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Ko et al.

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(54) **RF TREATMENT APPARATUS, METHOD OF CONTROLLING RF TREATMENT APPARATUS AND SKIN TREATMENT METHOD USING RF ENERGY**

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CPC ***A61B 18/1206*** (2013.01); ***A61B 18/14*** (2013.01); *A61B 2018/00452* (2013.01);
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CPC A61B 18/14; A61B 18/1206; A61B 2018/00702; A61B 2018/00779;
(Continued)

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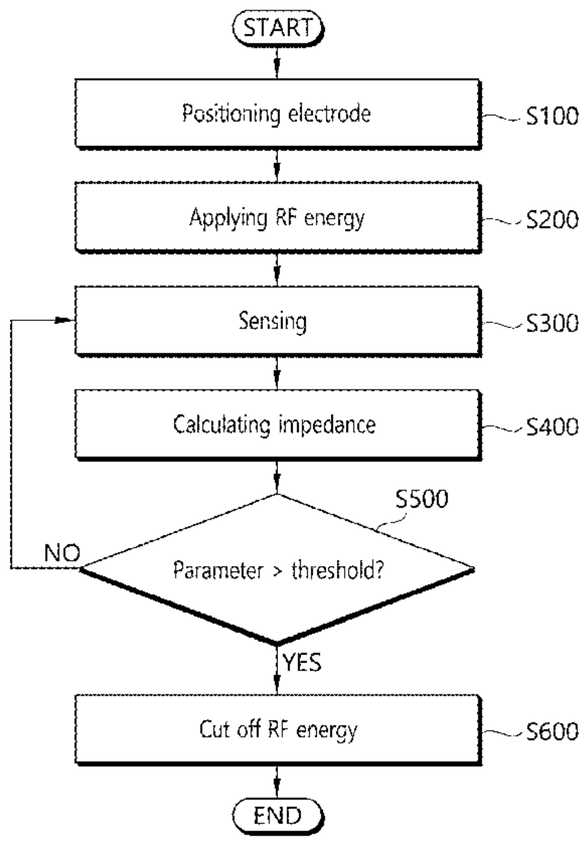
Primary Examiner — Michael F Peffley

(57) **ABSTRACT**

The present invention relates to an RF treatment apparatus, the method of controlling the RF treatment apparatus and the skin treatment method using RF energy according to the present invention have an effect in that they can improve the accuracy and efficiency of treatment because whether a target tissue corresponds to a treatment temperature is determined based on impedance of the tissue and the volume of the target tissue corresponding to the treatment temperature can be maximized while maintaining the target tissue to the treatment temperature for a predetermined time.

14 Claims, 21 Drawing Sheets



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CPC *A61B 2018/00678* (2013.01); *A61B 2018/00714* (2013.01); *A61B 2018/00767* (2013.01); *A61B 2018/00779* (2013.01); *A61B 2018/00827* (2013.01); *A61B 2018/00875* (2013.01); *A61B 2018/00892* (2013.01)

(58) **Field of Classification Search**
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See application file for complete search history.

