piece 2501.

[0221] With continued reference to Figure 60, as shown, the first contact 2503 on the trigger 2502 engages the first contact 2504 on the hand-piece 2501 when the jaws are in a fully opened position, but the first contacts 2503, 2504 are disconnected when the trigger 2502 is moved from the open position to close the jaws. In the illustrated case, with the jaws in the fully opened position, the second contact 2505 on the trigger 2502 engages the second contact 2506 on the hand-piece 2501. But, the second contacts 2505, 2506 are disconnected when the trigger 2502 is moved from the open position to close the jaws. As the jaws are closed further, the second contact 2505 on the trigger 2502 becomes engaged with the third contact 2507 on the hand-piece 2501, and the first contact 2503 on the trigger engages the second contact 2506 on the hand-piece 2501. This engagement allows switching of the polarity of the contacts 2507 as the hand-piece is closed further. As a result, and with reference to Figure 58b, the switching mechanism in Figure 60 allows for activation of the upper electrode 2307 and a lower coagulating electrode 2303 with opposing polarities in a fully open jaw position. With progressive tissue desiccation, the jaws start to close, and the upper electrode 2307 becomes electrically disengaged (by disconnecting contact 2503 and 2504 in Figure 60), whereas the lower electrode 2303 is switched to the same polarity as the second electrode 2302 (by connecting contact 2505 from 2506 to contact 2507 in Figure 60). In a separate step, the desiccated tissue between the upper and lower jaw elements can now be electrosurgically dissected.

[0222] With reference to Figure 61, another switching mechanism is illustrated with the jaw members in a fully opened position. In the illustrated case, concentric contact strips are disposed on the hand-piece and opposing contact pins are mounted on the trigger. In other cases, contact pins can be mounted on the hand-piece and contact strips positioned on the trigger. In the illustrated case, trigger movement allows the pin contacts (which are connected to specific electrodes) to be supplied with electrical energy at certain tool positions. In some cases, the polarity of a single pin (i.e., the same electrode) might change as the jaws are opened or closed.

[0223] One contact strip and pin arrangement is illustrated in Figure 61 for an electrode configuration of Figure 58B. In the illustrated case, pin 2601 is electrically coupled to the electrode 2307 (Figure 58b) on the upper jaw member and

is disengaged. As illustrated, pin 2602 is electrically coupled to one of the coagulating electrodes 2302, 2303 (Figure 58b) on the lower jaw. As illustrated, pin 2602 is engaged as the trigger is moved from the fully-open position to a partially closed position. With further advancement of trigger, pin 2602 changes to the same polarity as the second coagulating electrode so that both can be used as return electrodes for cutting.

[0224] While both Figure 60 and Figure 61 show active switching mechanisms in the hand tool (where active electrodes can be switched), which allows the tools to be used with conventional electrosurgical generators, Figure 62 shows a configuration for passive switching. Here, a momentary switch 2701 is mounted in the handle and is closed by a trigger 2702 when lever 2703 is brought into the fully open position.

[0225] Similarly, Figure 63 shows the incorporation of two momentary switches 2801 and 2802 that are closed by trigger 2803 and 2804 in the tool fully open and tool fully closed position, respectively. The closing of the momentary switches as shown in Figures 62 and 63 is then used for logic switching of multi-electrode generators, as described in the following.

[0226] Figure 64 shows a schematic of a multi-electrode switching power supply for directly connecting individual tool electrodes (such as all individual electrodes in Figures 58a through 58d) to an internal RF power source. Instead of switching two polarities of an external electrosurgical unit to different electrodes with active switches in the hand tools, this arrangement facilitates population of individually-connected electrodes with different polarities by switching within the power supply. Depending on the tool position, as determined by tool position switches shown in Figures 62 and 63, the electrodes can be populated differently as determined by pre-determined logic. As such, the five electrode connection points 2901 through 2905 are connected to a relay bank 2906 to a bus bar 2907. Through selected switching of all relays in the relay bank 2906, each outlet point 2901 through 2905 can be independently and/or concurrently connected to the plant connection points 2908 and 2909, respectively. The plant connection points 2908 and 2909 themselves can be connected through the relay bank 2910 to the two outlets of a tissue measurement circuit 2911, or an RF plant 2912.

[0227] With reference to Figure 65, methods of using an electrosurgical tool for substantially bloodless tissue dissection are schematically illustrated. The illustrated method includes a positioning step 2952, a tissue assessment step 2954, an applying- electrical- energy- to- coagulate step 2956, a tissue measurement step 2958, a switching step 2960, and an applying- electrical- energy- to- cut step 2962. In the positioning step 2952 an electrosurgical tool having a plurality of electrodes being configurable in one of a coagulation configuration and a cutting configuration is positioned adjacent to tissue to be dissected. The electrosurgical tool may comprise aspects of the electrosurgical tools discussed herein and illustrated in Figures 56 and 58- 63.

[0228] In the tissue assessment step 2954, a measurement signal is applied to the tissue by the coagulation electrodes to determine a future trigger level to switch from coagulation to cutting. This determination can be achieved by measuring the product of conductivity and permittivity of the tissue, pointing to the desired electrical phase shift switching level for the respective tissue. For example, in some cases, desirable cutting switching levels occur at 10 degrees to 40 degrees. More desirably, the preferred switching level for blood vessels is between 10 to 30 degrees phase shift, while for highly vascular tissue (such as organs) it is rather between 20 to 40 degrees.

[0229] In the applying- electrical- energy- to- coagulate step 2956, electrical energy is applied to the electrosurgical tool in a coagulation configuration to achieve hemostasis in the tissue. In various cases discussed herein, electrode configurations for coagulation are provided. For example, applying electrical energy to the electrosurgical tool in the coagulation configuration can comprise supplying one of a plurality of electrodes with electrical energy having a first polarity and supplying another of the plurality of electrodes with electrical energy having a second polarity generally opposite the first polarity. Desirably, a potential difference between the electrode having the first polarity and the electrode having the second polarity is no more than approximately 200 V.

[0230] During the coagulation process of the tissue the phase shift between applied voltage and incurred current is measured concurrently in step 2958 to provide feedback of the coagulation status. Once the pre-determined switching level is reached, the process will proceed to the switching step 2960.

[0231] In the switching step 2960, as discussed above, the electrosurgical tool can comprise a handle assembly including a switching mechanism. This switching mechanism can selectively configure the electrosurgical tool in either the coagulation configuration or the cutting configuration depending on a position of a trigger of the handle assembly. As discussed above, in some cases the switching mechanism can be configured such that with the electrosurgical tool in an open position, the electrodes are configured in the coagulation configuration. The switching mechanism can further be configured such that when the electrosurgical tool is moved towards a closed position, the electrodes are configured in the cutting configuration. Alternatively, switching of the configuration of electrodes from the coagulation configuration to the cutting configuration can occur at different predetermined positions of the trigger of the handle assembly. Alternatively, the switching can occur within a multi-electrode power supply as shown in Figure 64.

[0232] In the applying- electrical- energy- to- cut step 2962, electrical energy is applied to the electrosurgical tool in a cutting configuration to dissect the tissue. In various cases discussed herein, electrode configurations for cutting are provided. For example, applying electrical energy to the electrosurgical tool in the cutting configuration can comprise supplying one of a plurality of electrodes with electrical energy and configuring another of the plurality of electrodes as

a return electrode. Desirably, a potential difference between the cutting electrode and the return electrode is between approximately 300 V and approximately 500 V.

Claims

1. A electrosurgical system for the application of treatment energy to a patient and suitable for use in bipolar electrosurgery, the system comprising:
 - an electrosurgical generator (12, 12') configured to generate and output treatment energy along with a measurement signal;
 - an electrosurgical control unit (20, 20', 1800) configured to direct the output of treatment energy and a measurement signal; and
 - an electrosurgical tool (40) removably connected to one of the electrosurgical generator (12, 12') and the electrosurgical control unit (20, 20', 1800) and arranged to contact tissue and apply the treatment energy and the measurement signal to the tissue, the electrosurgical control unit (20, 20', 1800) measuring permittivity and conductivity of the tissue through the application of the measurement signal, whereby the electrosurgical control unit (20, 20', 1800) is configured to determine an end point to disrupt the application of the treatment energy based on the measured permittivity and conductivity of the tissue, **characterized in that** the end point corresponds to the attainment of a predetermined value by the phase difference between applied voltage and current of the treatment energy, the phase difference calculated as a function of the measured permittivity and conductivity and **in that** the control unit is configured to account for capacitance or impedance of the electrosurgical tool (40) and wherein the predetermined value of the phase difference increases as the capacitance or impedance of the electrosurgical tool (40) decreases or the predetermined value of the phase difference decreases as the impedance or the capacitance of the electrosurgical tool (40) increases.
2. The system of Claim 1 wherein the electrosurgical control unit (20, 20', 1800) is configured to apply the measurement signal prior to the application of the treatment energy.
3. The system of Claim 1 wherein the end point is determinable using a phase parameter of the treatment energy.
4. The system of Claim 3 wherein the end point is determinable using a derivative of the phase parameter of the treatment energy.
5. The system of Claim 1 wherein the end point is determinable using a derivative of the phase difference.
6. The system of Claim 1 wherein the electrosurgical control unit (20, 20', 1800) is configured to determine a treatment endpoint condition using the measurement signal, the treatment endpoint condition determined substantially independent of the dimensions of tissue positionable between the at least two jaw members (1132, 1134).
7. The system of Claim 1 wherein the electrosurgical control unit (20, 20', 1800) is configured to measure phase angle of a measurement signal applied to tissue of a patient via at least one electrode (2302, 2303, 2304, 2307, 2307', 2308) of the electrosurgical tool (40).
8. The system of claims 1 or 7 wherein the electrosurgical control unit (20, 20', 1800) is configured to apply the measurement signal to the tissue at a predetermined frequency prior to modification of the tissue by the electrosurgical tool (40).
9. The system of claim 1 wherein the electrosurgical control unit (20, 20', 1800) is configured to measure capacitance and impedance of the electrosurgical tool (40) and to adjust the determined end point based on the measured capacitance and impedance of the electrosurgical tool (40).
10. The system of claim 1 wherein the electrosurgical control unit (20, 20', 1800) is configured to periodically interrupt the output of treatment energy and to direct the output of the measurement signal while the output of treatment energy is interrupted.

Patentansprüche

1. Ein elektrochirurgisches System zum Beaufschlagen eines Patienten mit einer Behandlungsenergie und das zur Verwendung in der bipolaren Elektrochirurgie geeignet ist, wobei das System umfasst:

einen elektrochirurgischen Generator (12, 12'), der dazu konfiguriert ist, Behandlungsenergie zusammen mit einem Messsignal zu erzeugen und auszugeben;
 eine elektrochirurgische Steuereinheit (20, 20', 1800), die dazu konfiguriert ist, die Ausgabe von Behandlungsenergie und eines Messsignals zu leiten; und
 ein elektrochirurgisches Werkzeug (40), das entferntbar mit einem von dem elektrochirurgischen Generator (12, 12') und der elektrochirurgischen Steuereinheit (20, 20', 1800) verbunden ist und das dazu angeordnet ist, in Kontakt mit Gewebe zu kommen und das Gewebe mit der Behandlungsenergie zu beaufschlagen und das Messsignal an dem Gewebe anzulegen, wobei die elektrochirurgische Steuereinheit (20, 20', 1800) die Permittivität und Leitfähigkeit des Gewebes durch das Anlegen des Messsignals misst,
 wobei die elektrochirurgische Steuereinheit (20, 20', 1800) dazu konfiguriert ist, einen Endpunkt zu bestimmen, um die Beaufschlagung mit der Behandlungsenergie zu stören, basierend auf der gemessenen Permittivität und Leitfähigkeit des Gewebes, **dadurch gekennzeichnet, dass** der Endpunkt dem Erreichen eines vorbestimmten Werts mittels der Phasendifferenz zwischen der angelegten Spannung und dem Strom der Behandlungsenergie entspricht, wobei die Phasendifferenz als eine Funktion der gemessenen Permittivität und Leitfähigkeit berechnet wird und wobei die Steuereinheit dazu konfiguriert ist, die Kapazität oder Impedanz des elektrochirurgischen Werkzeugs (40) zu berücksichtigen, und wobei der vorbestimmte Wert der Phasendifferenz mit abnehmender Kapazität oder Impedanz des elektrochirurgischen Werkzeugs (40) zunimmt oder der vorbestimmte Wert der Phasendifferenz mit zunehmender Impedanz oder Kapazität des elektrochirurgischen Werkzeugs (40) abnimmt.

2. Das System gemäß Anspruch 1, wobei die elektrochirurgische Steuereinheit (20, 20', 1800) dazu konfiguriert ist, das Messsignal vor dem Beaufschlagen mit der Behandlungsenergie anzulegen.

3. Das System gemäß Anspruch 1, wobei der Endpunkt unter Verwendung eines Phasenparameters der Behandlungsenergie bestimmbar ist.

4. Das System gemäß Anspruch 3, wobei der Endpunkt unter Verwendung einer Ableitung des Phasenparameters der Behandlungsenergie bestimmbar ist.

5. Das System gemäß Anspruch 1, wobei der Endpunkt unter Verwendung einer Ableitung der Phasendifferenz bestimmbar ist.

6. Das System gemäß Anspruch 1, wobei die elektrochirurgische Steuereinheit (20, 20', 1800) dazu konfiguriert ist, einen Behandlungsendpunktzustand unter Verwendung des Messsignals zu bestimmen, wobei der bestimmte Behandlungsendpunktzustand im Wesentlichen unabhängig von den Abmessungen des Gewebes ist, das zwischen den mindestens zwei Backengliedern (1132, 1134) positioniert werden kann.

7. Das System gemäß Anspruch 1, wobei die elektrochirurgische Steuereinheit (20, 20', 1800) dazu konfiguriert ist, den Phasenwinkel eines Messsignals zu messen, das an Gewebe eines Patienten über mindestens eine Elektrode (2302, 3203, 2304, 2307, 2307', 2308) des elektrochirurgischen Werkzeugs (40) angelegt wird.

8. Das System gemäß Anspruch 1 oder 7, wobei die elektrochirurgische Steuereinheit (20, 20', 1800) dazu konfiguriert ist, das Messsignal bei einer vorbestimmten Frequenz an dem Gewebe anzulegen, bevor das Gewebe durch das elektrochirurgische Werkzeug (40) modifiziert wird.

9. Das System gemäß Anspruch 1, wobei die elektrochirurgische Steuereinheit (20, 20', 1800) dazu konfiguriert ist, die Kapazität und Impedanz des elektrochirurgischen Werkzeugs (40) zu messen und den vorbestimmten Endpunkt, basierend auf der gemessenen Kapazität und Impedanz des elektrochirurgischen Werkzeugs (40), anzupassen.

10. Das System gemäß Anspruch 1, wobei die elektrochirurgische Steuereinheit (20, 20', 1800) dazu konfiguriert ist, die Ausgabe der Behandlungsenergie periodisch zu unterbrechen und die Ausgabe des Messsignals zu leiten, während die Ausgabe der Behandlungsenergie unterbrochen ist.

Revendications

1. Système électrochirurgical destiné à l'application d'une énergie de traitement à un patient et approprié à une utilisation dans l'électrochirurgie bipolaire, le système comprenant :

un générateur électrochirurgical (12, 12") configuré pour générer et émettre de l'énergie de traitement ainsi qu'un signal de mesure ;

une unité de commande électrochirurgicale (20, 20', 1800) configurée pour diriger l'émission de l'énergie de traitement et un signal de mesure ; et

un outil électrochirurgical (40) connecté de manière amovible à l'un du générateur électrochirurgical (12, 12") et de l'unité de commande électrochirurgicale (20, 20', 1800) et conçu pour se mettre en contact avec le tissu et pour appliquer l'énergie de traitement et le signal de mesure au tissu, l'unité de commande électrochirurgicale (20, 20', 1800) mesurant la permittivité et la conductivité du tissu par l'application du signal de mesure,

l'unité de commande électrochirurgicale (20, 20', 1800) étant configurée pour déterminer une limite extrême afin d'interrompre l'application de l'énergie de traitement sur la base de la permittivité et de la conductivité mesurées du tissu, **caractérisée en ce que** la limite extrême correspond à l'atteinte d'une valeur prédéterminée par la différence de phase entre la tension appliquée et le courant de l'énergie de traitement, la différence de phase étant calculée en tant que fonction de la permittivité et de la conductivité mesurées et **en ce que** l'unité de commande est configurée pour tenir compte de la capacitance ou de l'impédance de l'outil électrochirurgical (40) et dans laquelle la valeur prédéterminée de la différence de phase augmente à mesure que la capacitance ou l'impédance de l'outil chirurgical (40) diminue ou la valeur prédéterminée de la différence de phase diminue à mesure que l'impédance ou la capacitance de l'outil électrochirurgical (40) augmente.

2. Système selon la Revendication 1, dans lequel l'unité de commande électrochirurgicale (20, 20', 1800) est configurée pour appliquer le signal de mesure avant l'application de l'énergie de traitement.

3. Système selon la revendication 1, dans lequel la limite extrême est déterminable en utilisant un paramètre de phase de l'énergie de traitement.

4. Système selon la Revendication 3, dans lequel la limite extrême est déterminée en utilisant une dérivation du paramètre de phase de l'énergie de traitement.

5. Système selon la Revendication 1, dans lequel la limite extrême est déterminable en utilisant une dérivation de la différence de phase.

6. Système selon la Revendication 1, dans lequel l'unité de commande électrochirurgicale (20, 20', 1800) est configurée pour déterminer une condition de limite extrême de traitement en utilisant le signal de mesure, la condition de limite extrême de traitement étant déterminée sensiblement en tant qu'étant indépendante des dimensions du tissu positionnable entre les au moins deux éléments de mâchoire (1132, 1134).

7. Système selon la Revendication 1, dans lequel l'unité de commande électrochirurgicale (20, 20', 1800) est configurée pour mesurer l'angle de phase d'un signal de mesure appliqué au tissu d'un patient par l'intermédiaire d'au moins une électrode (2302, 2303, 2304, 2307, 2307', 2308) de l'outil électrochirurgical (40).

8. Système selon les revendications 1 ou 7, dans lequel l'unité de commande électrochirurgicale (20, 20', 1800) est configurée pour appliquer le signal de mesure au tissu à une fréquence prédéterminée avant la modification du tissu par l'outil électrochirurgical (40).

9. Système selon la revendication 1, dans lequel l'unité de commande électrochirurgicale (20, 20', 1800) est configurée pour mesurer la capacitance et l'impédance de l'outil électrochirurgical (40) et pour ajuster la limite extrême déterminée en se basant sur la capacitance et l'impédance mesurées de l'outil chirurgical (40).

10. Système selon la revendication 1, dans lequel l'unité de commande électrochirurgicale (20, 20', 1800) est configurée pour interrompre périodiquement l'émission de l'énergie de traitement et pour diriger l'émission du signal de mesure tandis que l'émission de l'énergie de traitement est interrompue.

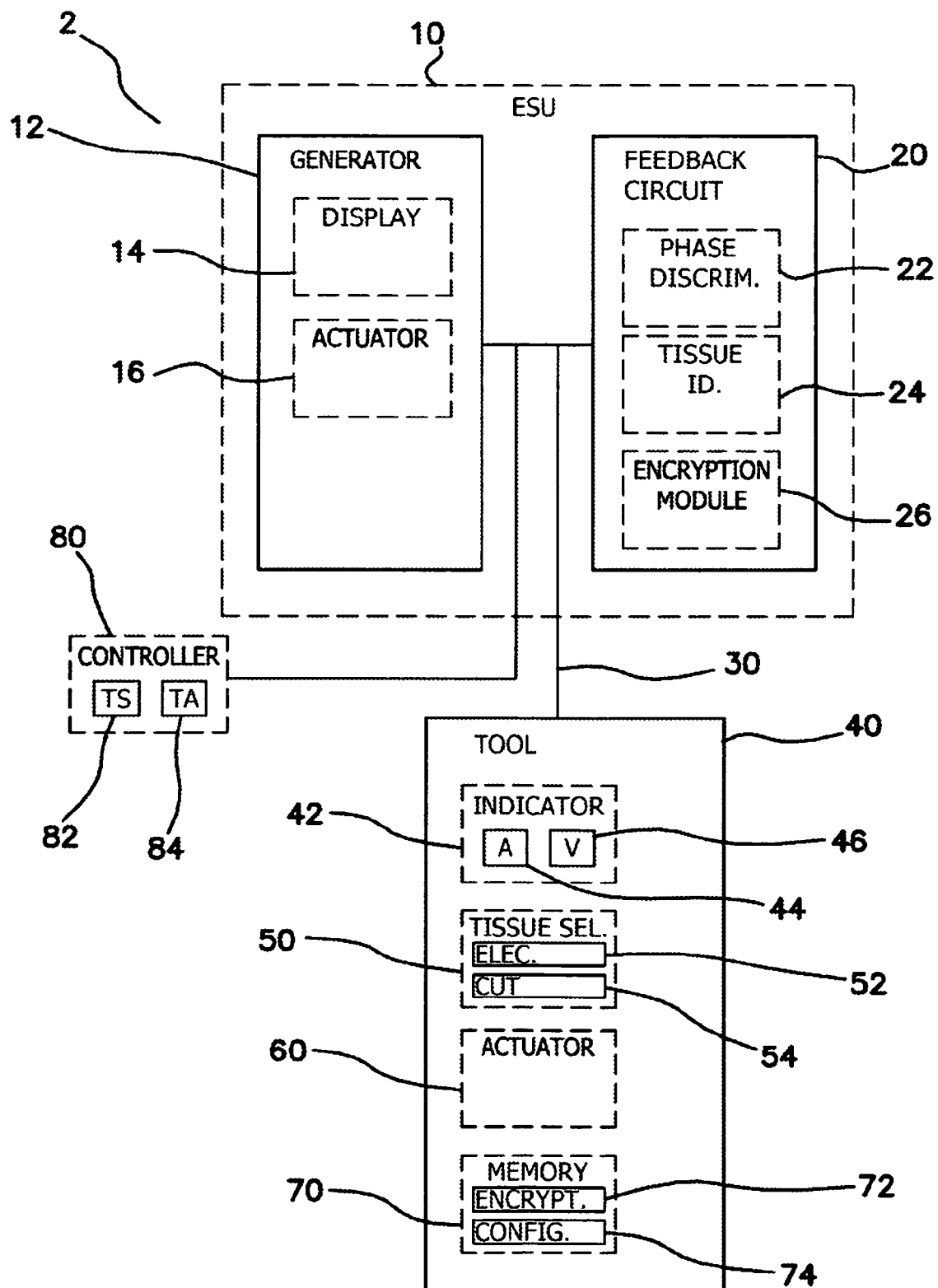
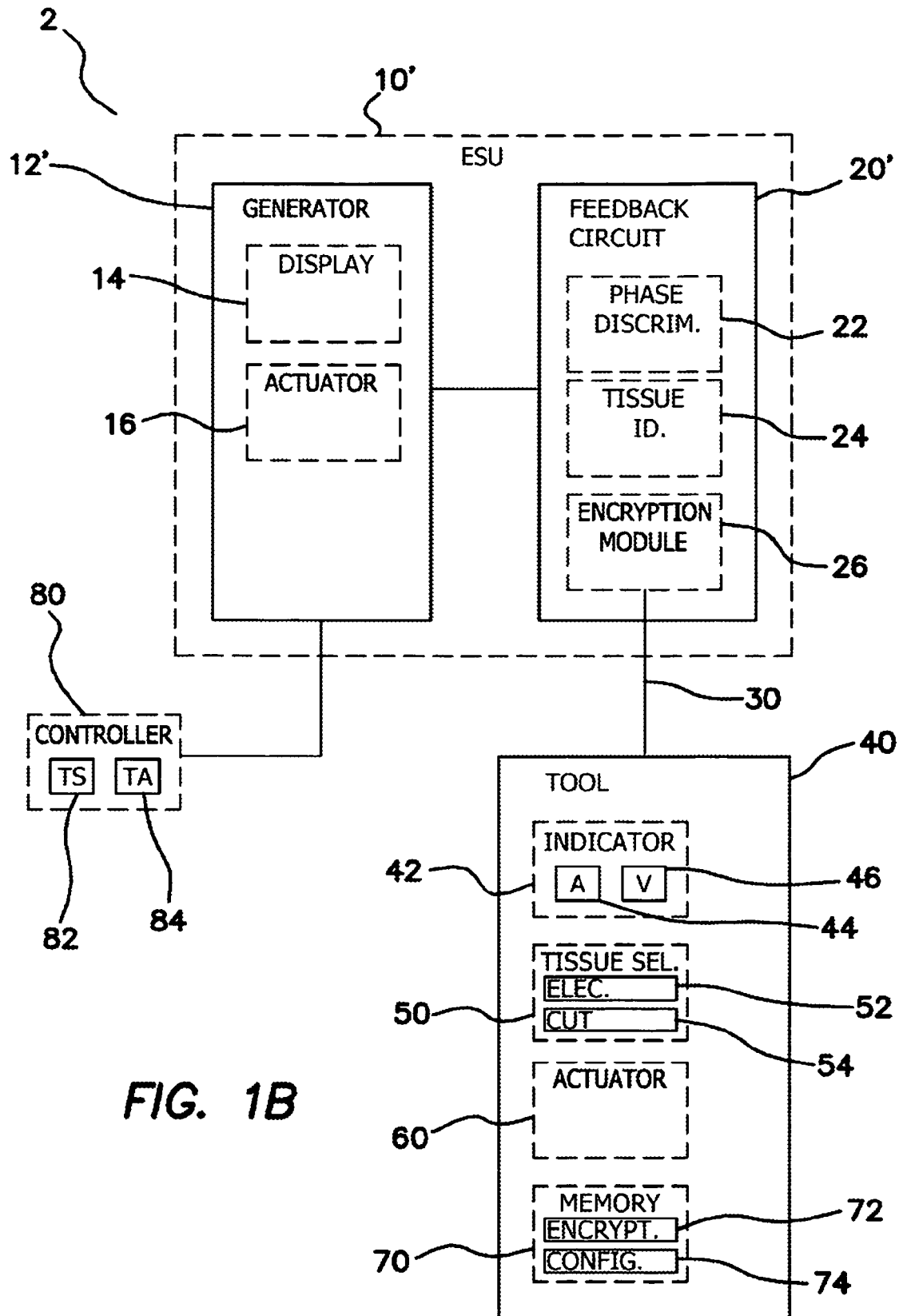


