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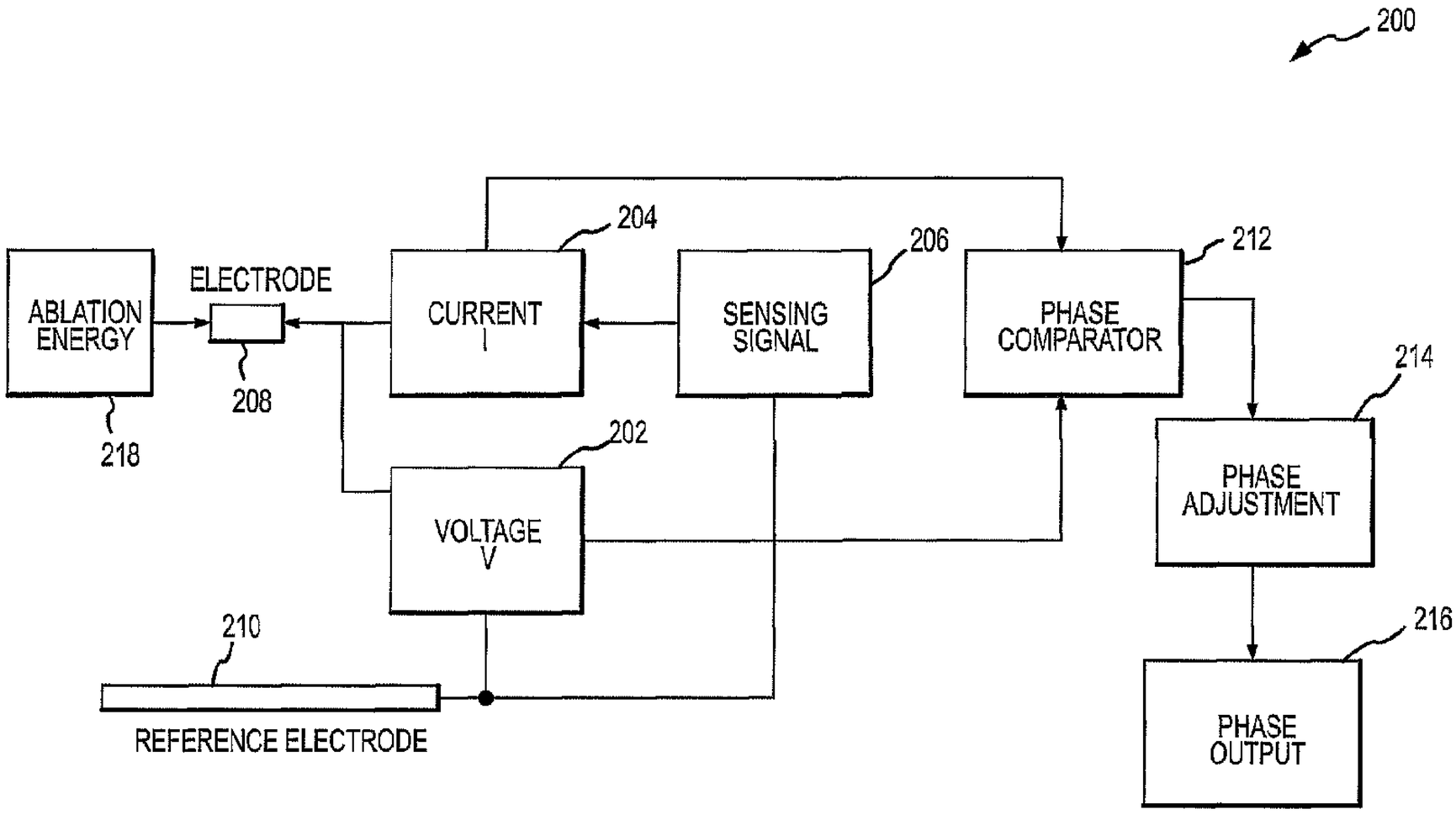
(54) **Titre : EVALUATION DE COUPLAGE D'ELECTRODE POUR ABLATION TISSULAIRE**
(54) **Title: ASSESSMENT OF ELECTRODE COUPLING FOR TISSUE ABLATION**



(57) **Abrégé/Abstract:**
An electrode catheter (14) and a method for assessing electrode-tissue contact and coupling are disclosed. An exemplary electrode catheter (14) comprises an electrode (20) adapted to apply electrical energy. A measurement circuit (42) is adapted to measure impedance between the electrode (20) and ground as the electrode approaches a target tissue (24). A processor (50) determines a contact and coupling condition for the target tissue (24) based at least in part on reactance of the impedance measured by the measurement circuit (42). In another exemplary embodiment, the electrode catheter (14) determines the contact and coupling condition based at least in part on a phase angle of the impedance.

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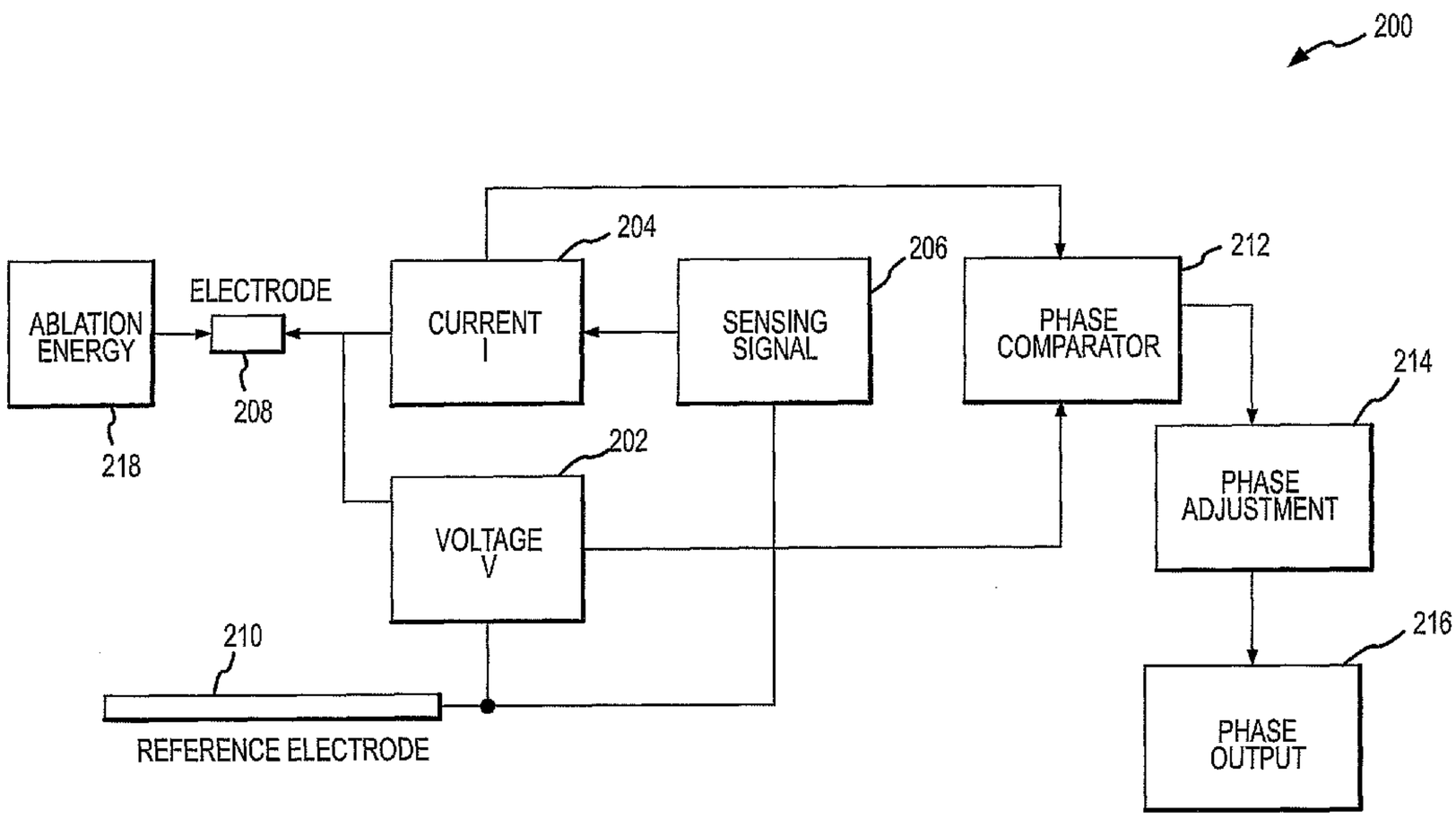
(54) Title: ASSESSMENT OF ELECTRODE COUPLING FOR TISSUE ABLATION



(57) Abstract: An electrode catheter (14) and a method for assessing electrode-tissue contact and coupling are disclosed. An exemplary electrode catheter (14) comprises an electrode (20) adapted to apply electrical energy. A measurement circuit (42) is adapted to measure impedance between the electrode (20) and ground as the electrode approaches a target tissue (24). A processor (50) determines a contact and coupling condition for the target tissue (24) based at least in part on reactance of the impedance measured by the measurement circuit (42). In another exemplary embodiment, the electrode catheter (14) determines the contact and coupling condition based at least in part on a phase angle of the impedance.

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ASSESSMENT OF ELECTRODE COUPLING FOR TISSUE ABLATION

BACKGROUND OF THE INVENTION

[0001] a. Field of the Invention

[0002] The instant invention is directed toward an electrode catheter and a method for using the electrode catheter for tissue ablation. In particular, the electrode catheter of the present invention may comprise a circuit to assess electrode-tissue contact and electrical coupling for applying ablative energy (e.g., RF energy) to target tissue.

[0003] b. Background Art

[0004] It is well known that benefits may be gained by forming lesions in tissue if the depth and location of the lesions being formed can be controlled. In particular, it can be desirable to elevate tissue temperature to around 50°C until lesions are formed via coagulation necrosis, which changes the electrical properties of the tissue. For example, lesions may be formed at specific locations in cardiac tissue via coagulation necrosis to lessen or eliminate undesirable atrial fibrillations.

[0005] Several difficulties may be encountered, however, when attempting to form lesions at specific locations using some existing ablation electrodes. One such difficulty encountered with existing ablation electrodes is how to ensure adequate tissue contact and electrical coupling. Electrode-tissue contact is not readily determined using conventional techniques such as fluoroscopy. Instead, the physician determines electrode-tissue contact based on his/her experience using the electrode catheter. Such experience only comes with time, and may be quickly lost if the physician does not use the electrode catheter on a regular basis. In addition, when forming lesions in a heart, the beating of the heart further complicates matters, making it difficult to determine and maintain sufficient contact pressure between the electrode and the tissue for a sufficient length of time to form a desired lesion. If the contact between the electrode and the tissue cannot be properly maintained, a quality lesion is unlikely to be formed. Similarly, information on electrical coupling between the electrode and the target tissue is not readily available a priori to determine how much ablative energy may be absorbed in the tissue during ablation.