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FIG. 1

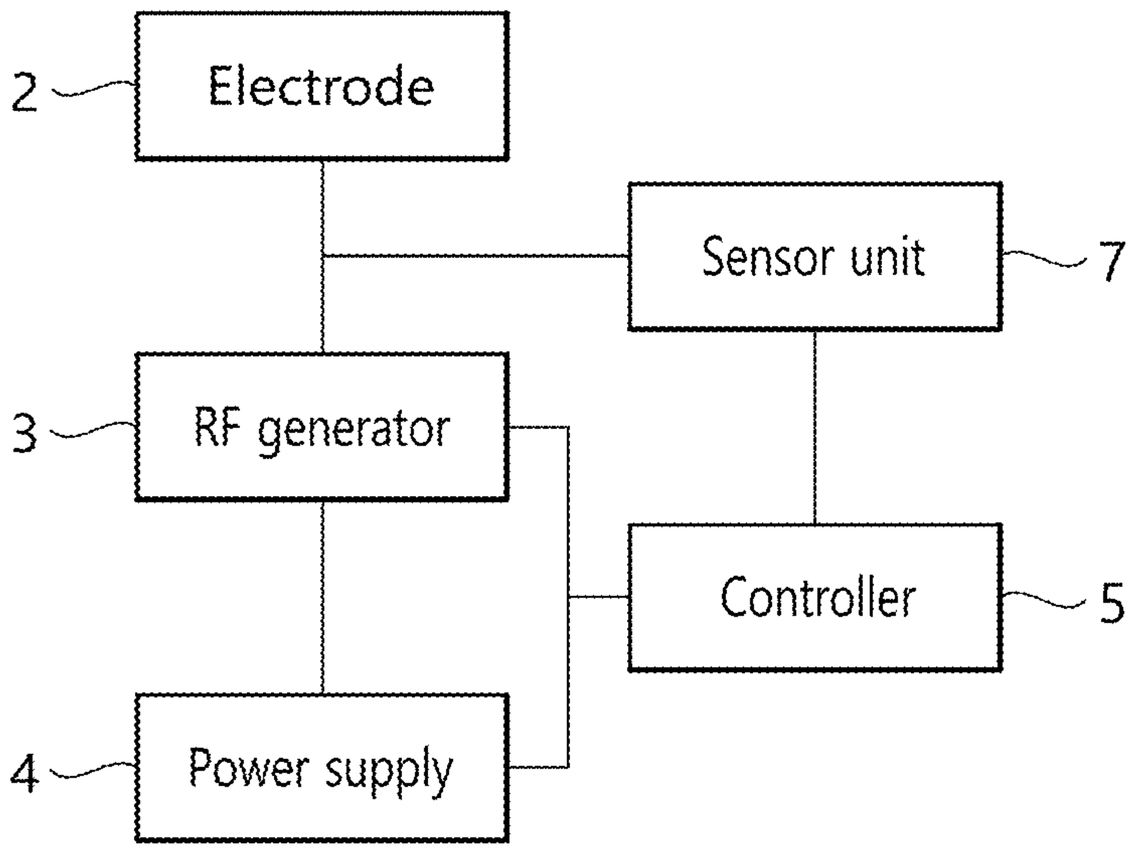

2
Electrode
Sensor unit
7
3
RF generator
Controller
5
4
Power supply

FIG. 2

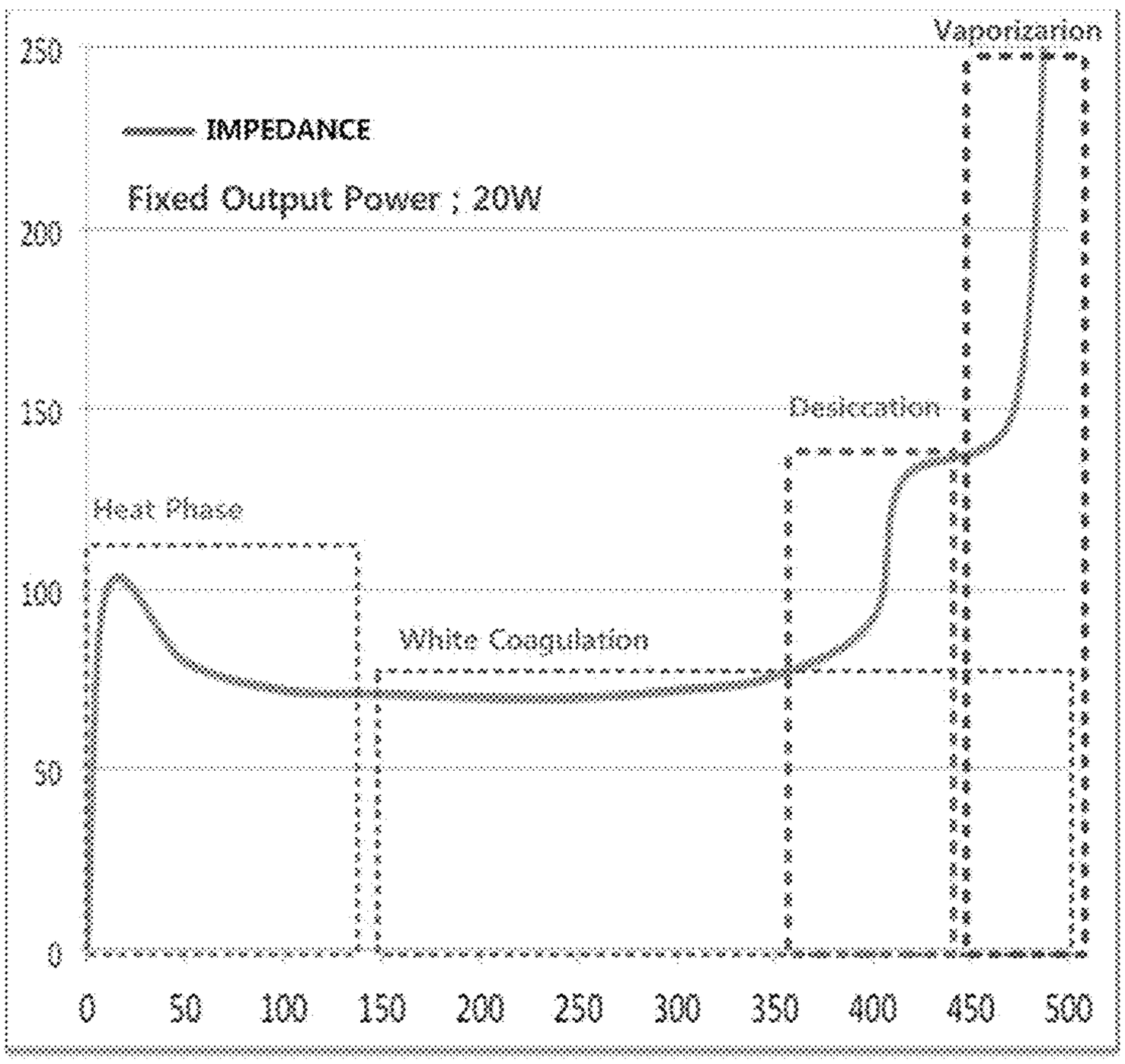

250
200
150
100
50
0
IMPEDANCE
Fixed Output Power ; 20W
Heat Phase
White Coagulation
Desiccation
Vaporizarion
0
50
100
150
200
250
300
350
400
450
500

FIG. 3a

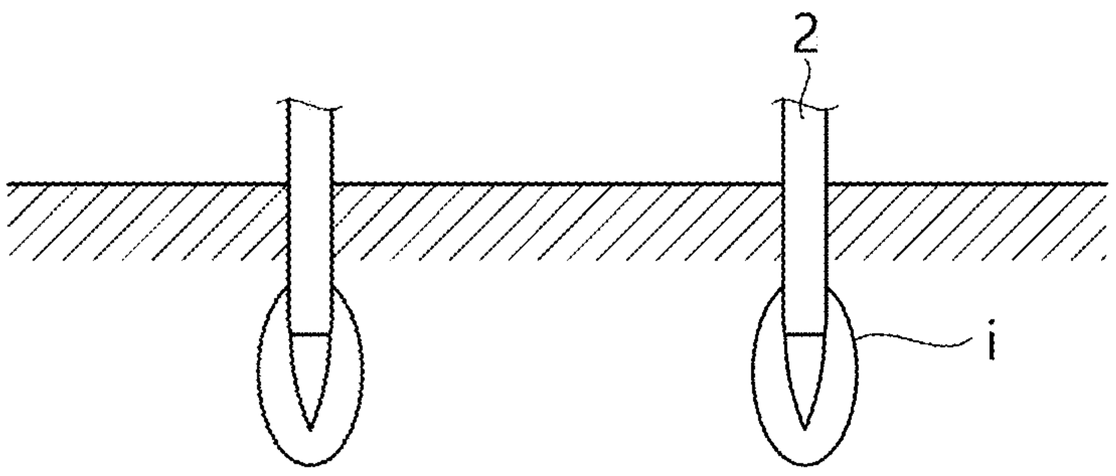


FIG. 3b

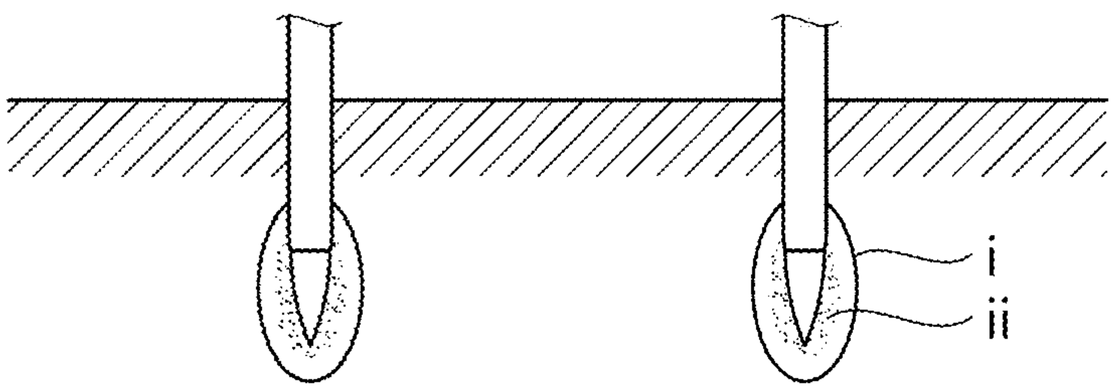


FIG. 4a

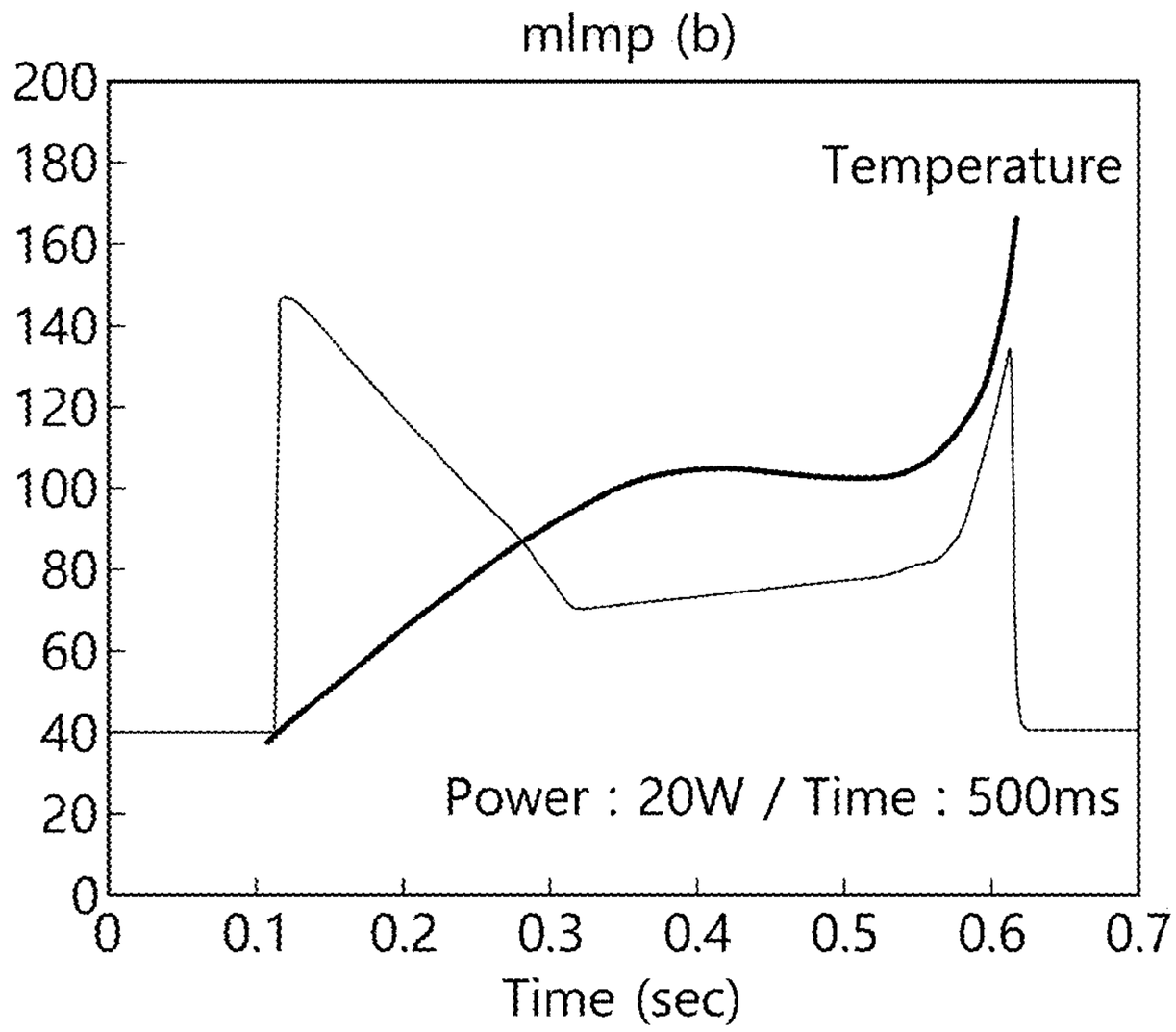

mlmp (b)
200
180
160
140
120
100
80
60
40
20
0
Temperature
Power : 20W / Time : 500ms
0
0.1
0.2
0.3
0.4
0.5
0.6
0.7
Time (sec)