FIG. 1A



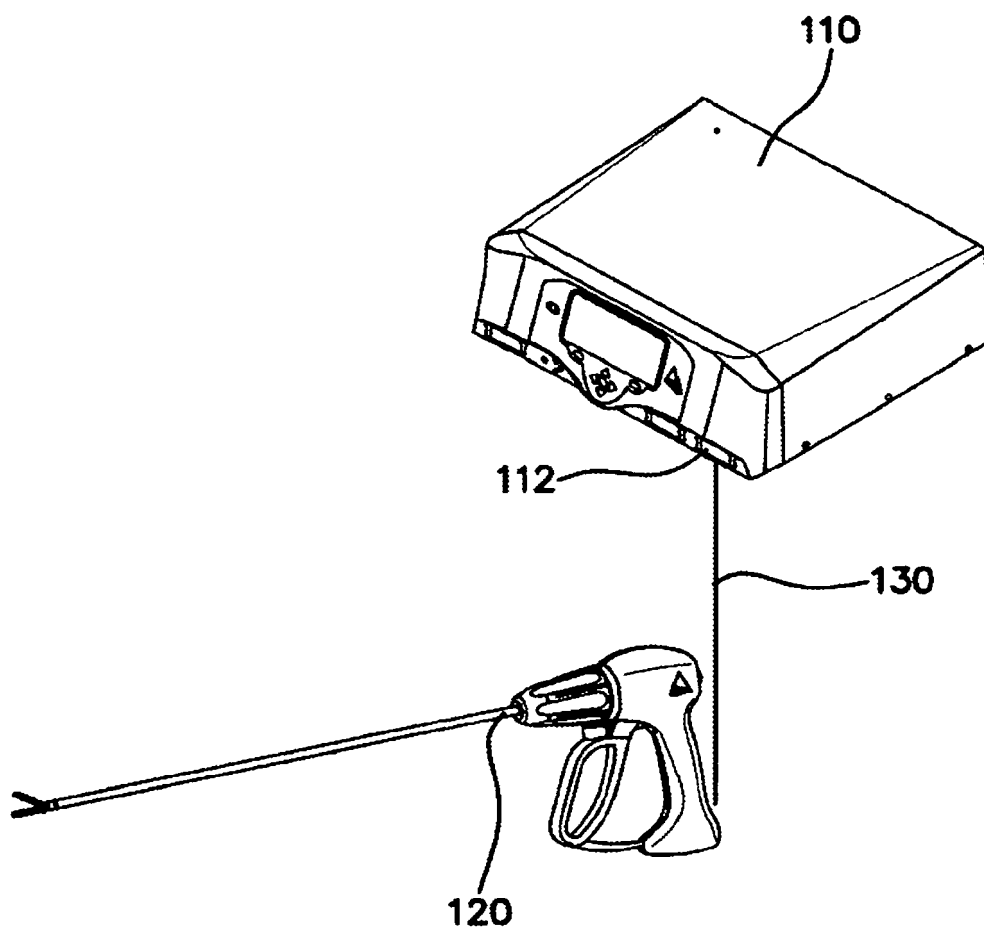


FIG. 2A

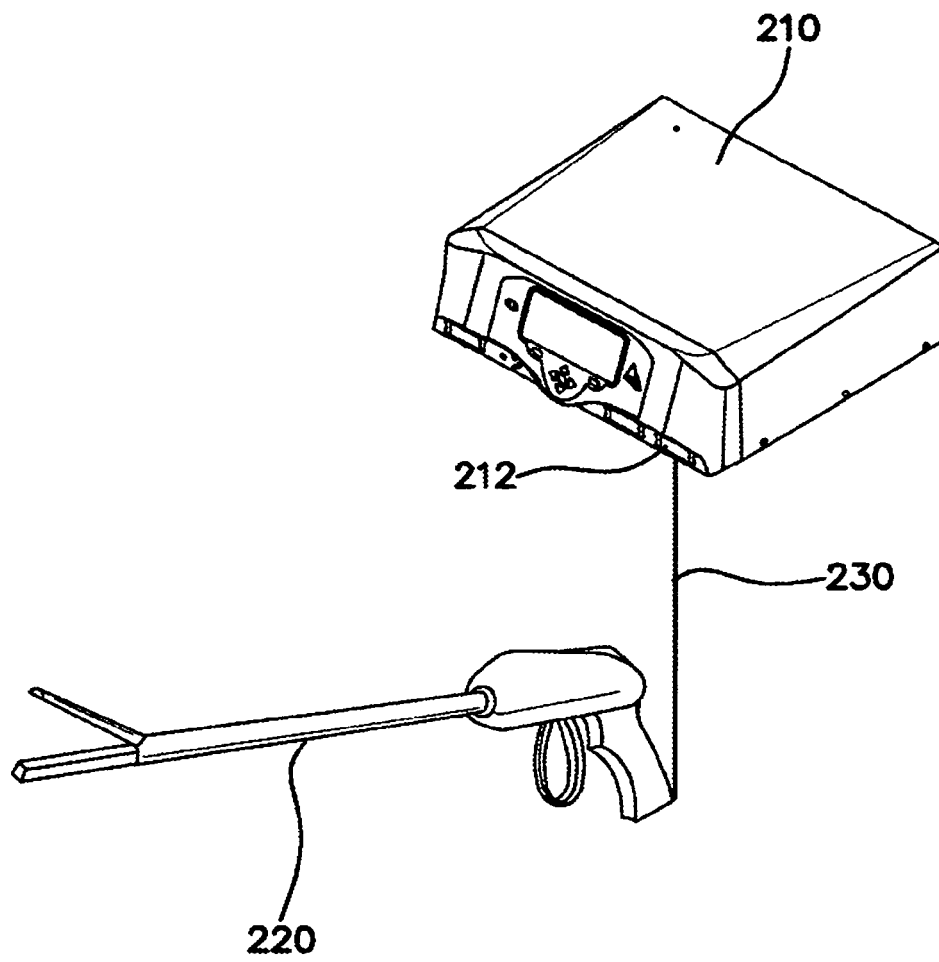


FIG. 2B

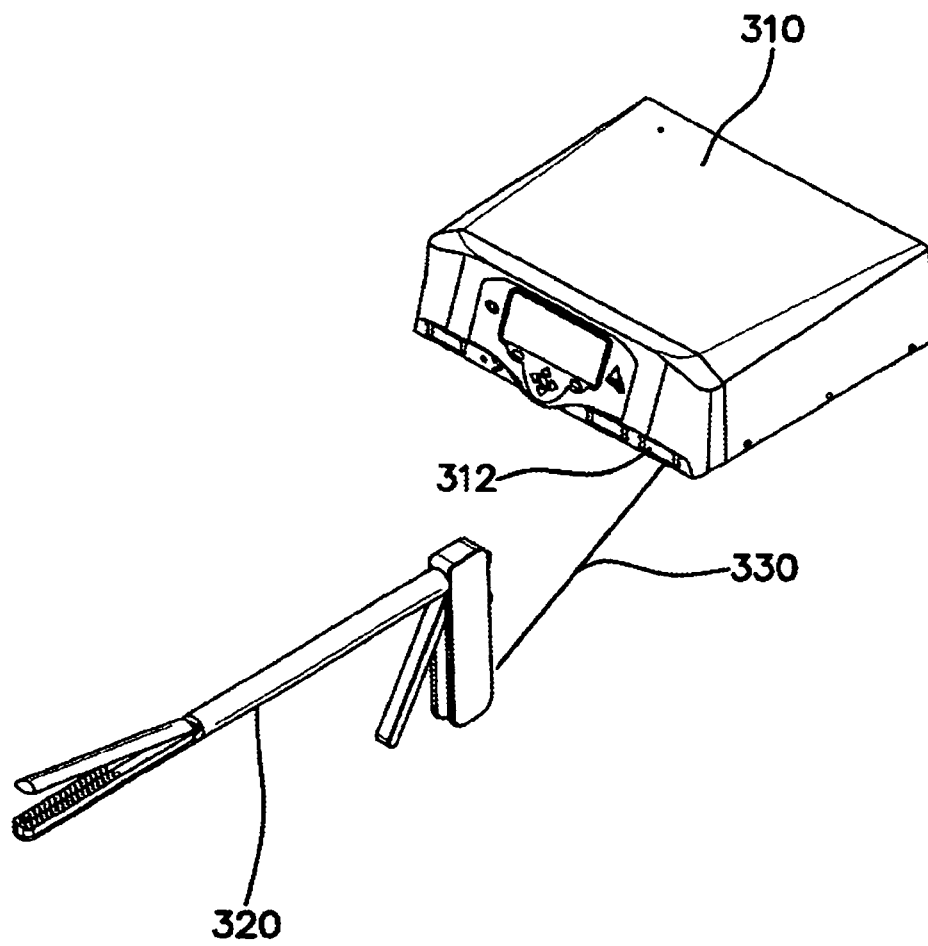


FIG. 2C

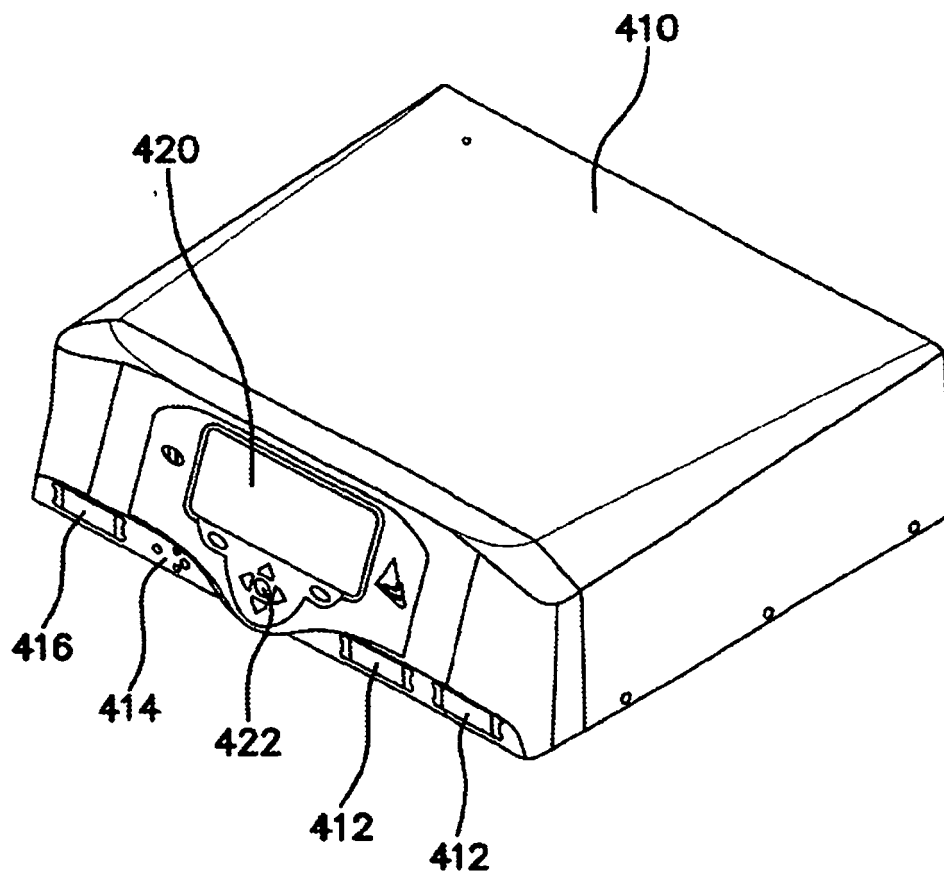


FIG. 3A

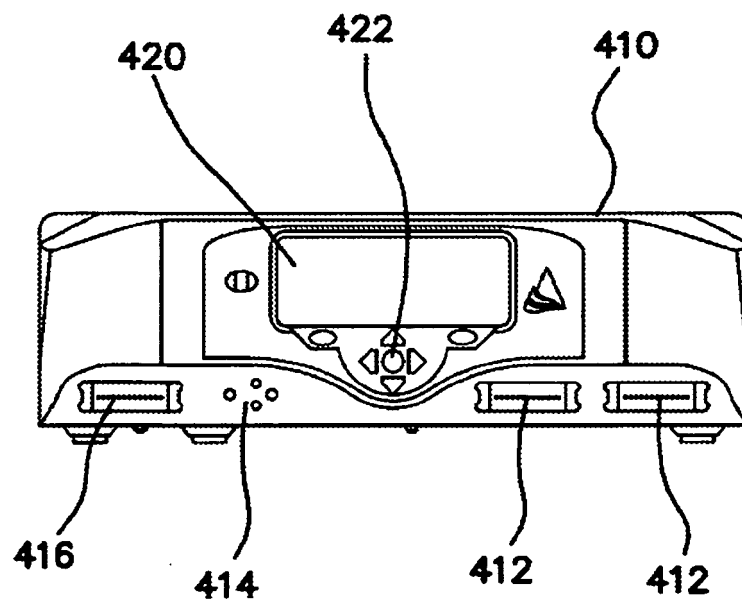


FIG. 3B

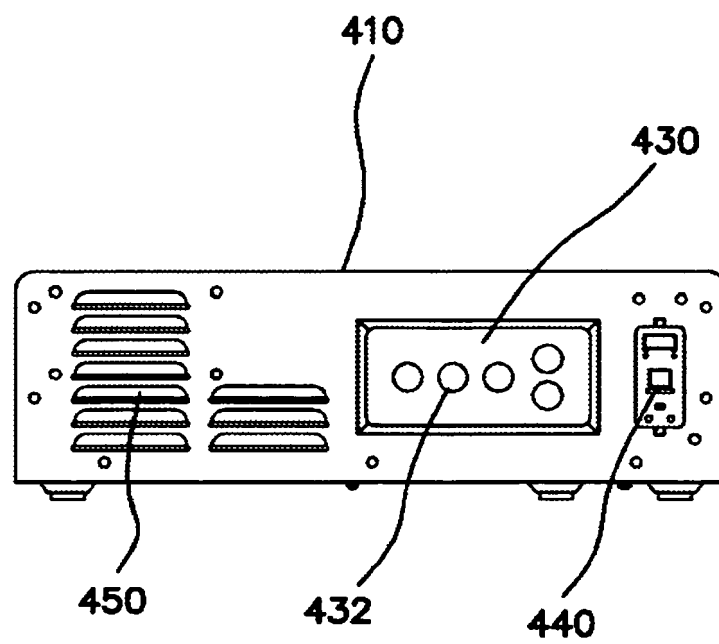
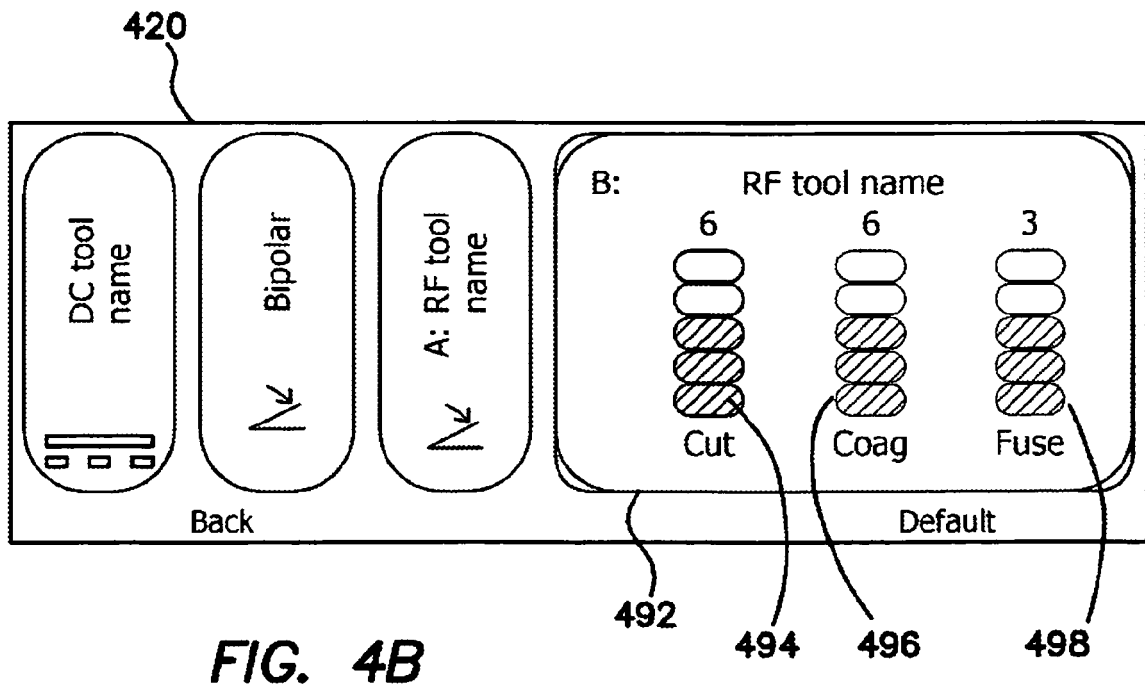
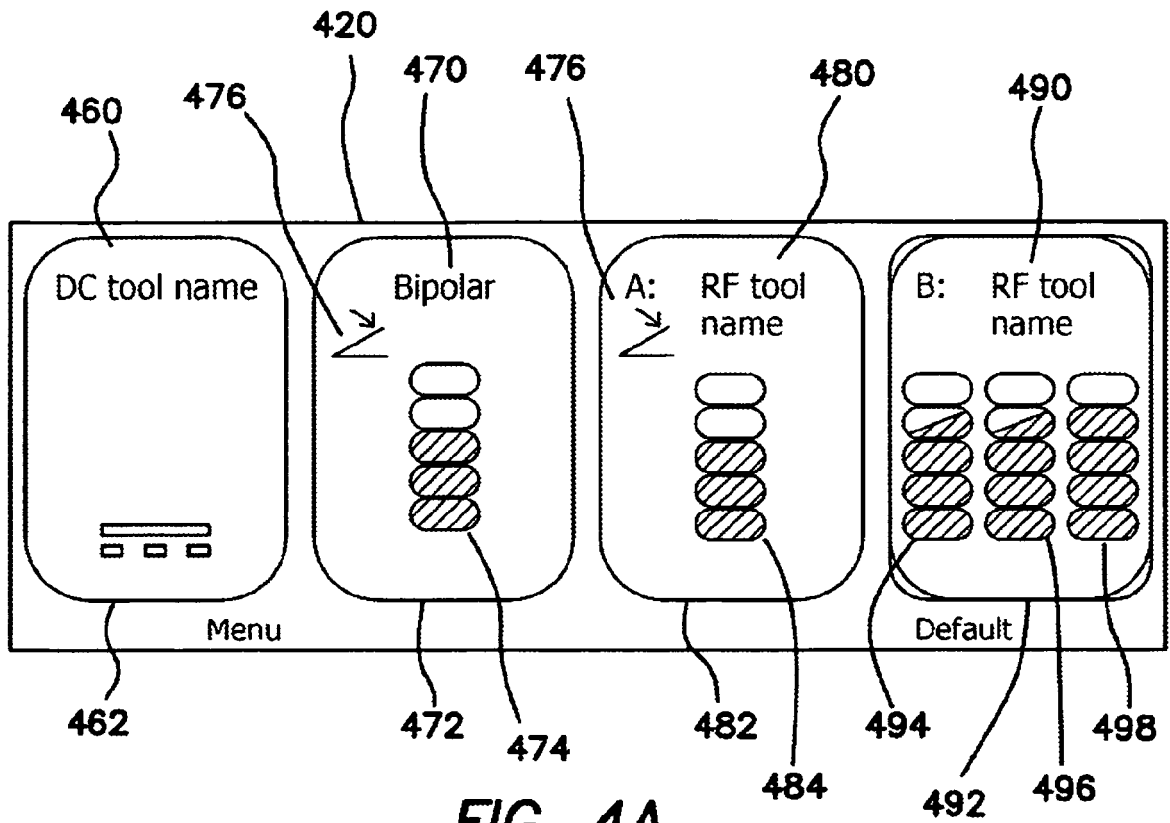