Instead, the physician uses generalized pre-determined ablation parameters, such as power and duration, based on his/her experience to perform ablation procedures with the electrode catheter. Such experience may lead to deficiencies, inefficiencies and complications, such as inadequate lesion formation, premature high impedance shut-off, tissue charring, and thrombus formation.

BRIEF SUMMARY OF THE INVENTION

[0006] It is desirable to be able to assess electrode-tissue contact and electrical coupling for electrode catheters used for tissue ablation procedures. Although radio frequency (RF) ablative energy is predominately resistive heating at typical operating frequencies of about 500 kHz, at lower frequencies there exist capacitances in the patient's blood and tissue. The combined effects of resistance and capacitance at the blood-tissue interface can be measured (e.g., as impedance) to automatically assess different contact conditions between the electrode and a target tissue.

[0007] An exemplary electrode catheter system may comprise an electrode adapted to apply electric energy. A measurement circuit adapted to measure impedance may be implemented between the electrode and ground as the electrode approaches a target tissue. A processor or processing units may be implemented to determine a contact condition for the target tissue based at least in part on reactance of the impedance measured by the measurement circuit. In another embodiment, the contact condition may be based on the phase angle of the impedance.

[0008] An exemplary electrode catheter system may comprise an electrode adapted to apply electric energy. A measurement circuit adapted to measure impedance may be implemented between the electrode and ground as the electrode approaches a target tissue. A processor or processing units may be implemented to determine an electrical coupling condition for the target tissue based at least in part on reactance of the impedance measured by the measurement circuit. In another embodiment, the electrical coupling condition may be based on the phase angle of the impedance.

[0009] An exemplary method of assessing electrode-tissue contact for tissue ablation may comprise: measuring impedance between an electrode and ground as the electrode approaches a target tissue, separating a reactance component from the measured impedance, and indicating a contact condition for the target tissue based at least in part on the reactance component.

[0010] An exemplary method of assessing electrode-tissue electrical coupling for tissue ablation may comprise: measuring impedance between an electrode and ground as the electrode approaches a target tissue, separating a reactance component from the measured impedance, and indicating electrical coupling condition for the target tissue based at least in part on the reactance component.

[0011] Another exemplary method of assessing electrode-tissue contact for tissue ablation may comprise: directly measuring a phase angle between an electrode and ground as the electrode approaches a target tissue, and indicating a contact condition for the target tissue based at least in part on the phase angle.

[0012] Another exemplary method of assessing electrode-tissue electrical coupling for tissue ablation may comprise: directly measuring a phase angle between an electrode and ground as the electrode approaches a target tissue, and indicating electrical coupling condition for the target tissue based at least in part on the phase angle.

[0013] The contact condition may be conveyed to the user (e.g., a physician or technician), e.g., at a display device or other interface. The user may then use the contact condition as feedback to properly position the electrode catheter on the target tissue with the desired level of contact for the ablation procedure. For example, the user may increase contact if the contact condition indicates insufficient contact. Or for example, the user may reduce contact if the contact condition indicates too much contact.

[0014] The electrical coupling condition may be conveyed to the user (e.g., a physician or technician), e.g., at a display device or other interface. The user may then use the electrical coupling condition as feedback to properly position the electrode catheter on the target tissue

with the desired level of coupling for the ablation procedure. For example, the user may increase coupling if the coupling condition indicates insufficient coupling. Or for example, the user may reduce coupling if the coupling condition indicates too much coupling.

[0015] It is also noted that in exemplary embodiments, a current source (or alternatively, a voltage source) may be used to administer the electrical energy. This source can be the same source that is used for the ablation procedure and is used to "ping" during positioning of the electrode, or it can be a separately provided source. In any event, a constant current source (or constant voltage source) may be used. Alternatively, a variable current source (or a variable voltage source), such as an ablation source operating in a mode that is adaptive to tissue temperature. Furthermore, a plurality of the current sources (or voltage sources) may be used. The plurality of current sources (or voltage sources) may be operative either in a concurrent, sequential, or temporally overlapping mode.

[0015a] Thus, in one aspect, there is provided a coupling sensing system comprising:

a measurement circuit adapted to measure impedance between an electrode of a catheter, adapted to apply electrical energy, and ground as the electrode approaches a target tissue;

a first data structure including a plurality of sets of empirically predetermined electrical coupling conditions for a corresponding plurality of types of tissue;

a processor configured to determine an electrical coupling condition at a particular moment in time for the target tissue based at least in part on the impedance measured by the measurement circuit relative to a baseline value determined in the blood and based on comparison of the impedance measurement between the electrode and the target tissue with one of the sets of empirically predetermined electrical coupling conditions for a type of tissue corresponding to the target tissue, wherein the electrical coupling condition corresponds to electrical energy passing between the electrode and the target tissue.

[0016] The foregoing and other aspects, features, details, utilities, and advantages of the present invention will be apparent from reading the following description and claims, and from reviewing the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] FIG. 1 is a diagrammatic illustration of an exemplary tissue ablation system which may be implemented to assess electrode-tissue contact during a tissue ablation procedure for a patient.

[0018] FIG. 1a is a detailed illustration of the patient's heart in FIG. 1, showing the electrode catheter after it has been moved into the patient's heart.

[0019] FIG. 2a illustrates exemplary levels of electrical contact or coupling between the electrode catheter and a target tissue.

[0020] FIG. 2b illustrates exemplary levels of mechanical contact or coupling between the electrode catheter and a target tissue.

[0021] FIG. 3 is a high-level functional block diagram showing the exemplary tissue ablation system of FIG. 1 in more detail.

[0022] FIG. 4 is a model of the electrode catheter hi contact with (or coupled to) target tissue.

[0023] FIG. 4a is a simplified electrical circuit for the model shown in FIG. 4.

[0024] FIG. 5 is an exemplary phase detection circuit which may be implemented in the tissue ablation system for assessing electrode-tissue contact or coupling.

[0025] FIG. 6 is an exemplary block diagram showing phase angle measurement for contact sensing and tissue sensing.

[0026] FIG. 7 is an exemplary block diagram showing phase angle measurement during ablation with both ablation energy and a contact sensing signal applied to the ablation electrode at the same time.

[0027] FIG. 8 is an exemplary block diagram showing phase angle measurement during ablation with switching between a sensing signal and ablation power.

DETAILED DESCRIPTION OF THE INVENTION

[0028] Exemplary embodiments of a tissue ablation system and methods of use to assess electrode-tissue contact and electrical coupling are depicted in the figures. As described further below, the tissue ablation system of the present invention provides a number of advantages, including, for example, the ability to apply a reasonable amount of ablative energy to a target tissue while mitigating electrode-tissue contact and coupling problems. The invention also facilitates enhanced tissue contact and electrical coupling in difficult environments (e.g., during lesion formation on a surface inside a beating heart).

[0029] FIG. 1 is a diagrammatic illustration of an exemplary electrode catheter system 10 which may be implemented to assess electrode-tissue contact during a tissue ablation procedure for a patient 12. Catheter system 10 may include an electrode catheter 14, which may be inserted into the patient 12, e.g., for forming ablative lesions inside the patient's heart 16. During an exemplary ablation procedure, a user (e.g., the patient's physician or a technician) may insert the electrode catheter 14 into one of the patient's blood vessels 18, e.g., through the leg (as shown in FIG. 1) or the patient's neck. The user, guided by a real-time fluoroscopy imaging device (not shown), moves the electrode catheter 14 into the patient's heart 16 (as shown in more detail in FIG. 1a).

[0030] When the electrode catheter 14 reaches the patient's heart 16, electrodes 20 at the tip of the electrode catheter 14 may be implemented to electrically map the myocardium 22 (i.e., muscular tissue in the heart wall) and locate a target tissue 24. After locating the target tissue 24, the user must move the electrode catheter 14 into contact and electrically couple the catheter electrode 14 with the target tissue 24 before applying ablative energy to form an ablative lesion or lesions. The electrode-tissue contact refers to the condition when the catheter electrode 14 physically touches the target tissue 24 thereby causing a mechanical coupling between the catheter electrode 14 and the target tissue 24. Electrical coupling refers to the

condition when a sufficient portion of electrical energy passes from the catheter electrode 14 to the target tissue 24 so as to allow efficient lesion creation during ablation. For target tissues with similar electrical and mechanical properties, electrical coupling includes mechanical contact. That is, mechanical contact is a subset of electrical coupling. Thus, the catheter electrode may be substantially electrically coupled with the target tissue without being in mechanical contact, but not vice-versa. In other words, if the catheter electrode is in mechanical contact, it is also electrically coupled. The range or sensitivity of electrical coupling, however, changes for tissues with different electrical properties. For example, the range of electrical coupling for electrically conductive myocardial tissue is different from the vessel walls. Likewise, the range or sensitivity of electrical coupling also changes for tissues with different mechanical properties, such as tissue compliance. For example, the range of electrical coupling for the relatively more compliant smooth atrial wall is different from the relatively less compliant pectinated myocardial tissue. The level of contact and electrical coupling are often critical to form sufficiently deep ablative lesions on the target tissue 24 without damaging surrounding tissue in the heart 16. The catheter system 10 may be implemented to measure impedance at the electrode-tissue interface and assess the level of contact (illustrated by display 11) between the electrode catheter 14 and the target tissue 24, as described in more detail below.

[0031] FIG. 2a illustrates exemplary levels of electrical contact or coupling between an electrode catheter 14 and a target tissue 24. FIG. 2b illustrates exemplary levels of mechanical contact or coupling between an electrode catheter 14 and a target tissue 24. Exemplary levels of contact or coupling may include "little or no contact" as illustrated by contact condition 30a, "light to medium contact" as illustrated by contact condition 30b, and "hard contact" as illustrated by contact condition 30c. In an exemplary embodiment, the catheter system 10 may be implemented to display or otherwise output the contact condition for the user, e.g., as illustrated by light arrays 31a-c corresponding to contact conditions 30a-c, respectively.

[0032] Contact condition 30a ("little or no contact") may be experienced before the electrode catheter 14 comes into contact with the target tissue 24. Insufficient contact may inhibit or even prevent adequate lesions from being formed when the electrode catheter 14 is operated to apply ablative energy. However, contact condition 30c ("hard contact") may result in

the formation of lesions which are too deep (e.g., causing perforations in the myocardium 22) and/or the destruction of tissue surrounding the target tissue 24. Accordingly, the user may desire contact condition 30b ("light to medium contact").