FIG. 4b

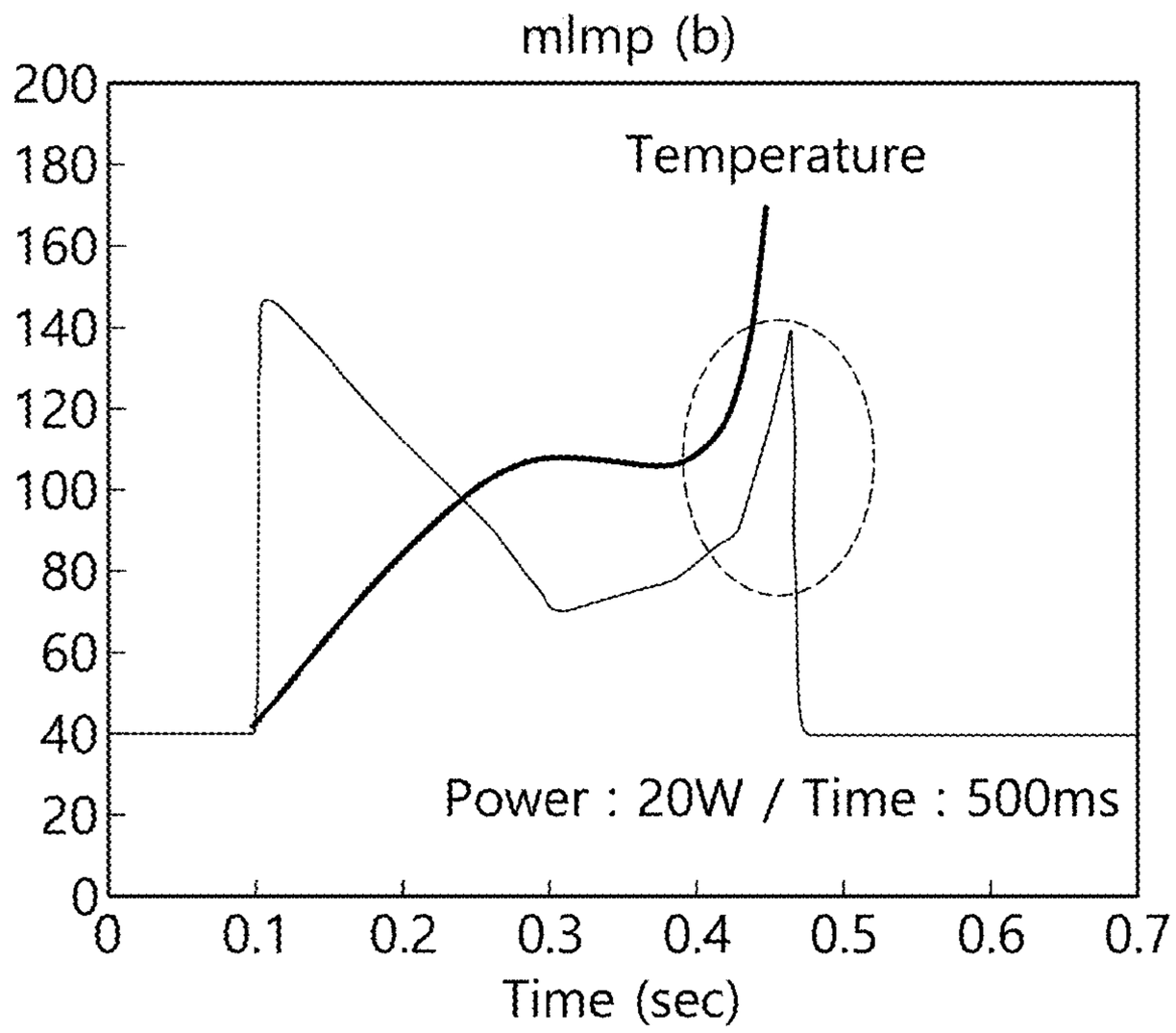

mImp (b)
Temperature
Power : 20W / Time : 500ms
200
180
160
140
120
100
80
60
40
20
0
0
0.1
0.2
0.3
0.4
0.5
0.6
0.7
Time (sec)