FIG. 3C



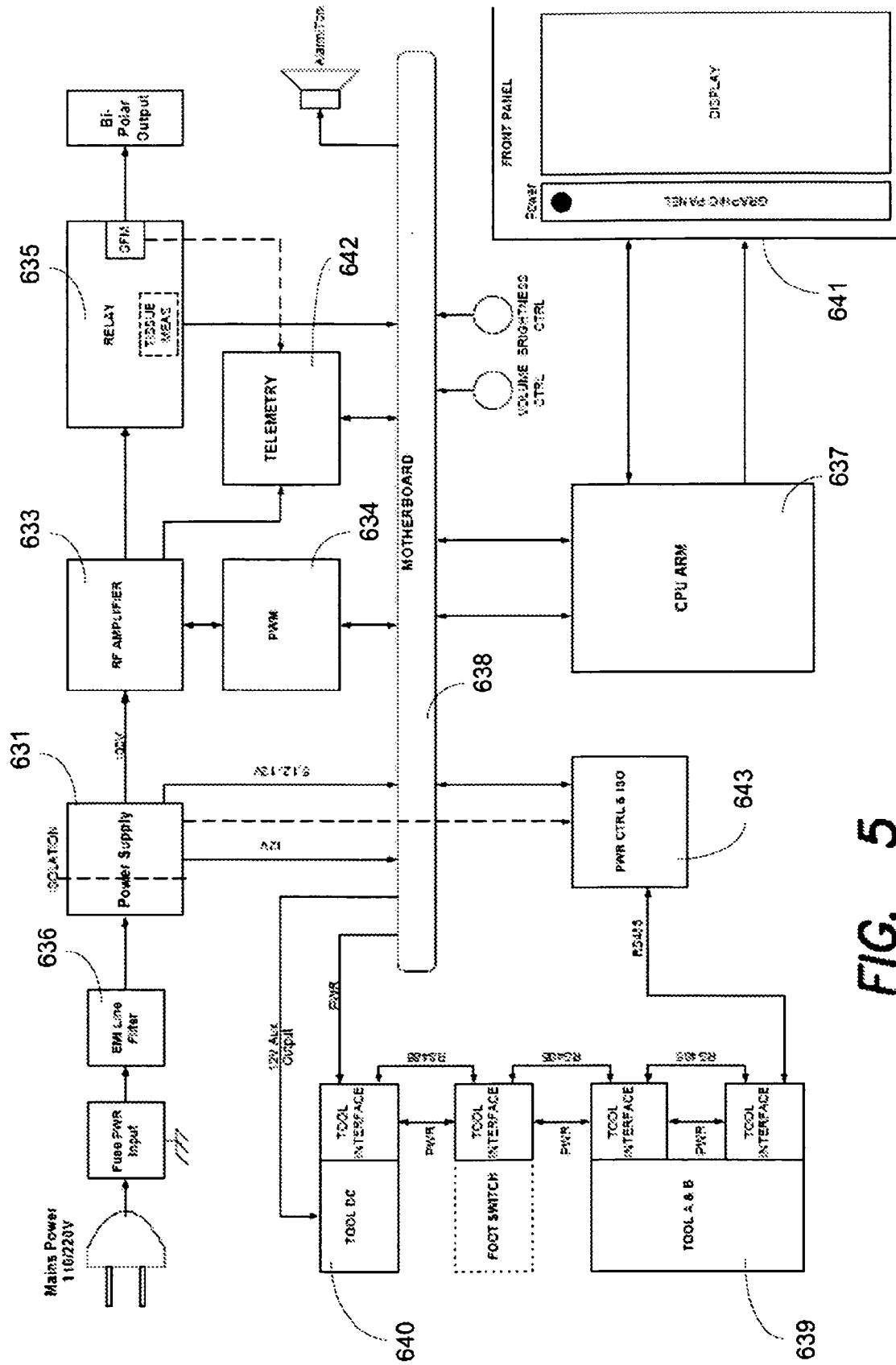


FIG. 5

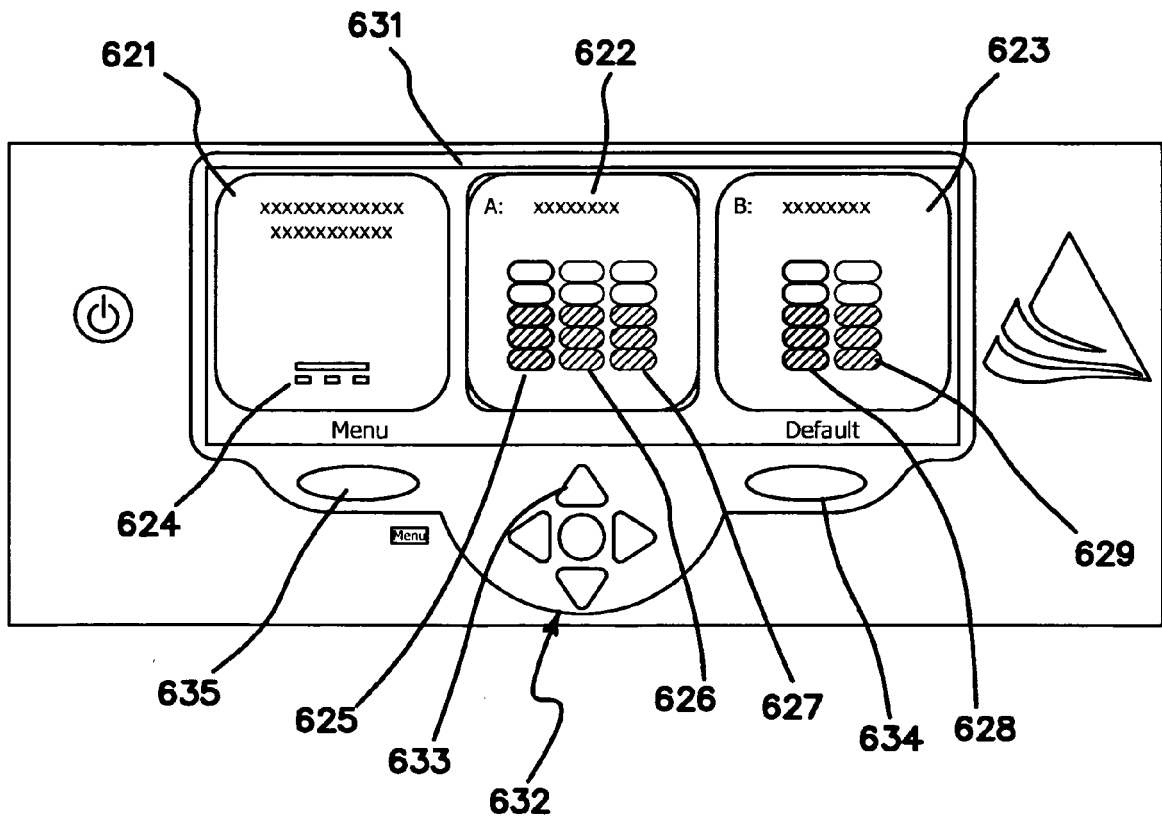


FIG. 6

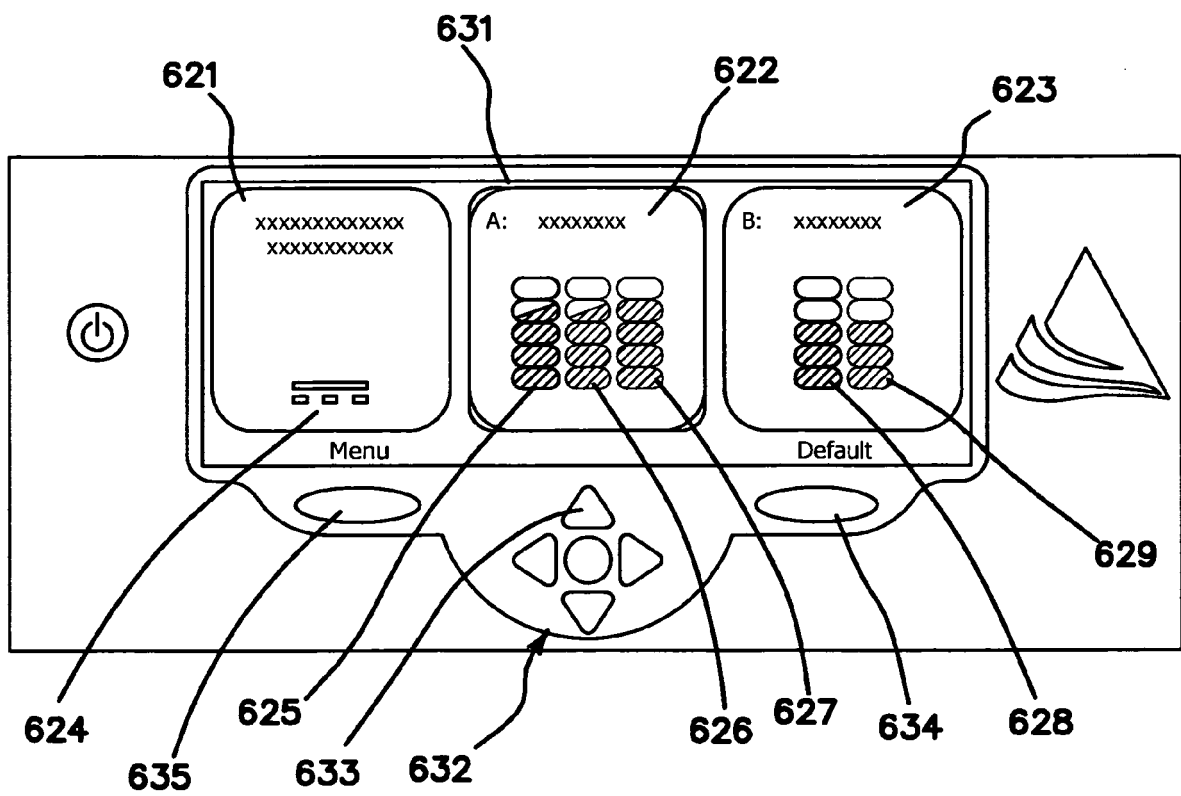


FIG. 7

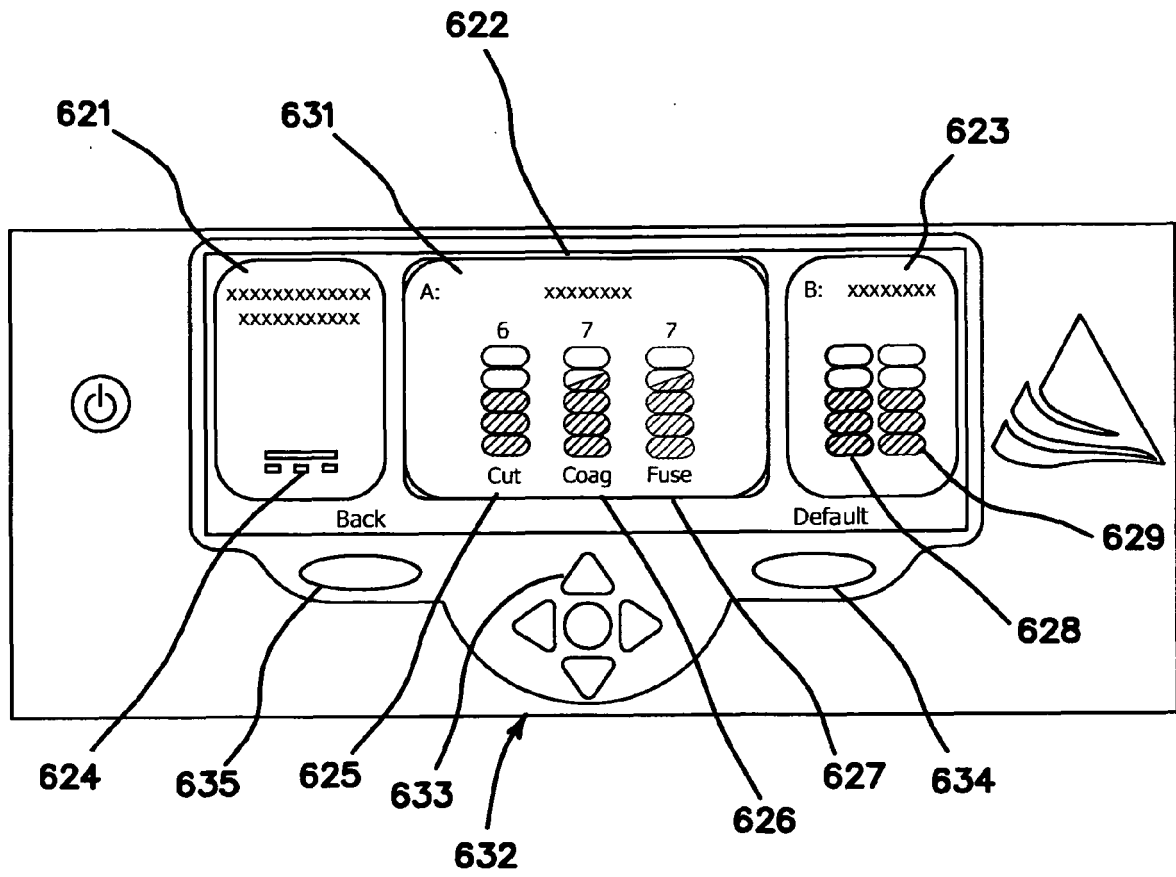


FIG. 8

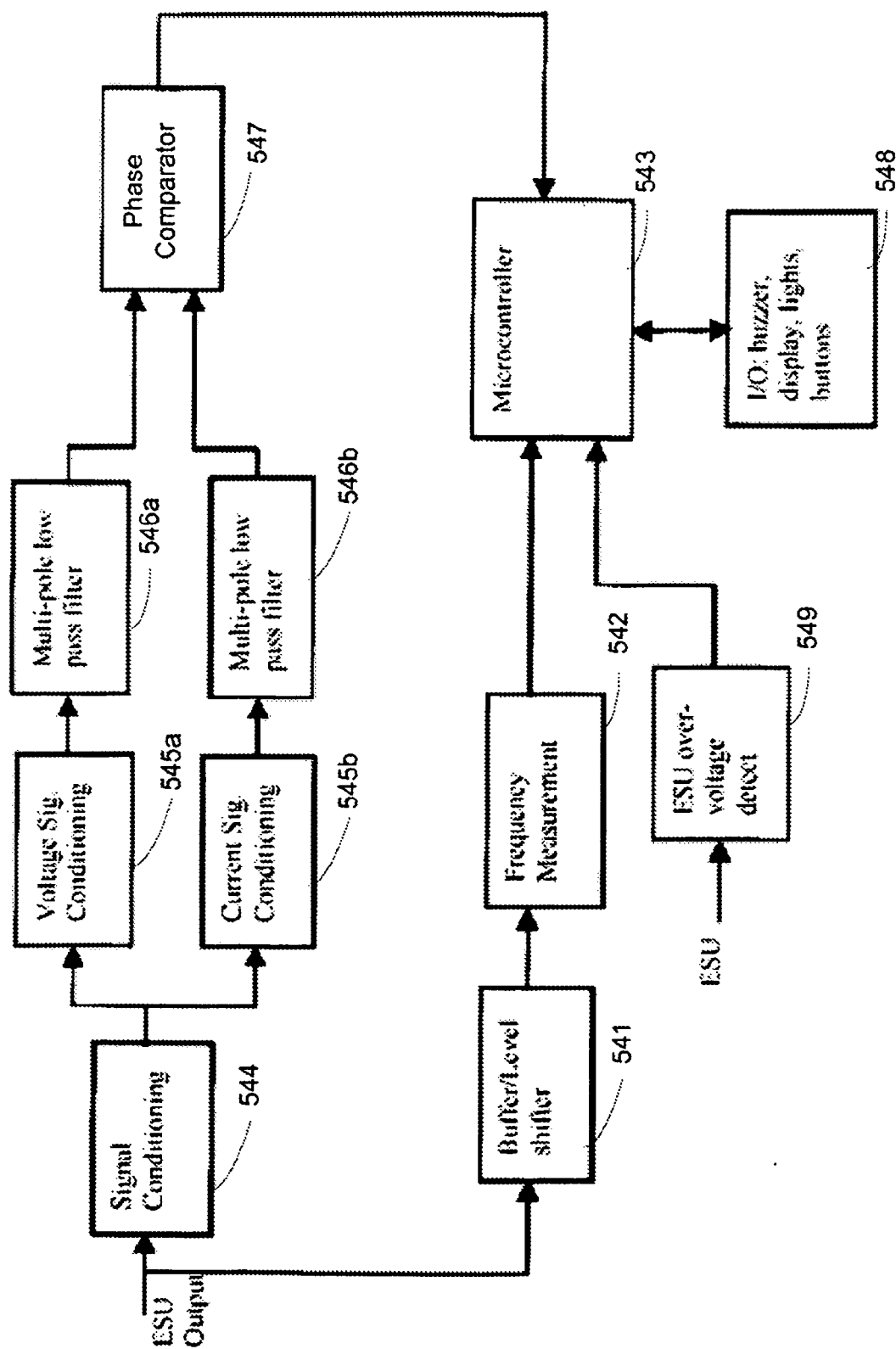


FIG. 9

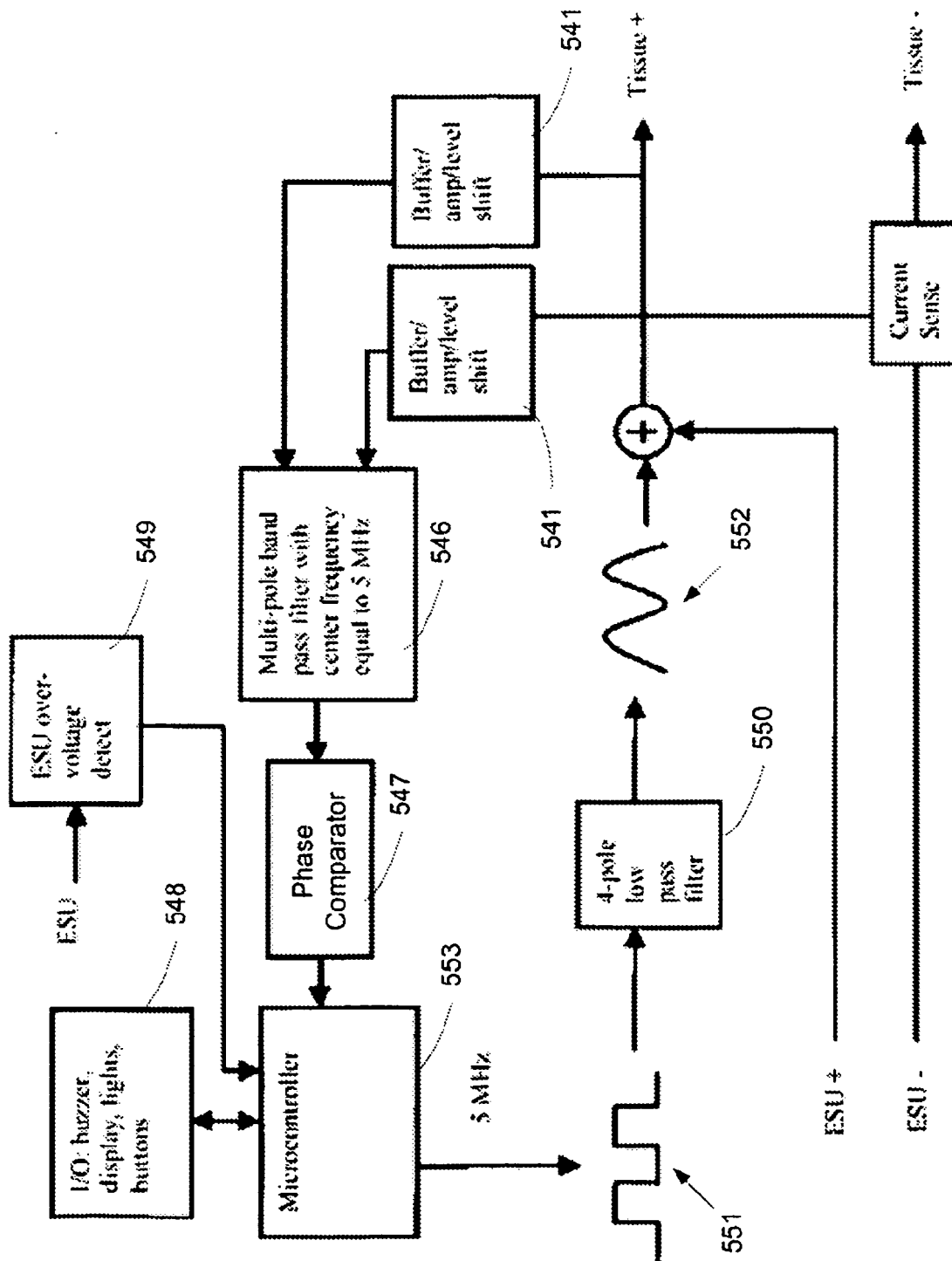


FIG. 10

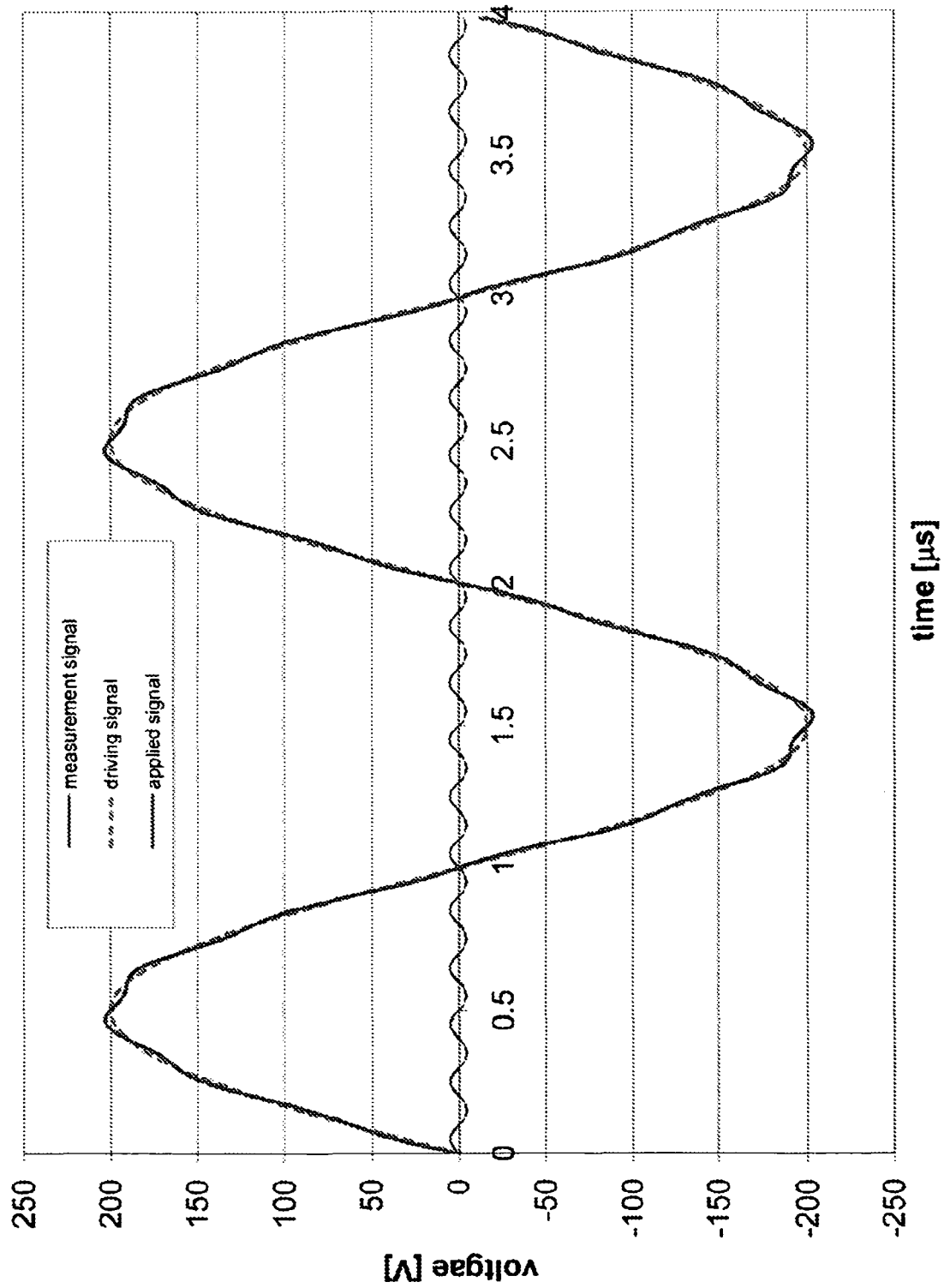


FIG. 11

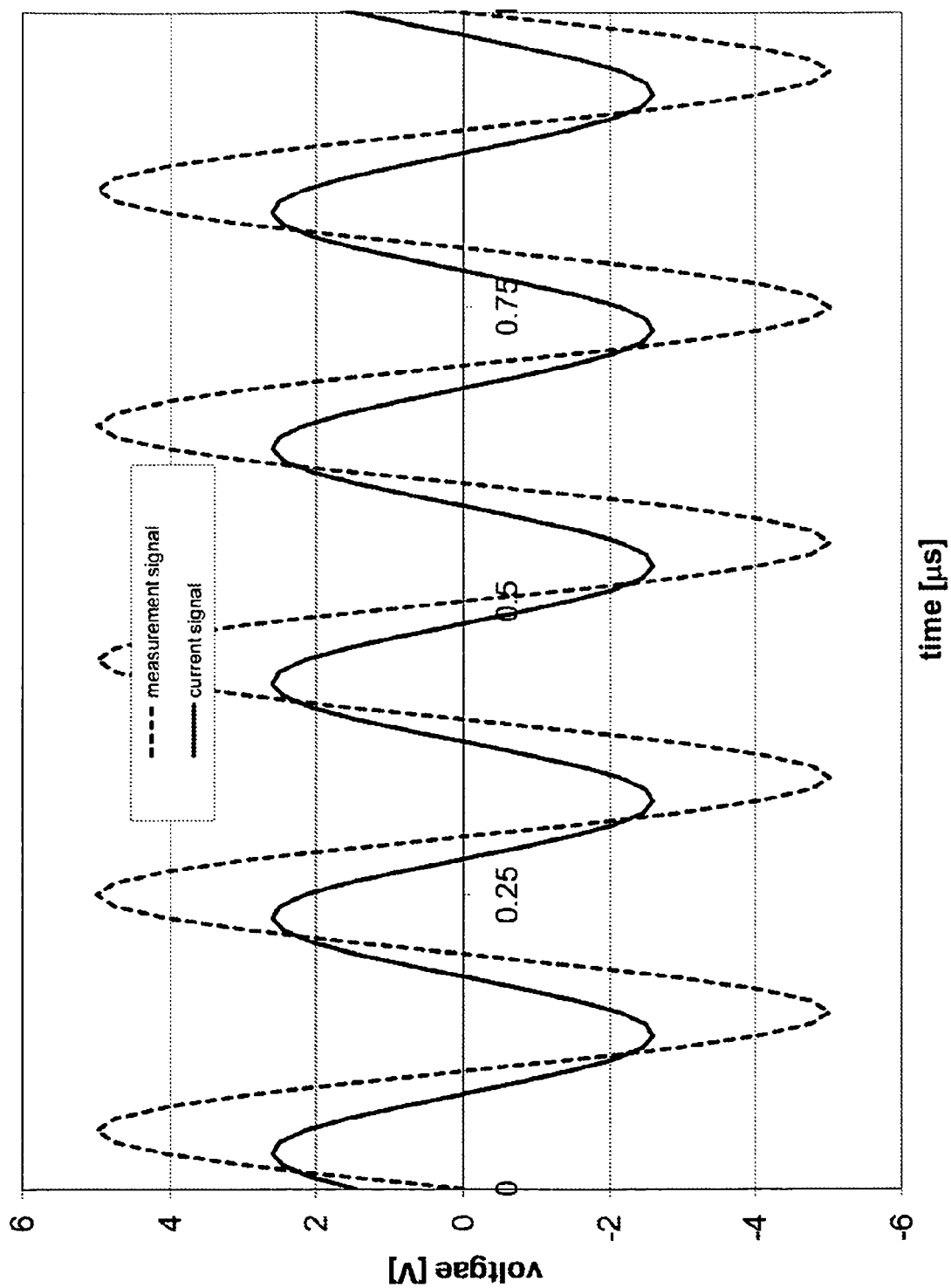


FIG. 12

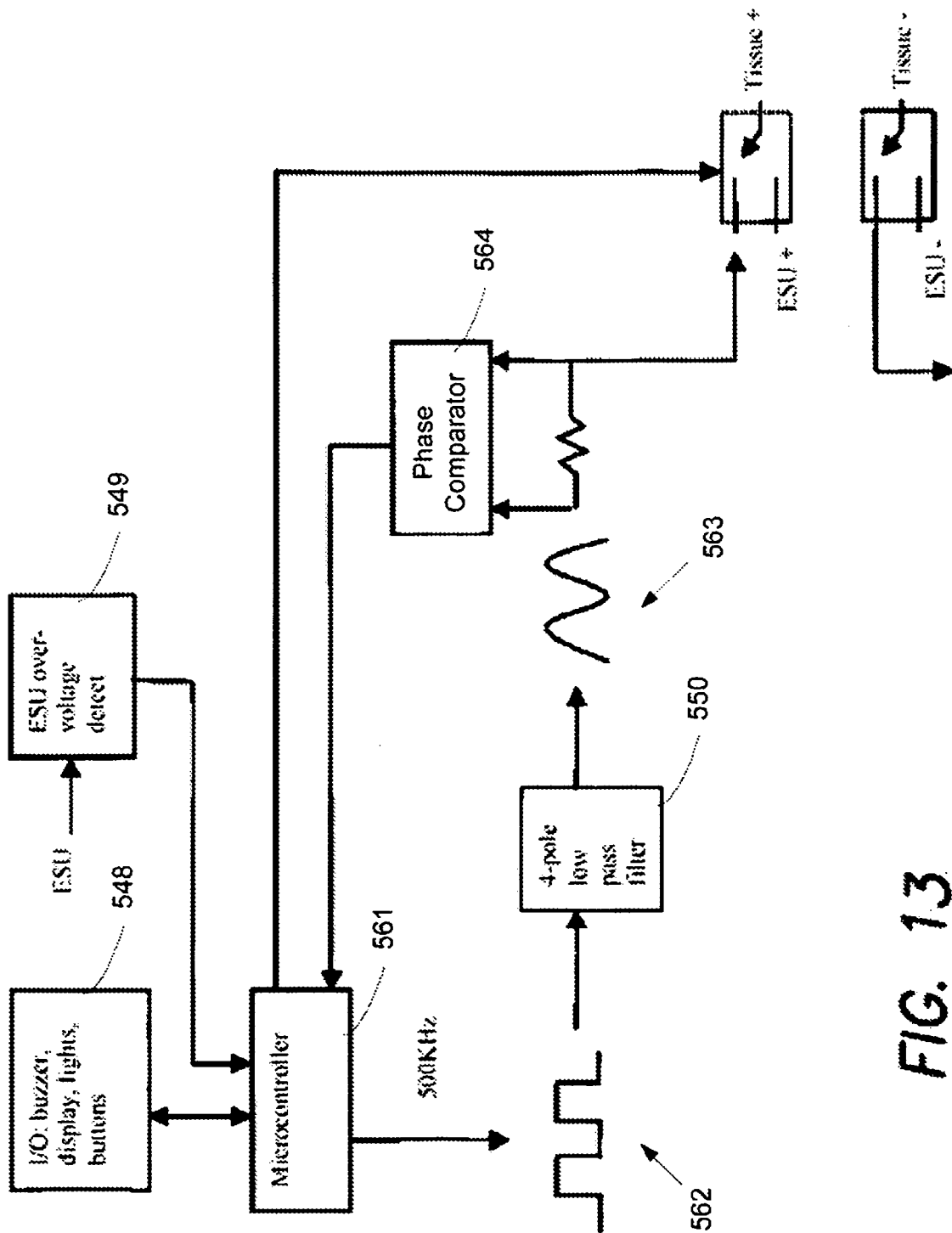


FIG. 13

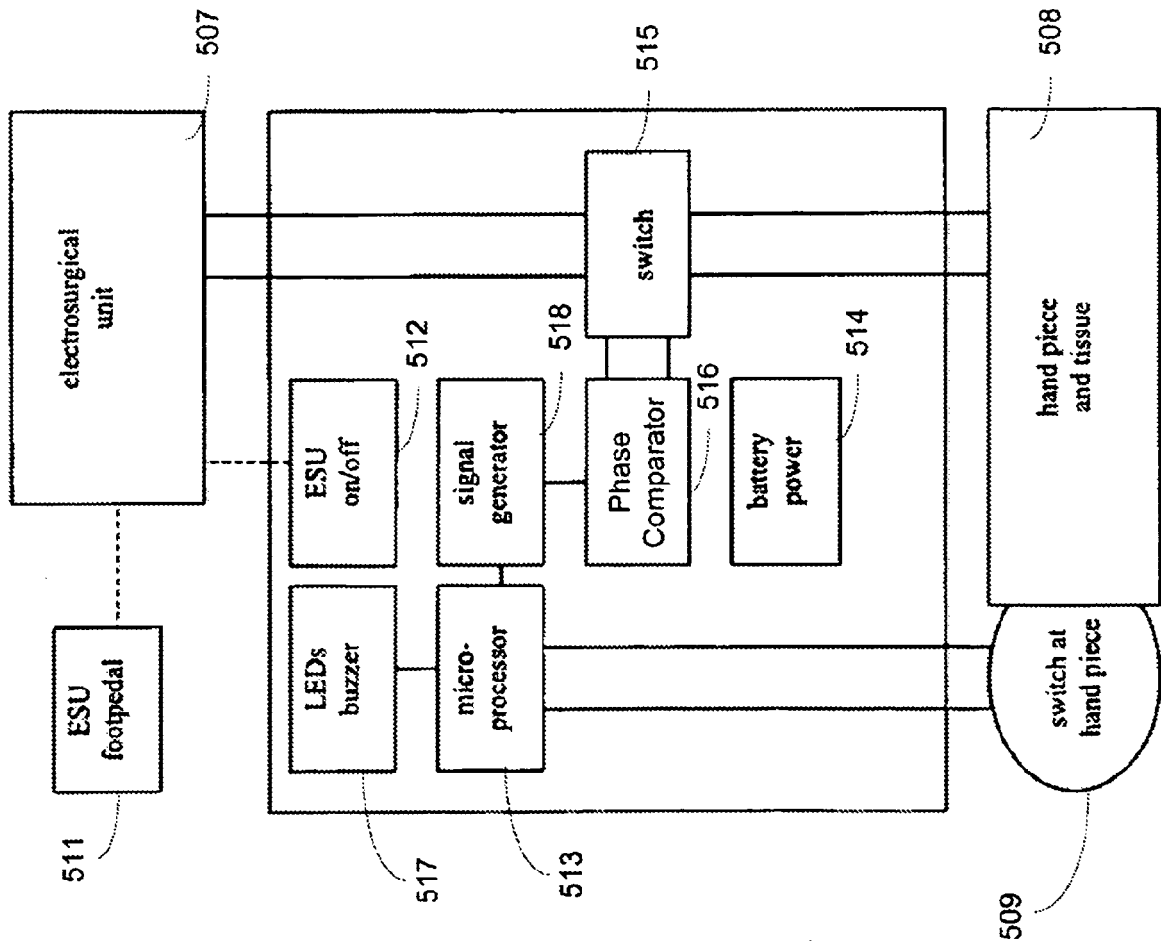
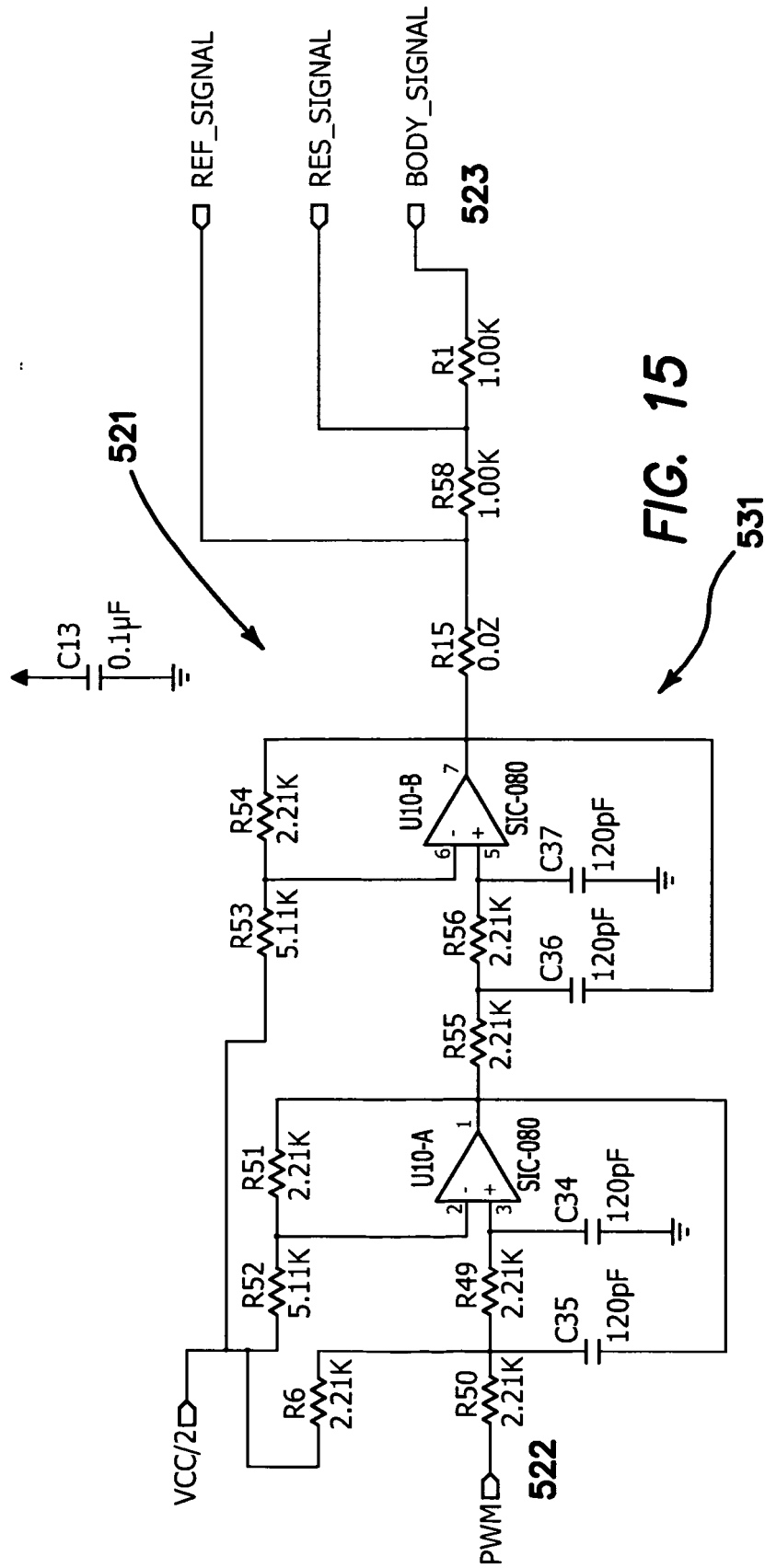
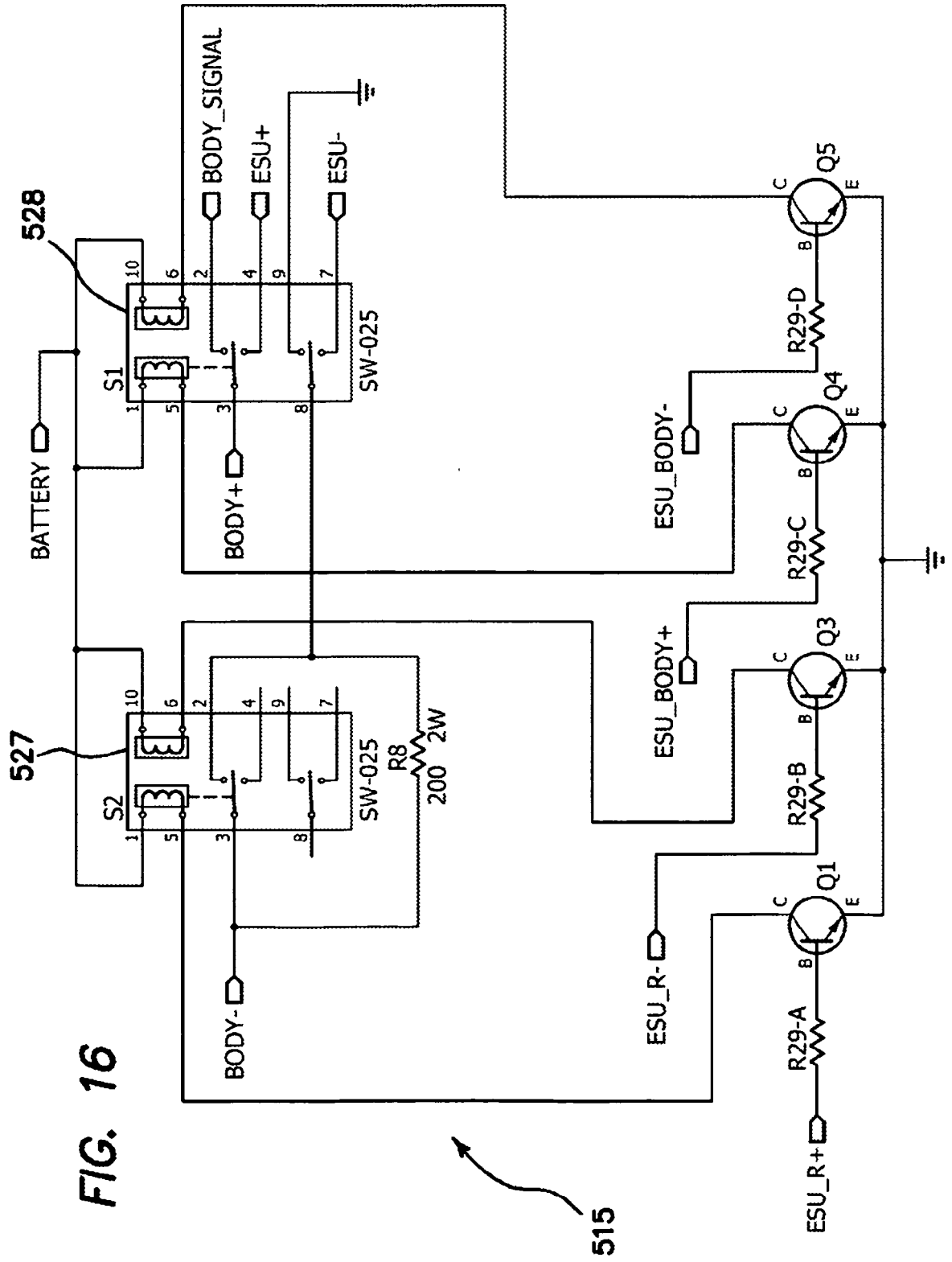


FIG. 14





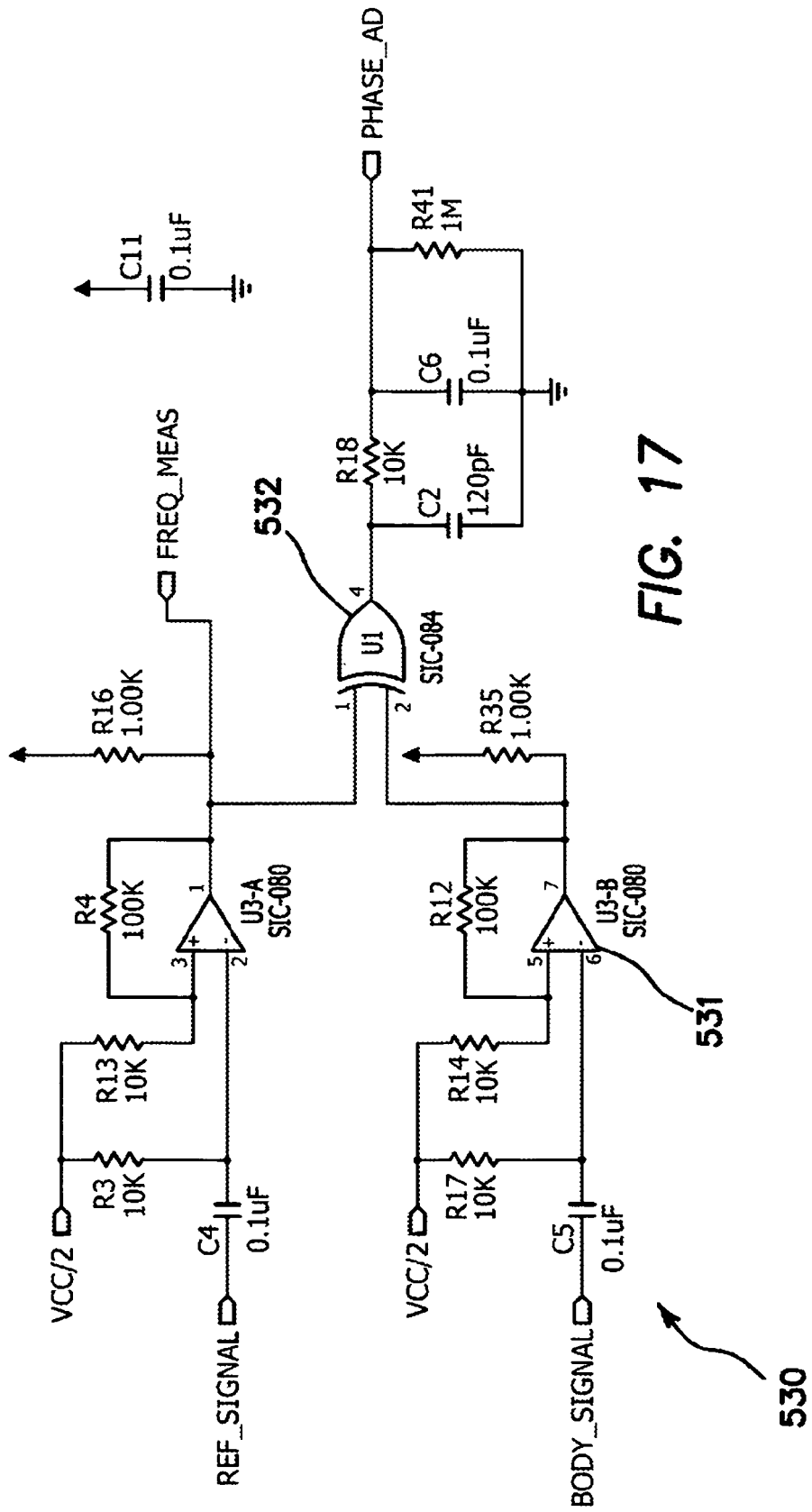


FIG. 17

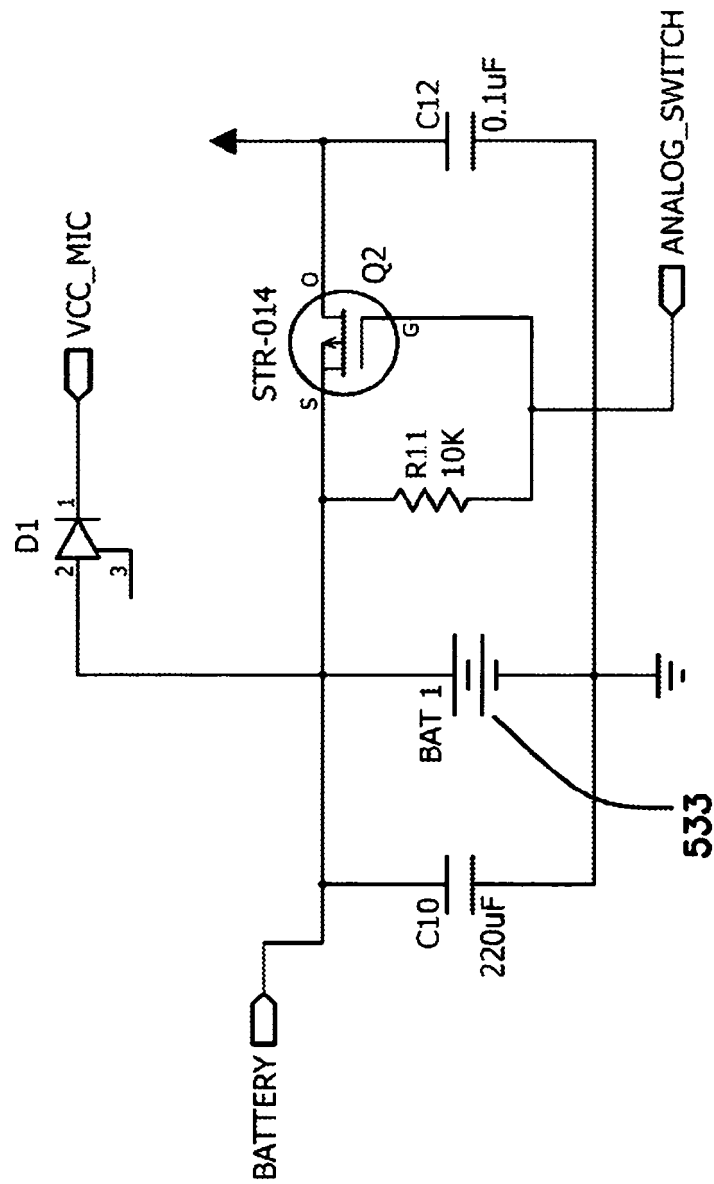


FIG. 18

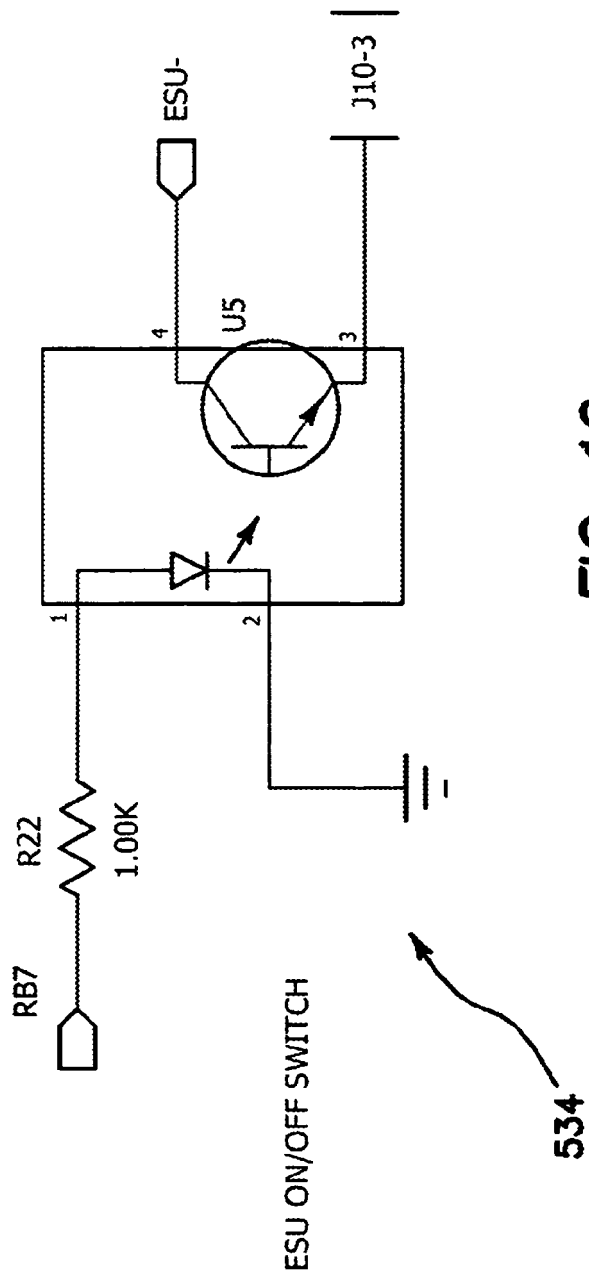
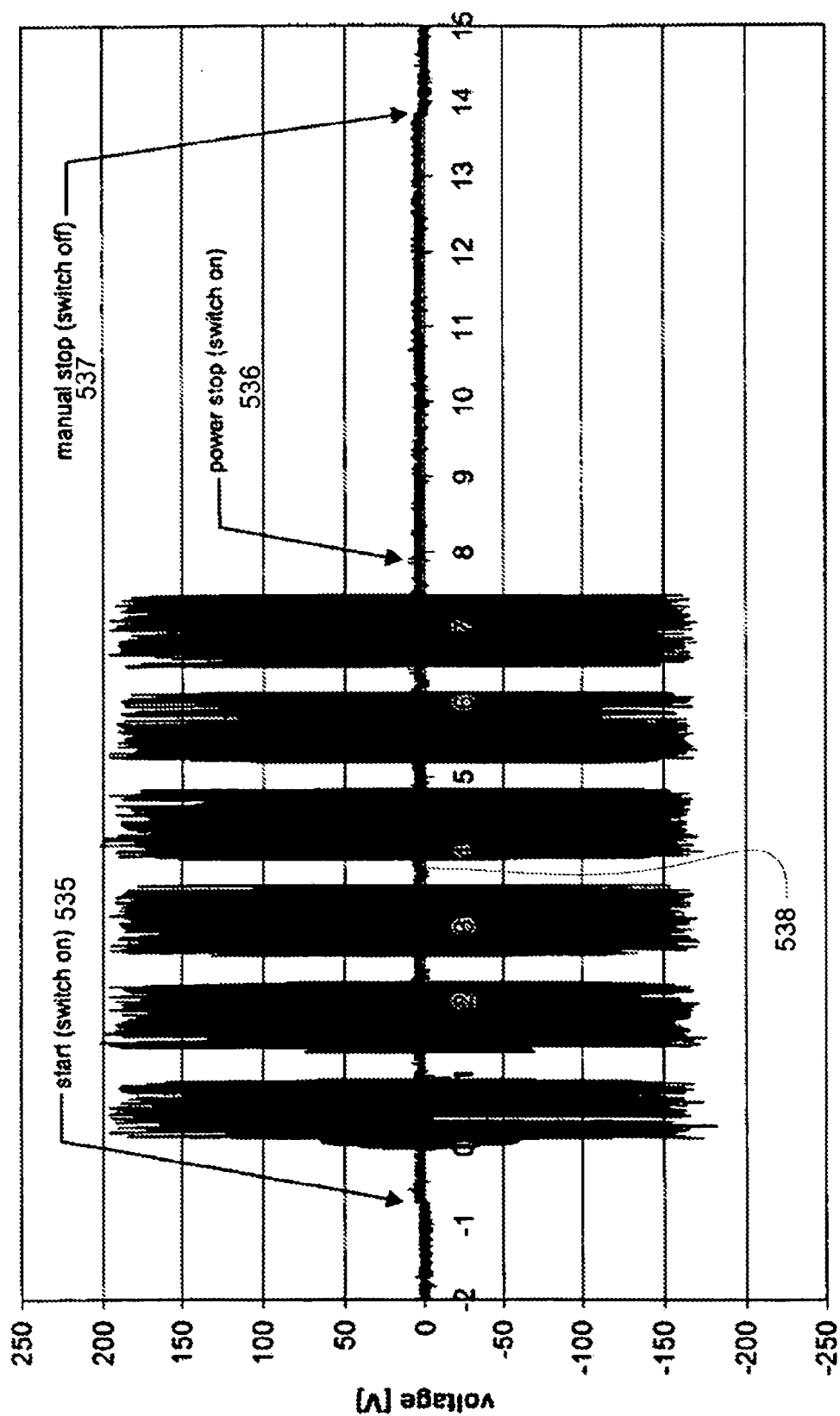


FIG. 19

fusion cycle



time [s]

FIG. 20

measurement cycle

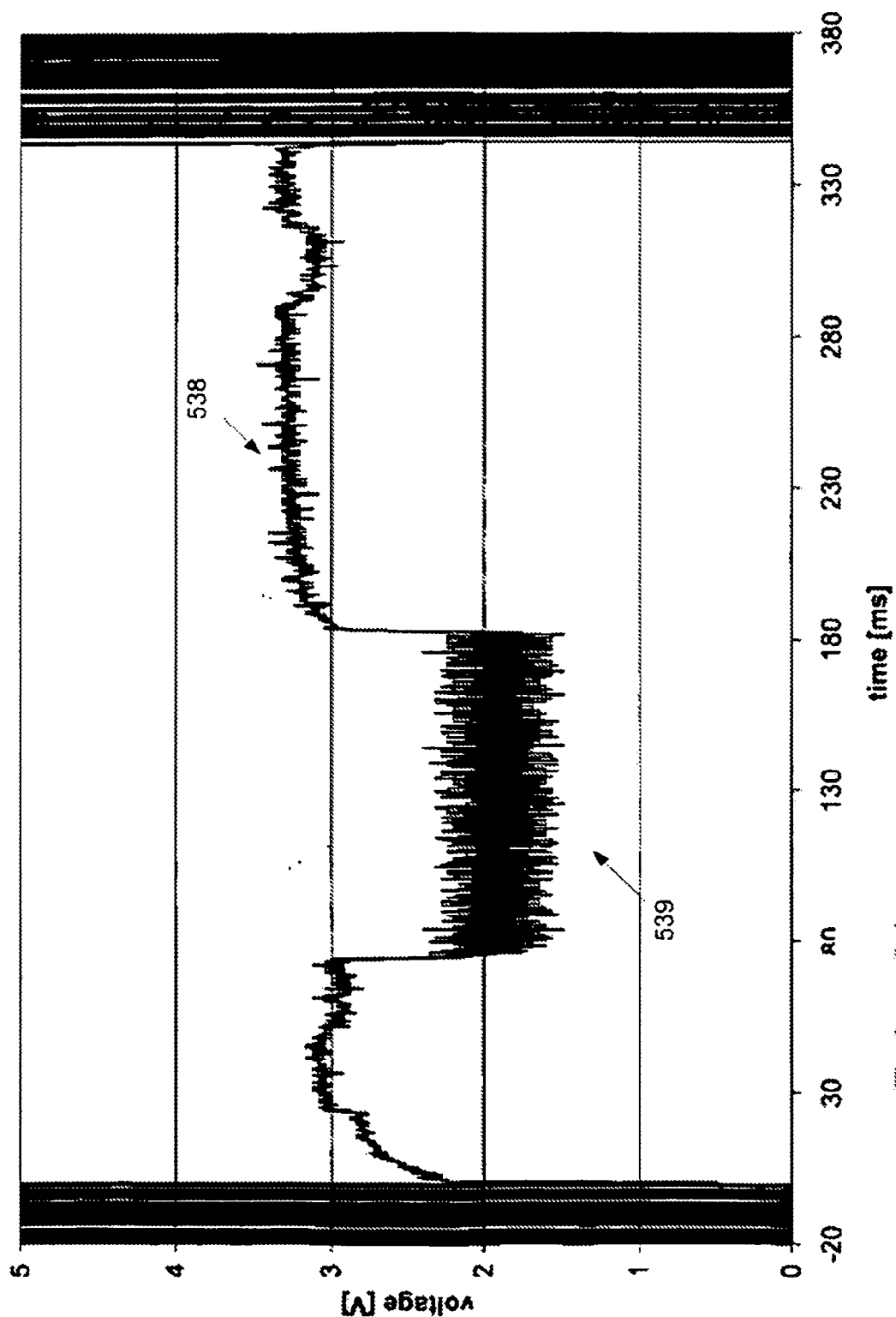


FIG. 21

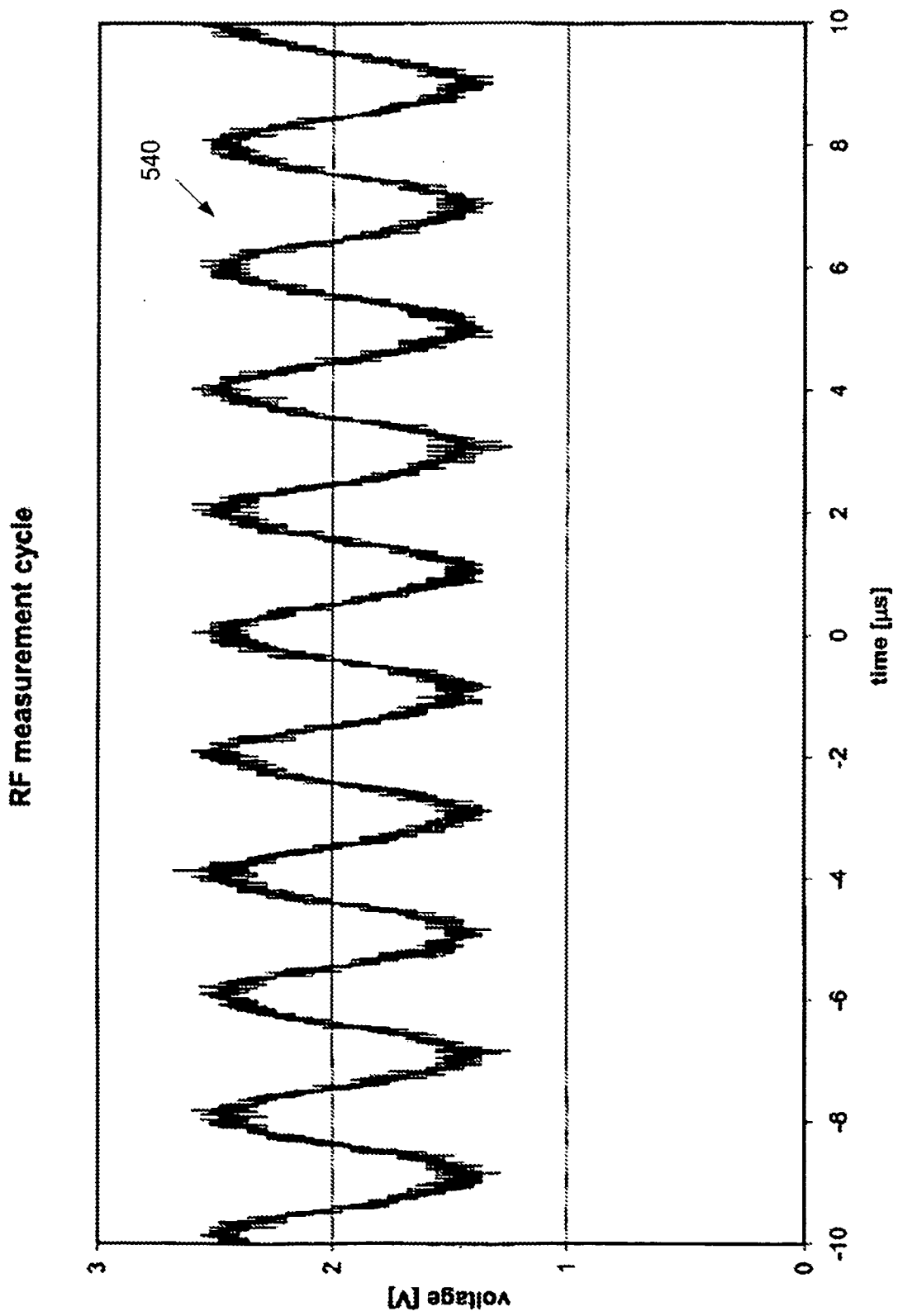
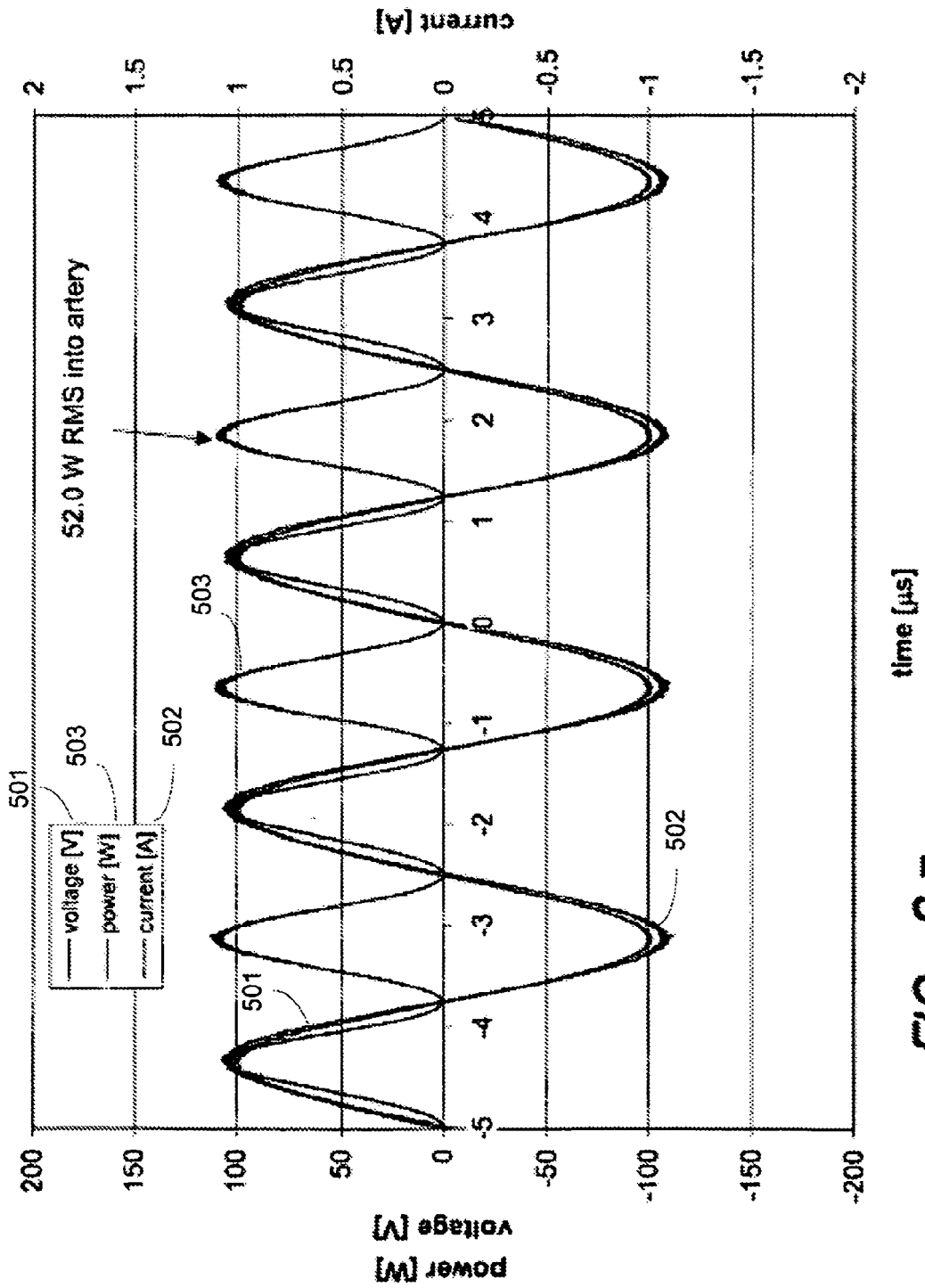


FIG. 22

4 mm artery on 0.75mm prototype - 60W setting
ca. 1s into fusion



time [μs]

FIG. 23

4 mm artery on 0.75mm prototype - 60W setting
harvested artery, kept in 1-normal saline solution

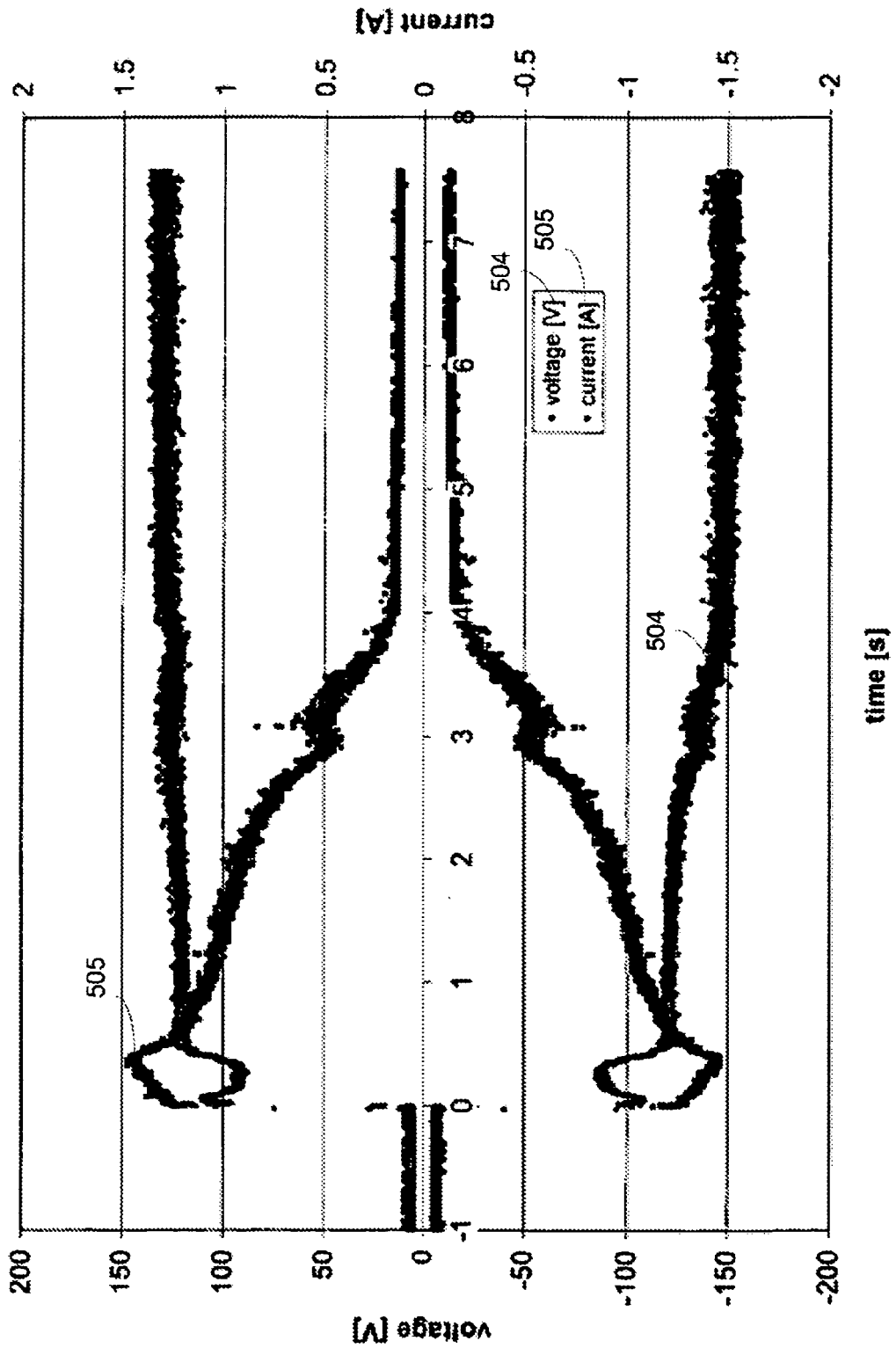


FIG. 24

4 mm artery on 0.75mm prototype - 60W setting
harvested artery, kept in 1-normal saline solution