[0033] It is noted that the exemplary contact or coupling conditions 30a-c in FIG. 2a-b are shown for purposes of illustration and are not intended to be limiting. Other contact or coupling conditions (e.g., finer granularity between contact conditions) may also exist and/or be desired by the user. The definition of such contact conditions may depend at least to some extent on operating conditions, such as, the type of target tissue, desired depth of the ablation lesion, and operating frequency of the RF radiation, to name only a few examples.

[0034] FIG. 3 is a high-level functional block diagram showing the catheter system 10 in more detail as it may be implemented to assess contact or coupling conditions for the electrode catheter 14. It is noted that some of the components typical of conventional tissue ablation systems are shown in simplified form and/or not shown at all in FIG. 1 for purposes of brevity. Such components may nevertheless also be provided as part of, or for use with the catheter system 10. For example, electrode catheter 14 may include a handle portion, a fluoroscopy imaging device, and/or various other controls, to name only a few examples. Such components are well understood in the medical devices arts and therefore further discussion herein is not necessary for a complete understanding of the invention.

[0035] Exemplary catheter system 10 may include a generator 40, such as, e.g., a radio frequency (RF) generator, and a measurement circuit 42 electrically connected to the electrode catheter 14 (as illustrated by wires 44 to the electrode catheter). The electrode catheter 14 may also be electrically grounded, e.g., through grounding patch 46 affixed to the patient's arm or chest (as shown in FIG. 1).

[0036] Generator 40 may be operated to emit electrical energy (e.g., RF current) near the tip of the electrode catheter 14. It is noted that although the invention is described herein with reference to RF current, other types of electrical energy may also be used for assessing contact conditions.

[0037] In an exemplary embodiment, generator 40 emits a so-called "pinging" (e.g., low) frequency as the electrode catheter 14 approaches the target tissue 24. The "pinging" frequency may be emitted by the same electrode catheter that is used to apply ablative energy for lesion formation. Alternatively, a separate electrode catheter may be used for applying the "pinging" frequency. In such an embodiment, the separate electrode may be in close contact with (or affixed to) the electrode for applying ablative energy so that a contact or coupling condition can be determined for the electrode which will be applying the ablative energy.

[0038] The resulting impedance at the electrode-tissue interface may be measured during contact or coupling assessment (or "pinging") using a measurement circuit 42. In an exemplary embodiment, the measurement circuit 42 may be a conventionally available resistance-capacitance-inductance (RCL) meter. Another exemplary measurement circuit which may be implemented for determining the phase angle component is also described in more detail below with reference to FIG. 5. Still other measurement circuits 42 may be implemented and the invention is not limited to use with any particular type or configuration of measurement circuit.

[0039] The reactance and/or phase angle component of the impedance measurements may be used to determine a contact or coupling condition. The contact or coupling condition may then be conveyed to the user in real-time for achieving the desired level of contact or coupling for the ablation procedure. For example, the contact or coupling condition may be displayed for the user on a light array (e.g., as illustrated in FIG. 2a-b). [0040] After the user has successfully guided the electrode catheter 14 into the desired contact or coupling condition with the target tissue 24, a generator, such as generator 40 or a second generator, may be operated to generate ablative (e.g., high frequency) energy for forming an ablative lesion or lesions on the target tissue 24. In an exemplary embodiment, the same generator 40 may be used to generate electrical energy at various frequencies both for the impedance measurements (e.g., "pinging" frequencies) and for forming the ablative lesion. In alternative embodiments, however, separate generators or generating units may also be implemented without departing from the scope of the invention.

[0041] In an exemplary embodiment, measurement circuit 42 may be operatively associated with a processor 50 and memory 52 to analyze the measured impedance. By way of example, processor 50 may determine a reactance and/or phase angle component of the impedance measurement, and based on the reactance component and/or phase angle, the processor 50 may determine a corresponding contact or coupling condition for the electrode catheter 14. In an exemplary embodiment, contact or coupling conditions corresponding to various reactance and/or phase angles may be predetermined, e.g., during testing for any of a wide range of tissue types and at various frequencies. The contact or coupling conditions may be stored in memory 52, e.g., as tables or other suitable data structures. The processor 50 may then access the tables in memory 42 and determine a contact or coupling condition corresponding to impedance measurement based on the reactance component and/or phase angle. The contact or coupling condition may be output for the user, e.g., at display device 54.

[0042] It is noted, that the catheter system 10 is not limited to use with processor 50 and memory 52. In other embodiments, analog circuitry may be implemented for assessing contact conditions based on the impedance measurement and for outputting a corresponding contact condition. Such circuitry may be readily provided by one having ordinary skill in the electronics arts after having become familiar with the teachings herein, and therefore further discussion is not needed.

[0043] It is also noted that display device 54 is not limited to any particular type of device. For example, display device 54 may be a computer monitor such as a liquid-crystal display (LCD). Alternatively, display device may be implemented as a light array, wherein one or more light emitting diodes (LED) are activated in the light array to indicate a contact condition (e.g., more lights indicating more contact). Indeed, any suitable output device may be implemented for indicating contact conditions to a user, and is not limited to a display device. For example, the contact condition may be output to the user as an audio signal or tactile feedback (e.g., vibrations) on the handle of the electrode catheter.

[0044] It is further noted that the components of catheter system 10 do not need to be provided in the same housing. By way of example, measurement circuit 42 and/or processor 50 and memory 52 may be provided in a handle portion of the electrode catheter 14. In another

example, at least part of the measurement circuit 42 may be provided elsewhere in the electrode catheter 14 (e.g., in the tip portion). In still other examples, processor 50, memory 52, and display device 54 may be provided as a separate computing device, such as a personal desktop or laptop computer which may be operatively associated with other components of the catheter system 10.

[0045] Assessing a contact or coupling condition between the electrode catheter 14 and target tissue 24 based on impedance measurements at the electrode-tissue interface may be better understood with reference to FIGs. 4 and 4a. FIG. 4 is a model of the electrode catheter 14 in contact with (or coupled to) target tissue 24. The electrode catheter 14 is electrically connected to the generator 40 (e.g., an RF generator). In an exemplary embodiment, the circuit may be completed through the target tissue 24, showing that current flows through the blood, myocardium, and other organs to the reference electrode, such as a grounding patch 46 on the patient's body (FIG. 1).

[0046] As described above, the generator 40 may be operated to generate electrical energy for emission by the electrode catheter 14. Emissions are illustrated in FIG. 4 by arrows 60. Also as described above, generator 40 may emit a "pinging" frequency as the electrode catheter 14 approaches the target tissue 24 for assessing electrode-tissue contact or coupling. In an exemplary embodiment, this "pinging" frequency may be selected such that inductive, capacitive, and resistive effects other than those at the blood-tissue interface do not appreciably affect the impedance measurements.

[0047] In an exemplary application, capacitive effects of the blood and at the electrode-blood interface (e.g., between the metal electrode catheter and the blood) were found be minimal or even non-existent at frequencies higher than about 50 kHz. Stray inductance (e.g., due to the relatively thin catheter wires), capacitance and resistance at the electrode interface, and capacitance effects of other organs (e.g., the lungs) were also found to be minimal or even non-existent at frequencies higher than about 50 kHz.

[0048] In addition, it was found that resistive effects dominate at the blood-tissue interface for frequencies below 50 kHz because the current flows into the target tissue 24

primarily via the interstitial fluid spaces 23, and the cell membranes 25 (e.g., bi-lipids or "fat") act as an insulator. However, at frequencies greater than about 50 kHz, the cell membranes 25 become conductive, and electrical current penetrates the target tissue 24 through both the interstitial fluid spaces 23 and the cell membranes 25. Accordingly, the cell membranes act as "capacitors" and the resistive effects are reduced at frequencies above about 50 kHz.

[0049] To avoid a risk of creating an ablation lesion during contact or coupling assessment, it can be desirable to use a low amount of current and power. A presently preferred range for a current of less than ImA is a working frequency in the 50~500 kHz range.

[0050] The frequency choice is mostly based on physiological aspect and engineering aspect and is within the purview of one of ordinary skill in the art. For physiological aspect, lower frequencies can introduce measurement errors due to electrode-electrolyte interface. When frequency goes higher to MHz range or above, the parasitic capacitance can become significant. It is noted, however, that the invention is not limited to use at any particular frequency or range of frequencies. The frequency may depend at least to some extent on operational considerations, such as, e.g., the application, the type of target tissue, and the type of electrical energy being used, to name only a few examples.

[0051] Assuming, that a desired frequency has been selected for the particular application, the model shown in FIG. 4 may be further expressed as a simplified electrical circuit 62, as shown in FIG. 4a. In the circuit 62, generator 40 is represented as an AC source 64. As discussed above, capacitance and resistance at the blood-tissue interface dominate impedance measurements at low frequency operation such as may be used for assessing electrode-tissue contact. Accordingly, other capacitive, inductive, and resistive effects may be ignored and the capacitive-resistive effects at the blood-tissue interface may be represented in circuit 62 by a resistor-capacitor (R-C) circuit 66.

[0052] The R-C circuit 66 may include a resistor 68 representing the resistive effects of blood on impedance, in parallel with a resistor 70 and capacitor 72 representing the resistive and capacitive effects of the target tissue 24 on impedance. When the electrode catheter 14 has no or little contact with the target tissue 24, resistive effects of the blood affect the R-C circuit

66, and hence also affect the impedance measurements. As the electrode catheter 14 is moved into contact with the target tissue 24, however, the resistive and capacitive effects of the target tissue 24 affect the R-C circuit 66, and hence also affect the impedance measurements.

[0053] The effects of resistance and capacitance on impedance measurements may be better understood with reference to a definition of impedance. Impedance (Z) may be expressed as:

$$Z = R + jX$$

where:

R is resistance from the blood and/or tissue;

j an imaginary number indicating the term has a phase angle of +90 degrees; and

X is reactance from both capacitance and inductance.

[0054] It is observed from the above equation that the magnitude of the reactance component responds to both resistive and capacitive effects of the circuit 62. This variation corresponds directly to the level of contact or coupling at the electrode-tissue interface, and therefore may be used to assess the electrode-tissue contact or coupling. By way of example, when the electrode catheter 14 is operated at a frequency of 100 kHz and is primarily in contact with the blood, the impedance is purely resistive and the reactance (X) is close to 0 Ohms. When the electrode catheter 14 contacts the target tissue, the reactance component becomes negative. As the level of contact or coupling is increased, the reactance component becomes more negative.

[0055] Alternatively, contact or coupling conditions may be determined based on the phase angle. Indeed, determining contact or coupling conditions based on the phase angle may be preferred in some applications because the phase angle is represented as a trigonometric ratio between reactance and resistance. Although the magnitude of the reactance component may be different under varying conditions (e.g., for different patients), the phase angle is a relative measurement which tends to be insensitive to external conditions.