FIG. 5a

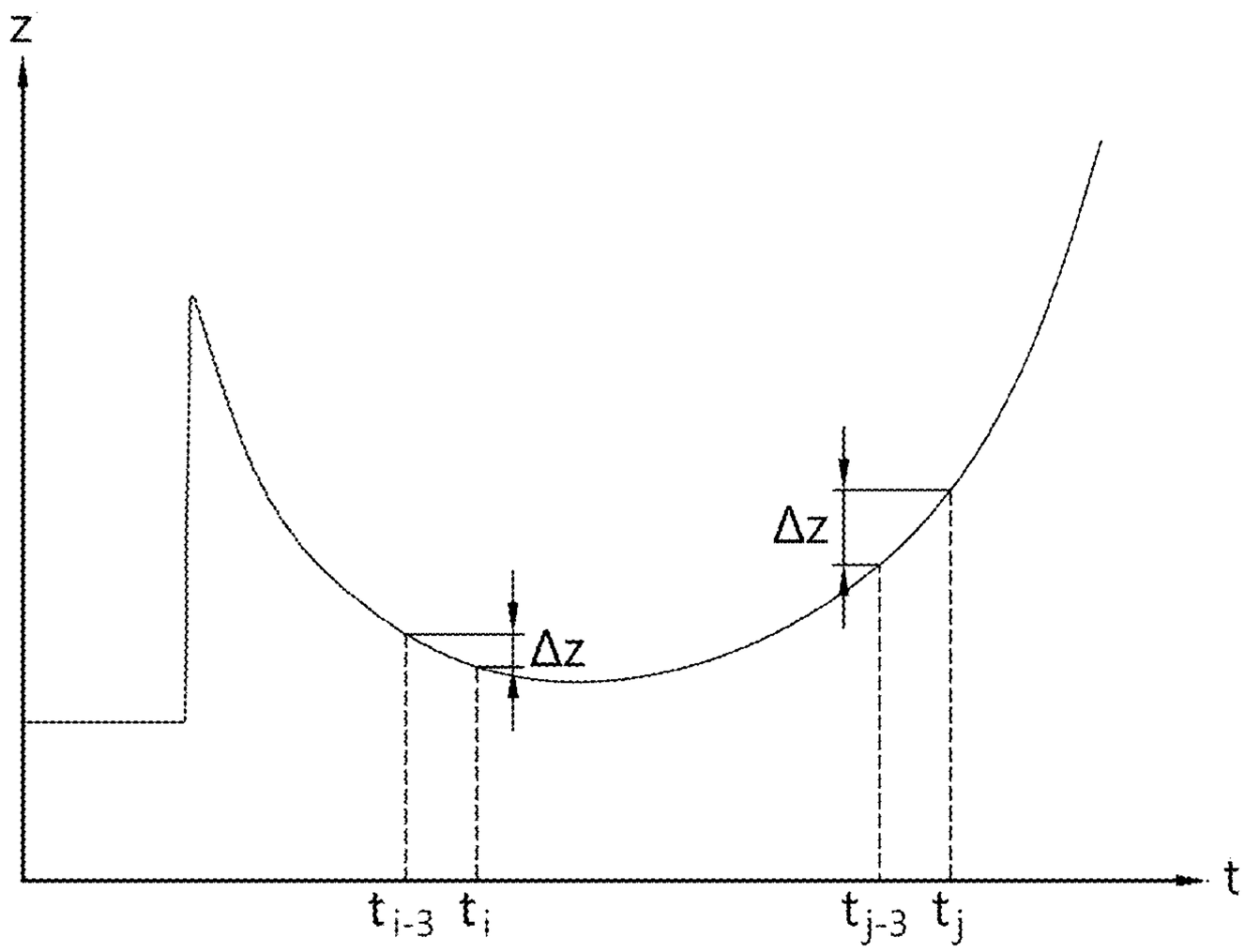


FIG. 5b

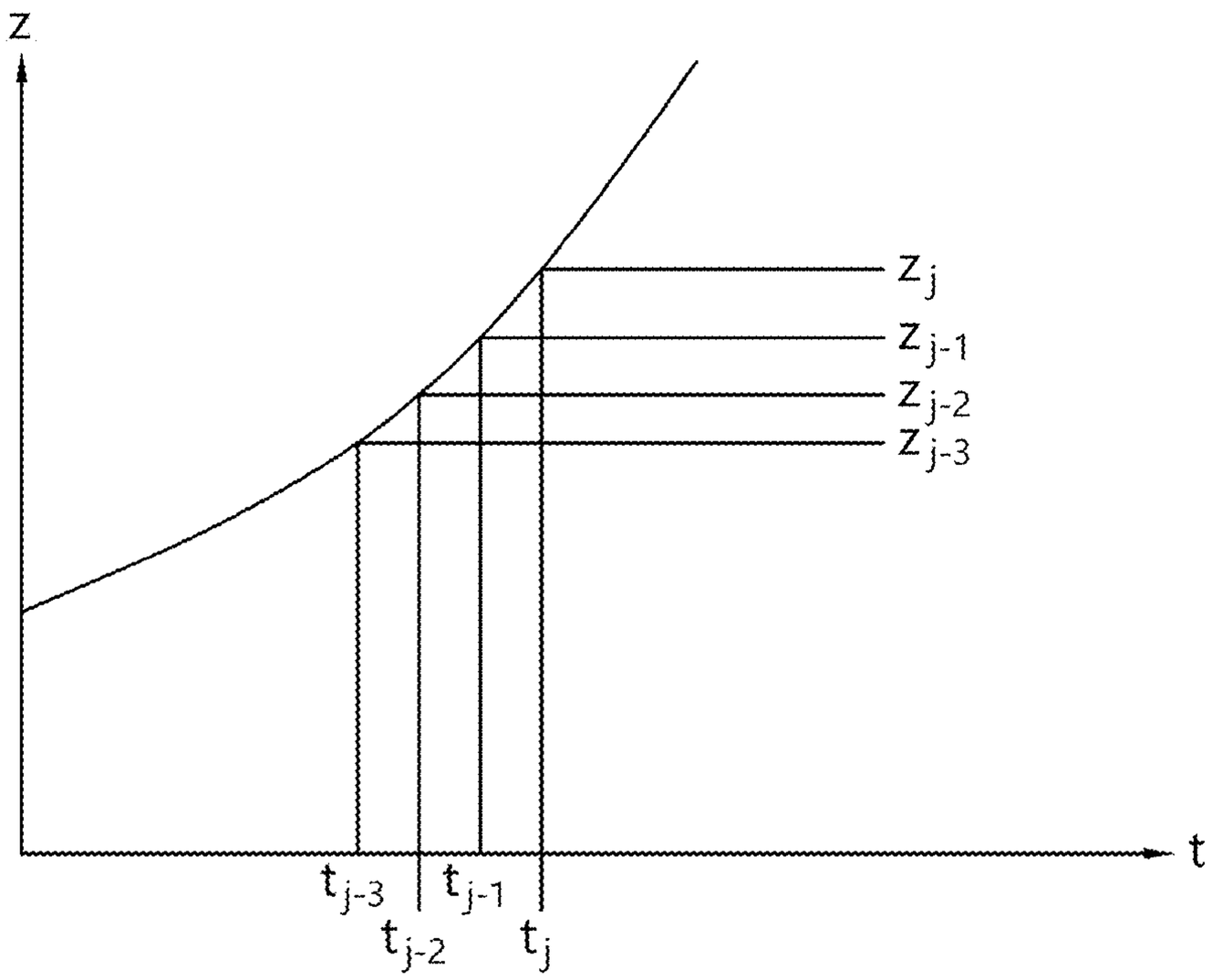


FIG. 6

START
Positioning electrode
S100
Applying RF energy
S200
Sensing
S300
Calculating impedance
S400
S500
Parameter > threshold?
NO
YES
Cut off RF energy
S600
END

FIG. 7a

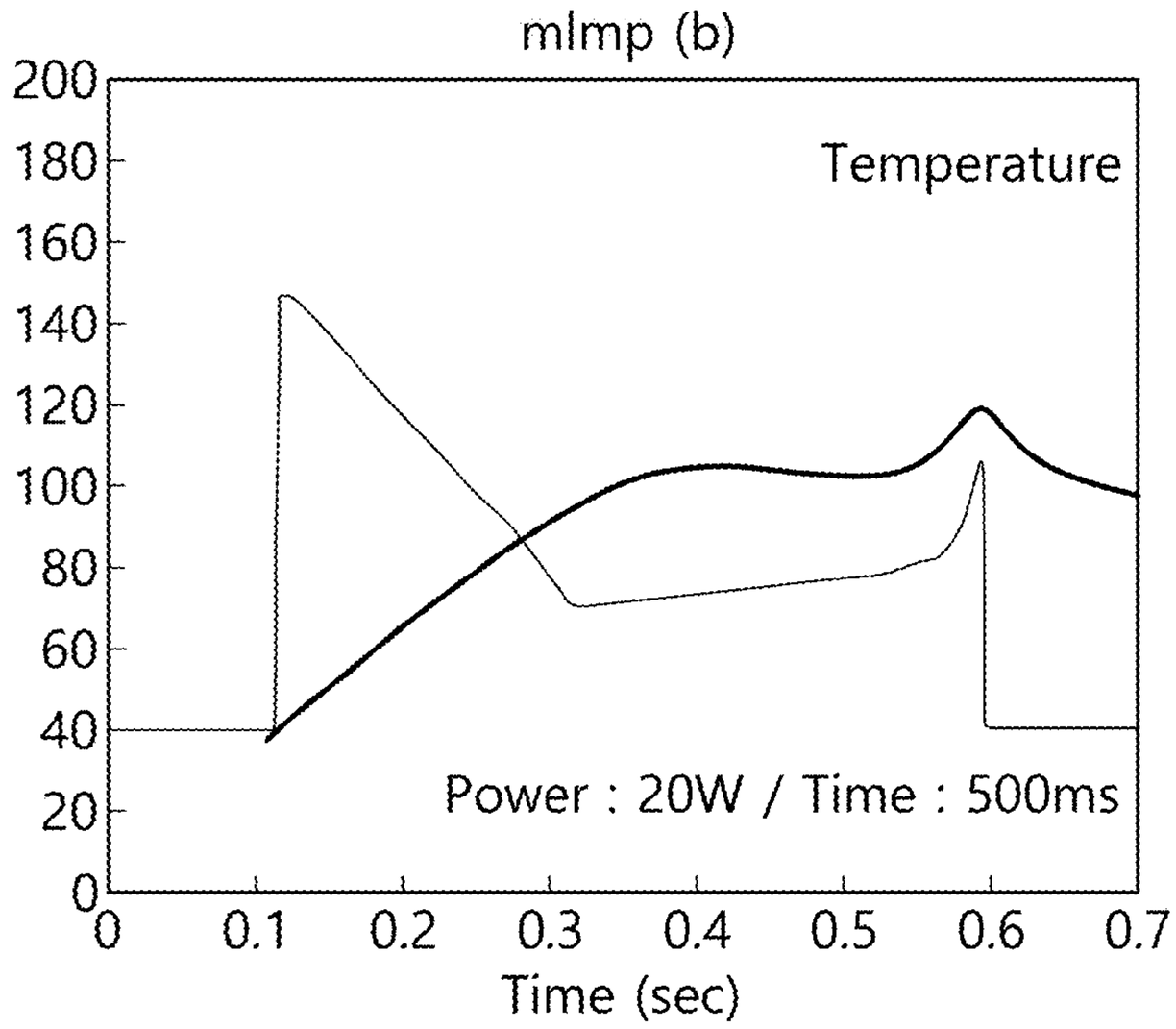

mlmp (b)
Temperature
Power : 20W / Time : 500ms
200
180
160
140
120
100
80
60
40
20
0
0
0.1
0.2
0.3
0.4
0.5
0.6
0.7
Time (sec)