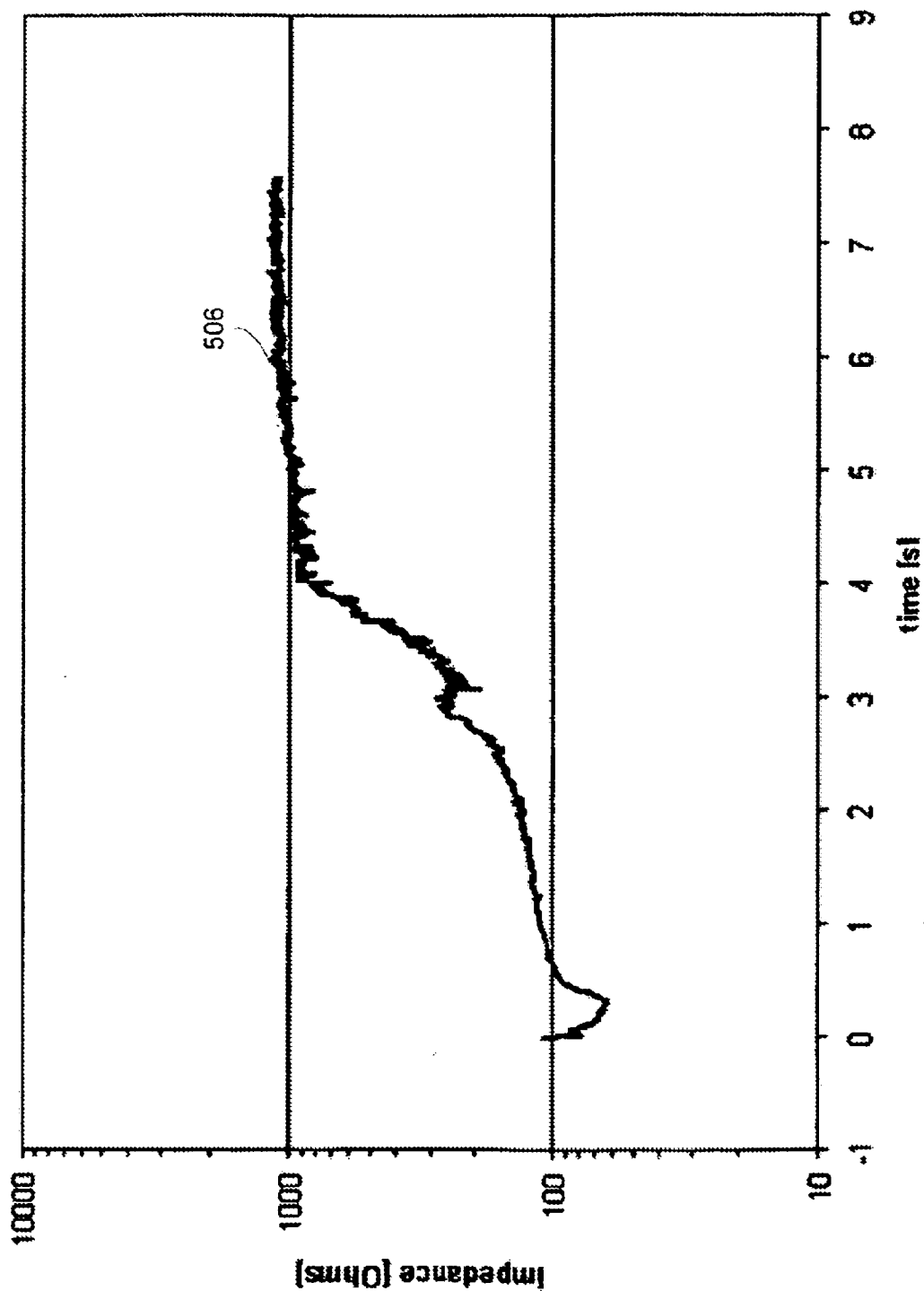


FIG. 25

relative resistance with 0.75mm prototype - 60W setting

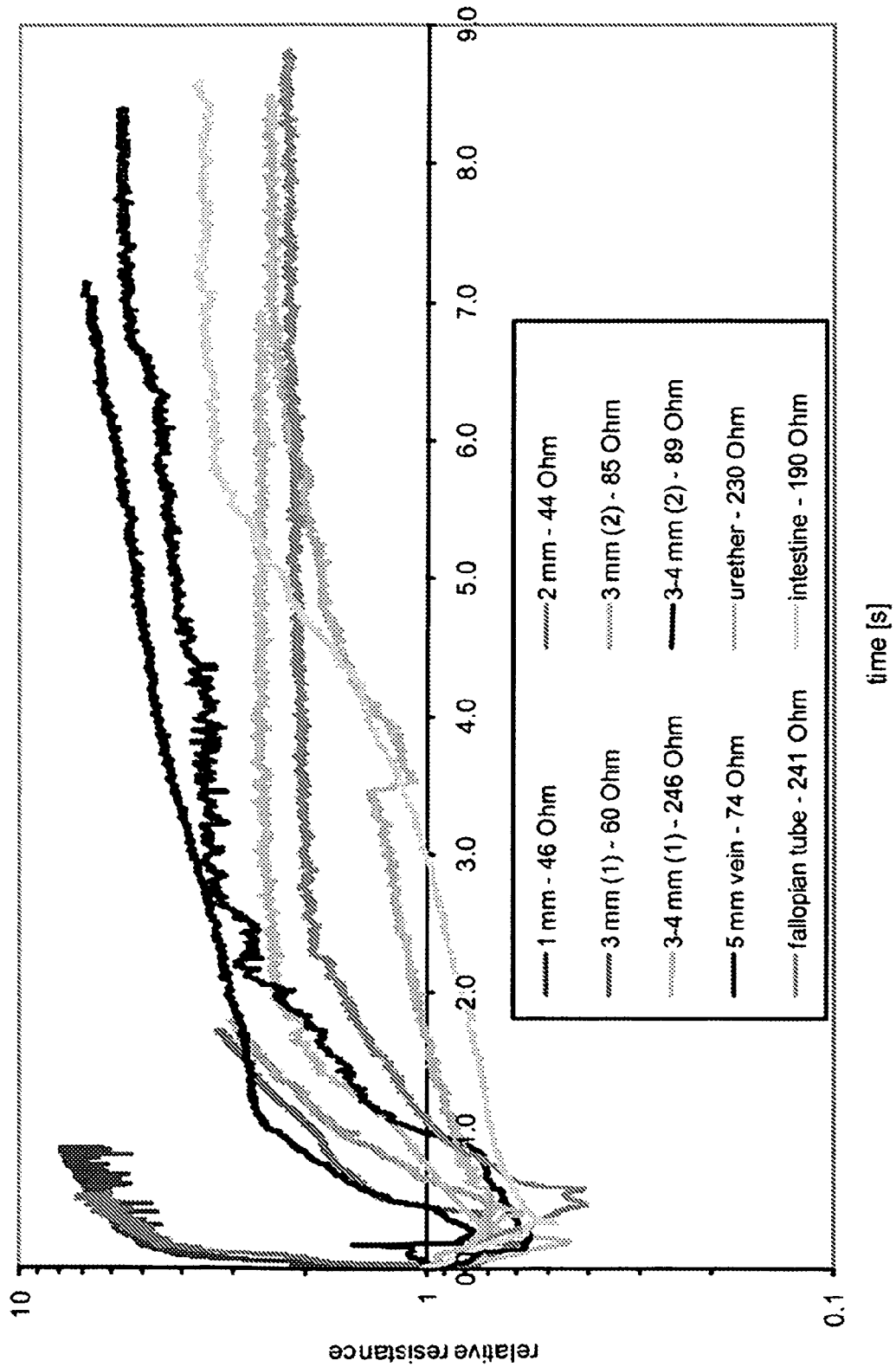
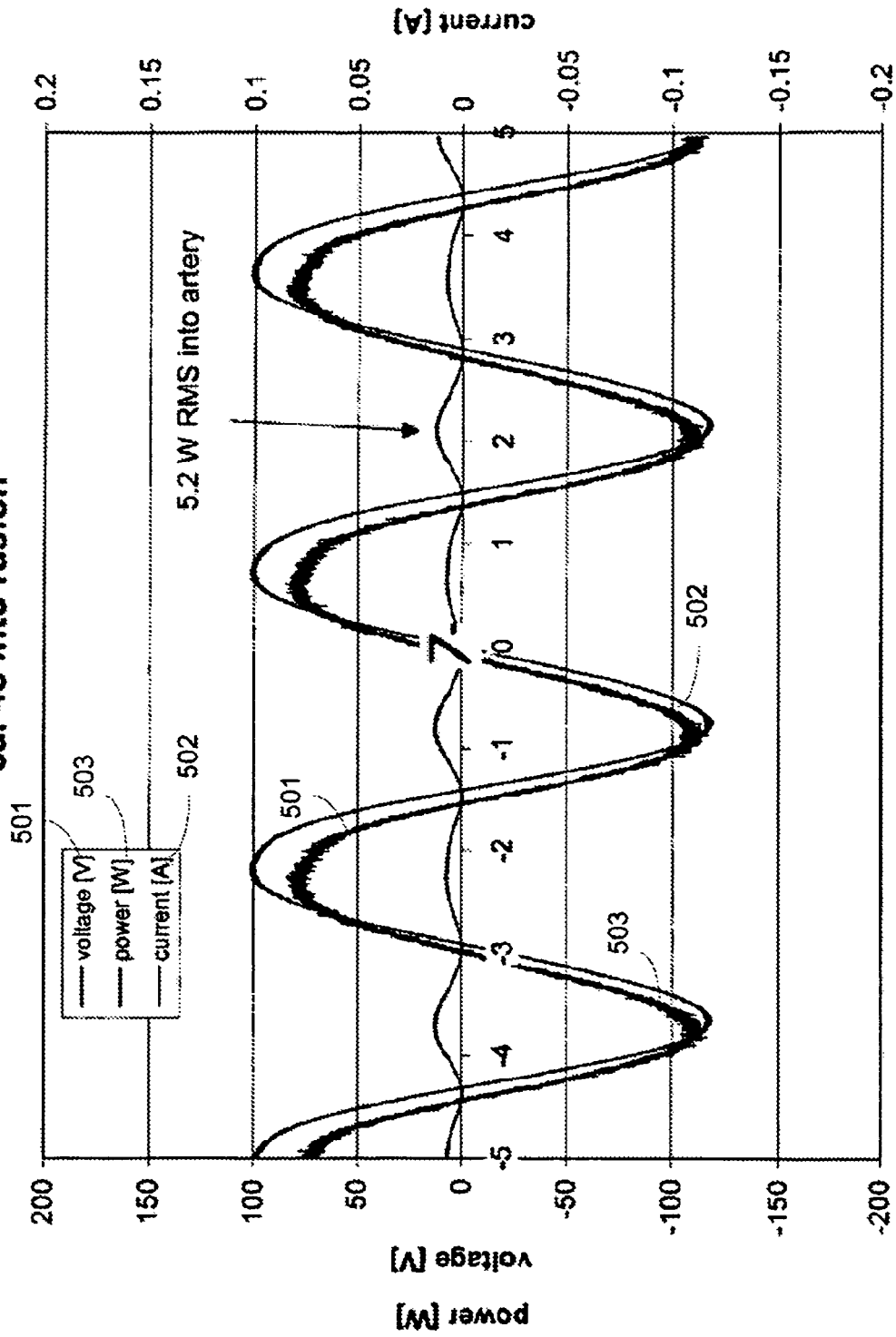


FIG. 26

4 mm artery on 0.75mm prototype - 60W setting
ca. 4s into fusion



time [μs]

FIG. 27

4 mm artery on 0.75mm prototype - 60W setting
ca. 7s into fusion

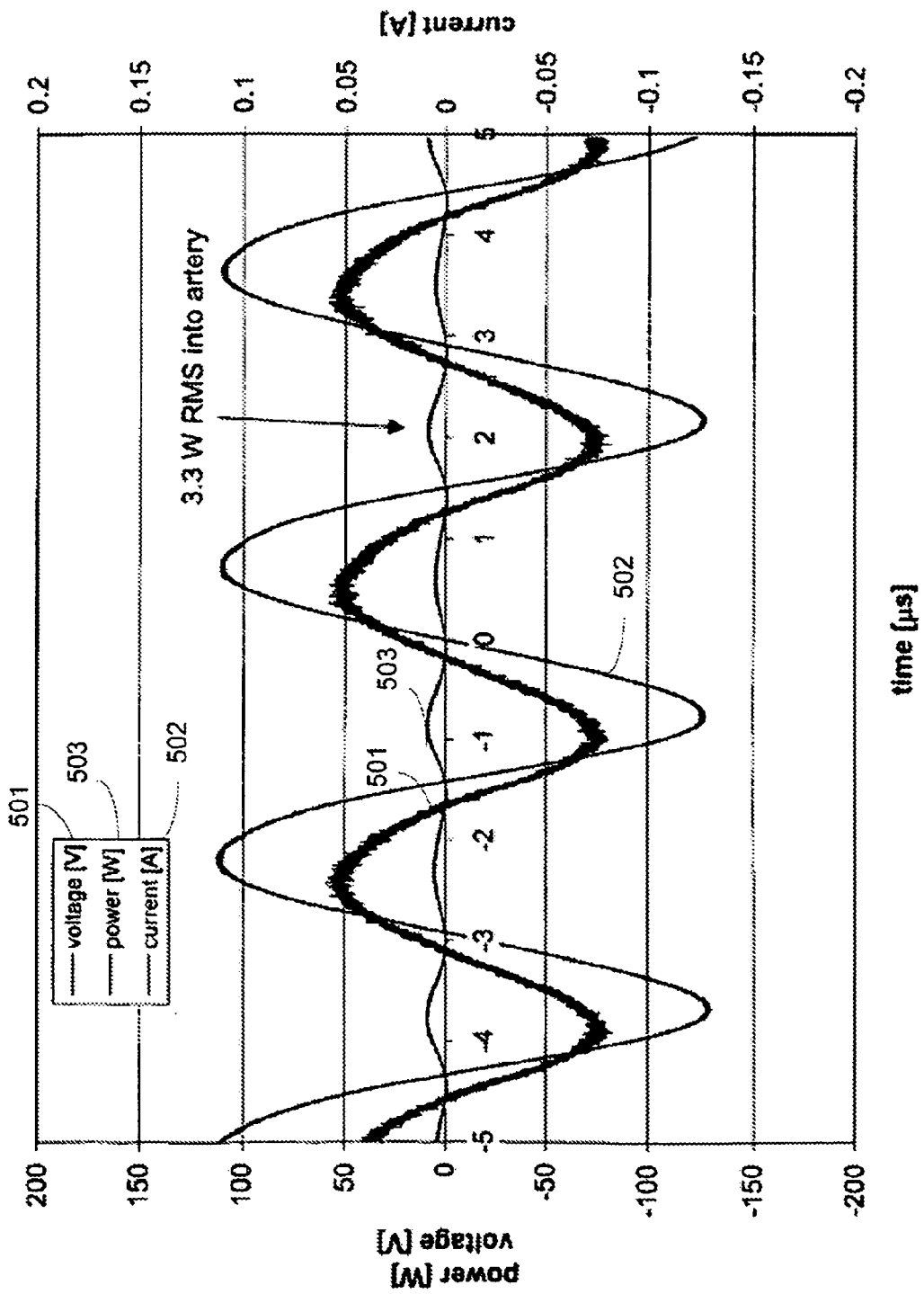


FIG. 28

Double-row jaws; 12 lb.; 100W setting

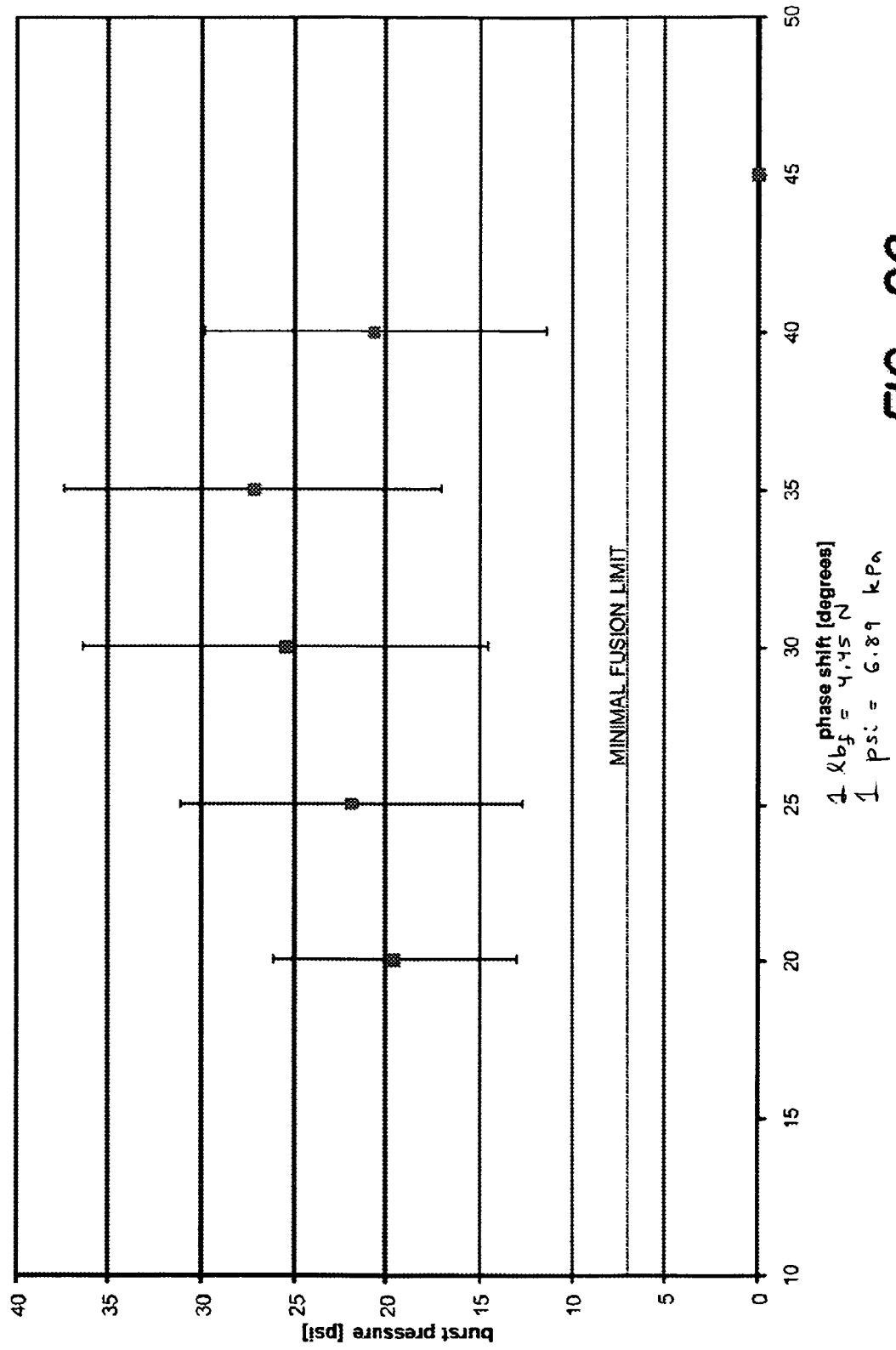


FIG. 29

Tissue name	ρ [S/m]	ϵ	$\epsilon \times \rho$
BoneMarrow	0.003852	48.969	0.18862859
BreastFat	0.025428	30.711	0.78091931
Fat	0.024833	34.559	0.85820365
BoneCortical	0.022165	174.5	3.8677925
Nail	0.022165	174.5	3.8677925
Tooth	0.022165	174.5	3.8677925
SkinDry	0.0043646	1062	4.6352052
BoneCancellous	0.086731	308.16	26.727025
Tendon	0.39075	200.69	78.4196175
GallBladder	0.90019	101.18	91.0812242
Aorta	0.32389	312.32	101.157325
BloodVessel	0.32389	312.32	101.157325
Bladder	0.22787	534.55	121.807909
LungInflated	0.12301	1025	126.08525
Dura	0.50258	264.43	132.897229
BodyFluid	1.5003	91.35	137.052405
VitreousHumor	1.5003	91.35	137.052405
Nerve	0.11094	1487.6	165.034344
SpinalCord	0.11094	1487.6	165.034344
GallBladderBile	1.4	120	168
BrainGreyMatter	0.15187	1187	180.26969
CerebroSpinalFluid	2	109	218
Cerebellum	0.17248	1475	254.408
Ovary	0.35016	873.26	305.780722
Cervix	0.55686	614.02	341.923177
Cartilage	0.20078	1938.6	389.232108
Spleen	0.14706	2789	410.15034
Liver	0.1481	2769.8	410.20738
Trachea	0.35907	1157.6	415.659432
Lens	0.35278	1502.1	529.910838
LungDeflated	0.30697	1884.3	578.423571
MucousMembrane	0.17798	3610	642.5078
SkinWet	0.17798	3610	642.5078
Colon	0.27777	2370.3	658.398231
Kidney	0.22834	3443.3	786.243122
Uterus	0.54947	1489.4	818.380618
Heart	0.28072	3264.5	916.41044
Tongue	0.33099	3252	1076.37948
Duodenum	0.55397	2064.7	1143.78186