[0056] In an exemplary embodiment, the phase angle may be determined from the impedance measurements (e.g., by the processor 50 in FIG. 3). That is, impedance may be expressed as:

$$Z = |Z| \angle \phi$$

where:

|**Z**| is the magnitude of the impedance; and

ϕ is the phase angle.

[0057] The terms |Z| and ϕ may further be expressed as:

$$|Z| = \sqrt{R^2 + X^2} \text{ ; and}$$

$$\tan \phi = \frac{X}{R}$$

[0058] The phase angle also corresponds directly to the level of contact or coupling at the electrode-tissue interface, and therefore may be used to assess the electrode-tissue contact or coupling. By way of example, when the electrode catheter 14 is operated at a frequency of 100 kHz and is primarily in contact with the blood, the phase angle is close to zero (0). When the electrode catheter 14 contacts the target tissue, the phase angle becomes negative, and the phase angle becomes more negative as the level of contact or coupling is increased. An example is shown in Table 1 for purposes of illustration.

TABLE 1: Phase Angle Relation to Contact Conditions

Phase Angle	Contact Condition
$\phi > -3°$	little or no contact or coupling
$-3° < \phi < -7°$	medium contact or coupling
$-7° < \phi < -10°$	high contact or coupling
$\phi < -10°$	excessive contact or coupling

[0059] Although impedance measurements may be used to determine the phase angle, in an alternative embodiment, the measurement circuit 42 may be implemented as a phase

detection circuit to directly determine the phase angle. An exemplary phase detection circuit 80 is shown in FIG. 5. Phase detection circuit 80 is shown and described with reference to functional components. It is noted that a particular hardware configuration is not necessary for a full understanding of the invention. Implementation of the phase detection circuit 80 in digital and/or analog hardware and/or software will be readily apparent to those having ordinary skill in the electronics art after becoming familiar with the teachings herein.

[0060] Exemplary phase detection circuit 80 may include a current sensor 82 and voltage sensor 84 for measuring current and voltage at the electrode-tissue interface. The current and voltage measurements may be input to a phase comparator 86. Phase comparator 86 provides a direct current (DC) output voltage proportional to the difference in phase between the voltage and current measurements.

[0061] Optionally, current measurements may be phase shifted by phase shift circuit 88 to facilitate operation of the phase comparator 86 by "correcting" phase lag between the measured current and the measured voltage. Also optionally, output from the phase comparator 86 may be "corrected" by phase adjustment circuit 90 to compensate for external factors, such as the type of grounding patch 46 being used. A signal scaling circuit 92 may also be provided to amplify the output (e.g., from milli-volts to volts) for use by various devices (e.g., the processor 50 and display device 54 in FIG. 3).

[0062] During ablation, the measured impedance, and its component's resistance and reactance, change with tissue temperature. In such conditions, the change due to changes in tissue temperature provides a measure of lesion formation during ablation.

[0063] It is noted that phase detection circuit 80 shown in FIG. 5 is provided as one example, and is not intended to be limiting. Other implementations may also be readily provided by those having ordinary skill in the electronics arts after becoming familiar with the teachings herein without departing from the scope of the invention.

[0064] Having described exemplary systems for electrode contact assessment, exemplary operational modes may now be better understood with reference to the block diagrams shown in FIG. 6-8. FIG. 6 is an exemplary block diagram 100 showing phase angle

measurement for sensing contact or coupling. FIG. 7 is an exemplary block 200 diagram showing phase angle measurement during ablation with both ablation energy and a contact sensing signal applied to the ablation electrode at the same time. FIG. 8 is an exemplary block diagram 300 showing phase angle measurement during ablation with switching between sensing signal and ablation power. It is noted that 200-series and 300-series reference numbers are used in FIG. 7 and FIG. 8, respectively, to denote similar elements and these elements may not be described again with reference to FIG. 7 and FIG. 8.

[0065] As noted above, the phase angle method of sensing contact or coupling is based on the fact that (1) tissue is both more resistive and capacitive than blood, and (2) measured electrode impedance is mostly dependent on the immediate surrounding materials. Thus, when an electrode moves from blood to myocardium, the measured impedance value increases and phase angles change from 0° to negative values (capacitive). Phase angle may be used to represent the contact or coupling levels because phase angle is a relative term of both resistance and reactance. That is, it provides a 0° base line when the electrode is in contact with blood, and becomes increasingly more negative as more contact or coupling is established. It also minimizes the influence of the catheter, instrumentation, and physiological variables.

[0066] The phase angle measurement may be made by sampling both electrical voltage (V) 102 and current (I) 104 of a load and calculating the lag between those signals as the phase angle. As shown in FIG. 6, a sensing signal 106 is applied between the ablation electrode 108 and a reference electrode 110. This sensing signal 106 can, for example, be between 50 to 500 kHz at a small amplitude (<1 mA).

[0067] Exemplary instruments may be operated as frequencies of, for example but not limited to, 100 kHz, 400 kHz and 485 kHz, depending on the reference electrode configuration. Both current 104 and voltage 102 are sensed. These two signals are transmitted to a phase comparator 112 to calculate phase angle, which corresponds to the contact or coupling condition of the electrode 108. The raw phase angle signal is adjusted in block 114 to compensate for external influence on the phase angle, e.g., caused by the catheter, instrumentation, and physiological variables. It is also conditioned for easy interpretation and interface and then output in block 116 to other equipment for display or further processing.

[0068] The phase compensation may be achieved at the beginning of an ablation procedure. First, the catheter electrode is maneuvered to the middle of the heart chamber (e.g., the right atrium or left atrium) so that the electrode 108 only contacts blood. The system measures the phase angle and uses this value as a baseline for zero contact level. This adjustment compensates the fixed phase angles caused by catheter and patient such as catheter wiring, location of the reference electrode and skin or adiposity if external patch is used.

[0069] After the initial zero adjustment, the user may maneuver the catheter electrode to one or more desired sites to ablate arrhythmic myocardium. In an exemplary embodiment, the phase angle starts to change when the electrode 108 approaches to say within 3mm from the myocardium and becomes increasingly more negative as more contact or coupling is established. The user may judge the quality of electrode contact or coupling before administering the ablation energy based on phase angle output. In an exemplary embodiment, this phase angle value is about -3° when a 4mm ablation electrode actually contacts the myocardium. It is noted that there are at least two methods to measure phase angle during ablation, as described in more detail now with reference to FIG. 7 and FIG. 8.

[0070] In FIG. 7, ablation power 218 is applied to the electrode 208 while the sensing signal 206 is applied as well. The ablation and contact sensing operate at different frequencies. Accordingly, with filtering, the phase angle can be measured during ablation without disturbing the ablation of the myocardium.

[0071] Another option is to switch the phase measurement between the sensing signal 306 and ablation power 318, as indicated by switch 320 in FIG. 8. When the ablation power 318 is switched off during approach, the small amplitude sensing signal 306 is switched on and used to measure phase angle for sensing contact or coupling. When the ablation power 318 is switched on for the ablation procedure, the voltage and current of the large amplitude ablation power 318 are sensed and used as the contact or coupling indicator during ablation.

[0072] Although several embodiments of this invention have been described above with a certain degree of particularity, those skilled in the art could make numerous alterations to the disclosed embodiments without departing from the scope of the invention as defined in the appended claims. References are only used for identification purposes to aid the reader's understanding of the present invention, and do not create limitations as to the position, orientation, or use of the invention. It is intended that all matter contained in the above description or shown in the accompanying drawings shall be interpreted as illustrative only and not limiting. Changes in detail or structure may be made without departing from the scope of the invention as defined in the appended claims.

WHAT IS CLAIMED IS:

1. A coupling sensing system comprising:

a measurement circuit adapted to measure impedance between an electrode of a catheter, adapted to apply ablation energy, and ground as the electrode approaches a target tissue;

a first data structure including a plurality of sets of empirically predetermined electrical coupling conditions indicative of amount of ablative energy absorbed by a corresponding plurality of types of tissue;

a processor configured to determine an electrical coupling condition indicative of an amount of ablative energy that will be absorbed by the target tissue upon application of said ablation energy to said electrode, wherein said determination is based at least in part on a difference between the impedance measured by the measurement circuit relative to a baseline value determined in the blood proximate to the target tissue and comparison of said difference with one of said sets of empirically predetermined electrical coupling conditions for a type of tissue corresponding to the target tissue; and an output device for indicating said electrical coupling condition to a user prior to application of said ablation energy to said electrode.

2. The system of claim 1, wherein said electrical coupling condition indicates if said ablative energy is sufficient to create a lesion during ablation.

3. The system of claim 1, wherein a level of electrical coupling condition directly corresponds to a reactance of the measured impedance.

4. The system of claim 3, wherein a reactance approaching zero (0) indicates little or no electrical coupling.

5. The system of claim 3, wherein an increasingly negative reactance indicates increasing electrical coupling condition between the electrode and the target tissue.

6. The system of claim 1, wherein a level of said electrical coupling condition directly corresponds to a phase angle of the measured impedance.

7. The system of claim 6, wherein a phase angle approaching zero (0) indicates little or no electrical coupling.

8. The system of claim 6, wherein increasingly negative phase angles indicate increasing electrical coupling condition between the electrode and the target tissue.

9. The system of claim 1, wherein the output device includes analog output corresponding to the electrical coupling condition.

10. The system of claim 1, wherein the measurement circuit includes an RCL meter.

11. The system of claim 1, wherein the measurement circuit includes a phase detection circuit.

12. The system of claim 1, wherein the electrode is adapted to apply electrical energy for both coupling assessment and tissue ablation.

13. The system of claim 1, further comprising a constant current source to apply electrical energy for coupling assessment.

14. The system of claim 1, further comprising a variable current source to apply electrical energy for coupling assessment.

15. The system of claim 1, further comprising a constant voltage source to apply electrical energy for coupling assessment.

16. The system of claim 1, further comprising a variable voltage source to apply electrical energy for coupling assessment.