FIG. 7b

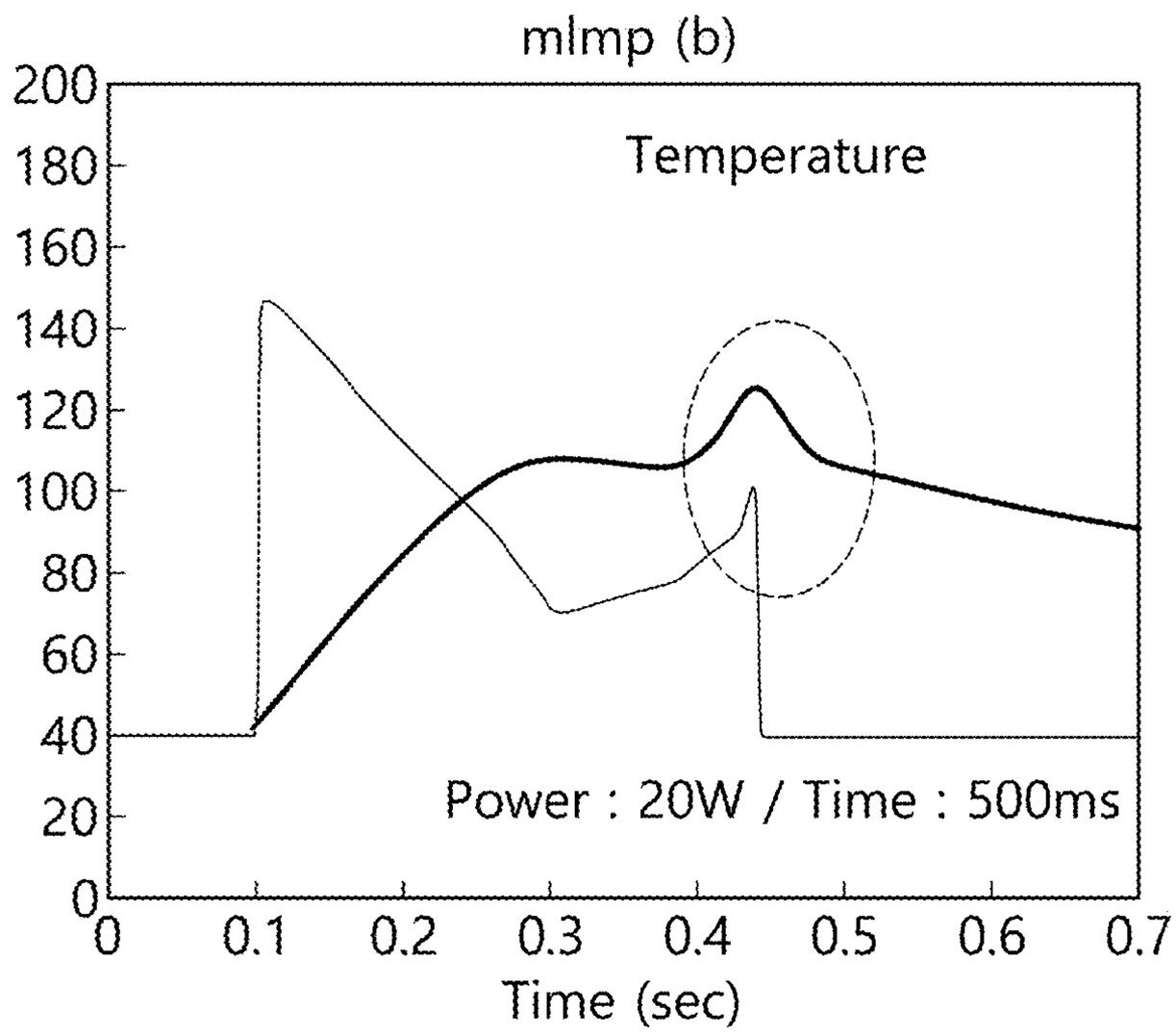

mImp (b)
Temperature
Power : 20W / Time : 500ms
200
180
160
140
120
100
80
60
40
20
0
0
0.1
0.2
0.3
0.4
0.5
0.6
0.7
Time (sec)