FIG. 30

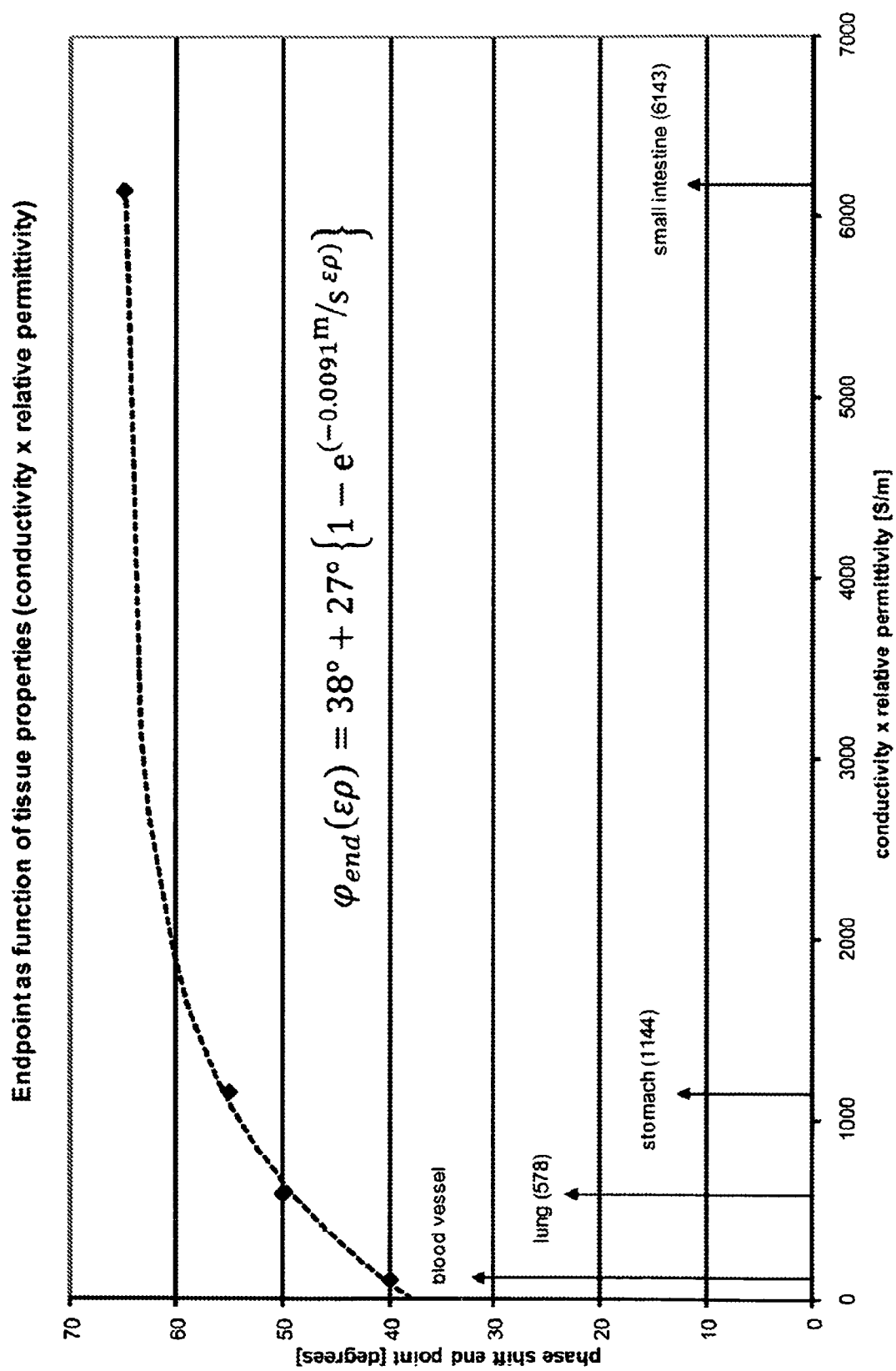


FIG. 31

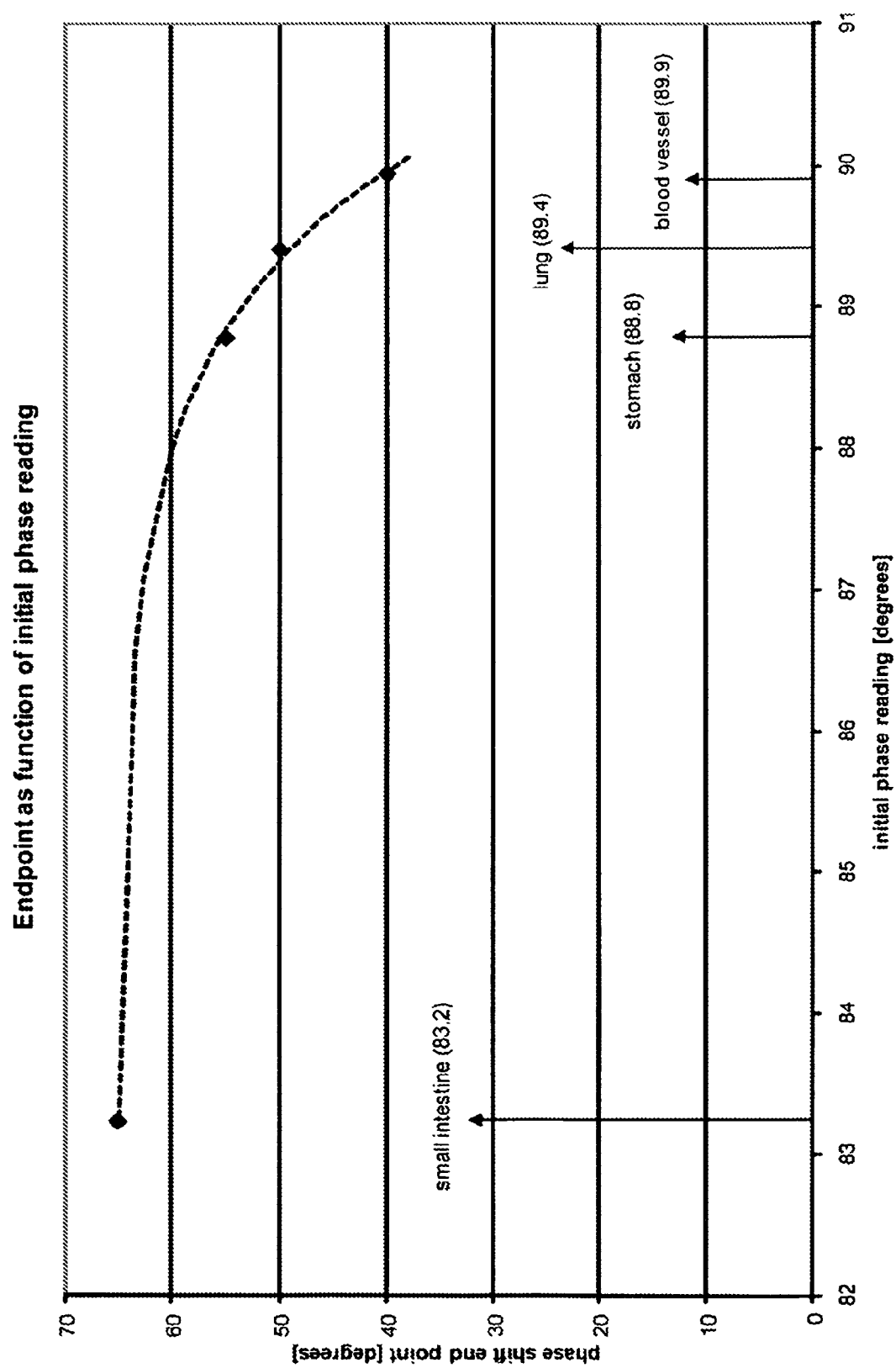


FIG. 32

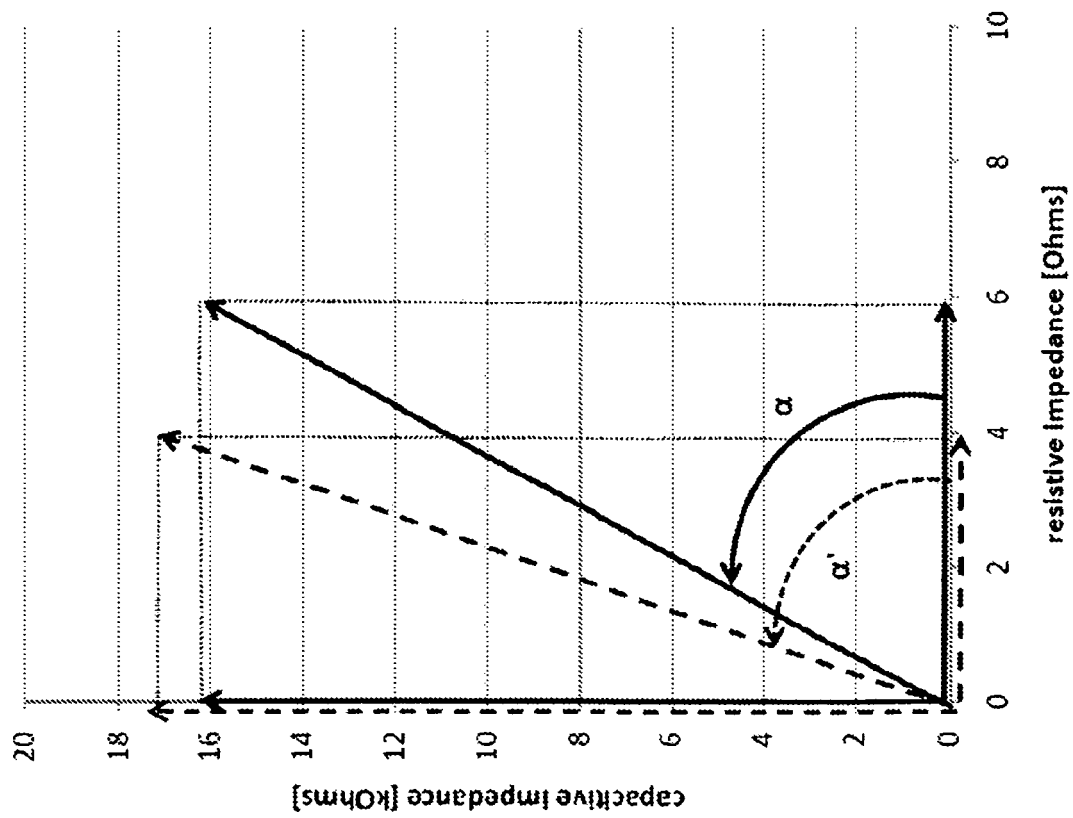


FIG. 33

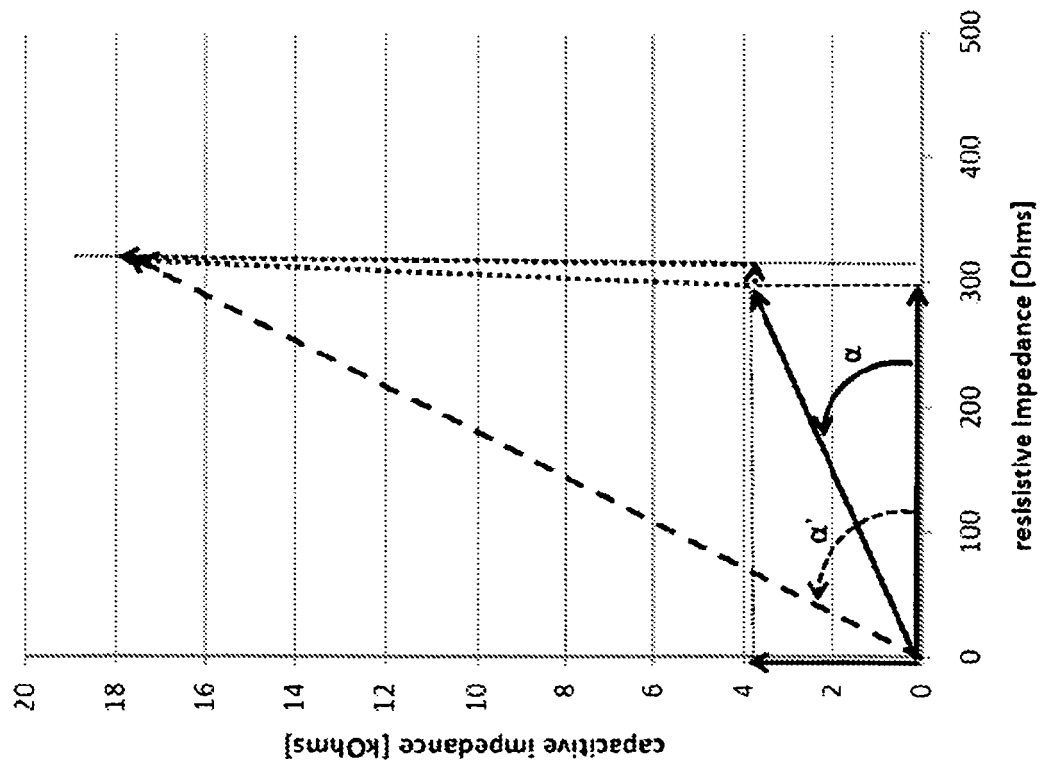


FIG. 34

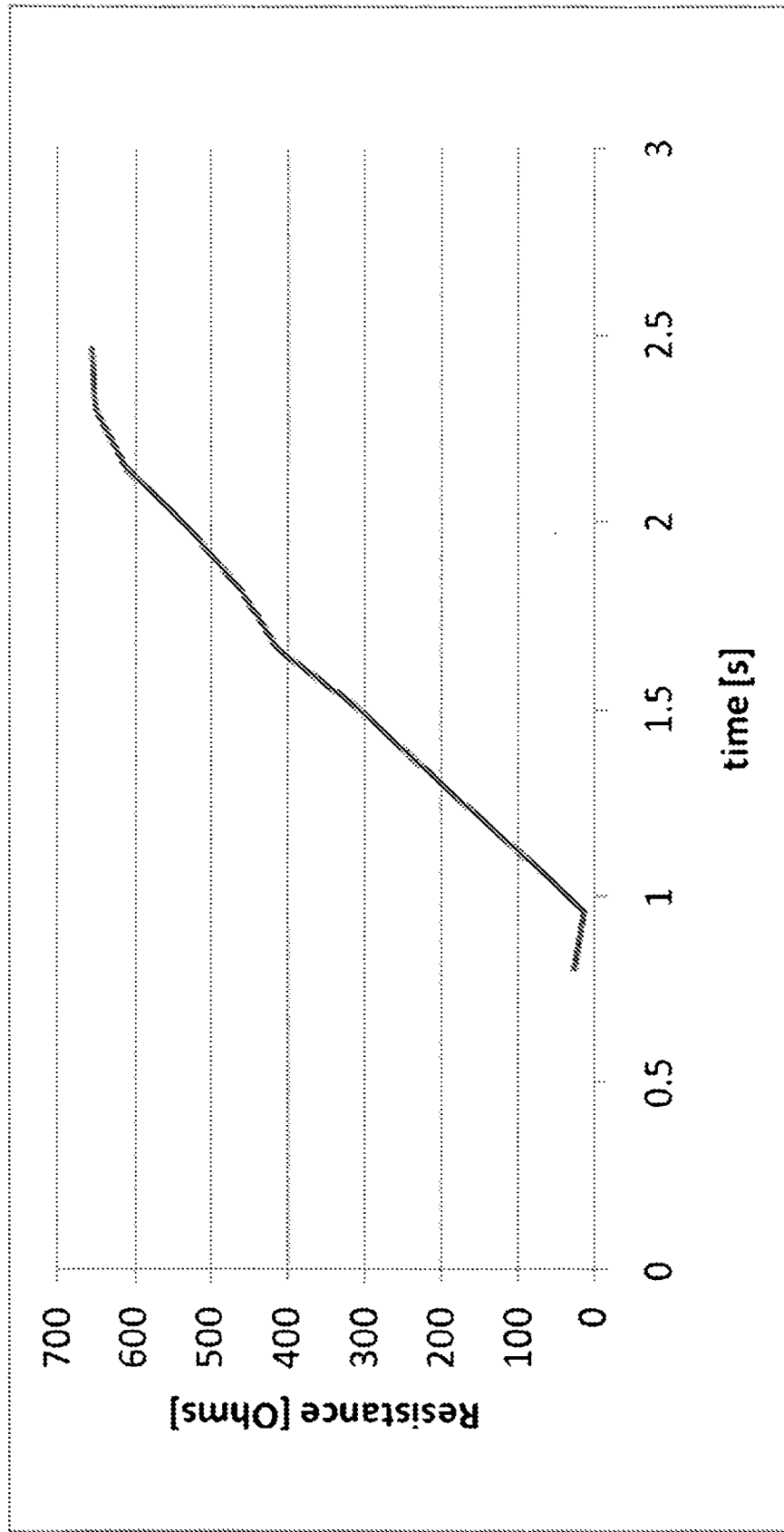


FIG. 35

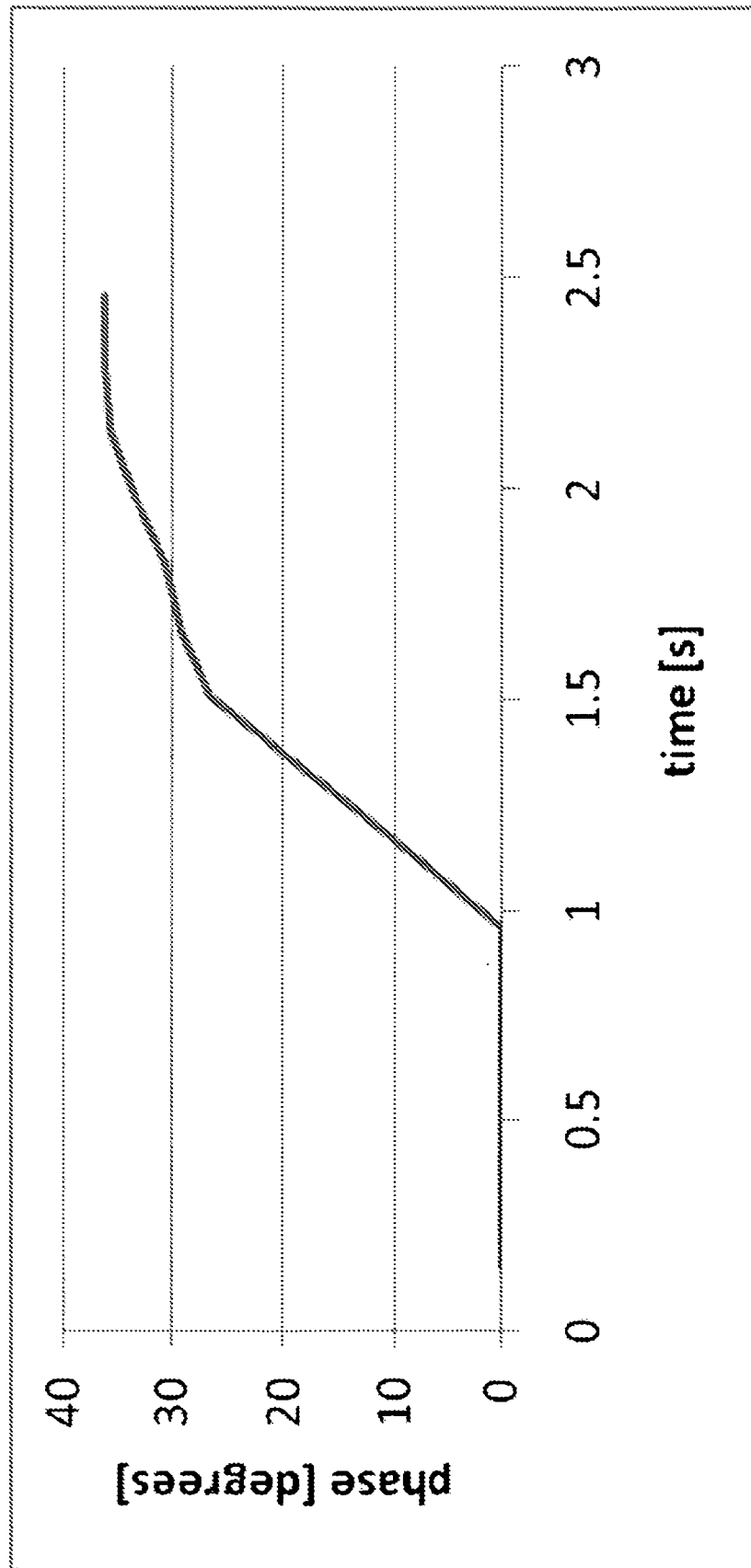
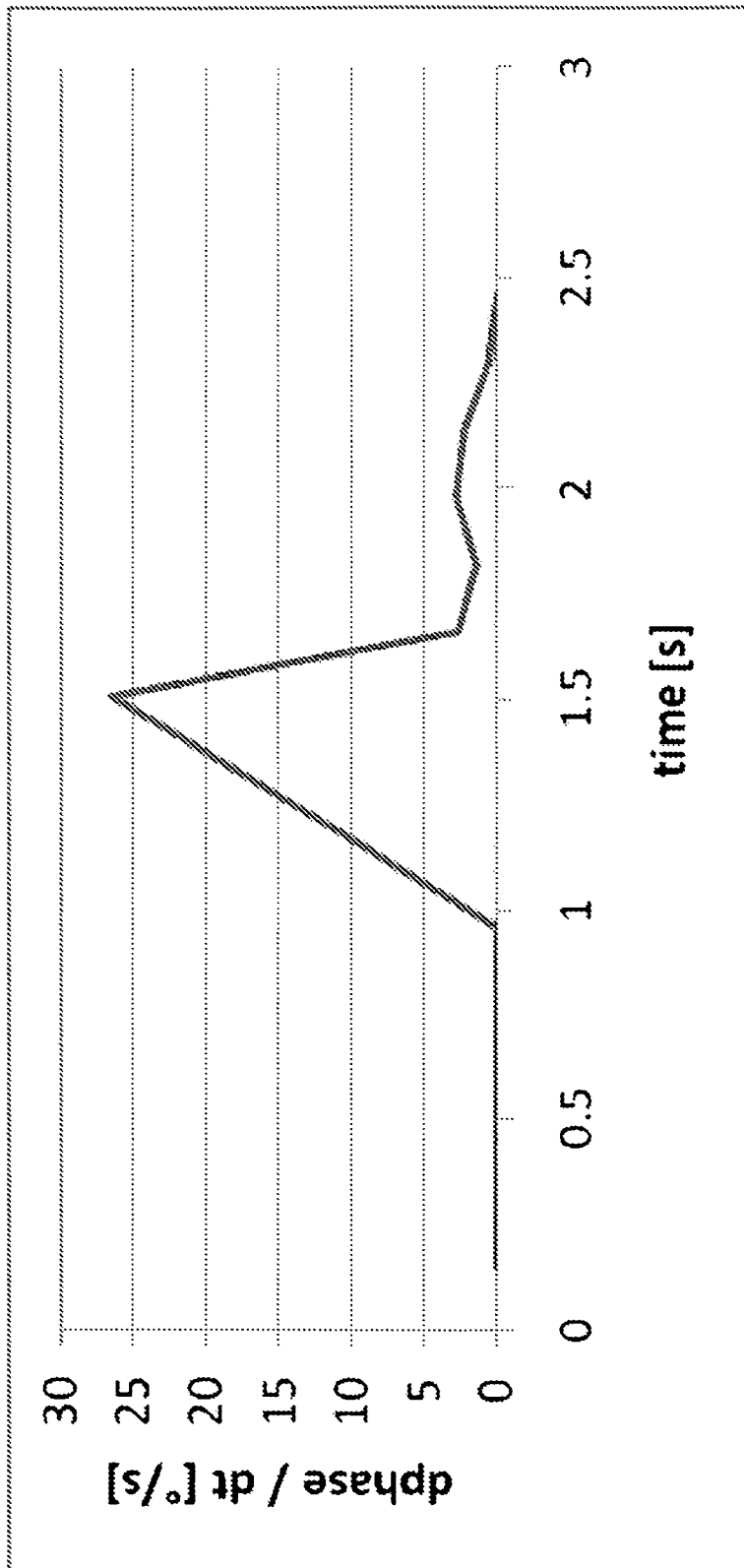
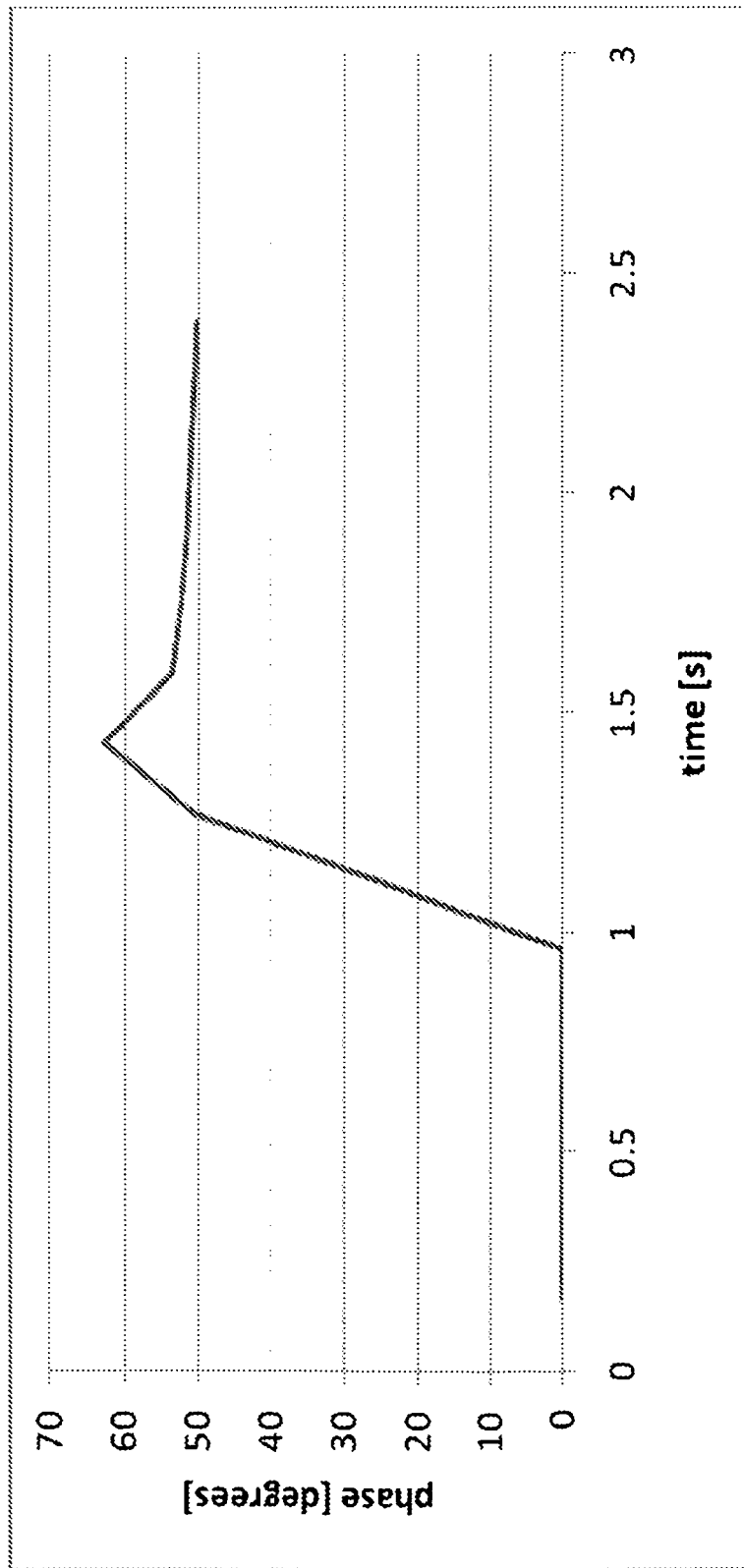


FIG. 36

**FIG. 37**

**FIG. 38**

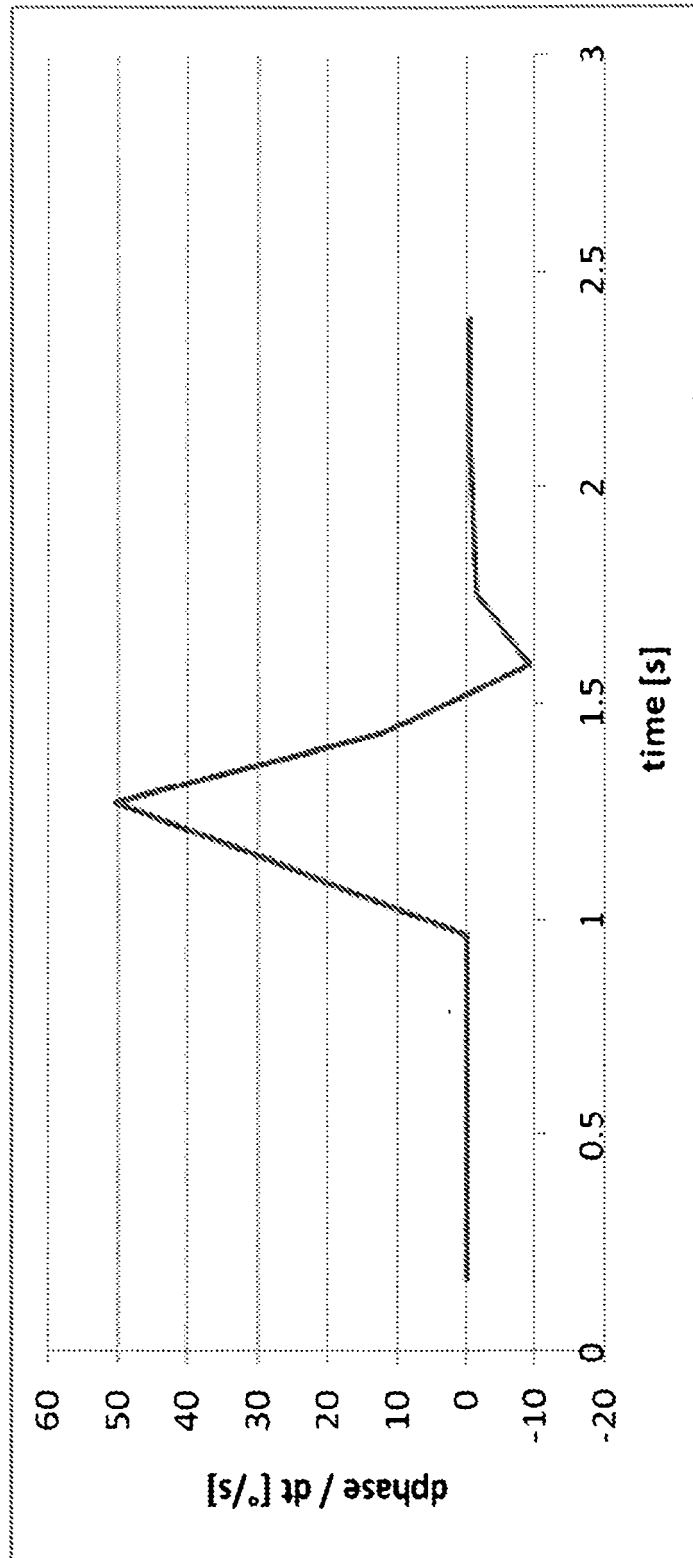
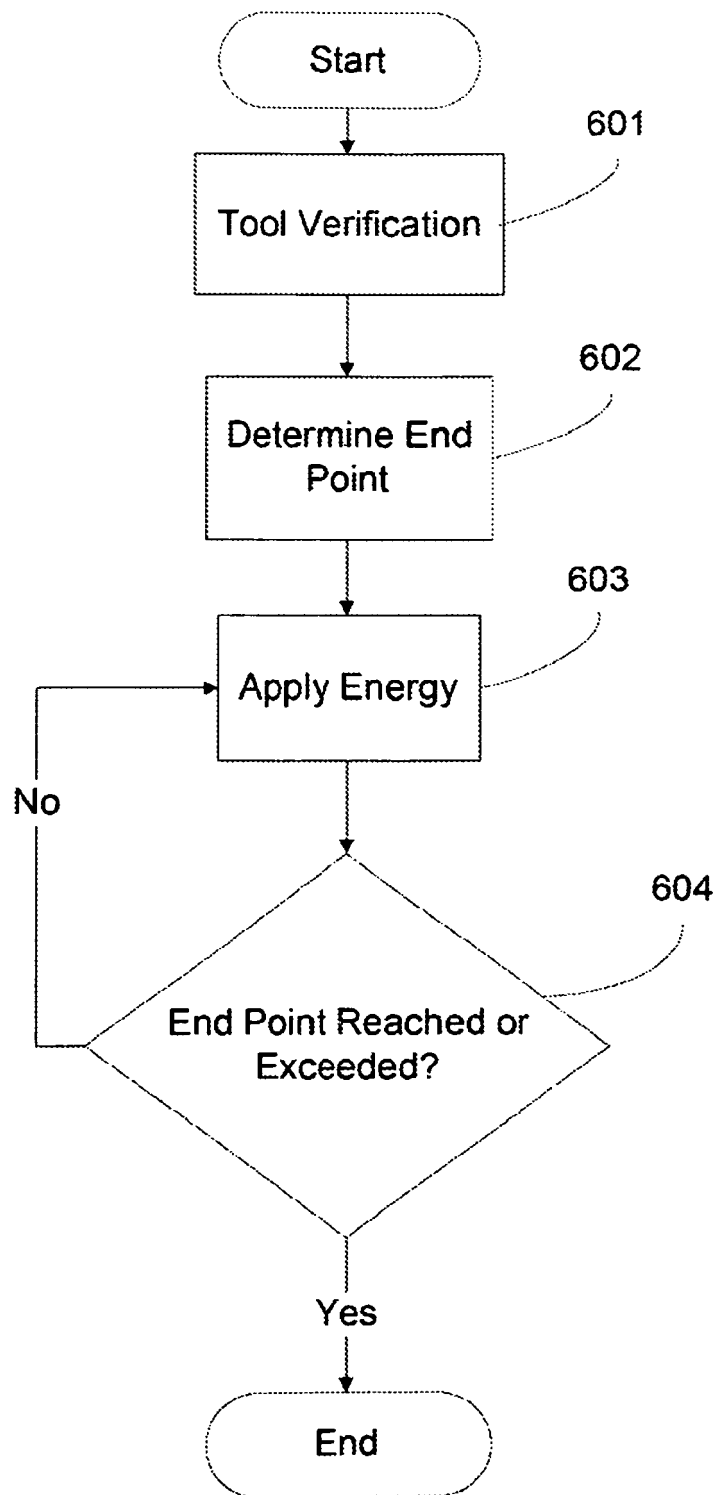