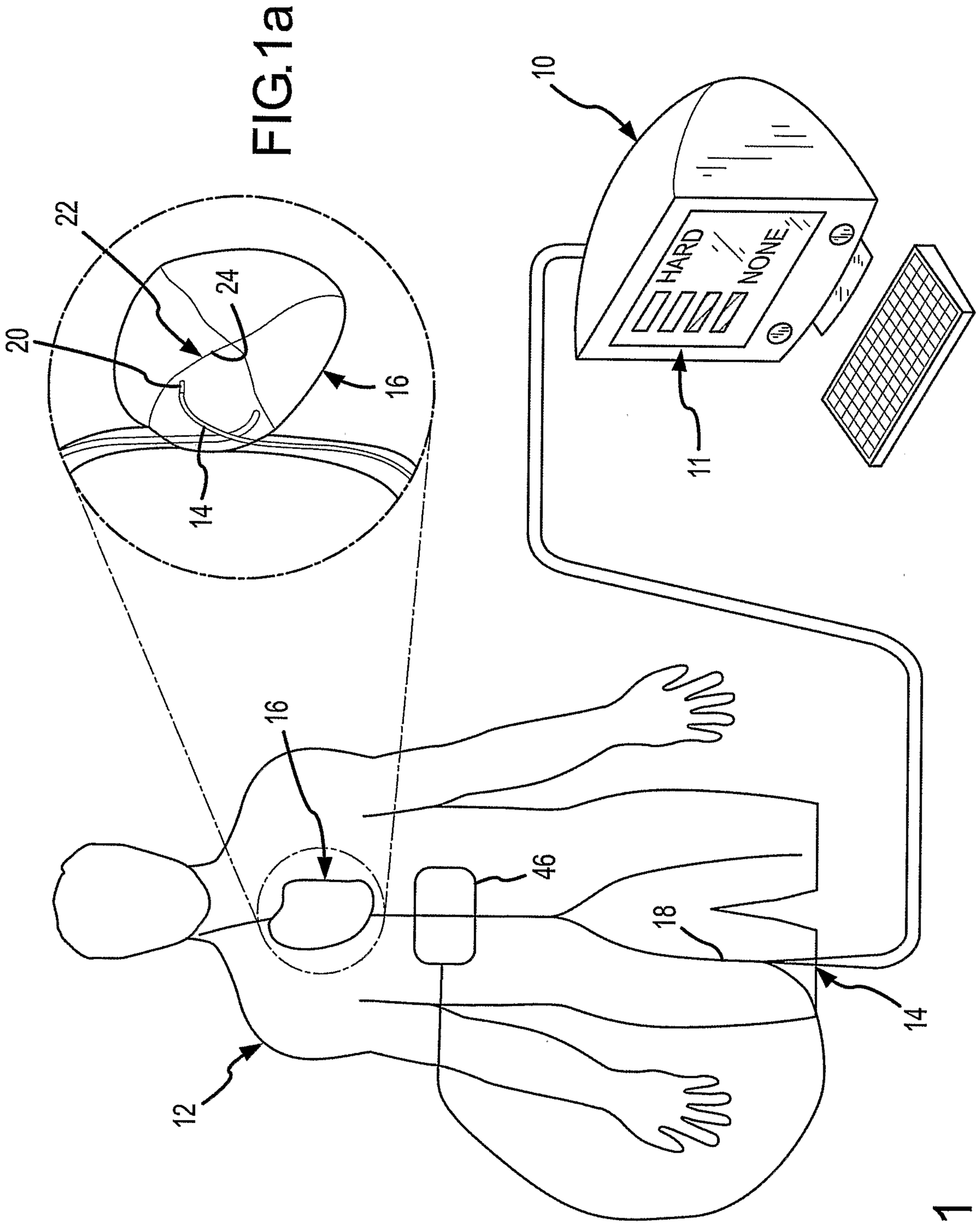
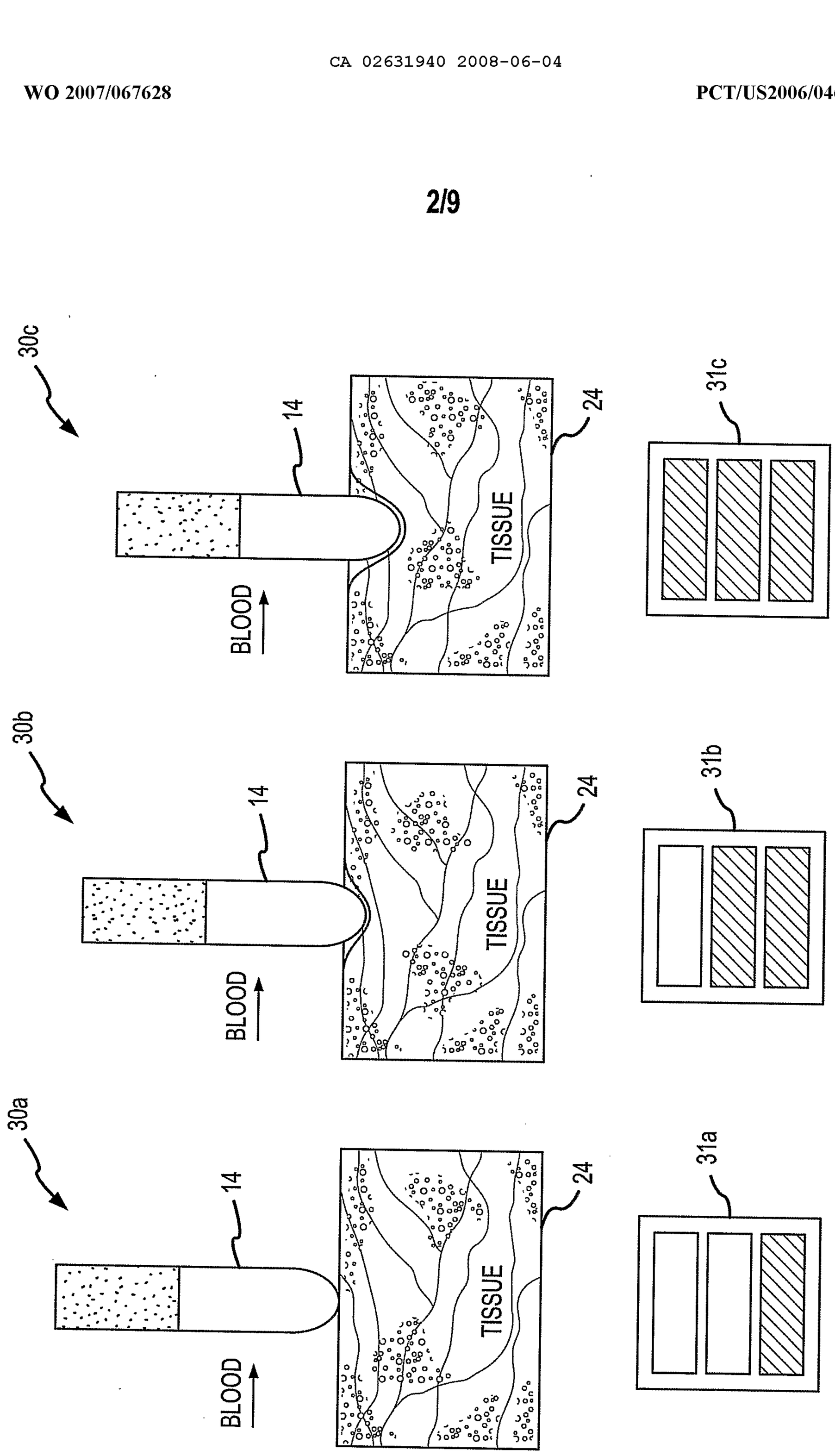


FIG.1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14
24
TISSUE
BLOOD
31c
30b
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24
TISSUE
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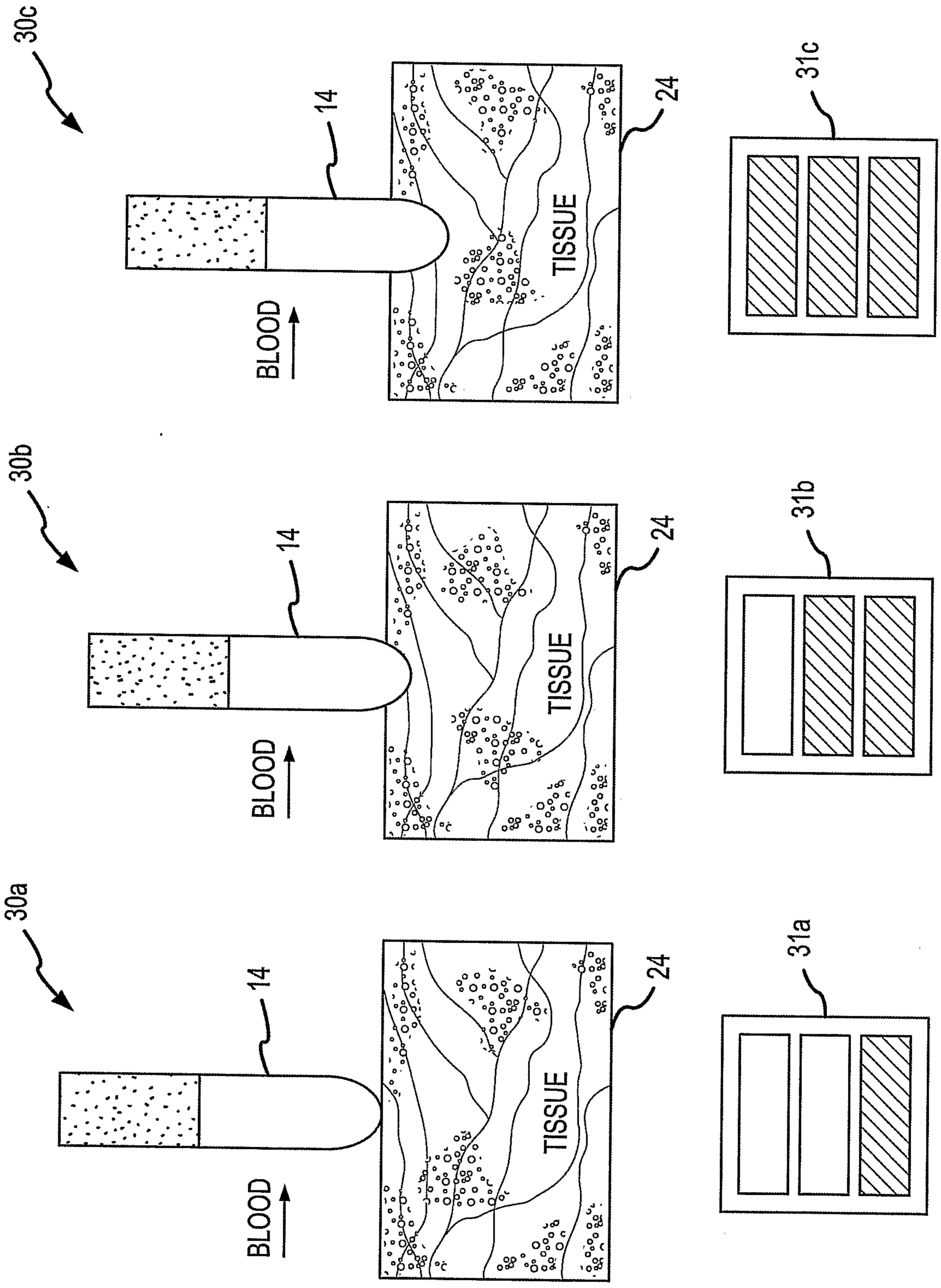
31b
30a
14
24
TISSUE
BLOOD
31a