FIG.8a

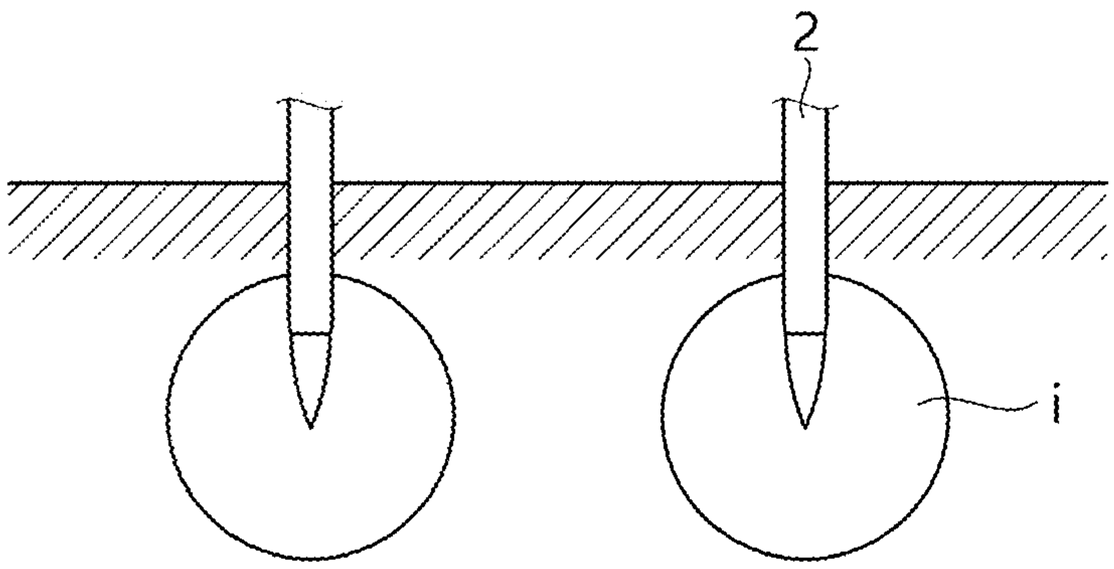


FIG.8b

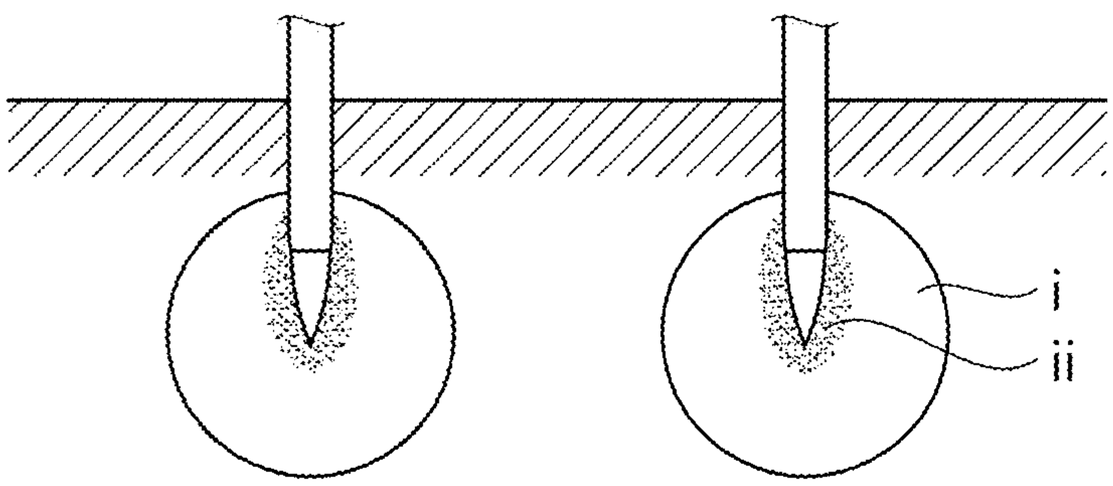


FIG. 8c

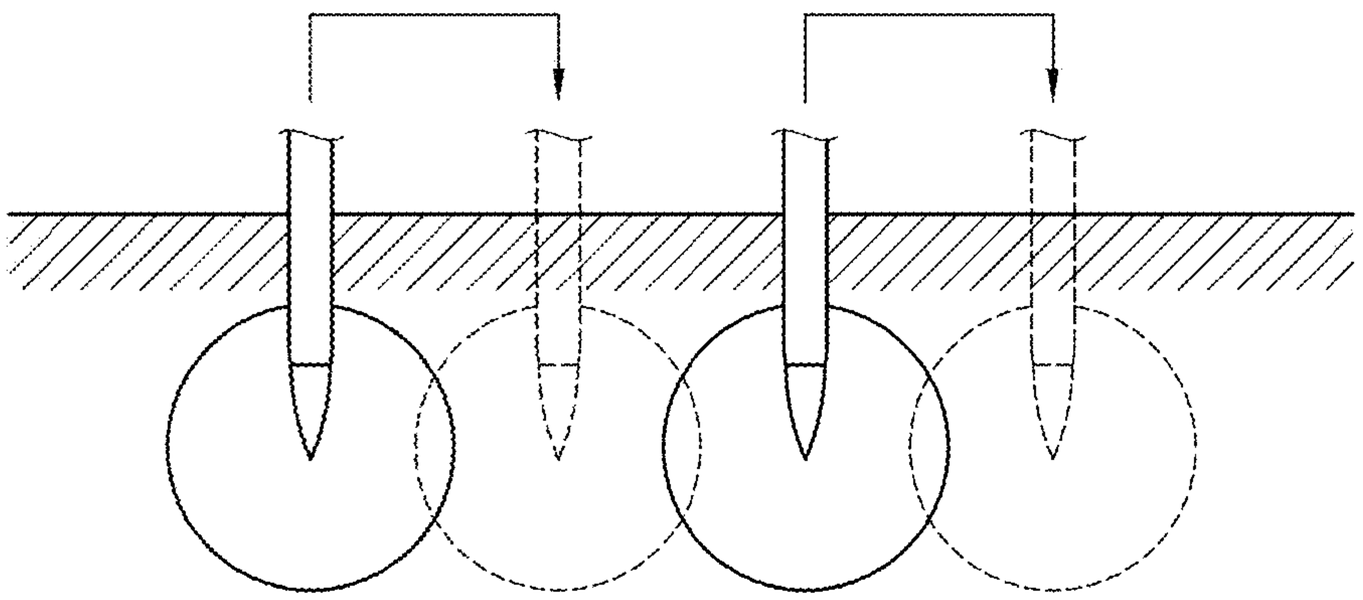


FIG. 9

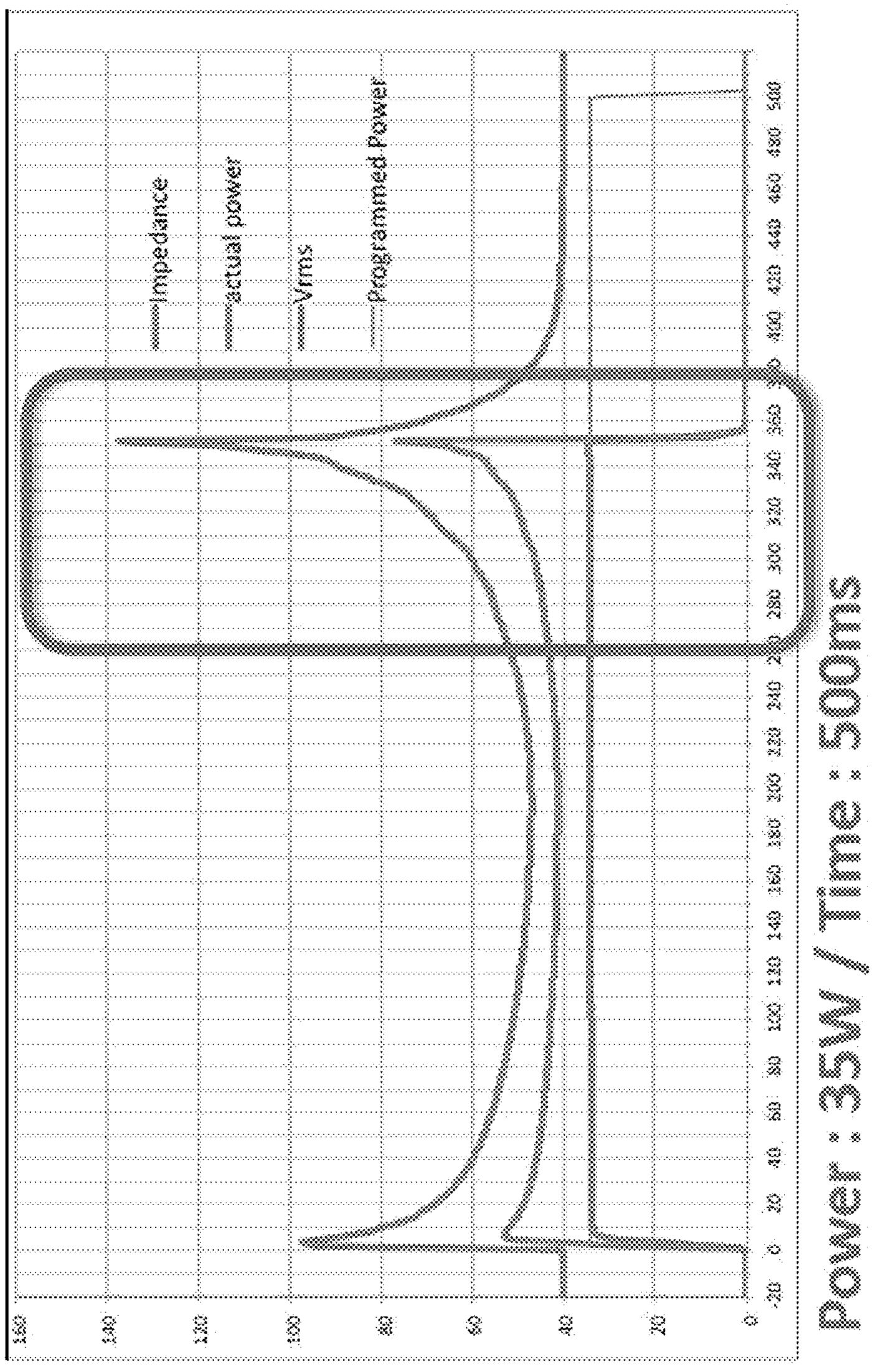

Impedance
actual power
Vrms
Programmed Power
Power : 35W / Time : 50ms

FIG. 10

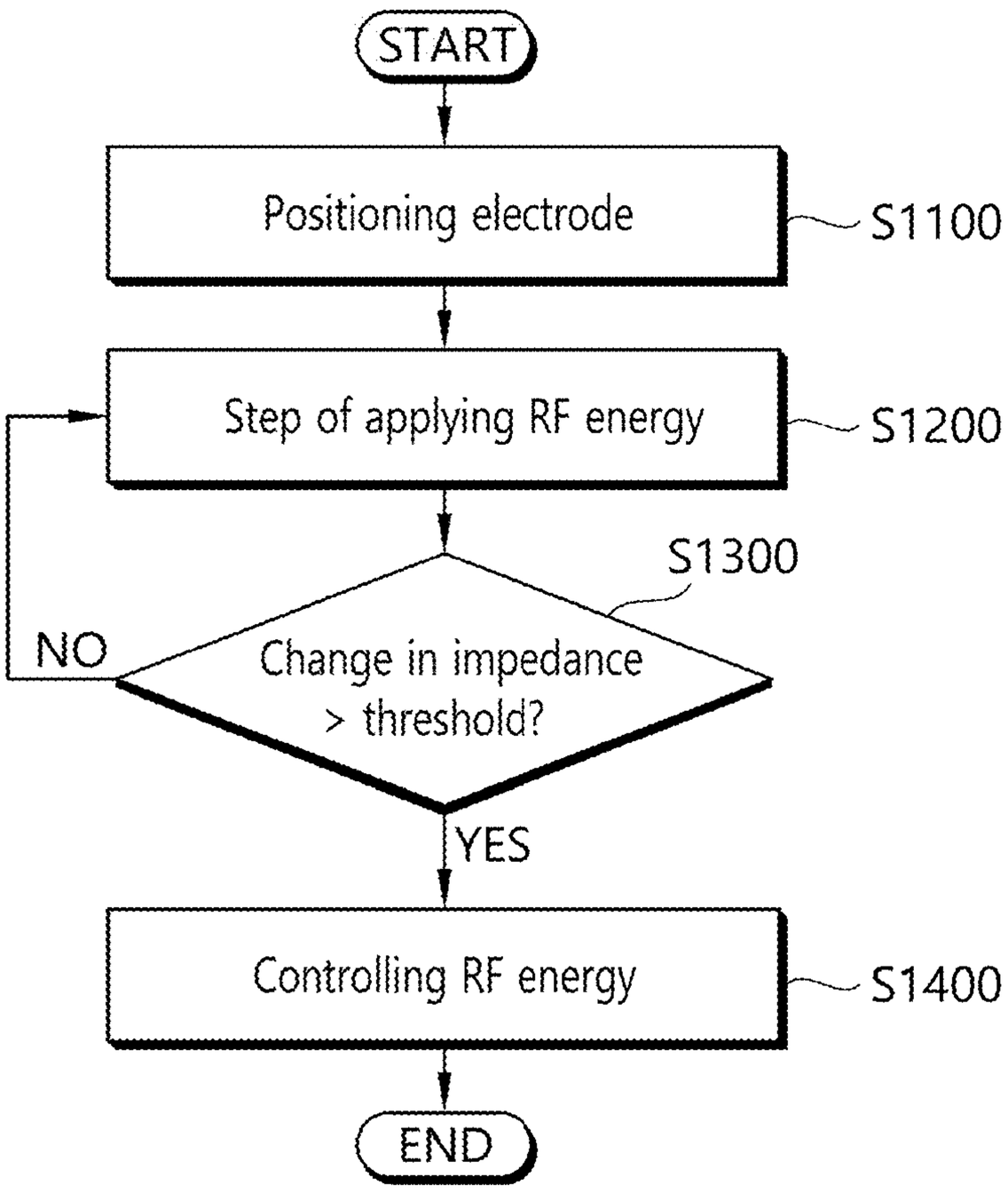

START
Positioning electrode
S1100
Step of applying RF energy
S1200
S1300
Change in impedance > threshold?
NO
YES
Controlling RF energy
S1400
END