FIG. 39

**FIG. 40**

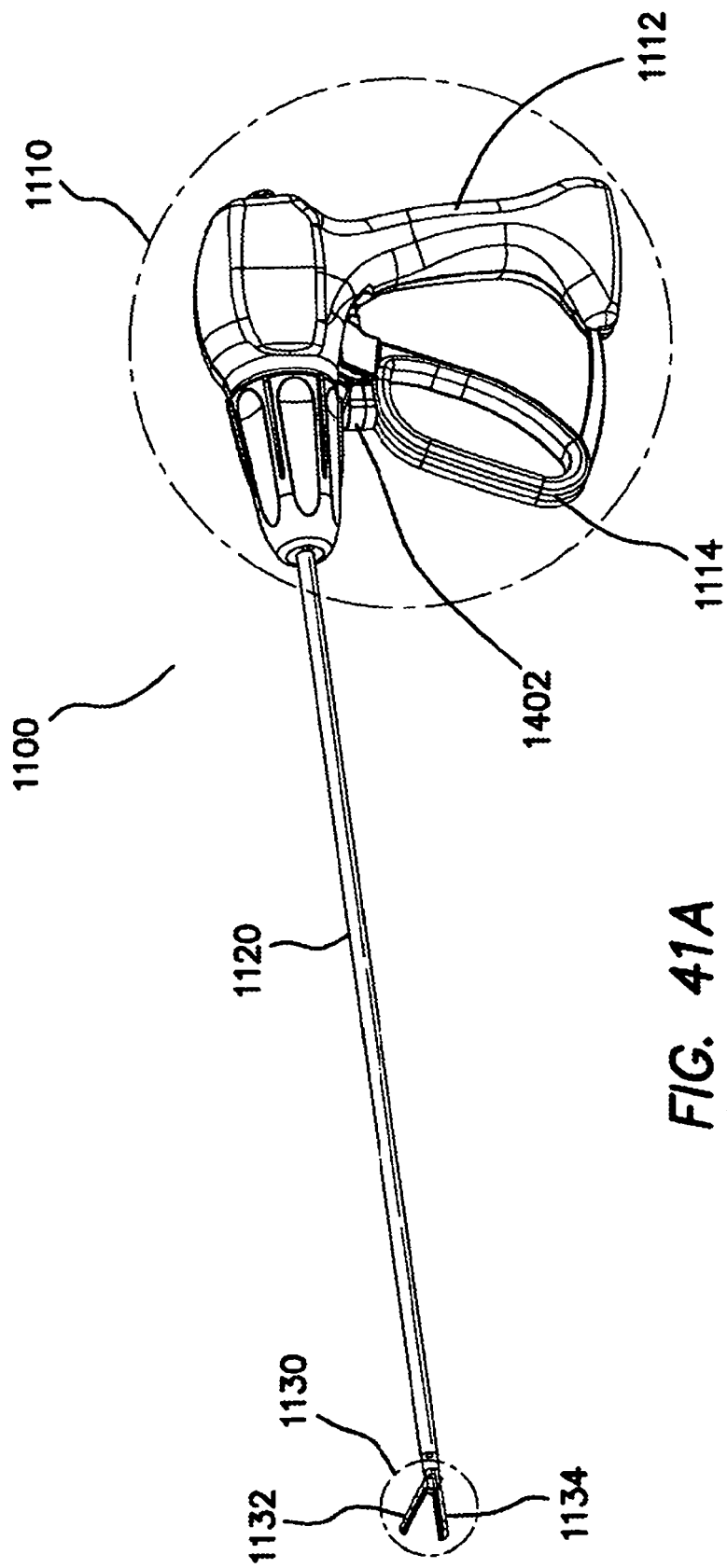


FIG. 41A

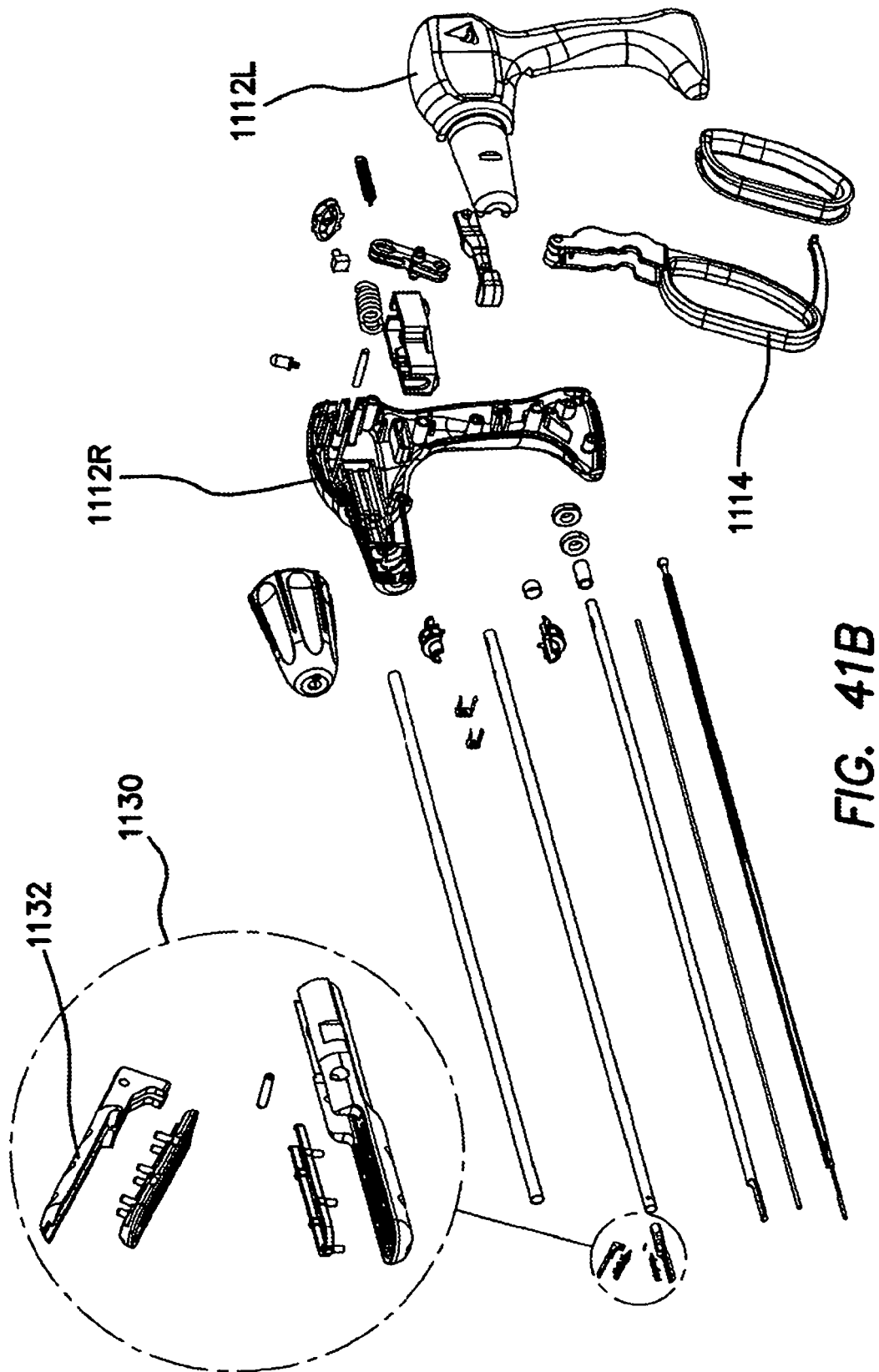


FIG. 41B

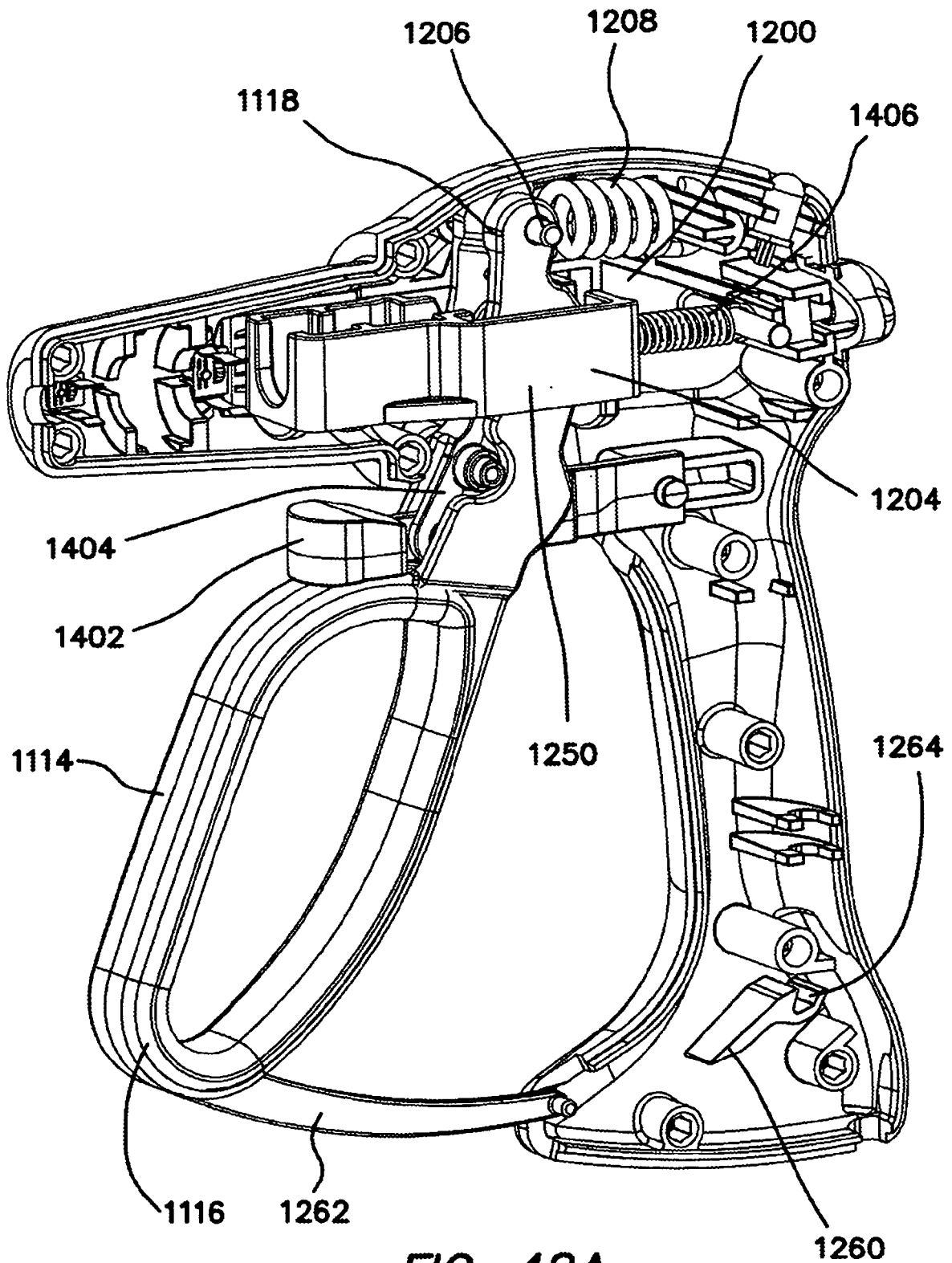


FIG. 42A

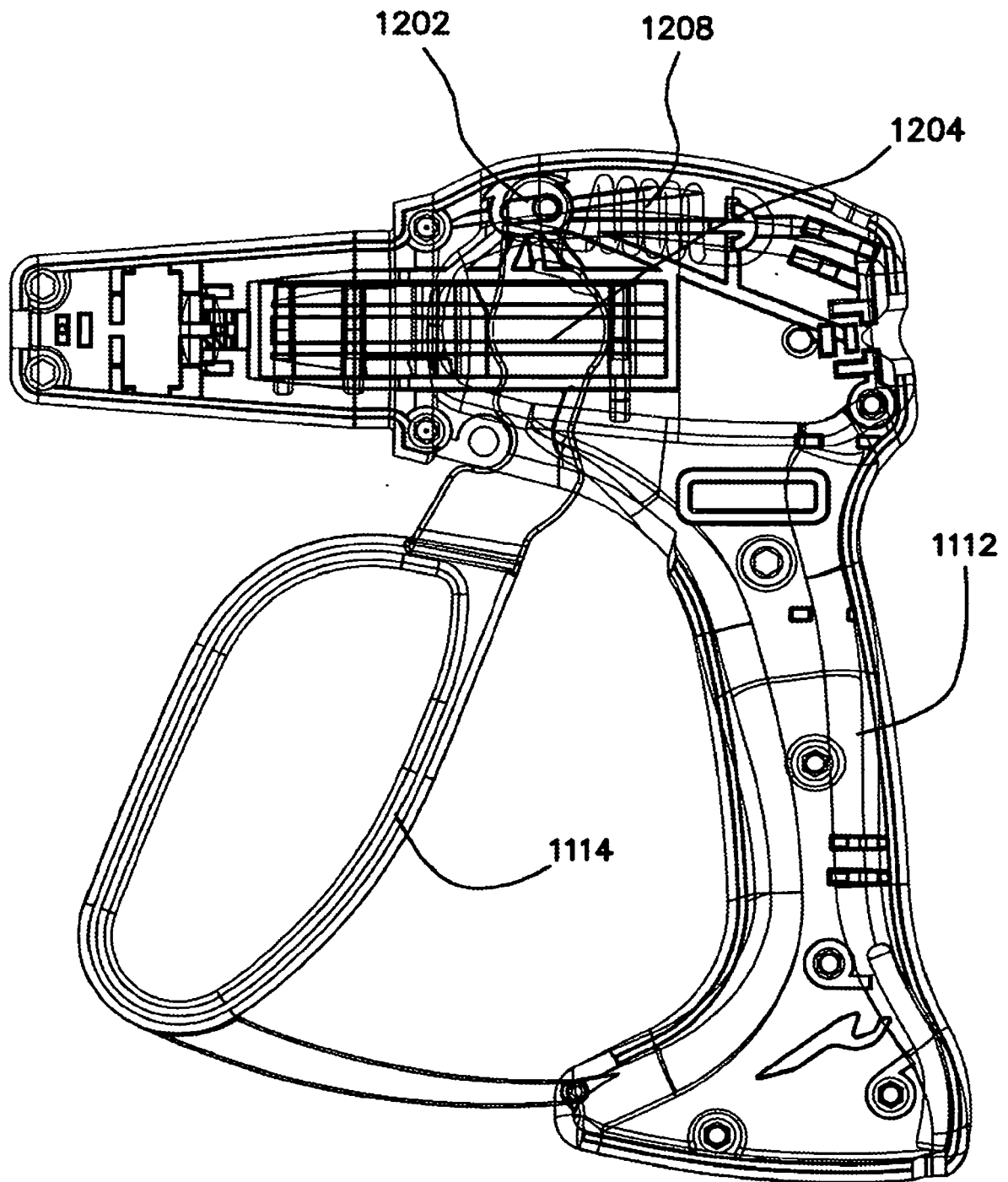


FIG. 42B

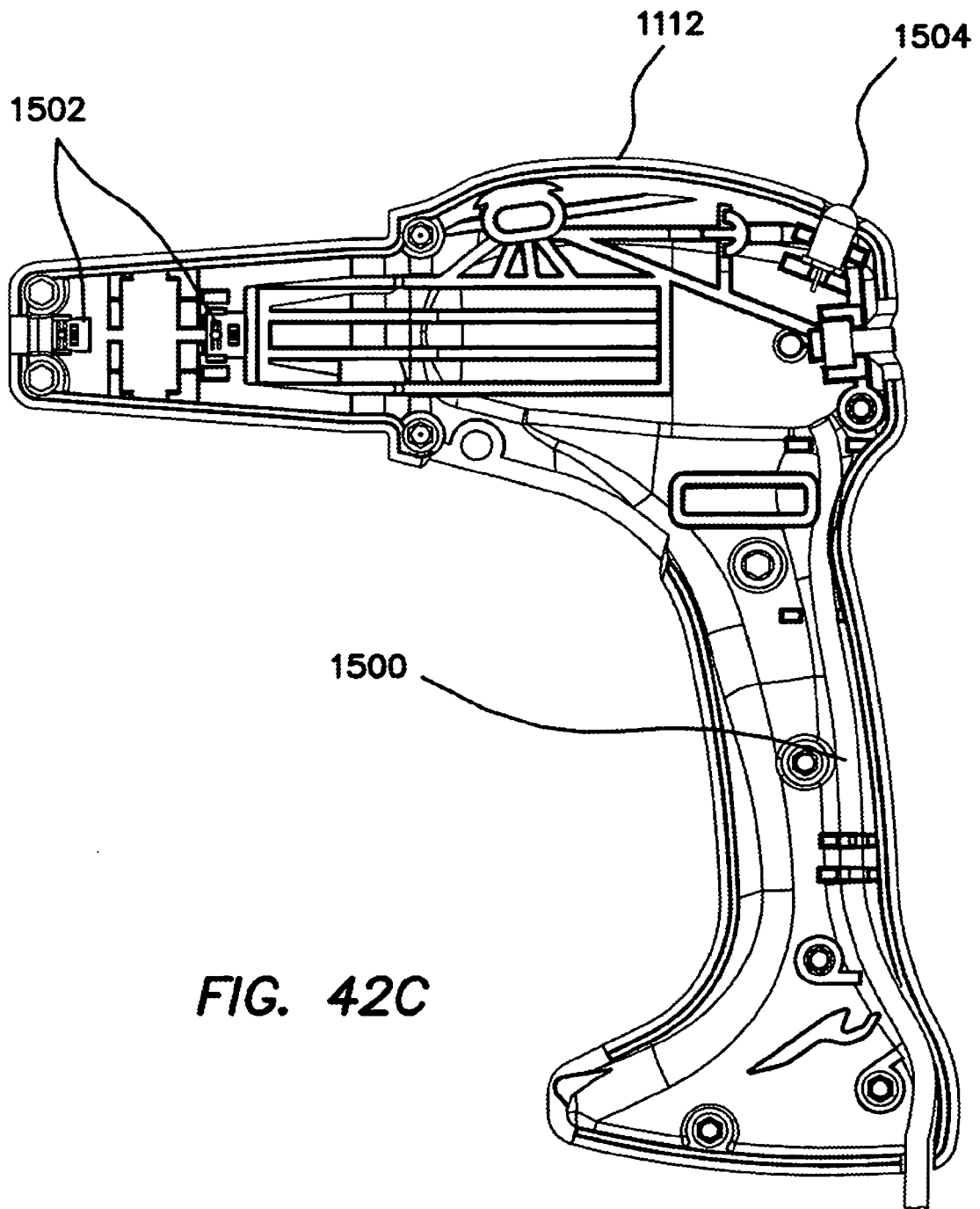


FIG. 42C

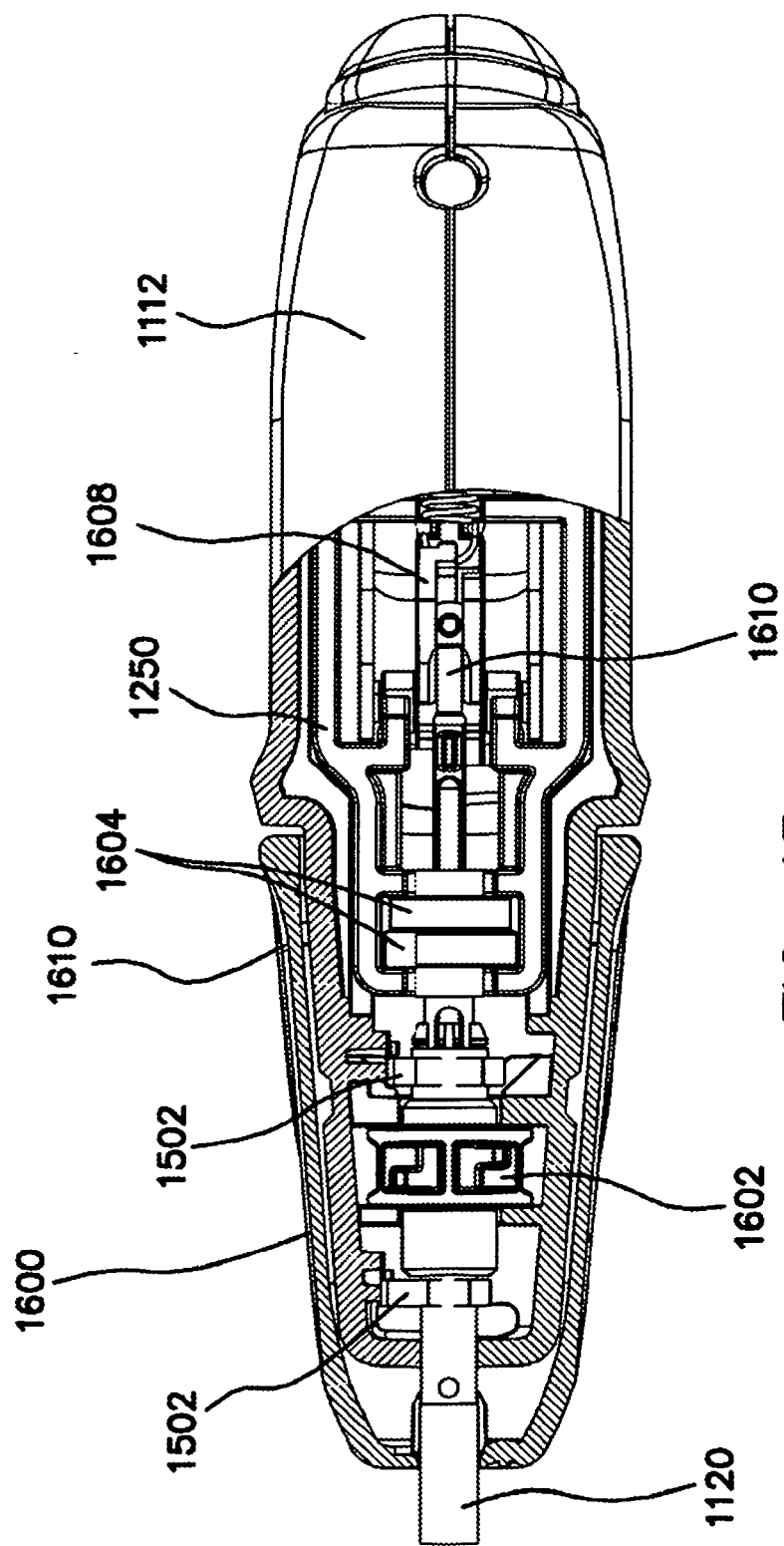


FIG. 43

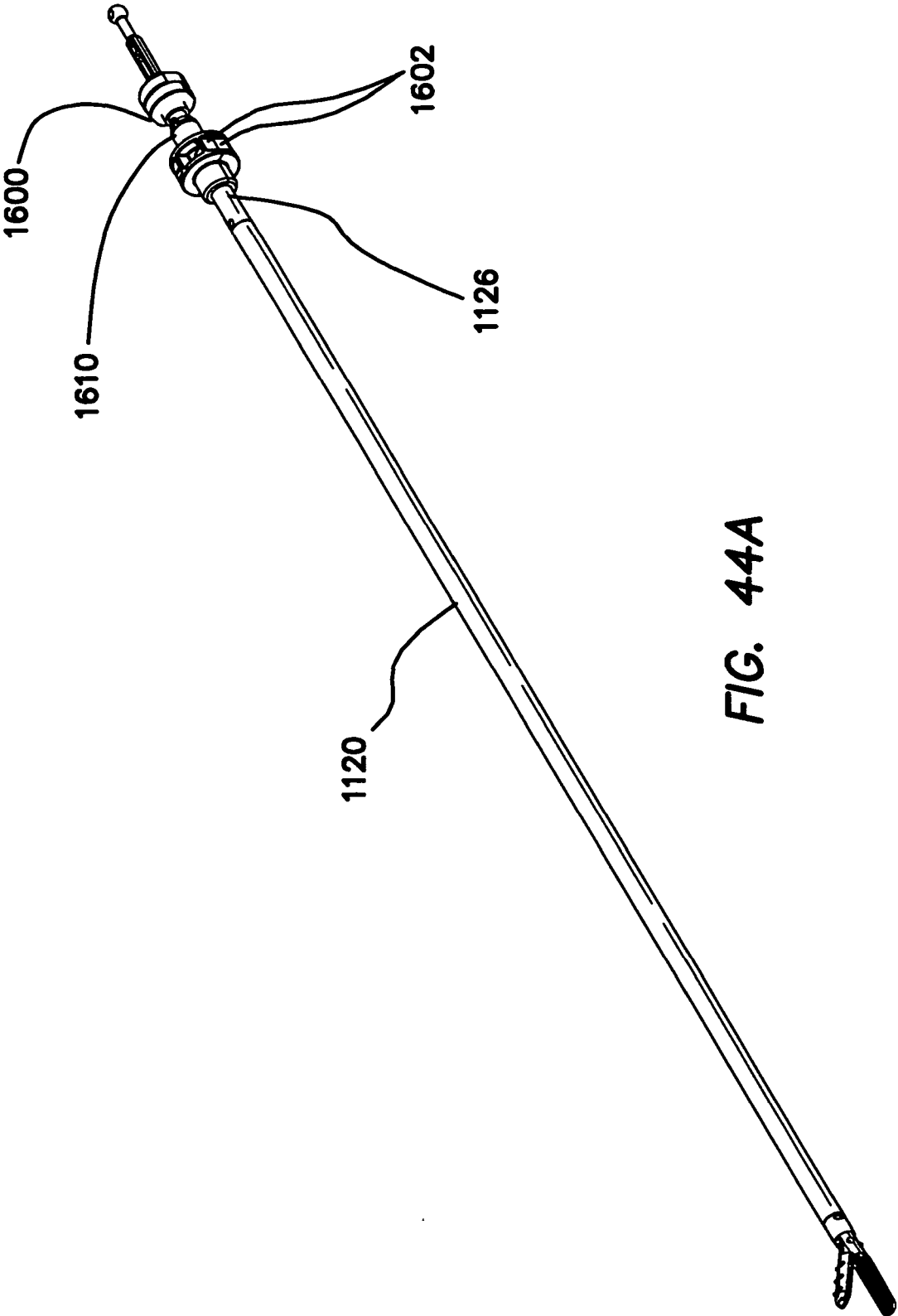
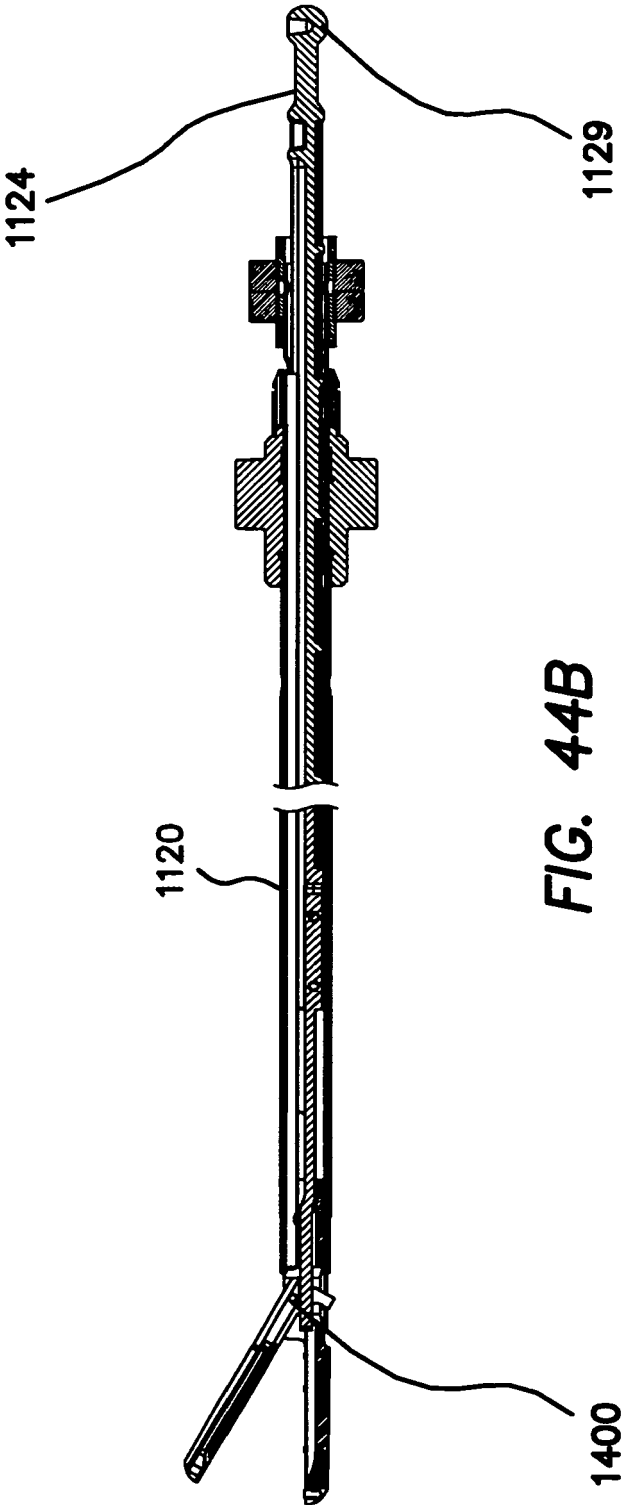


FIG. 44A



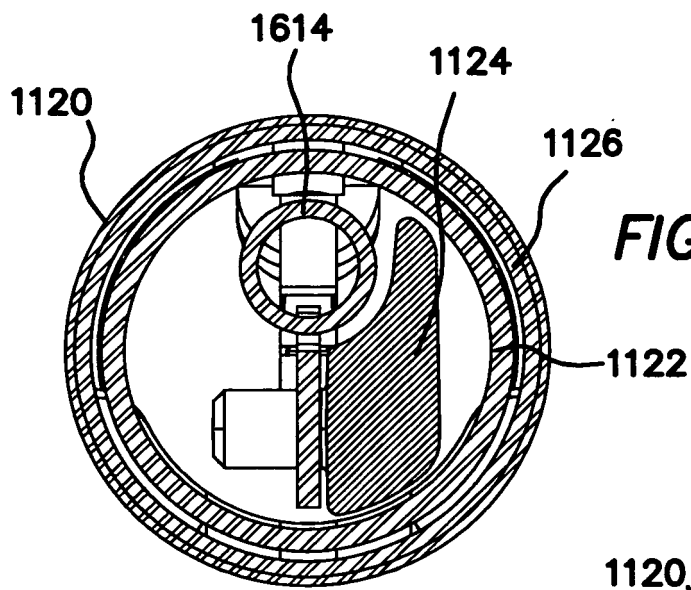


FIG. 44C-1

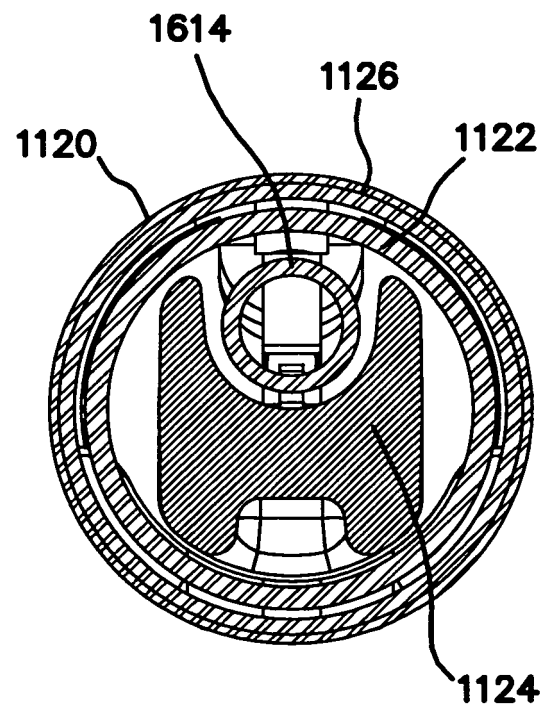


FIG. 44C-2

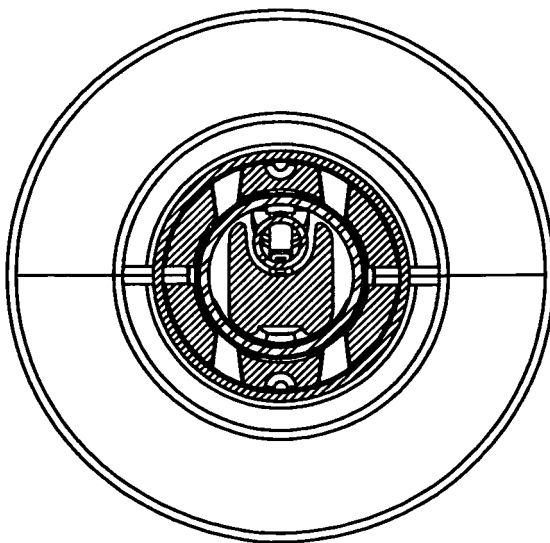


FIG. 44C-3

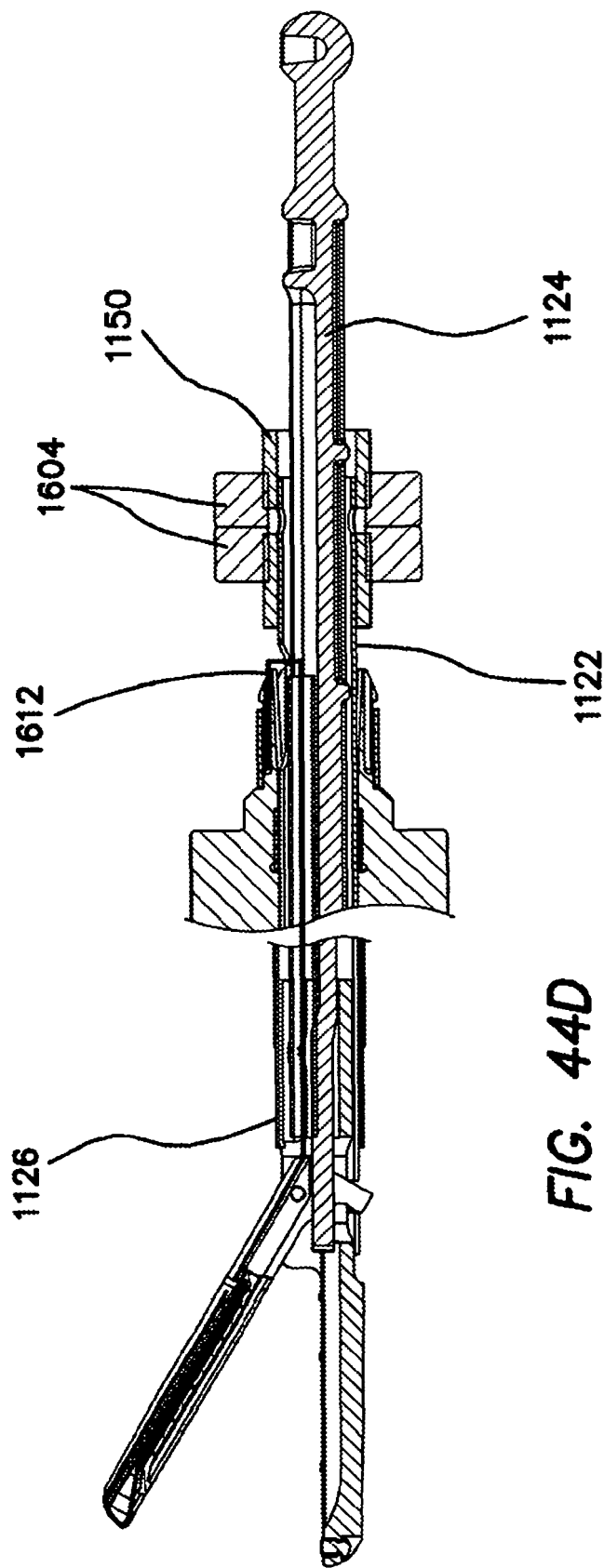


FIG. 44D

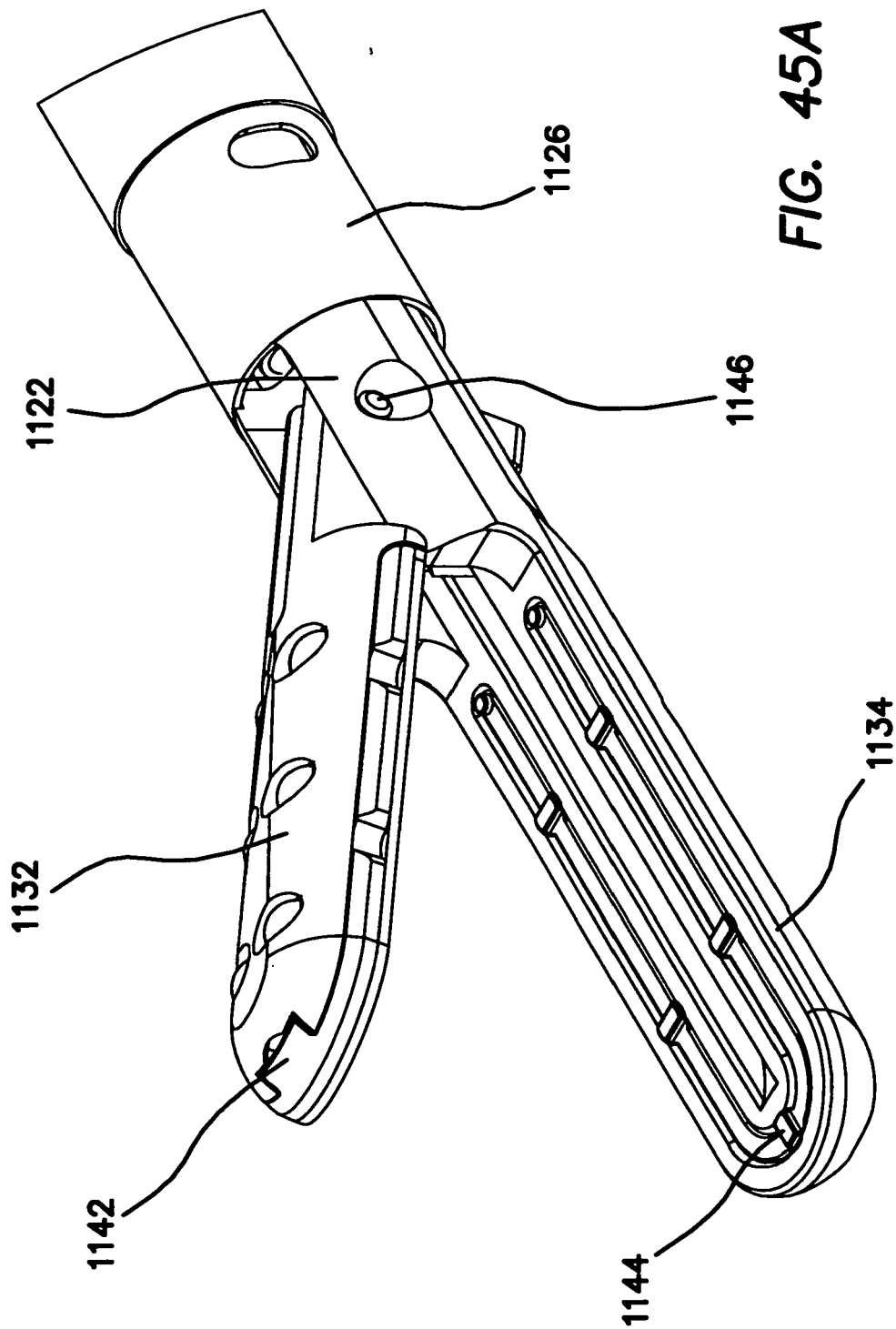
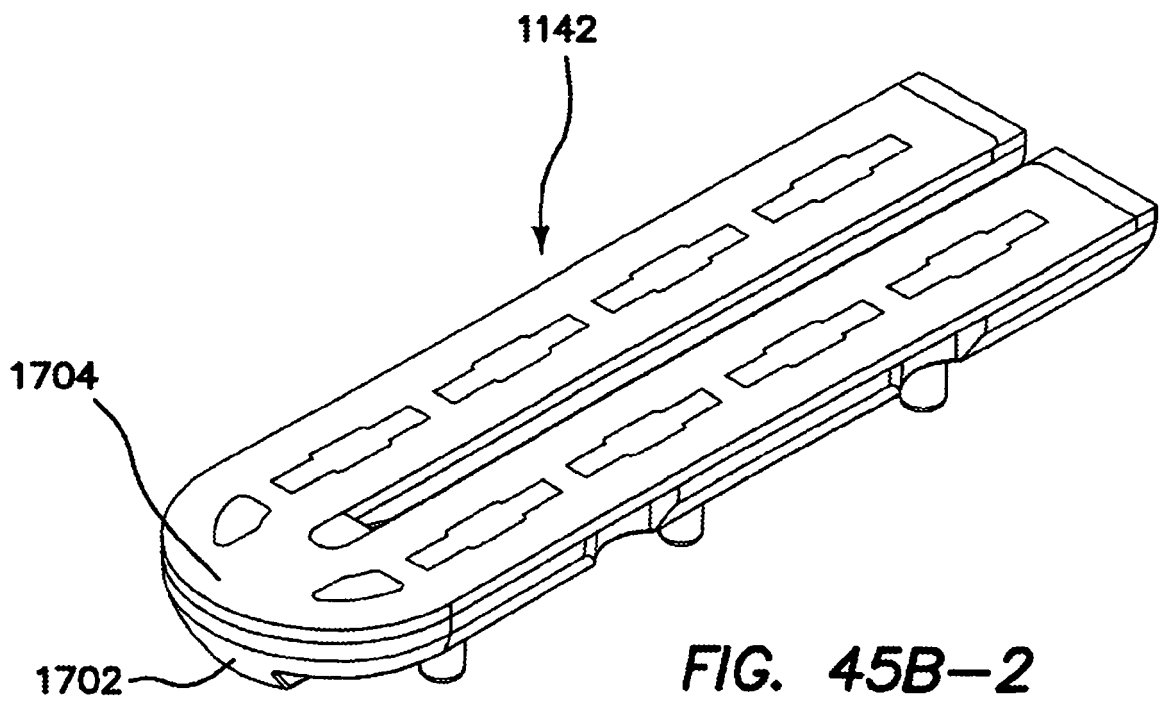
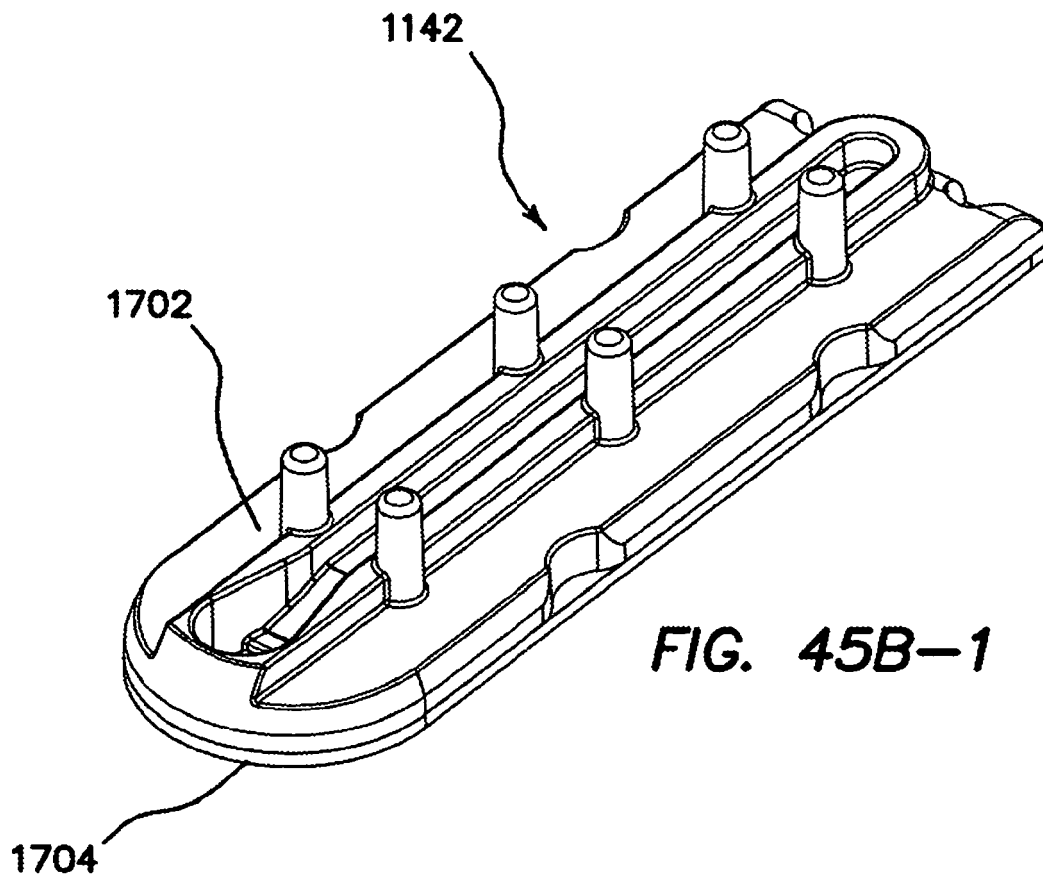
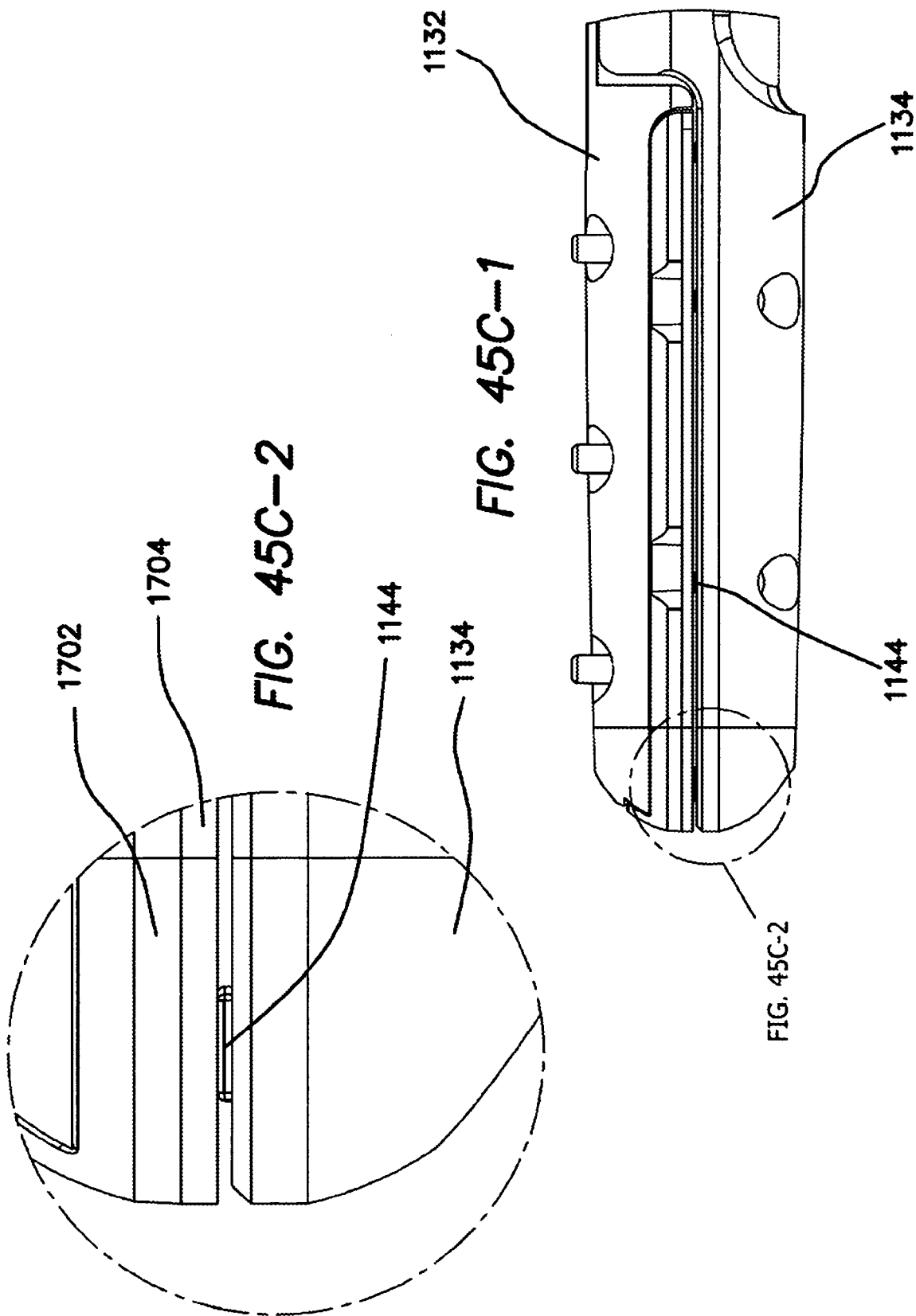


FIG. 45A





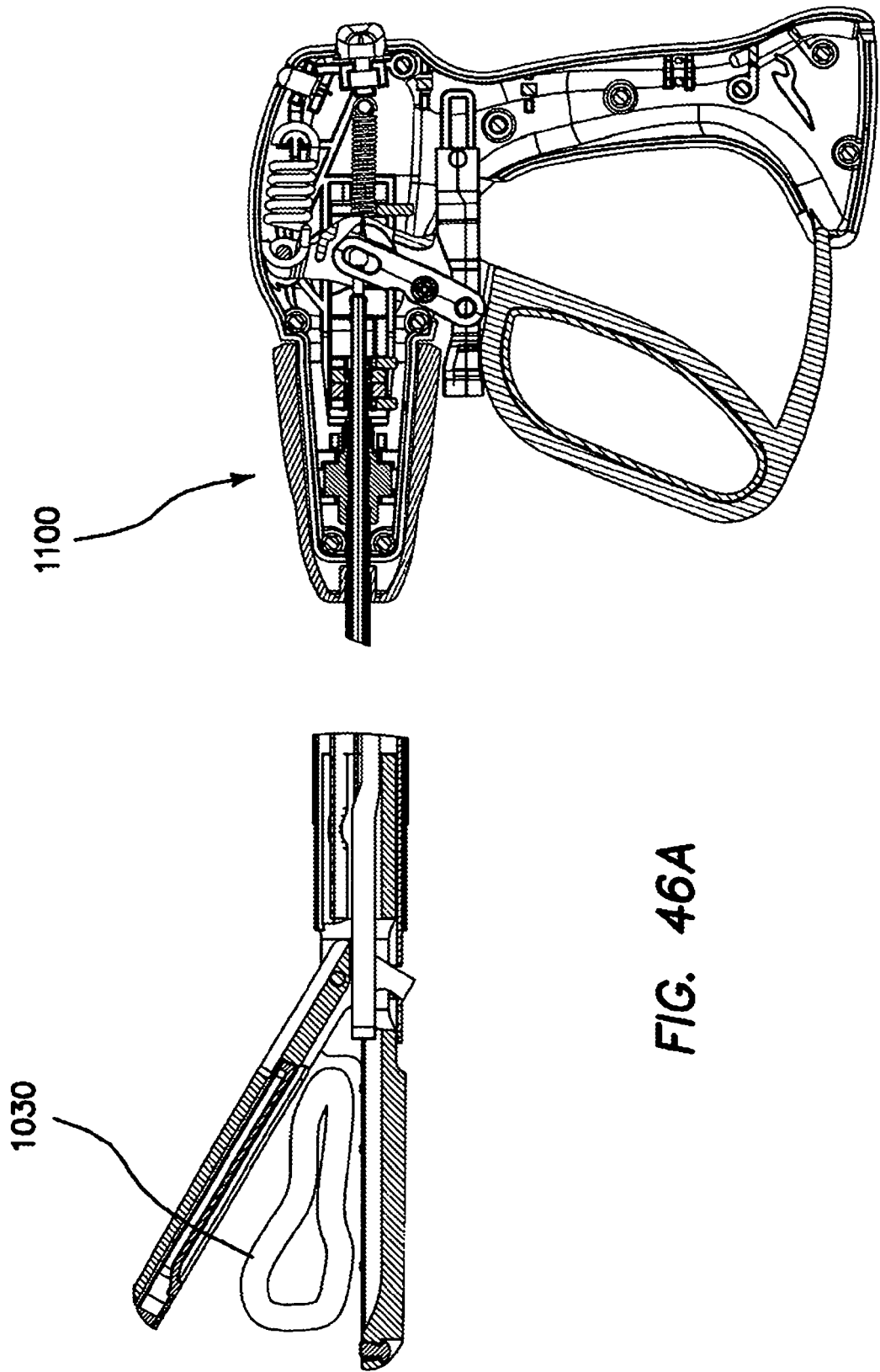
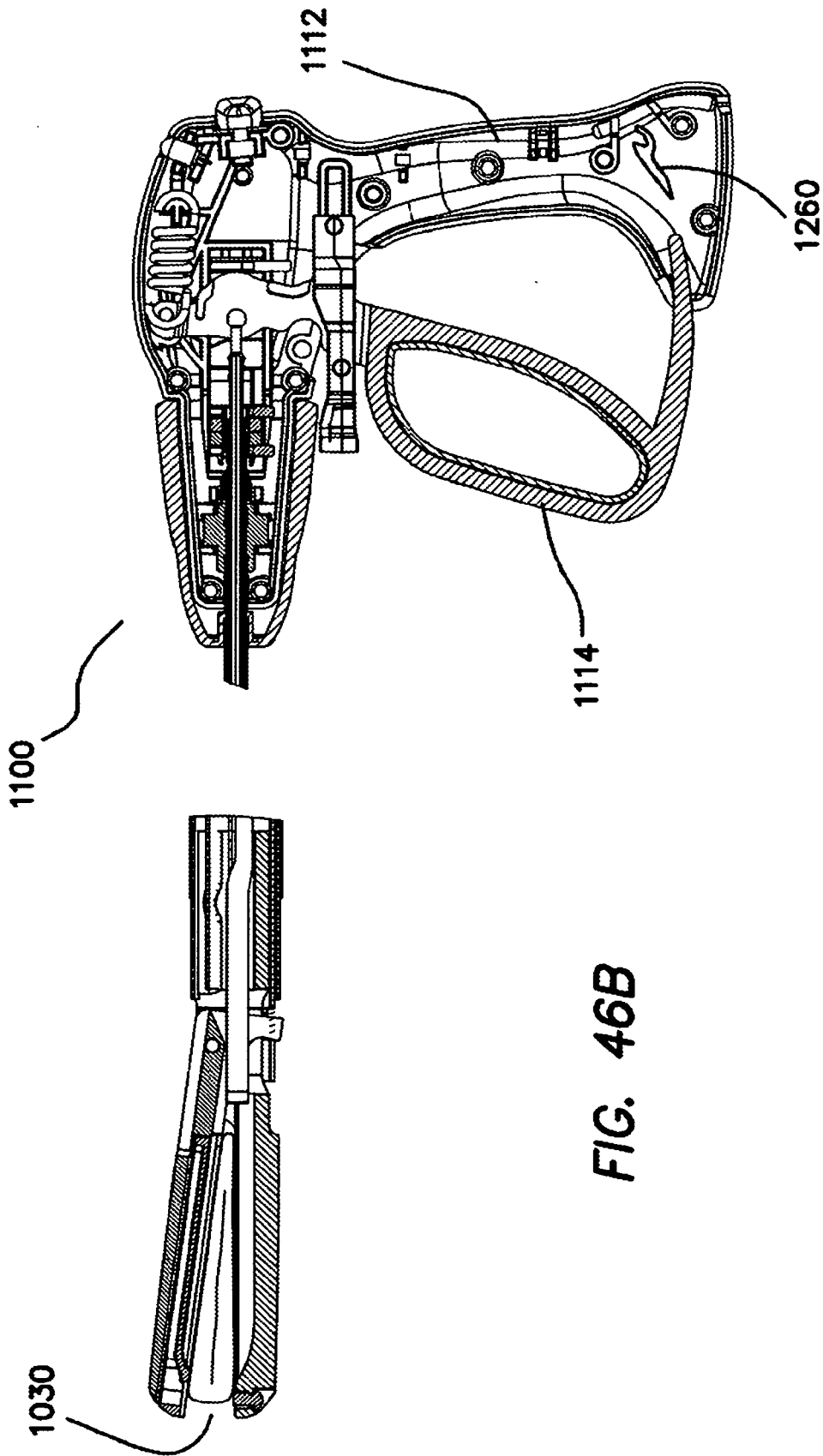
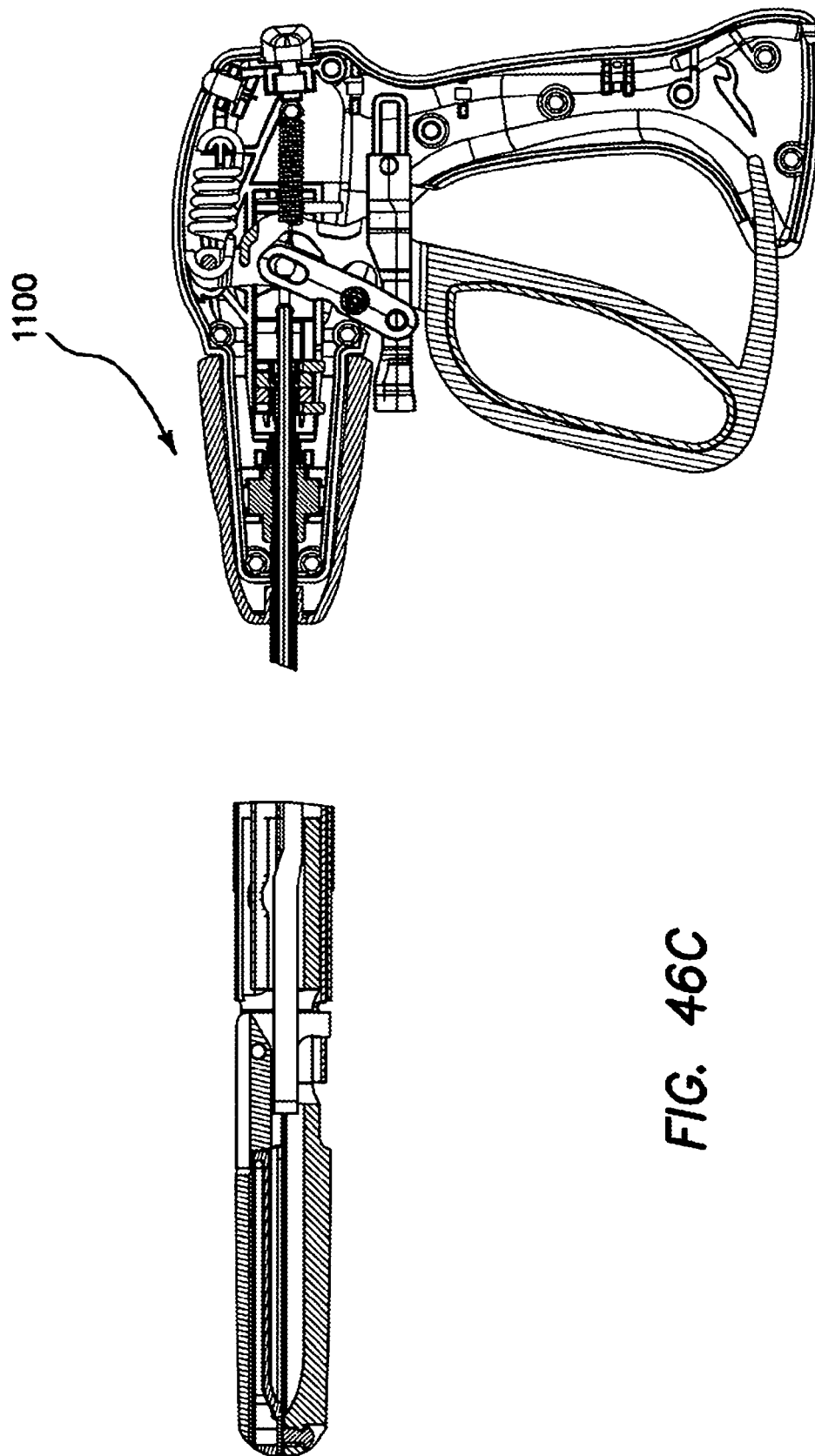
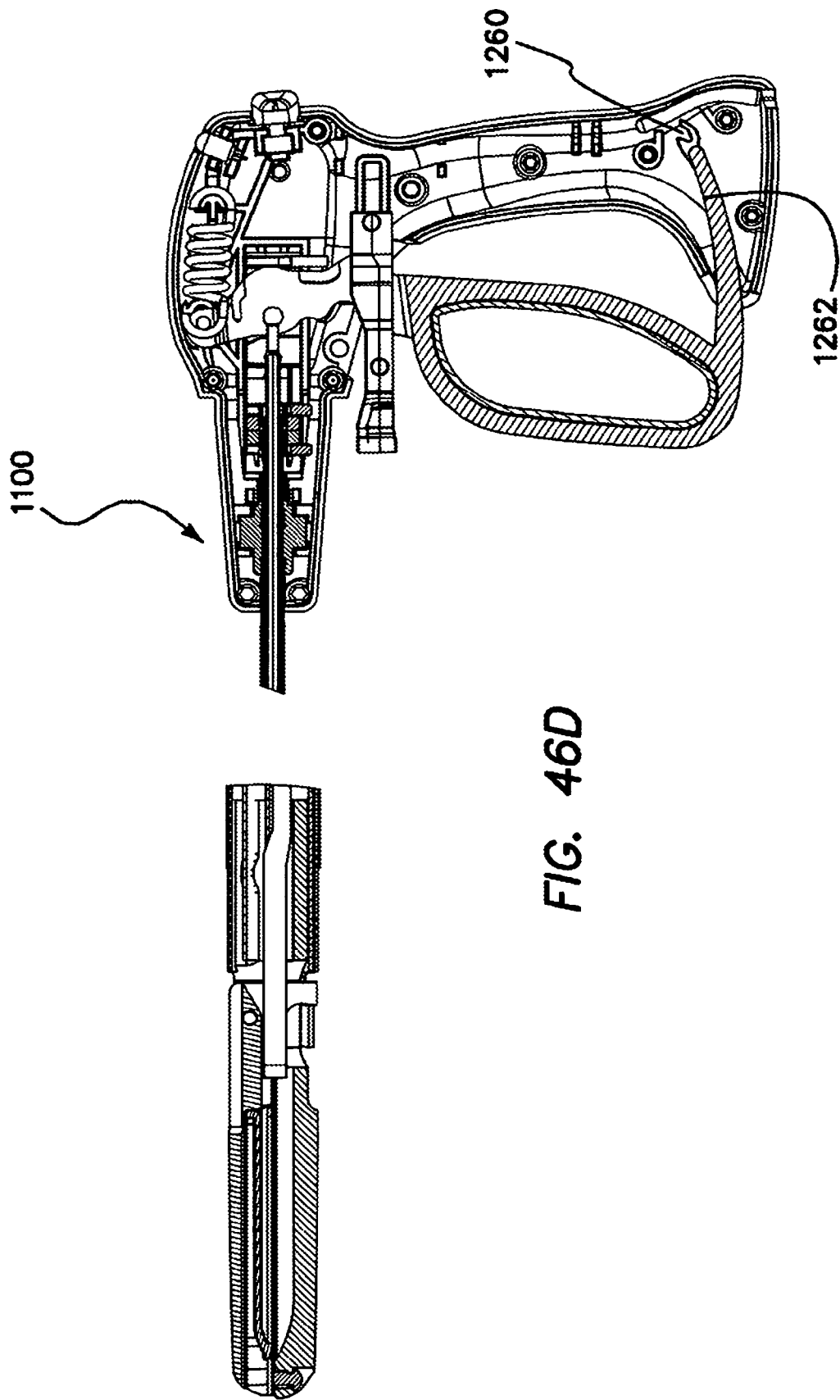