FIG.2a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24
TISSUE
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31c
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24
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30a
14
24
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BLOOD
31a

FIG.2b

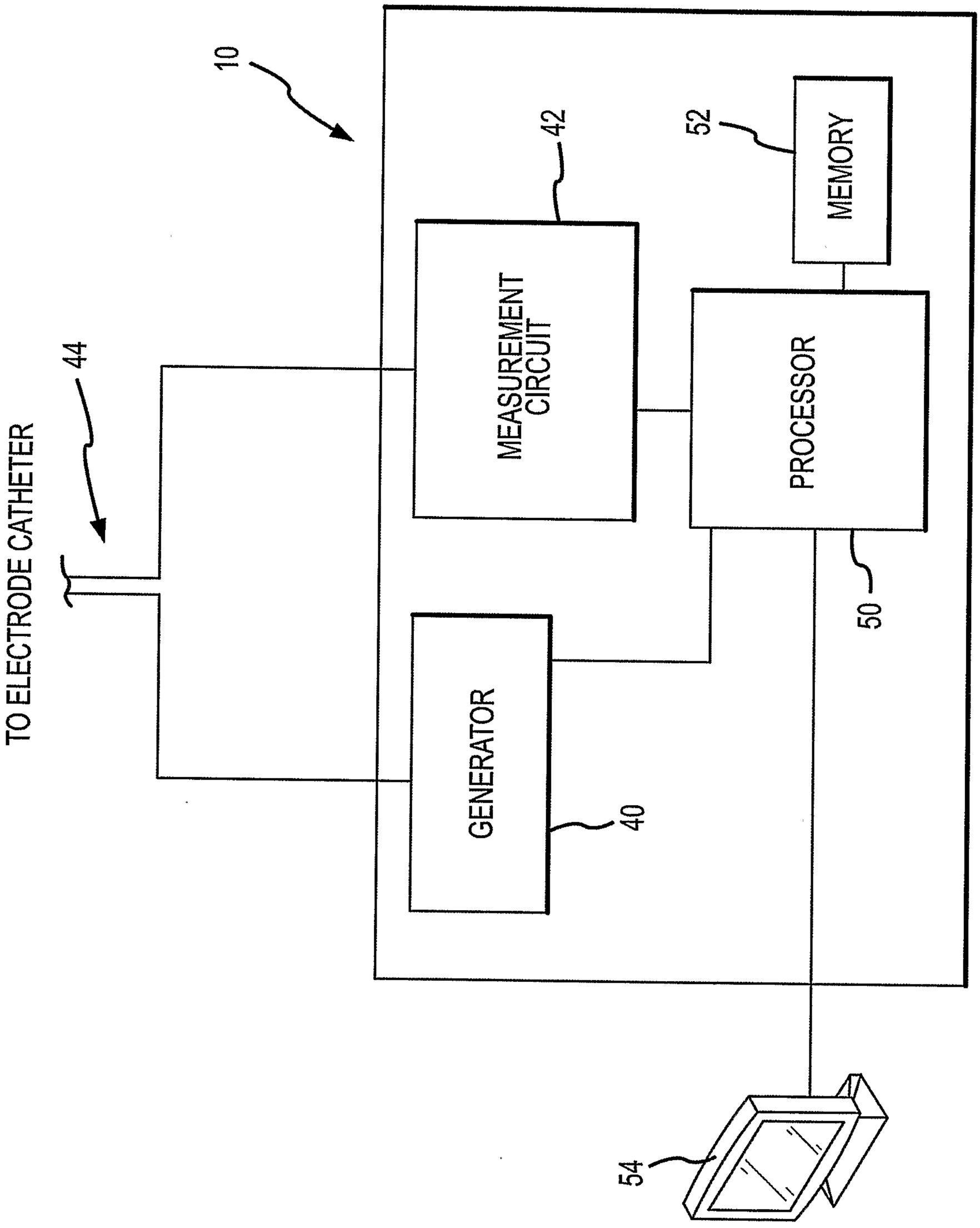
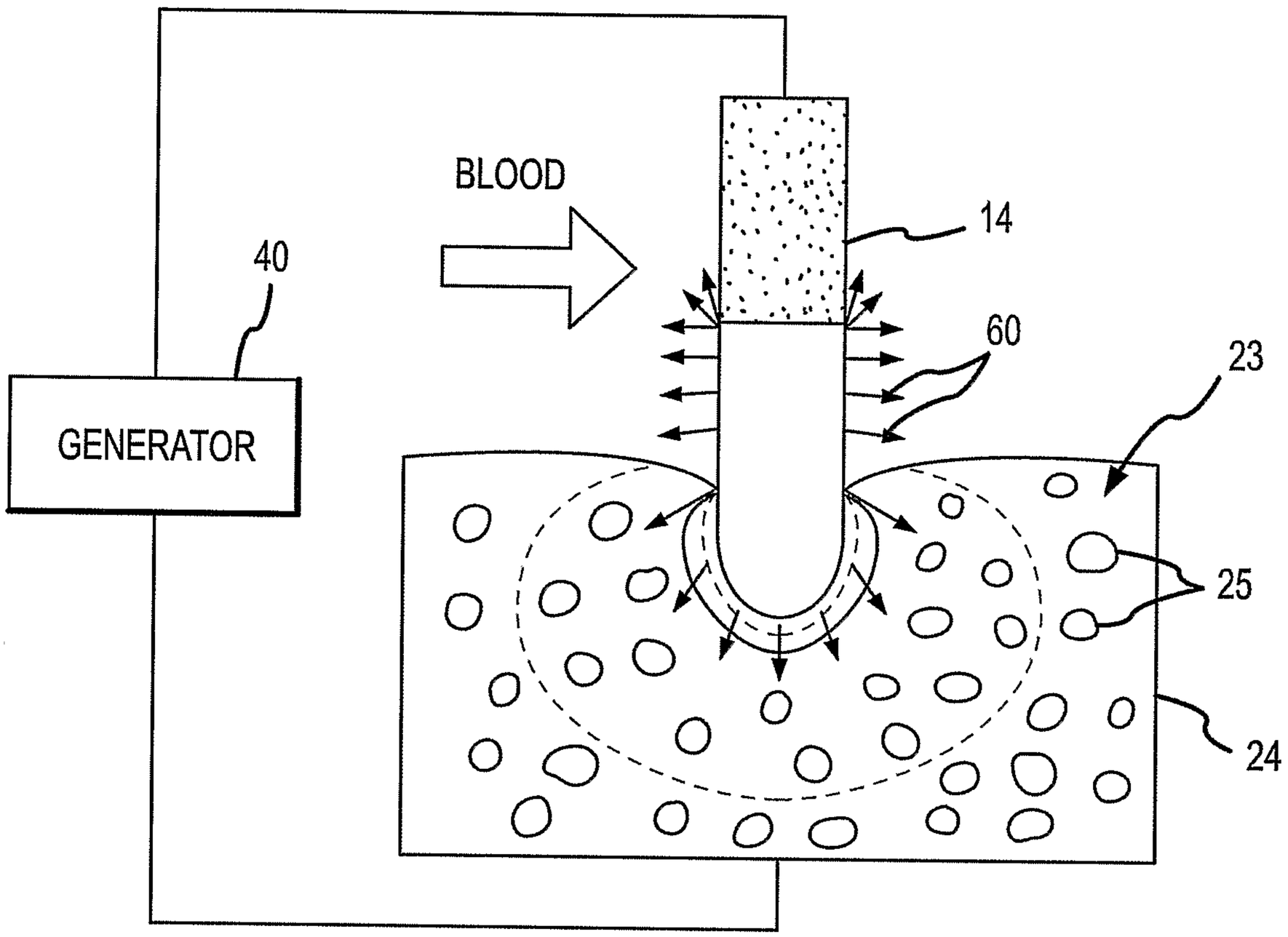

10
42
MEASUREMENT CIRCUIT
52
MEMORY
PROCESSOR
44
TO ELECTRODE CATHETER
GENERATOR
40
50
54

FIG.3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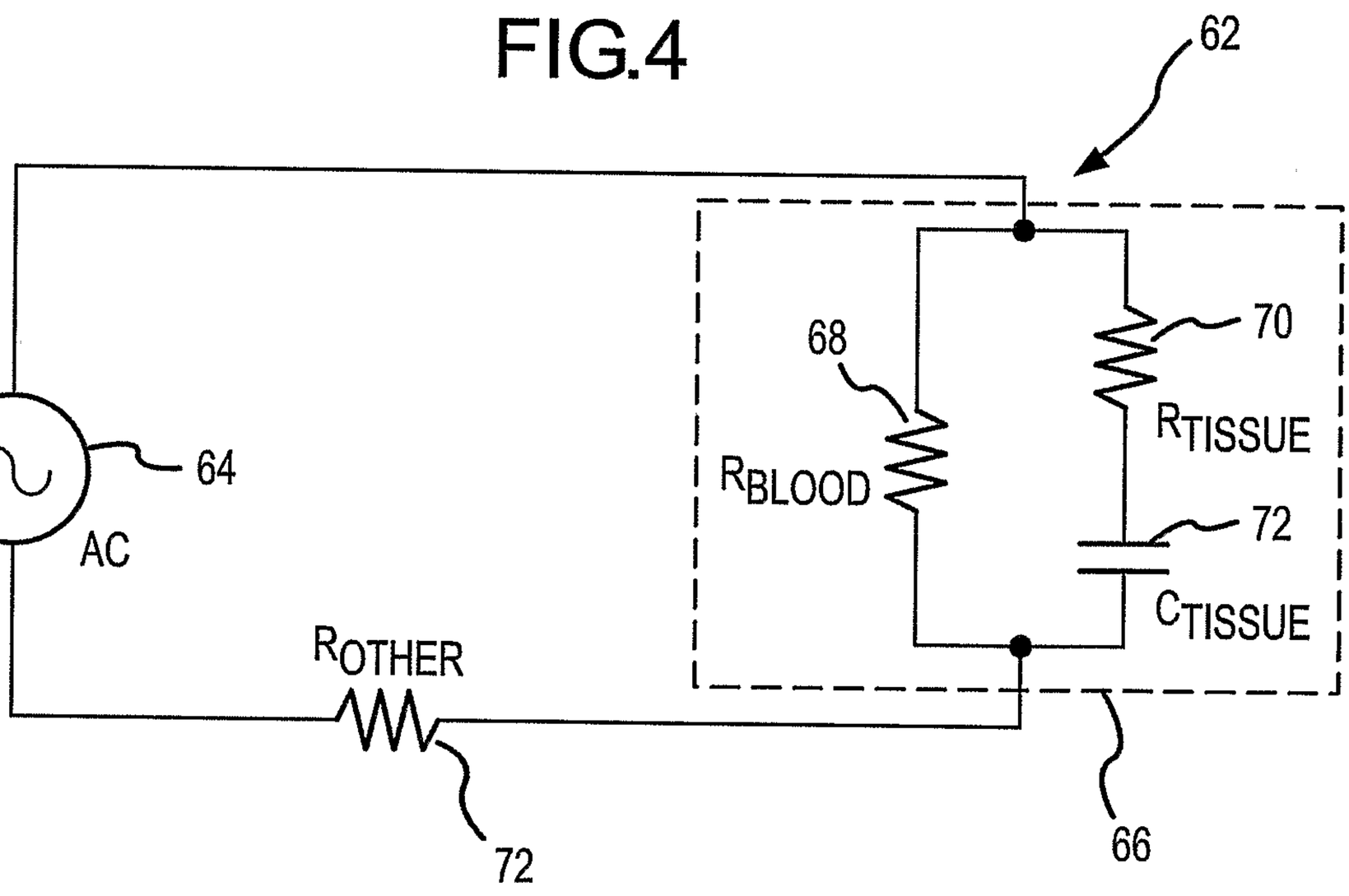
40
GENERATOR
60
23
25
24