FIG. 11

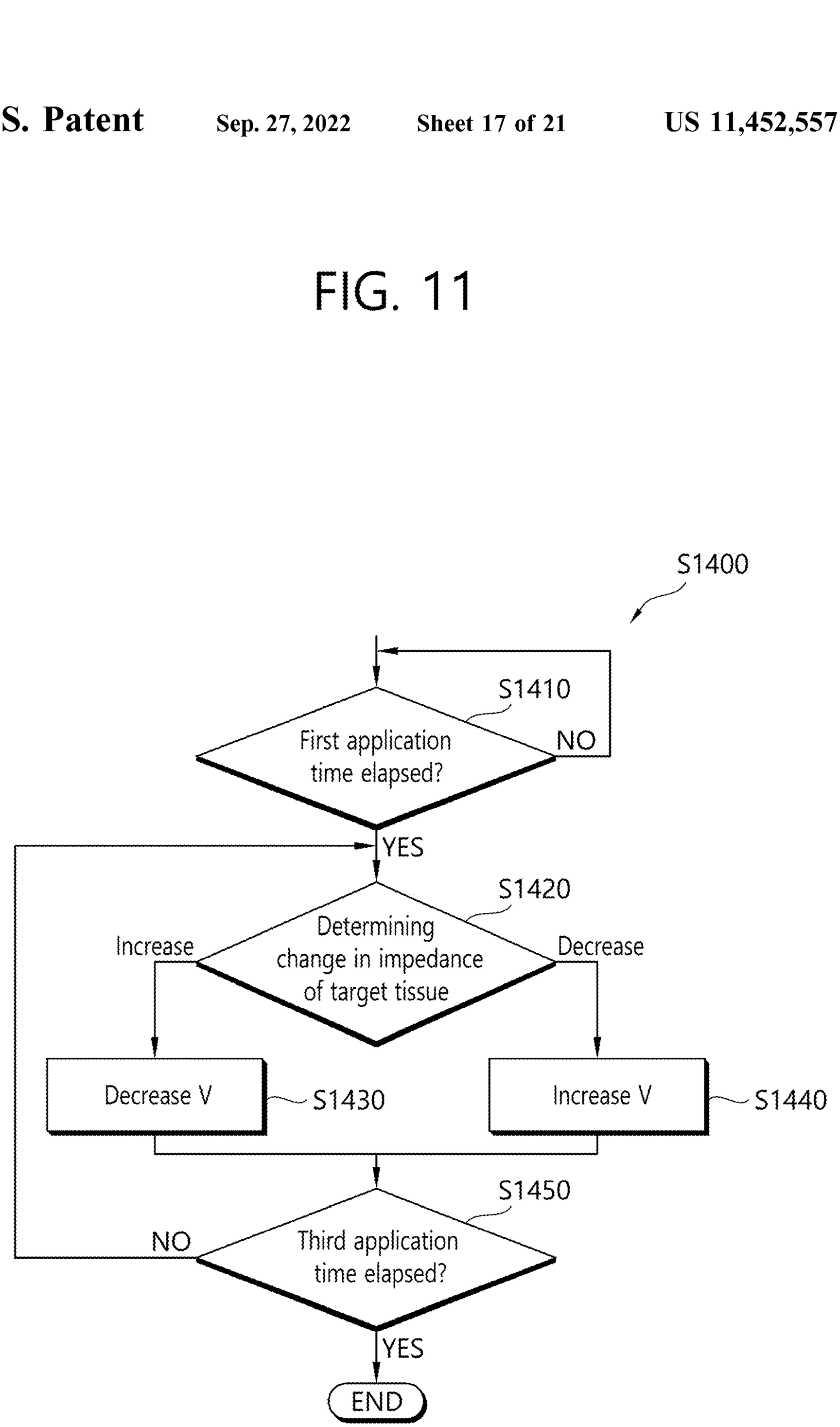

S1400
S1410
First application time elapsed?
NO
YES
S1420
Determining change in impedance of target tissue
Increase
Decrease
Decrease V
S1430
Increase V
S1440
S1450
Third application time elapsed?
NO
YES
END