FIG. 46A







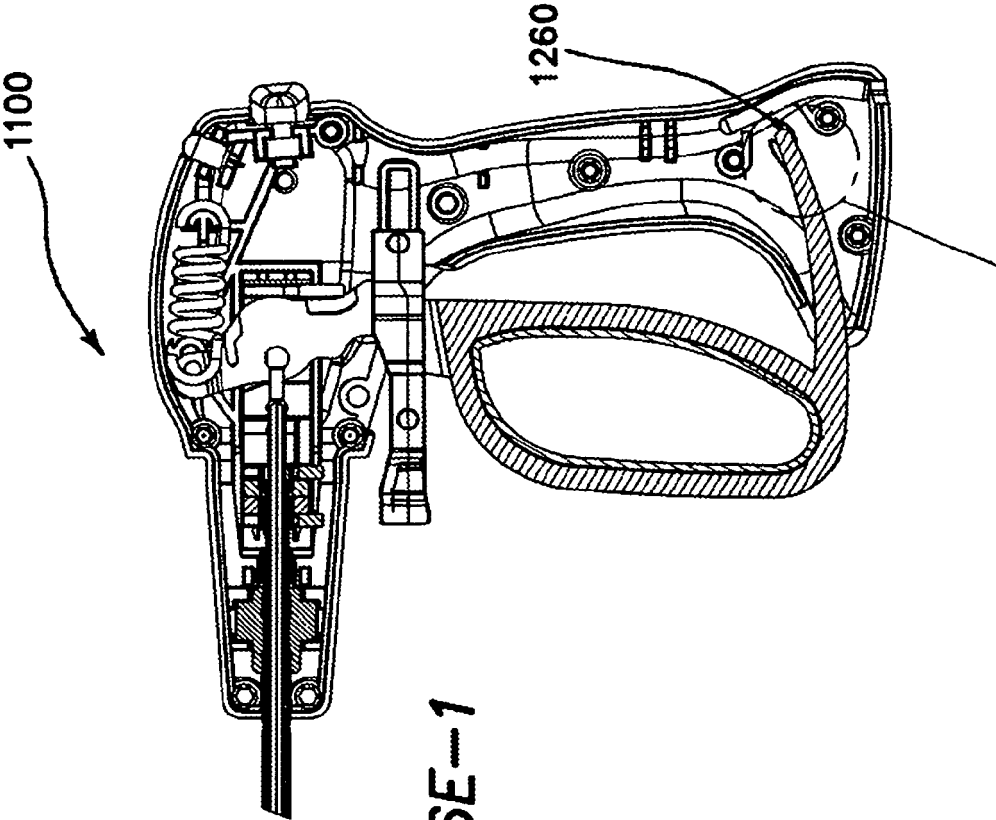


FIG. 46E-1

FIG. 46E-2

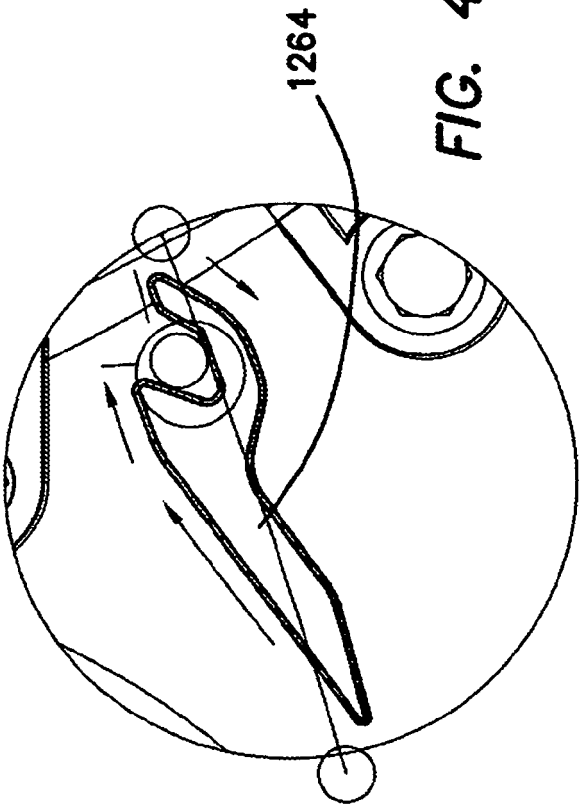
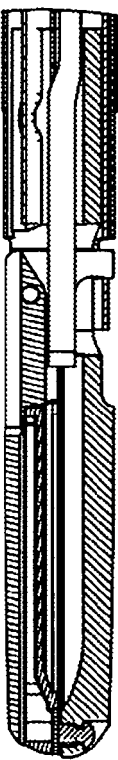


FIG. 46E-2

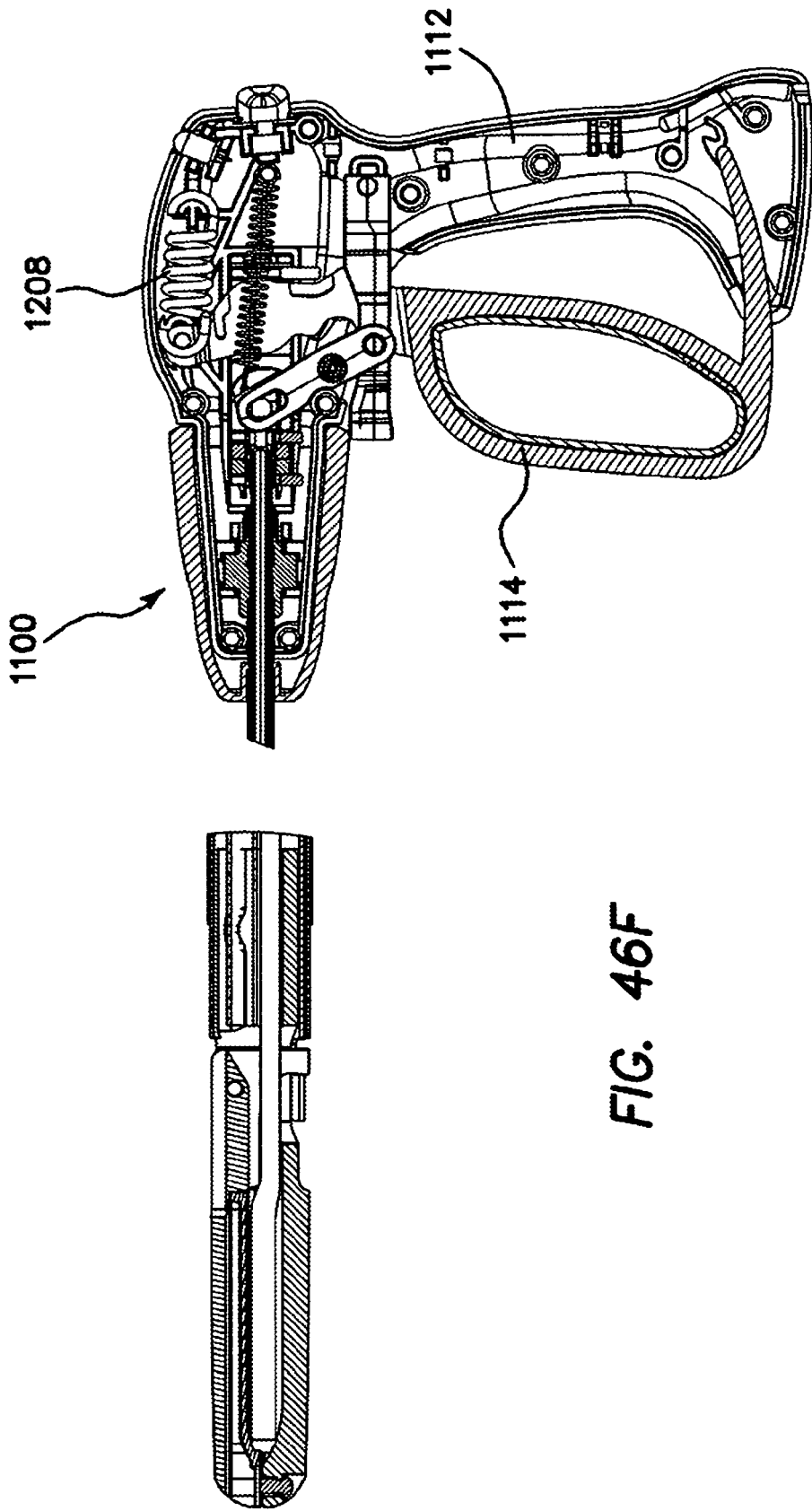


FIG. 46F

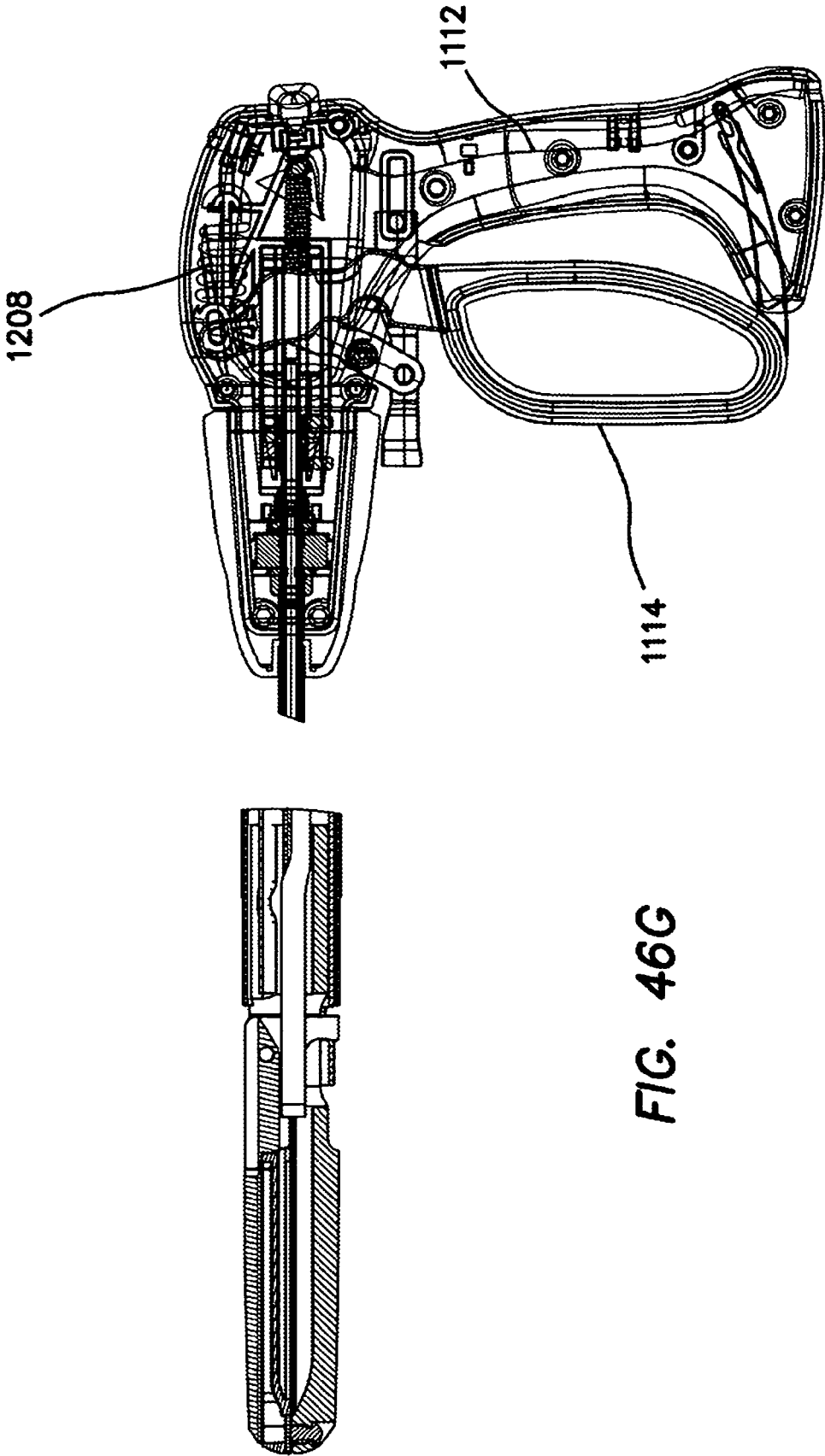
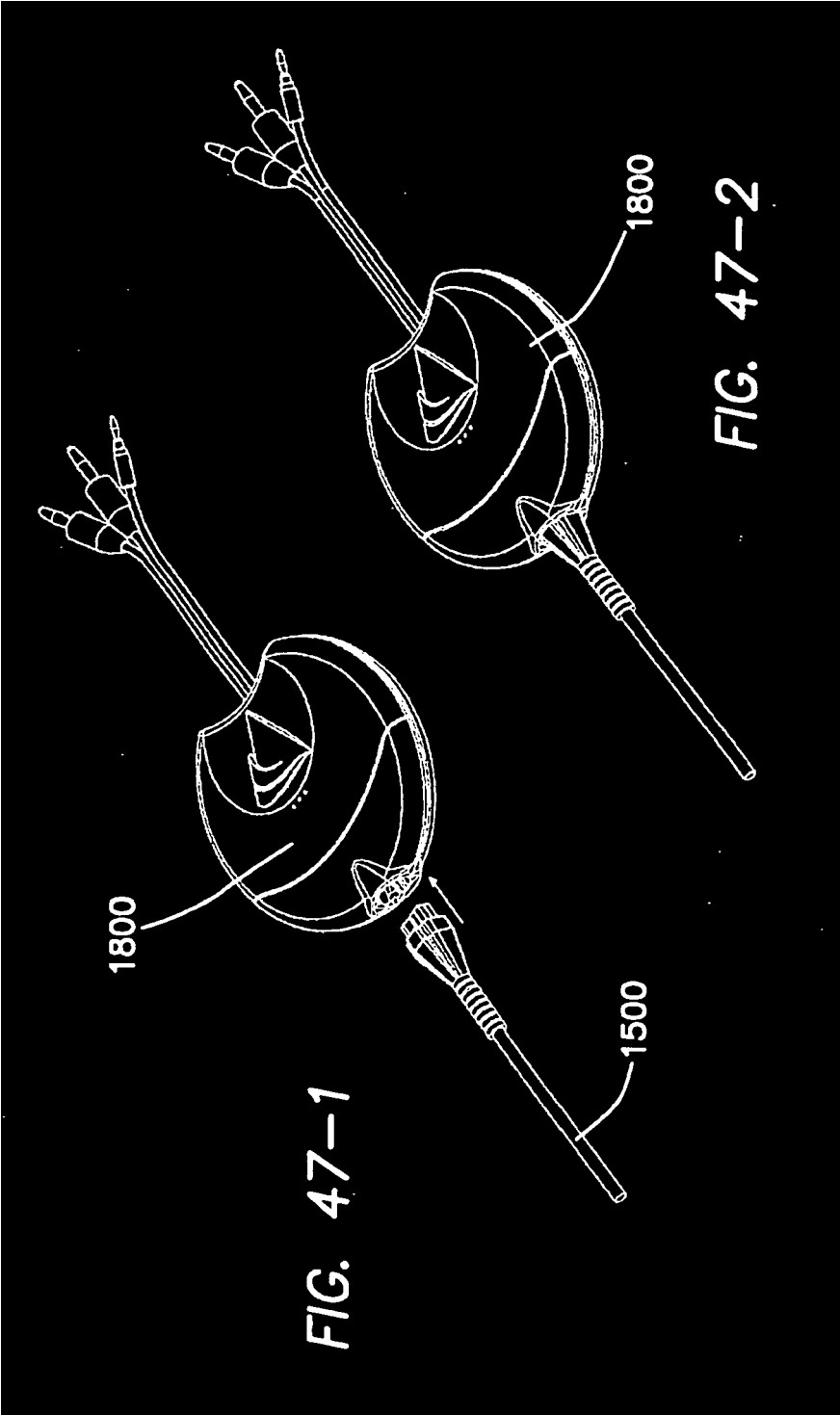


FIG. 46G



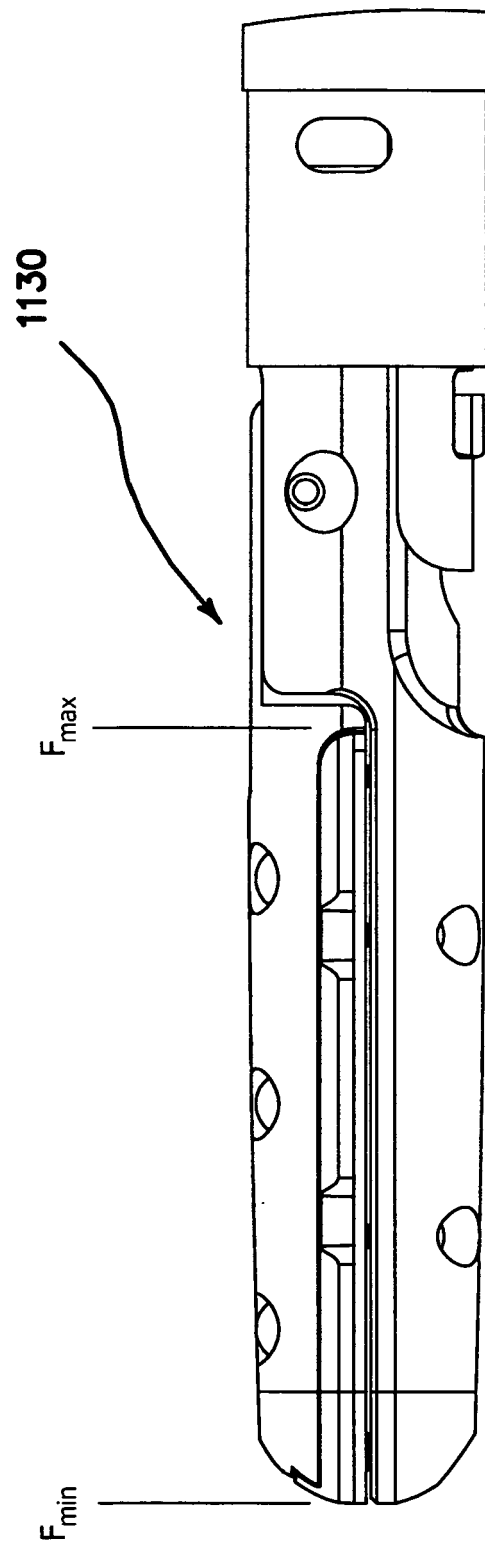


FIG. 48A

0.11 kN for 9.5 mm wide electrode
SEALING OF Ø 5mm RENAL ARTERIES
AT CONSTANT APPLIED PRESSURE
(25 lb. FOR 3/8" WIDE ELECTRODE)

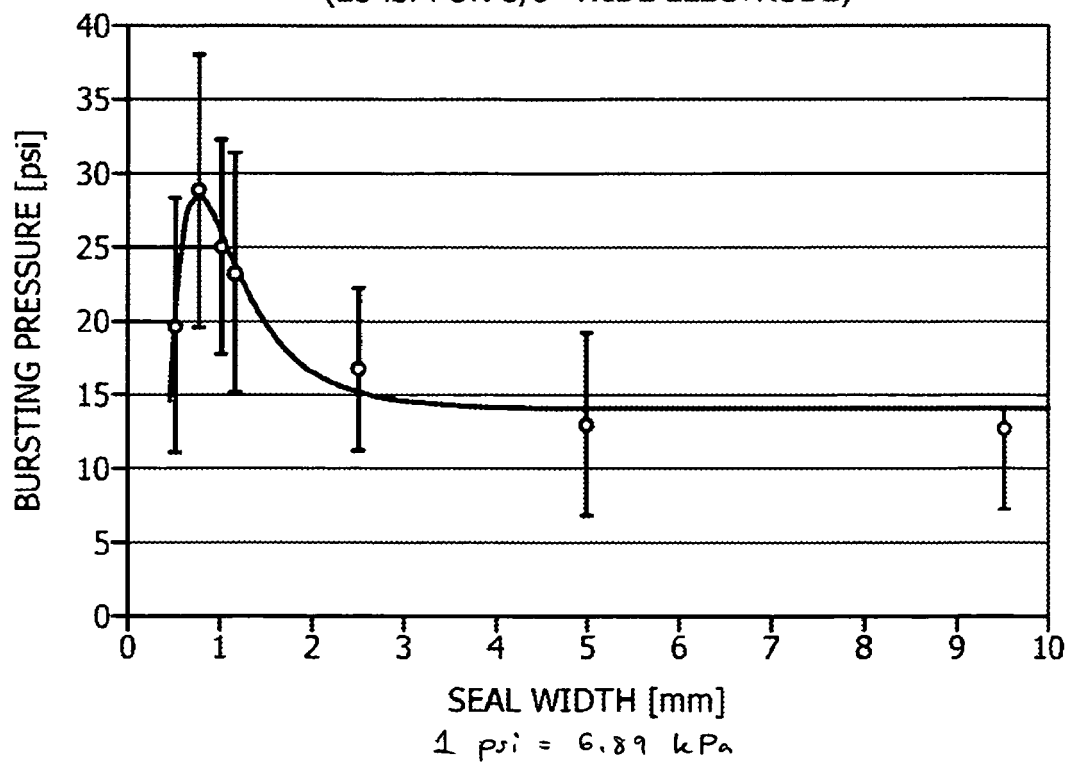
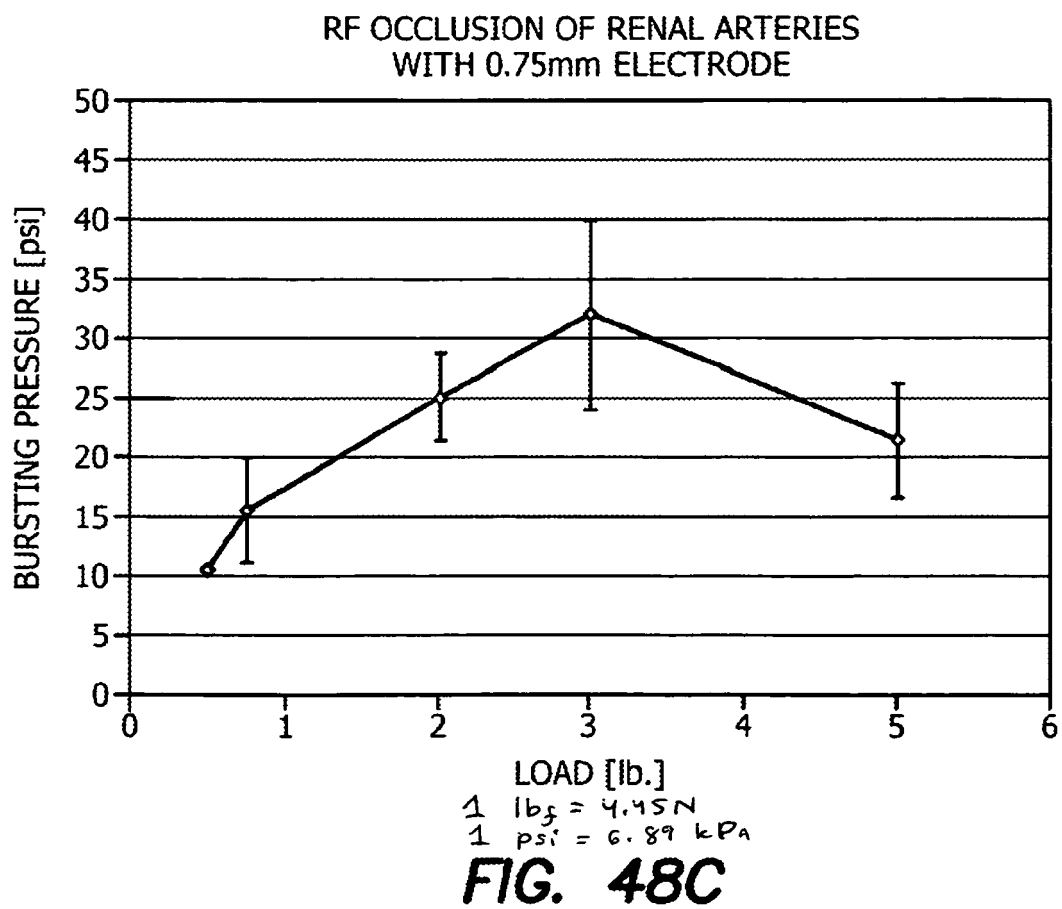
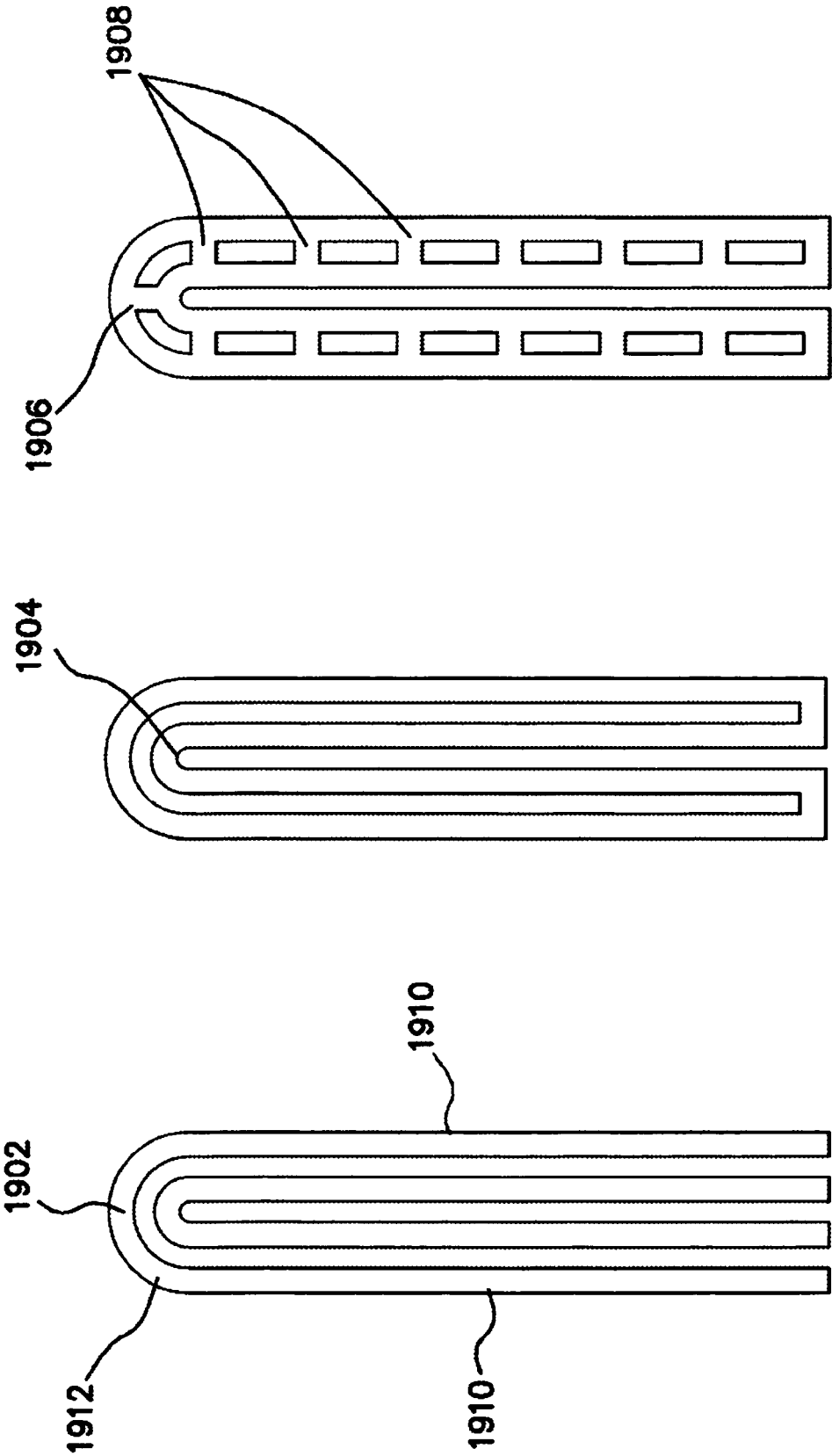


FIG. 48B





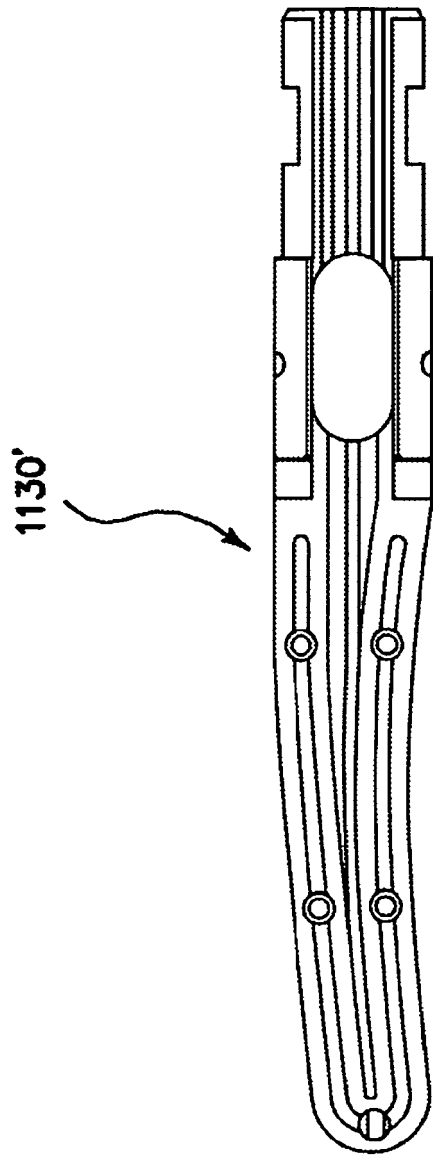


FIG. 50

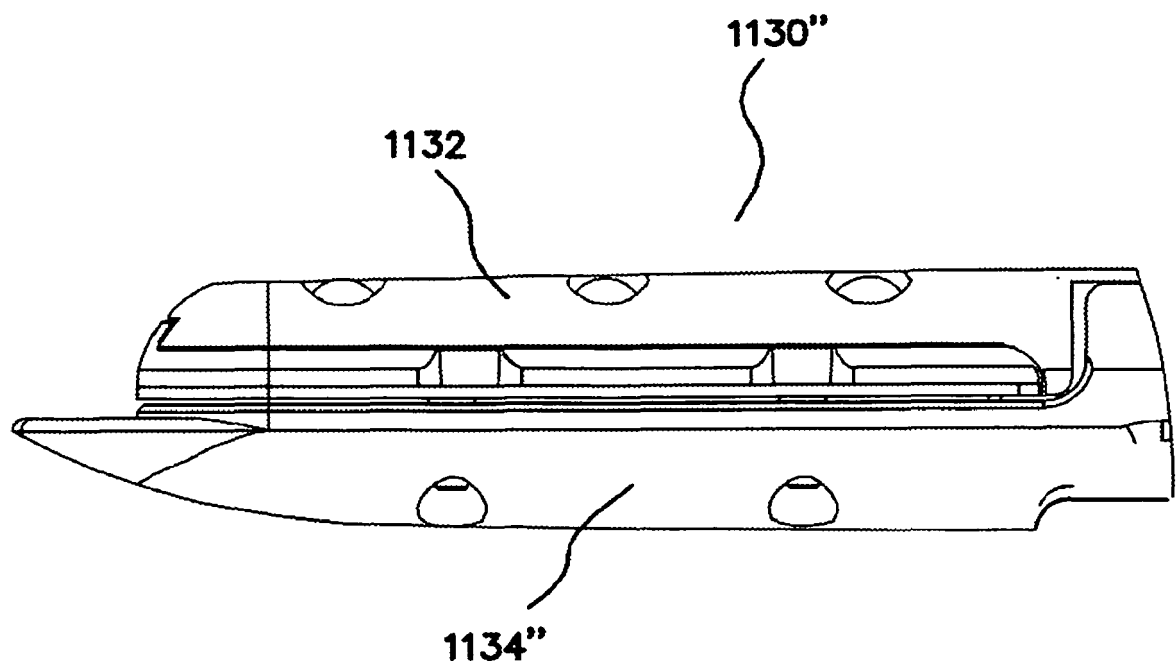


FIG. 51

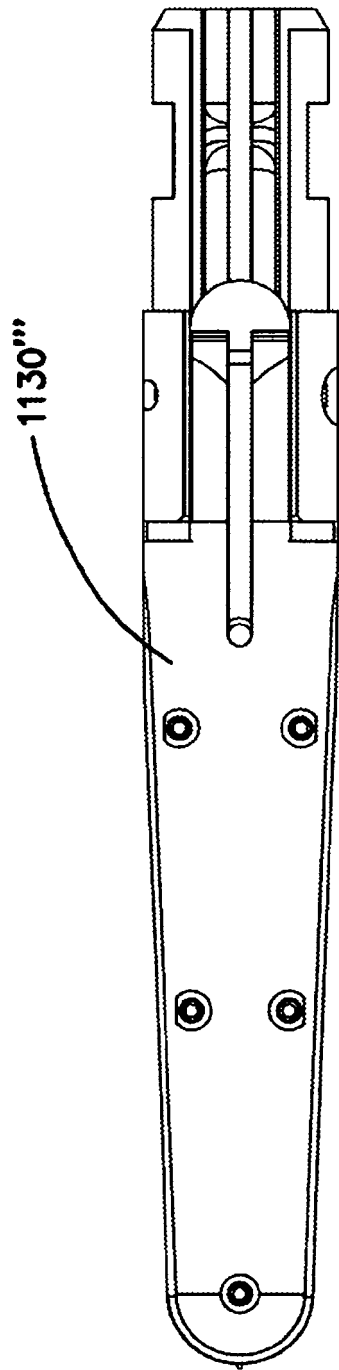


FIG. 52-1

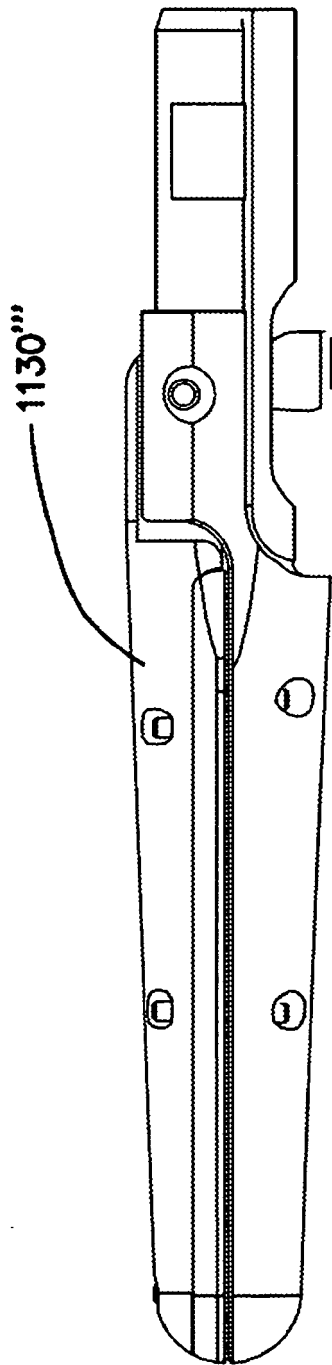
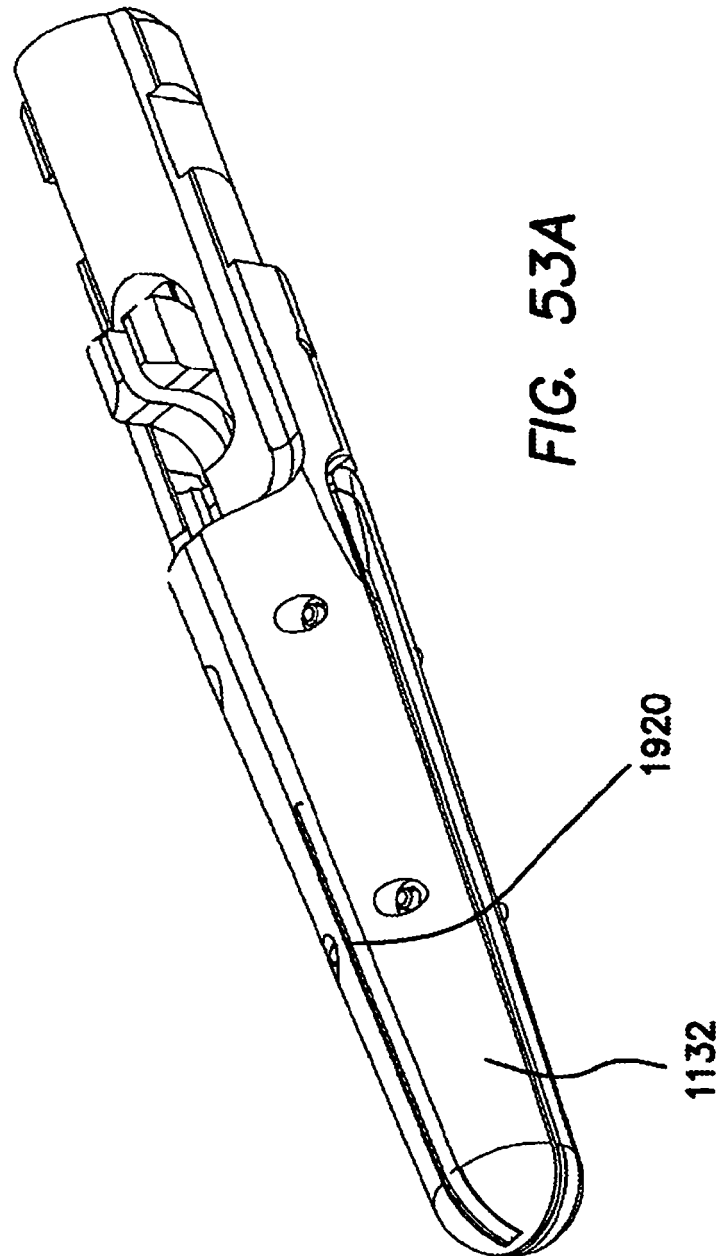