FIG.4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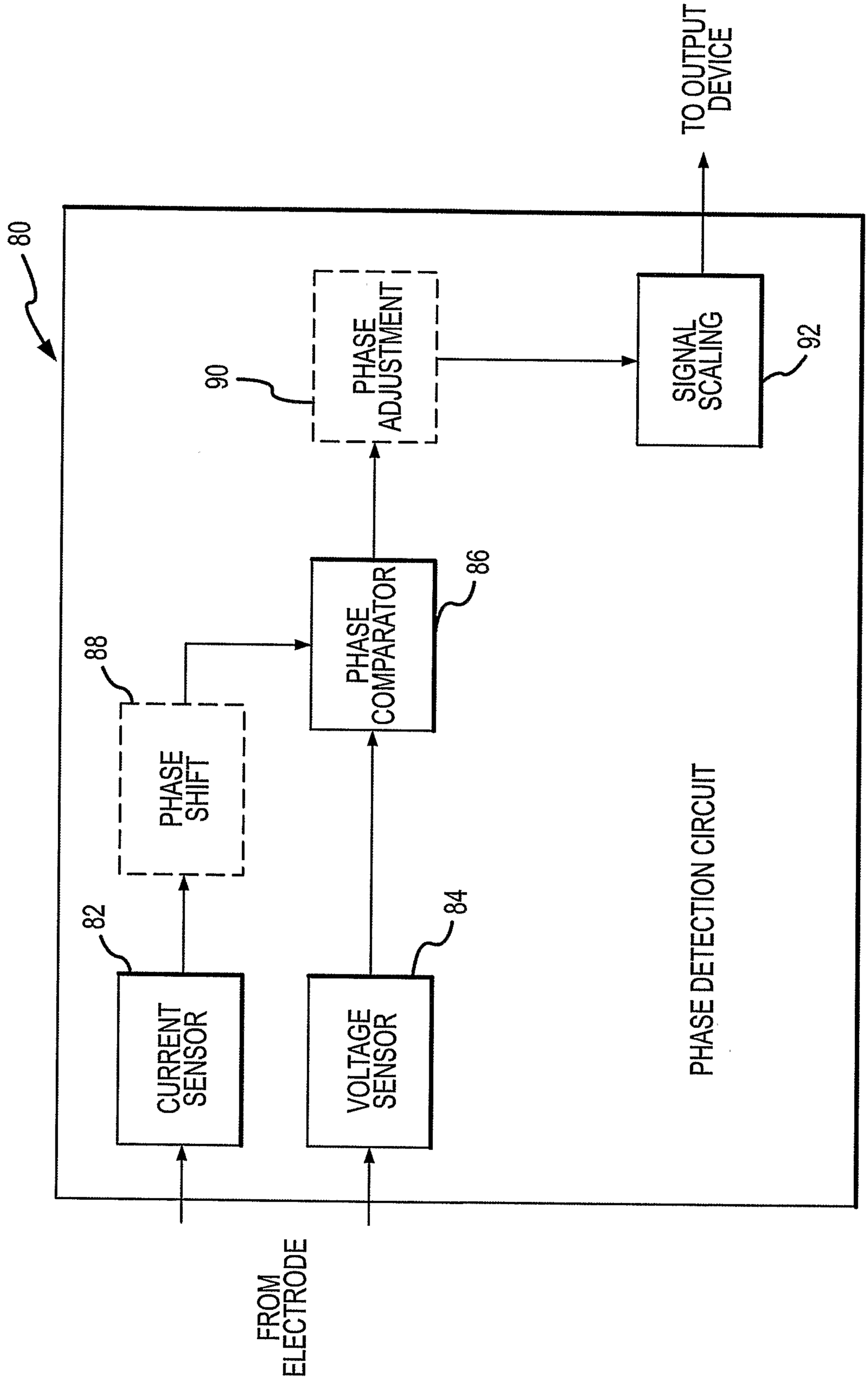
64
AC
68
R_{BLOOD}
70
R_{TISSUE}
72
C_{TISSUE}
R_{OTHER}
72
66

FIG.4a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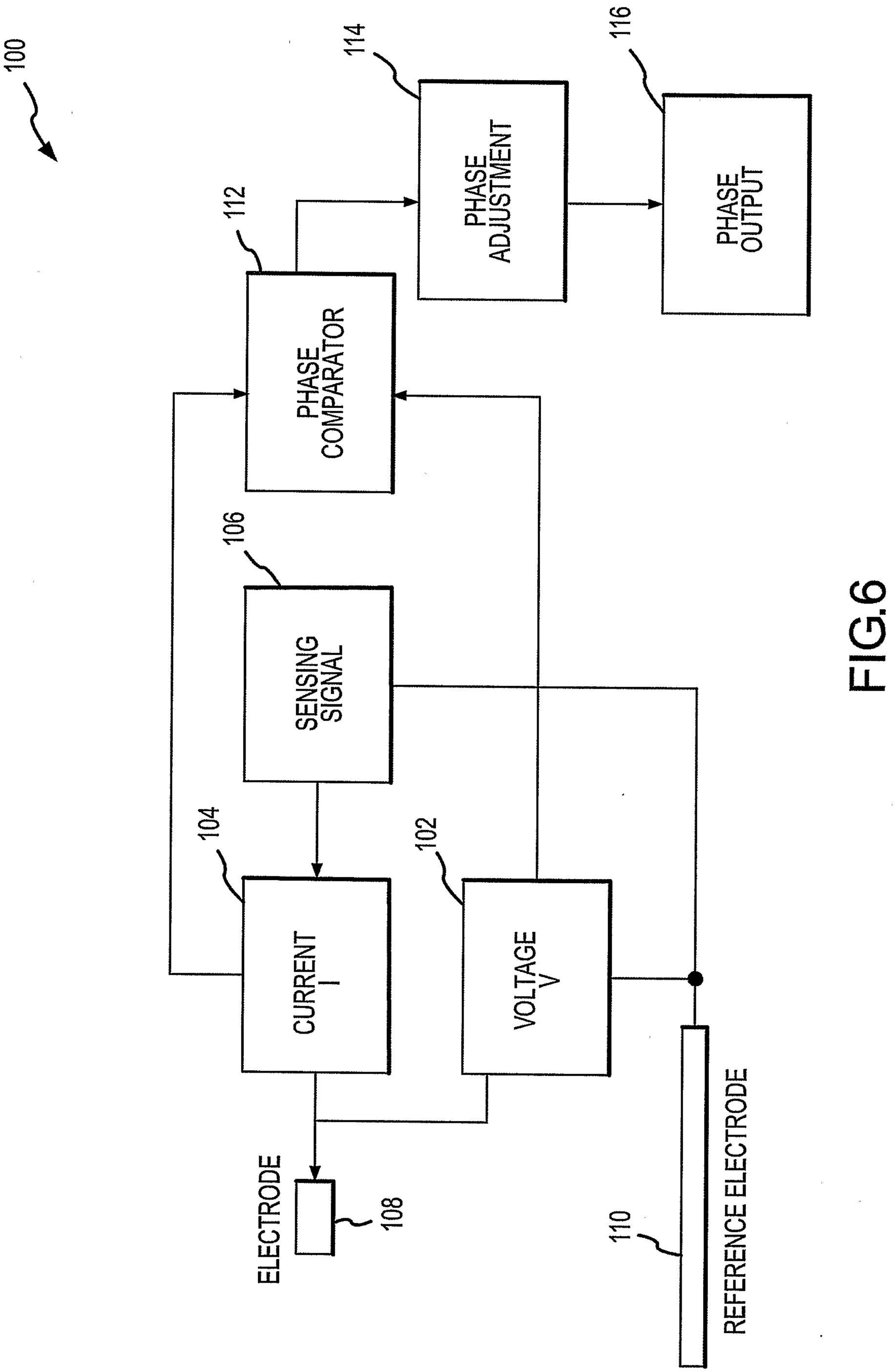
90
PHASE ADJUSTMENT
SIGNAL SCALING
92
TO OUTPUT DEVICE
88
PHASE SHIFT
PHASE COMPARATOR
86
82
CURRENT SENSOR
VOLTAGE SENSOR
84
PHASE DETECTION CIRCUIT
FROM ELECTRODE

FIG.5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PHASE OUTPUT
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PHASE COMPARATOR
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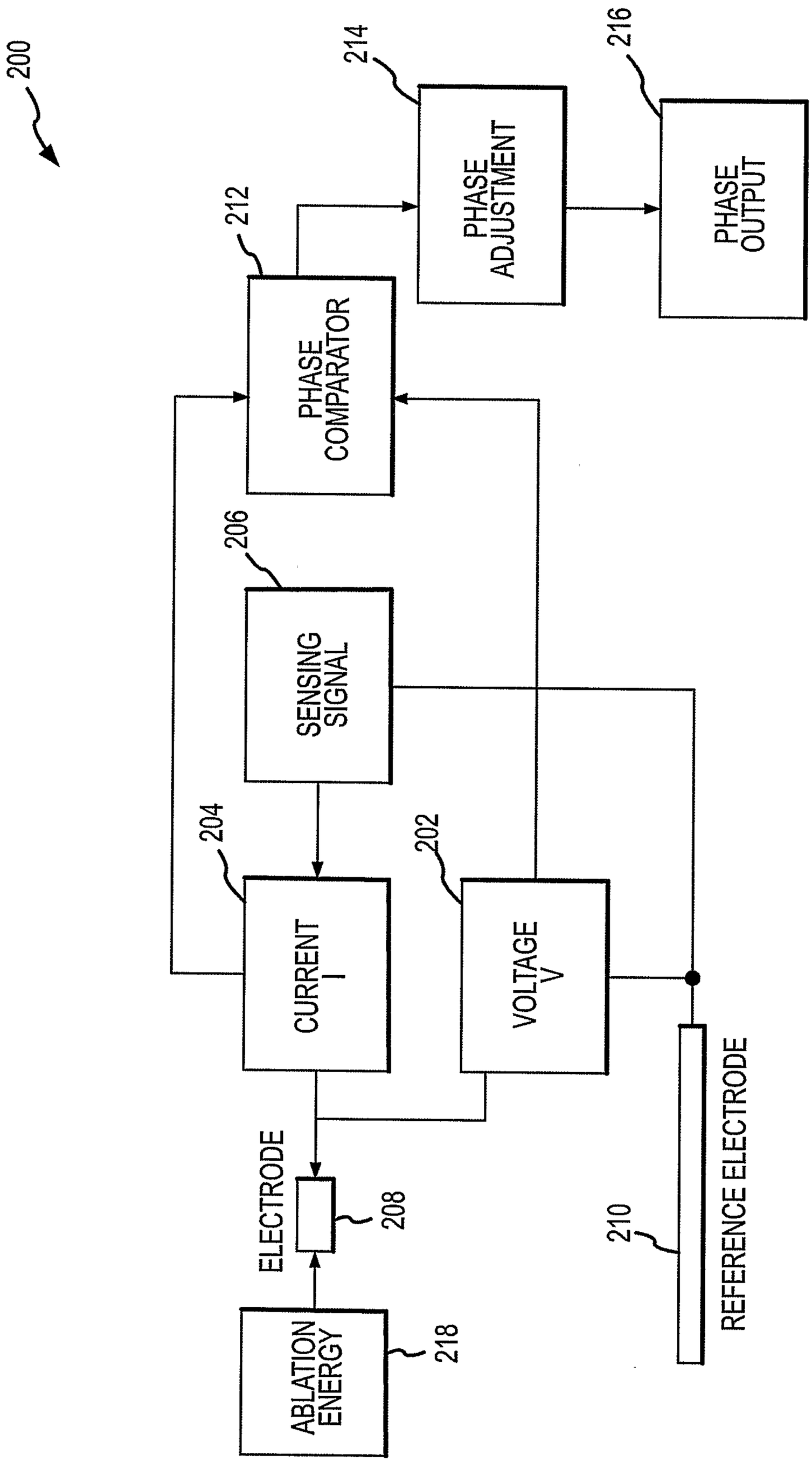
SENSING SIGNAL
104
CURRENT I
102
VOLTAGE V
ELECTRODE
108
110
REFERENCE ELECTRODE

FIG.6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PHASE OUTPUT
212
PHASE COMPARATOR
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SENSING SIGNAL
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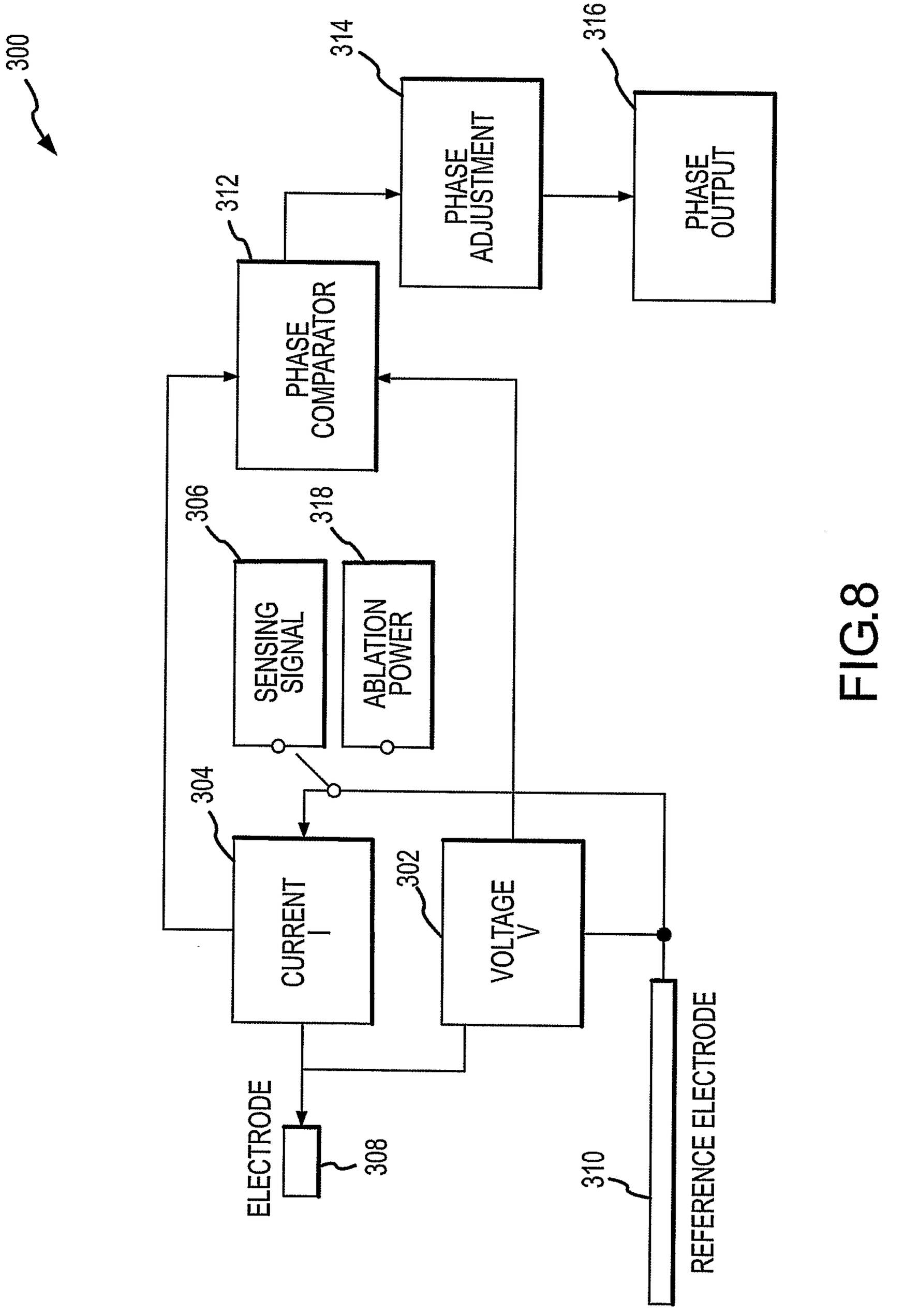
CURRENT I
202
VOLTAGE V
ELECTRODE
208
ABLATION ENERGY
218
210
REFERENCE ELECTRODE

FIG.7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PHASE ADJUSTMENT
312
PHASE COMPARATOR
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ABLATION POWER
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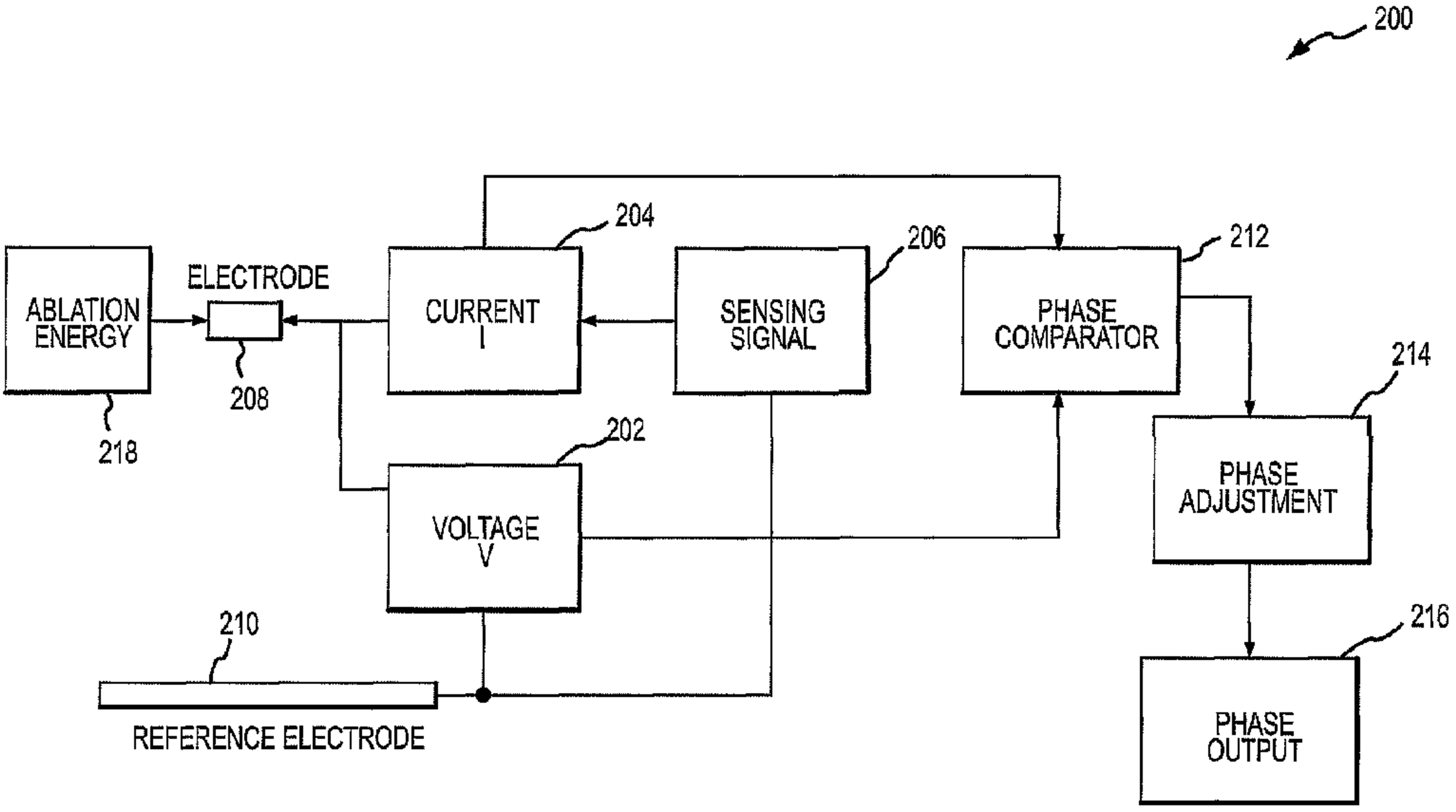
VOLTAGE V
ELECTRODE
308
310
REFERENCE ELECTRODE

FIG.8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ABLATION ENERGY
ELECTRODE
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CURRENT I
204
SENSING SIGNAL
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PHASE COMPARATOR
212
214
PHASE ADJUSTMENT
VOLTAGE V
202
210
REFERENCE ELECTRODE
216
PHASE OUTPUT