FIG. 52-2



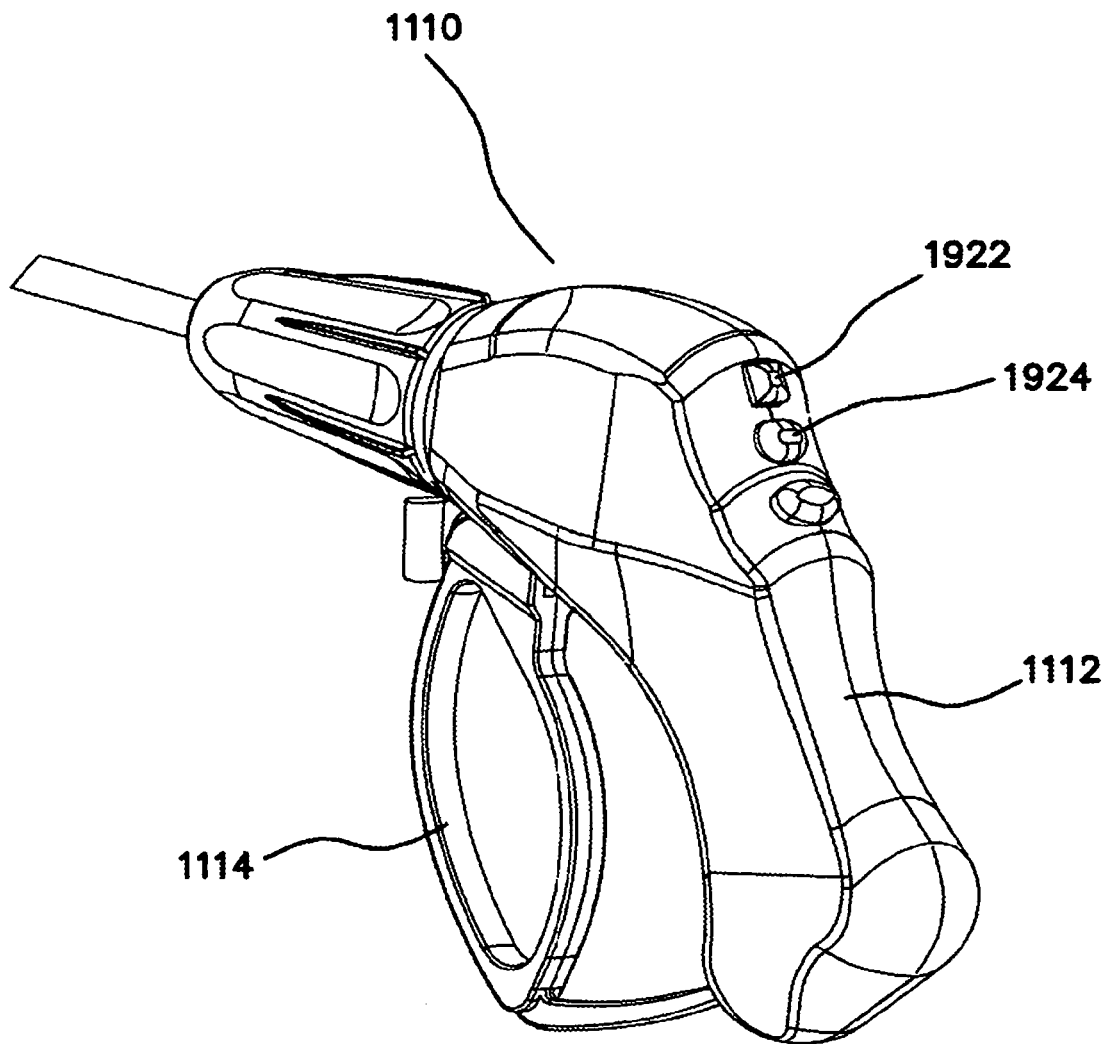


FIG. 53B

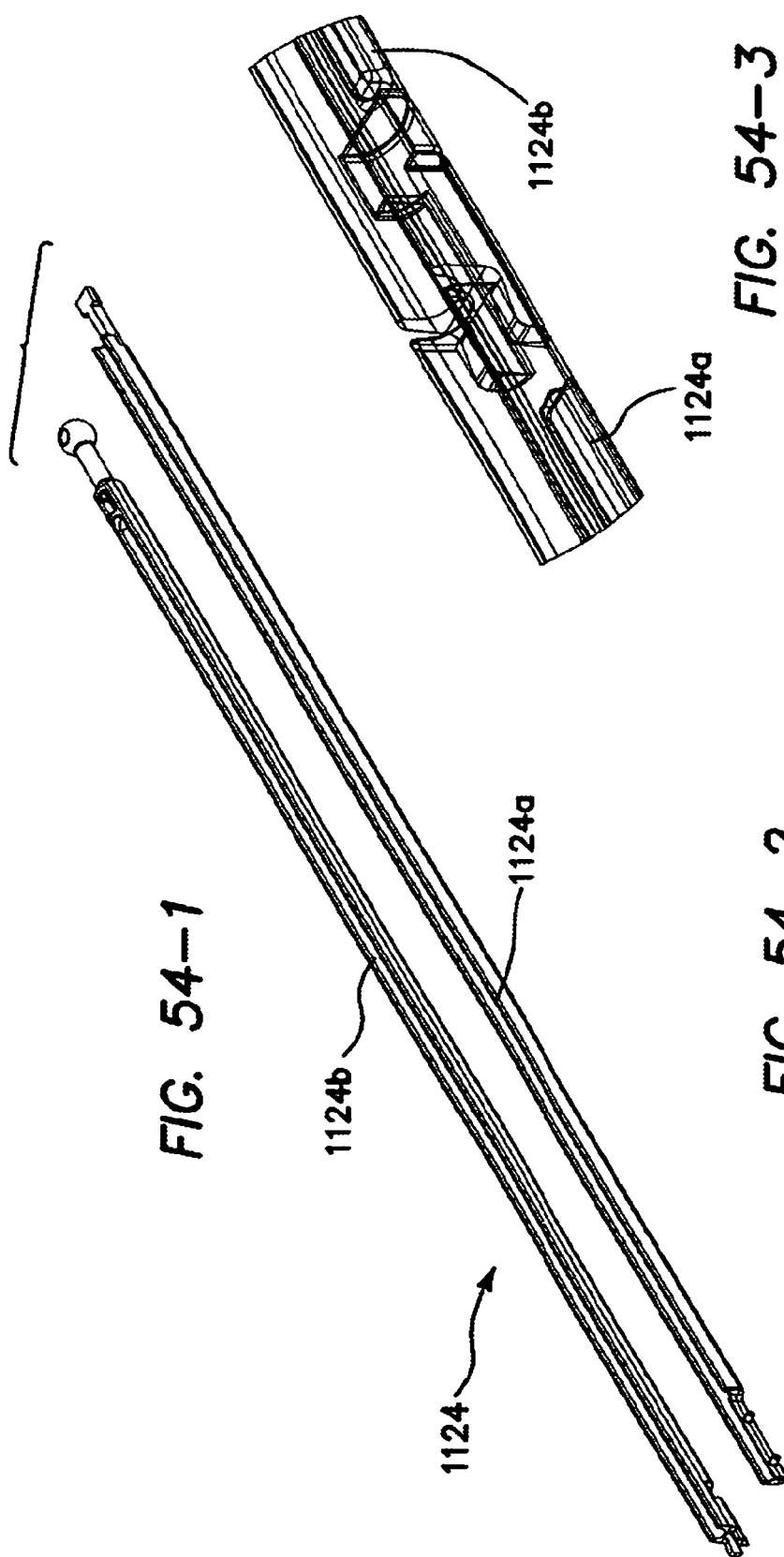


FIG. 54-3

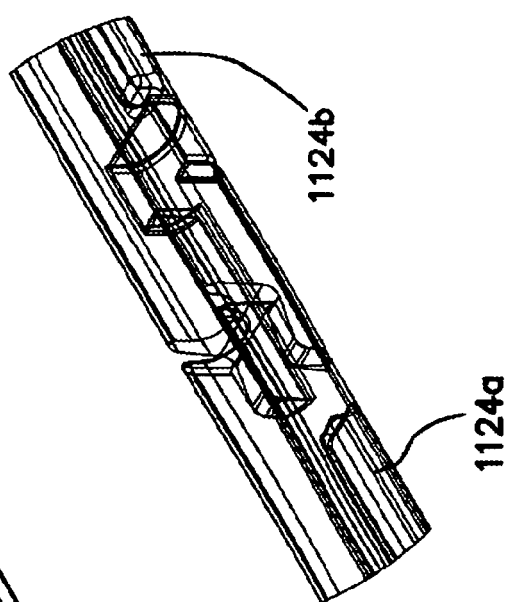
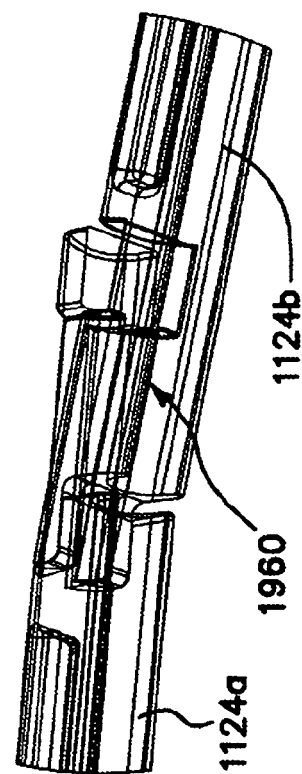
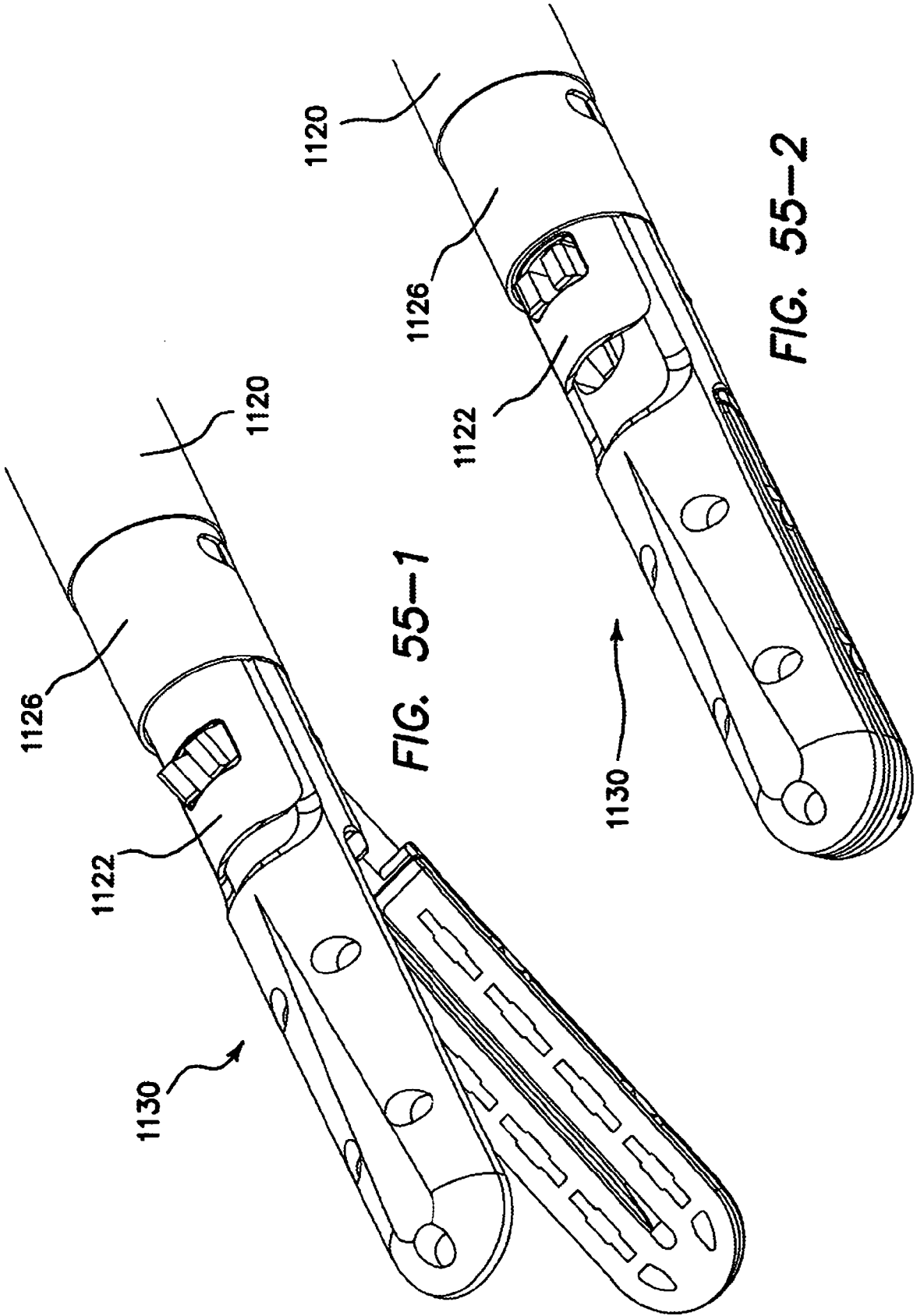


FIG. 54-2





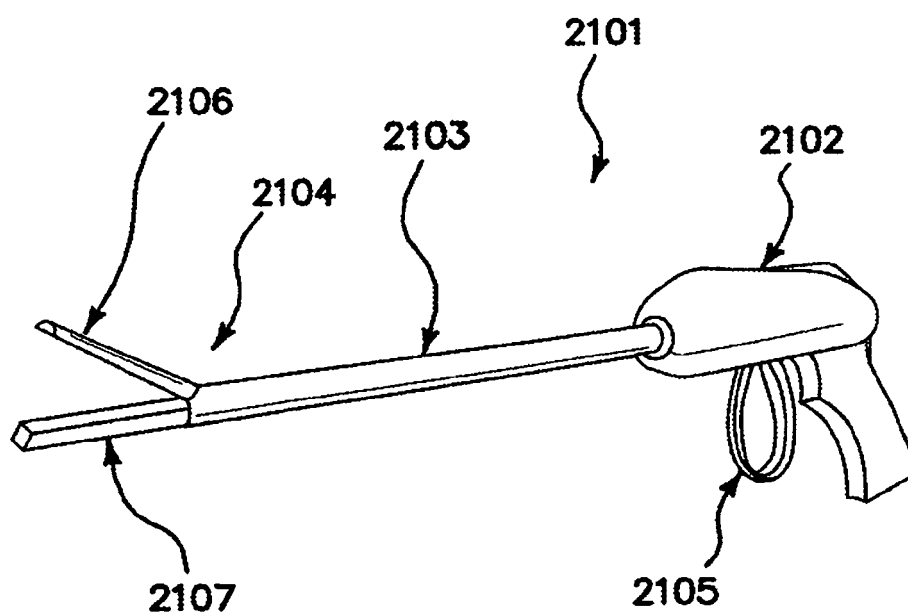


FIG. 56

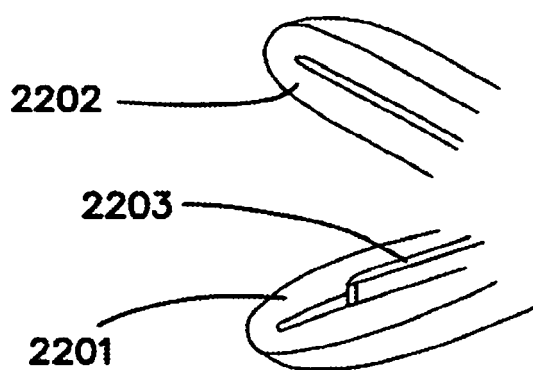


FIG. 57

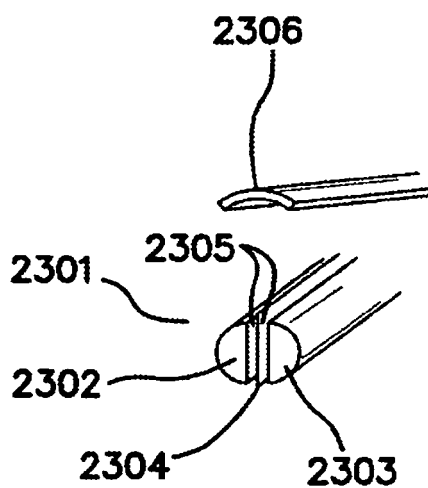


FIG. 58A

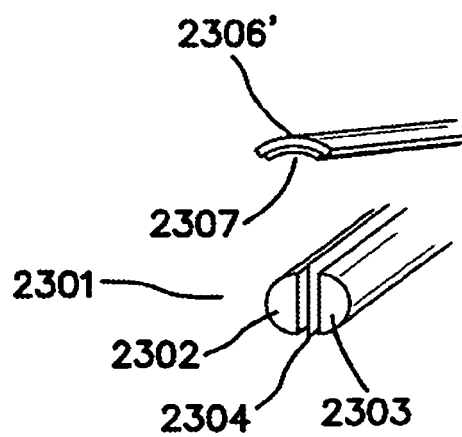


FIG. 58B

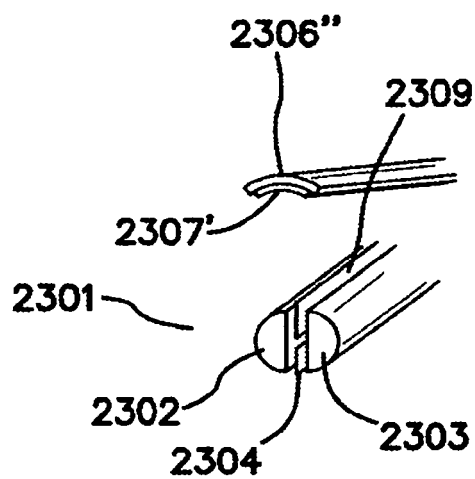


FIG. 58C

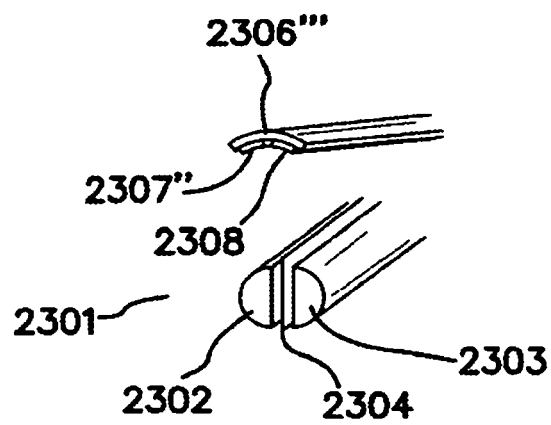
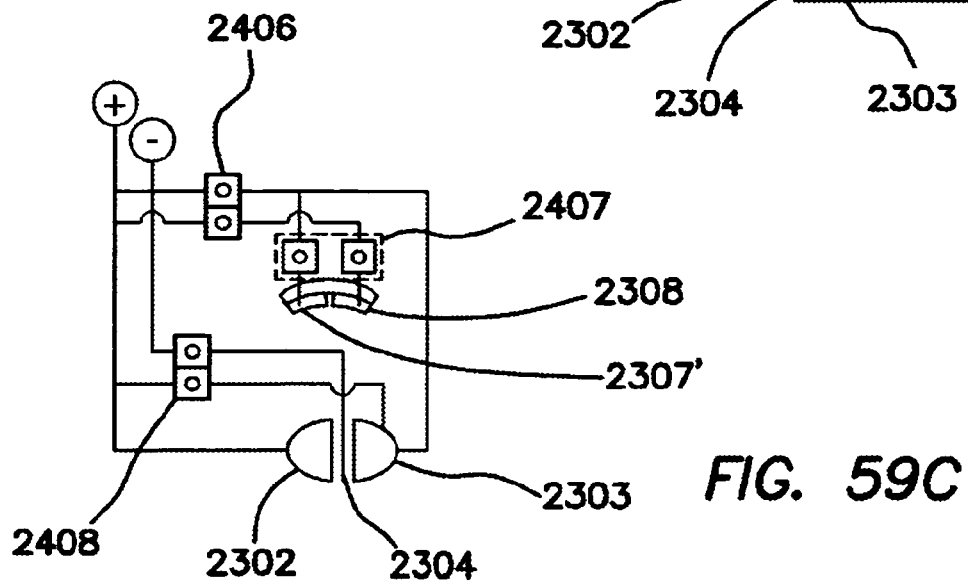
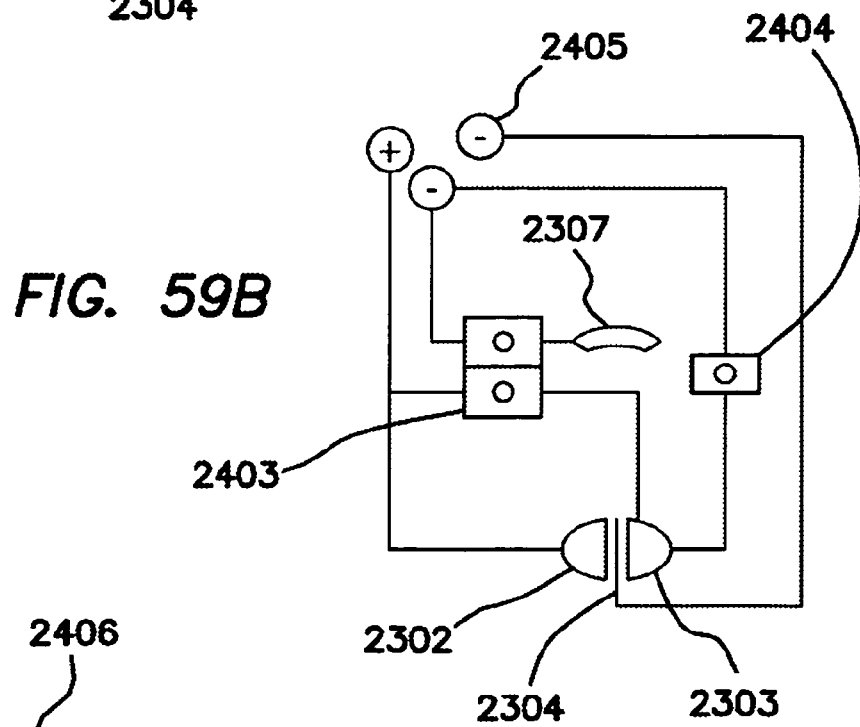
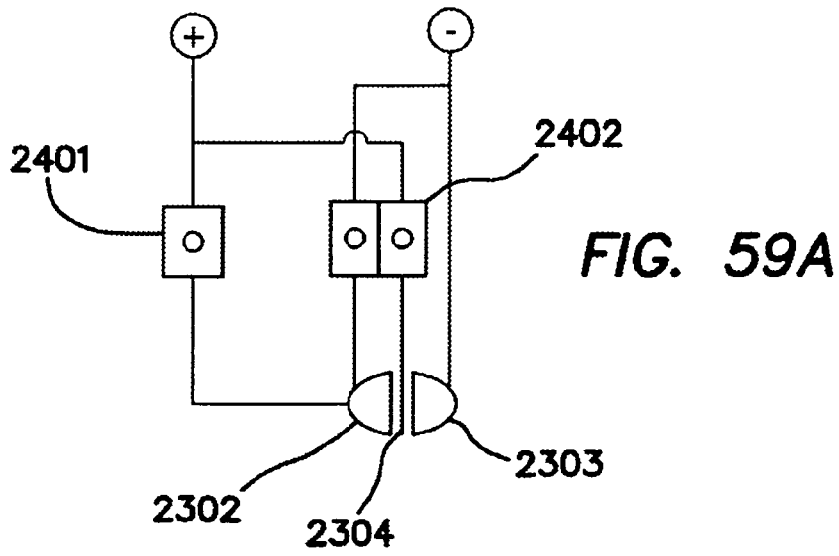


FIG. 58D



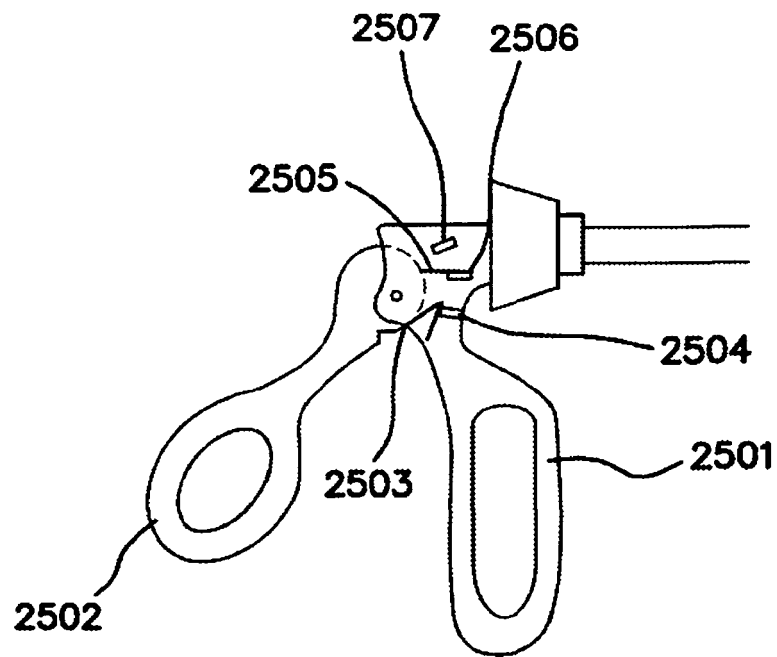


FIG. 60

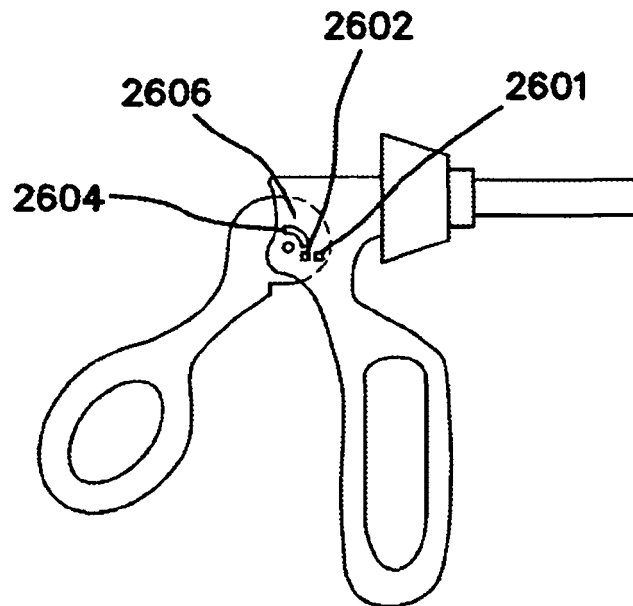


FIG. 61

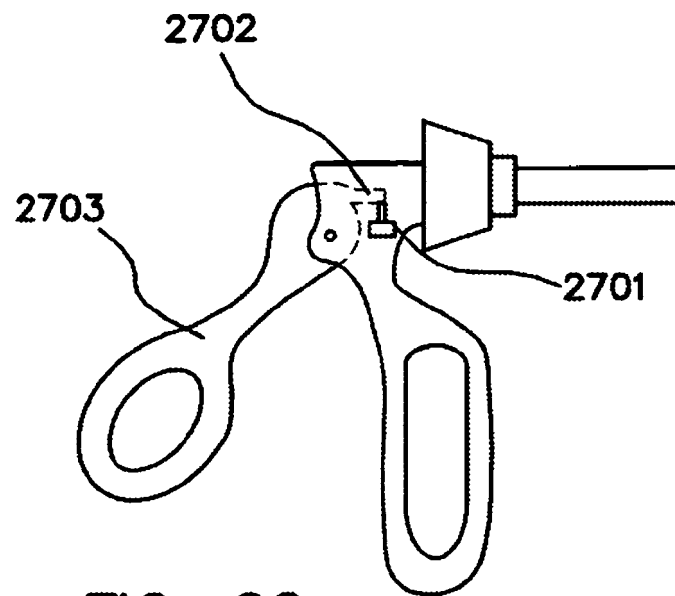


FIG. 62

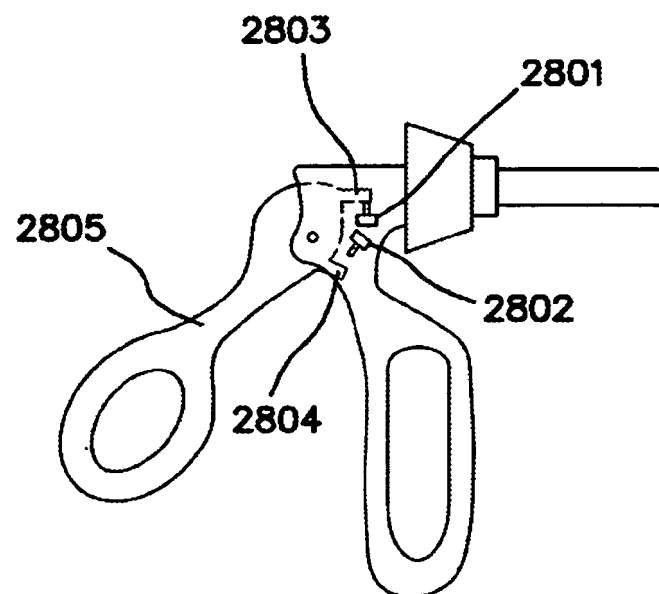


FIG. 63

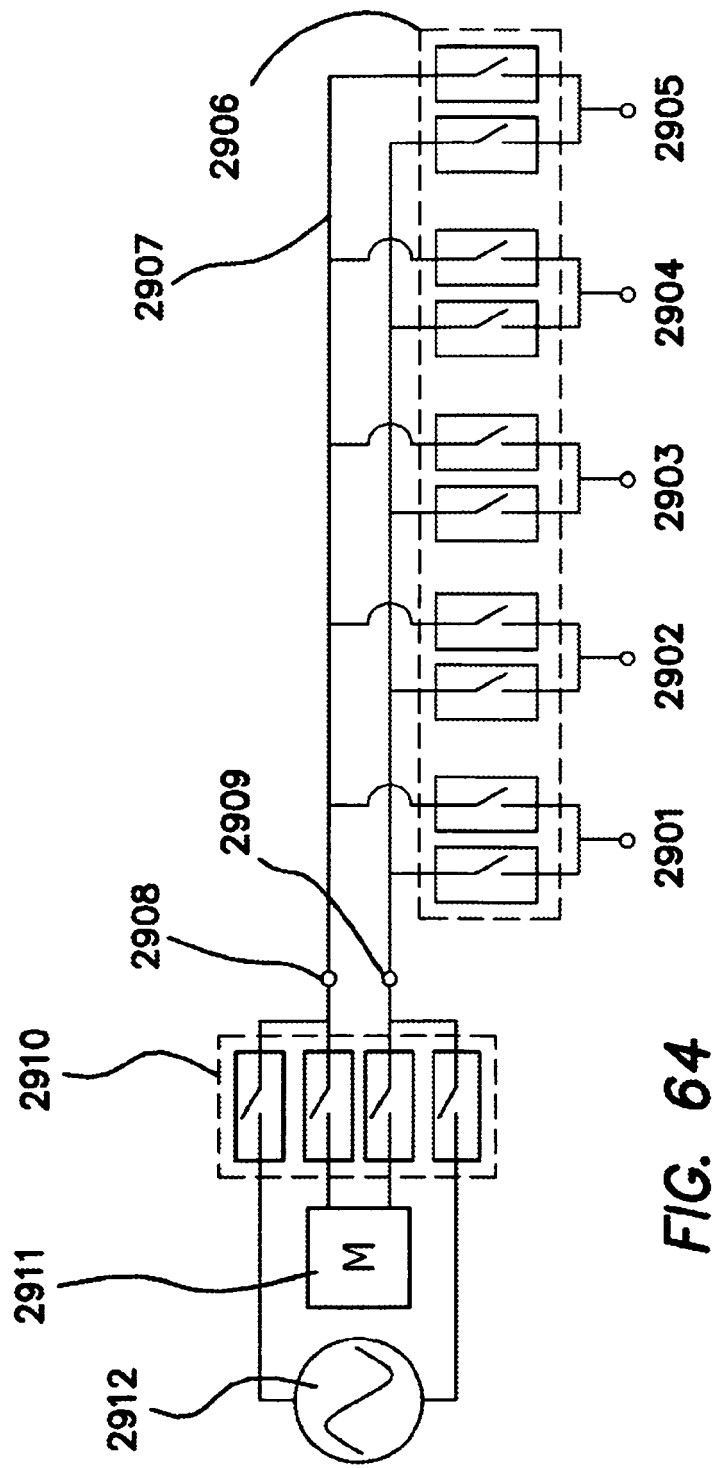
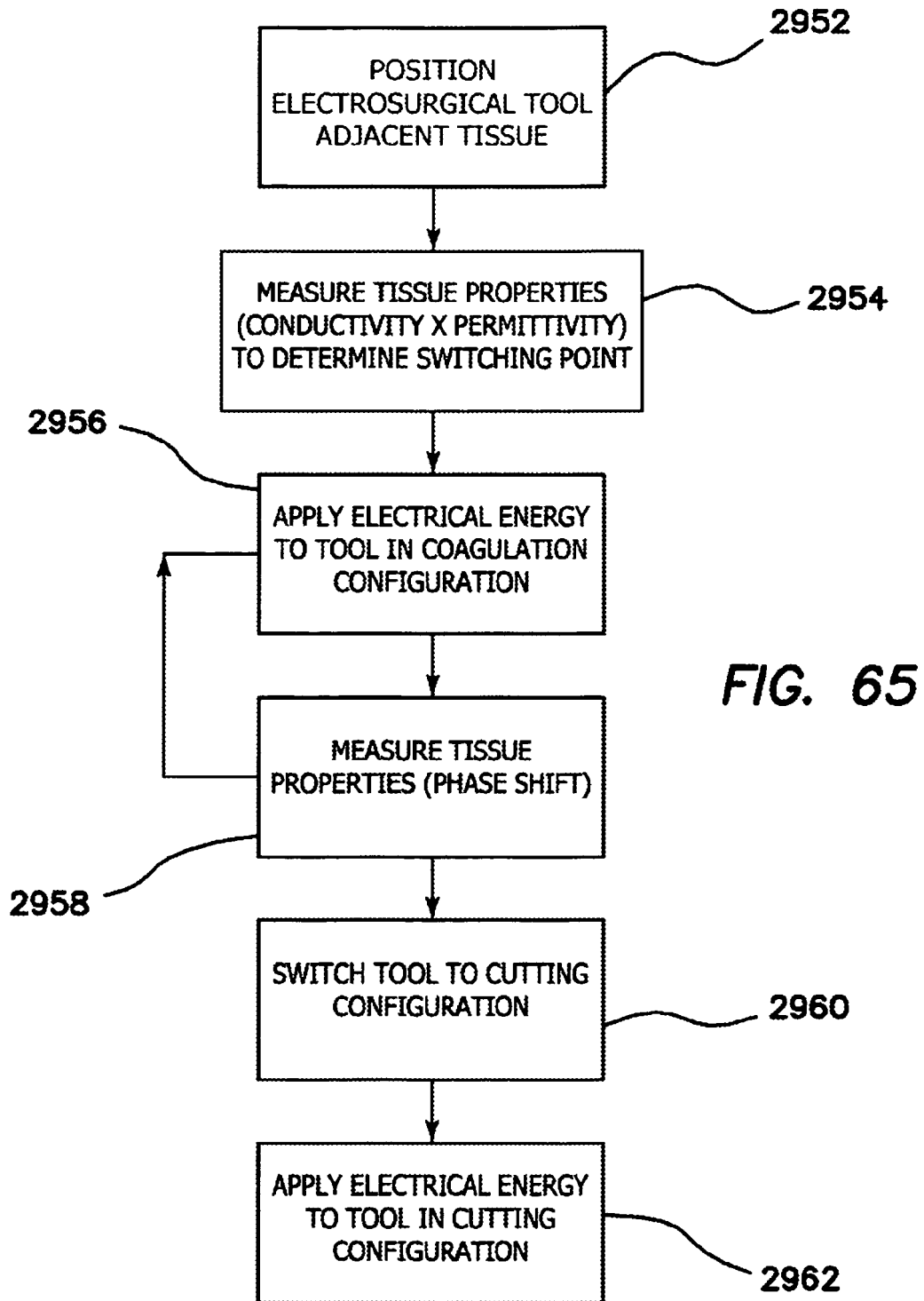


FIG. 64



REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- US 6053172 A [0002]