FIG. 12a

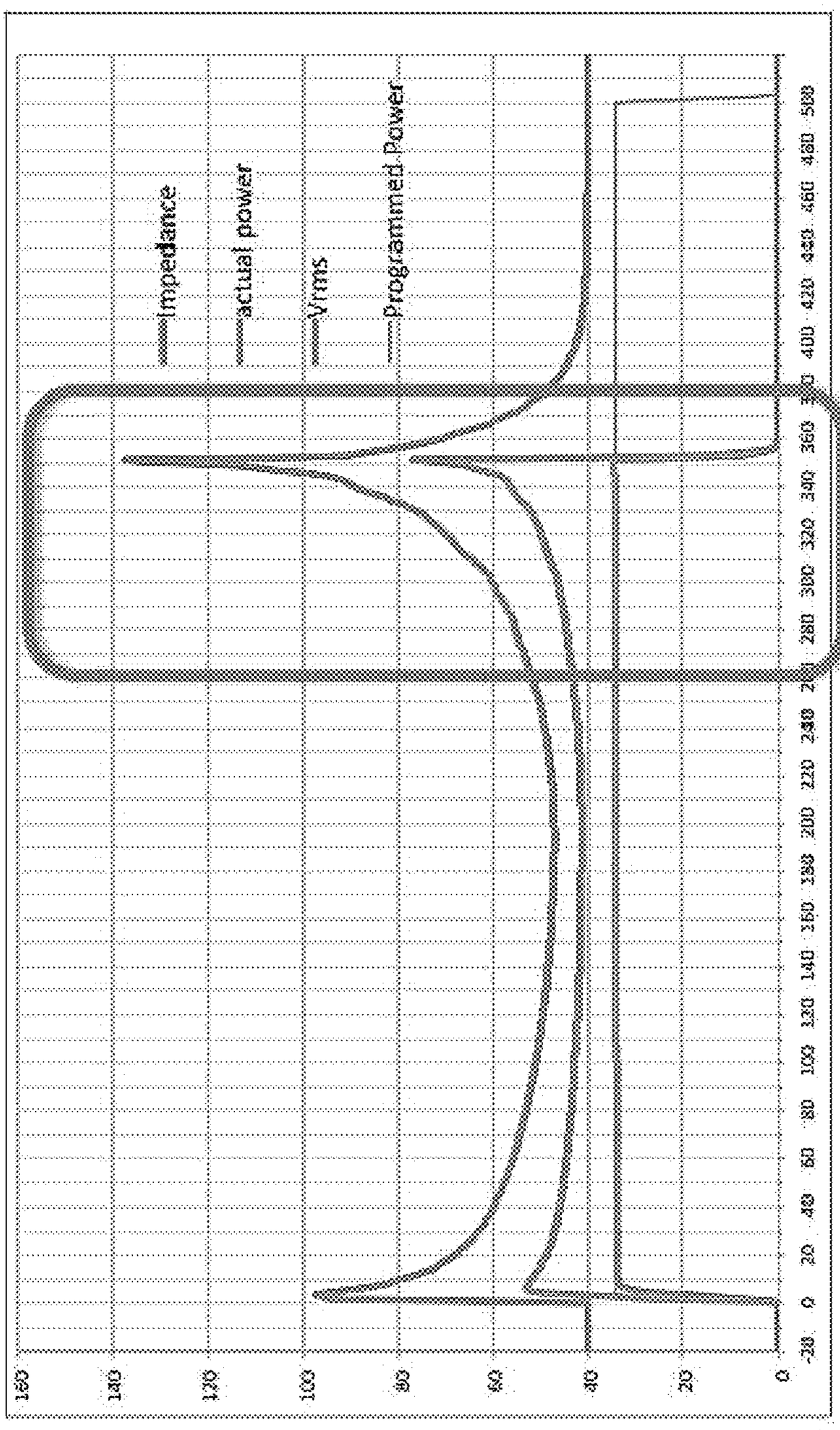

Impedance
actual power
Vrms
Programmed Power
Power * 3SW / Time : 50ms

FIG. 12b

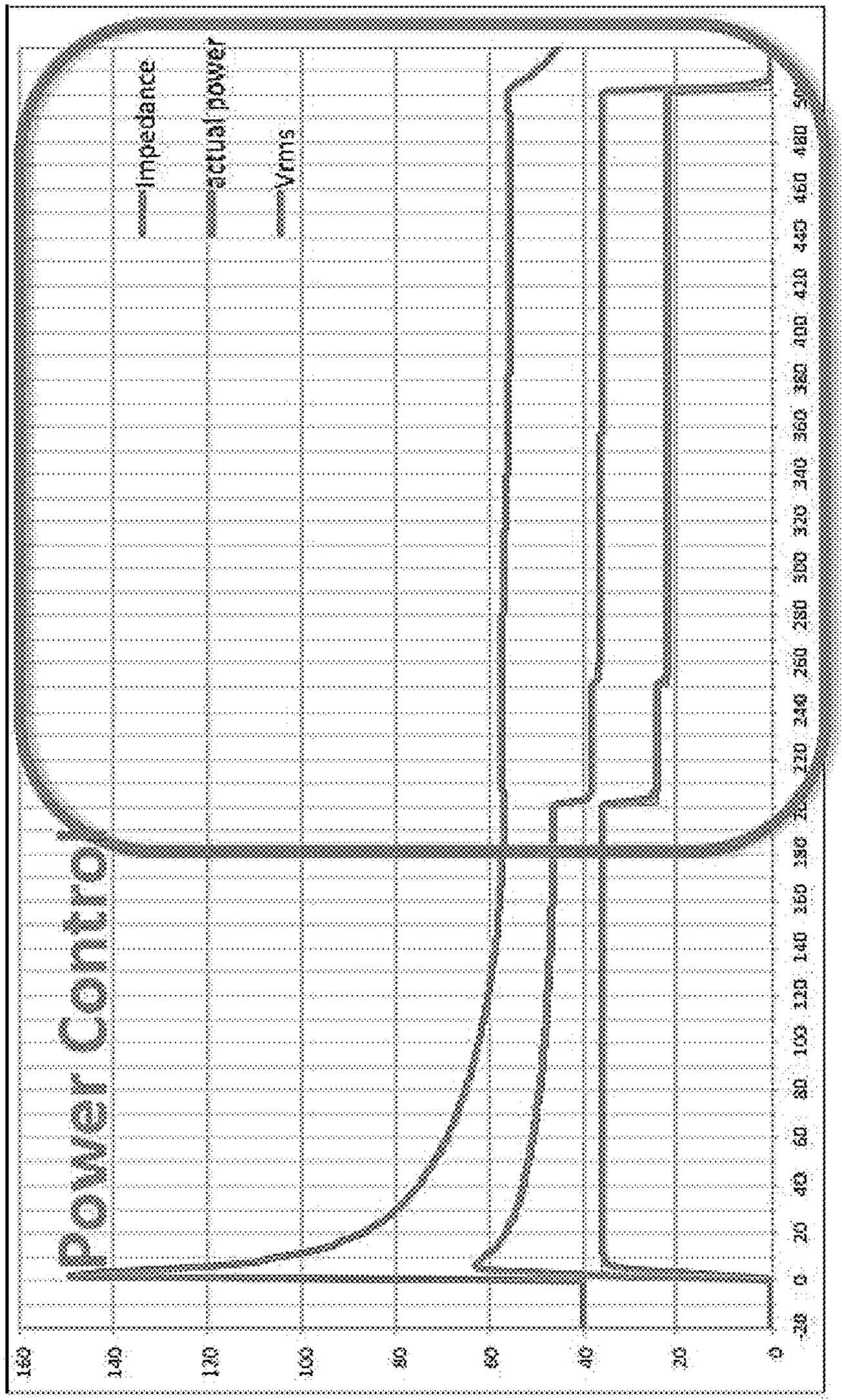

Impedance
actual power
Vrms
Power Control
Power
Power : 35W / Time : 50ms

FIG. 13

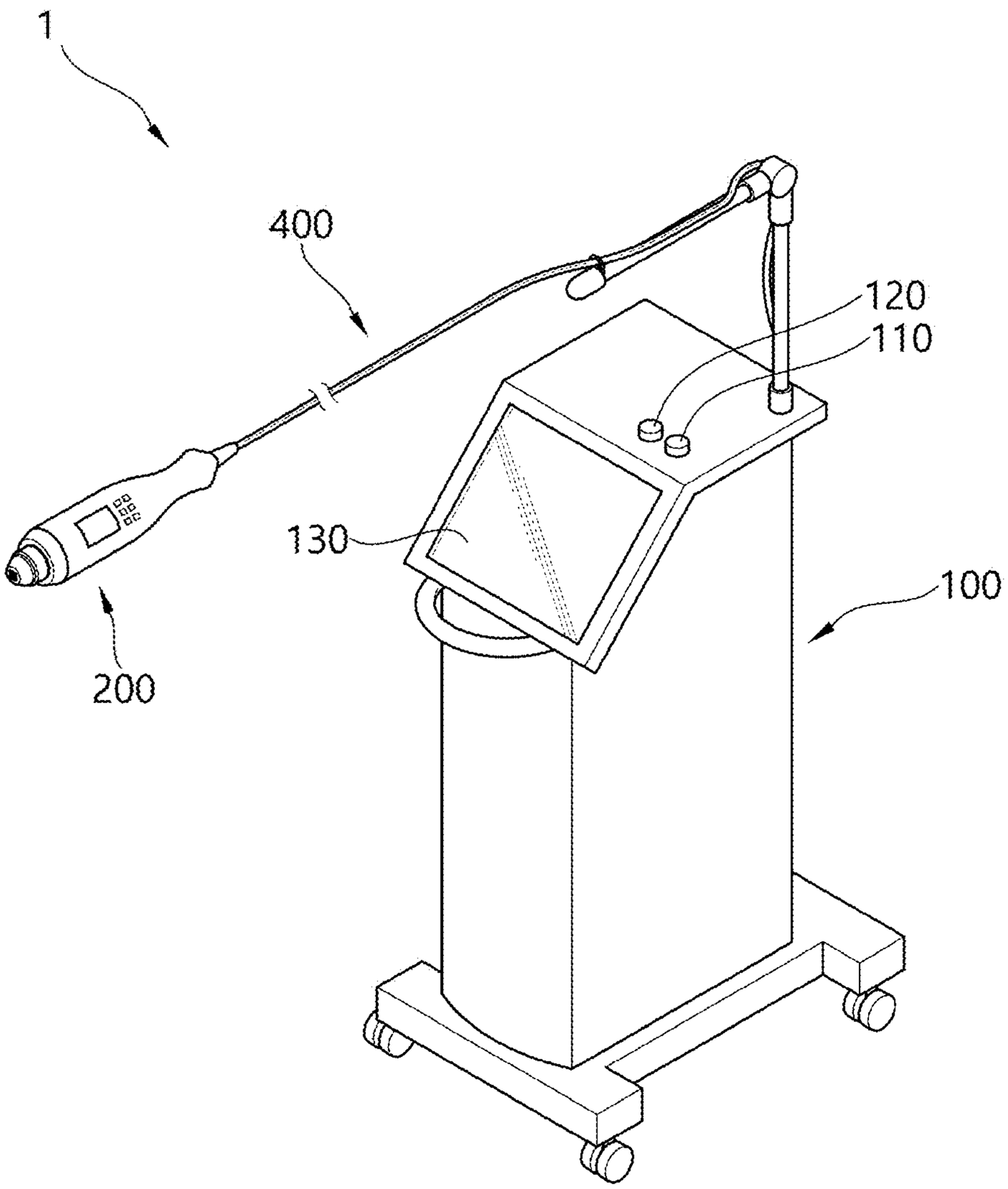
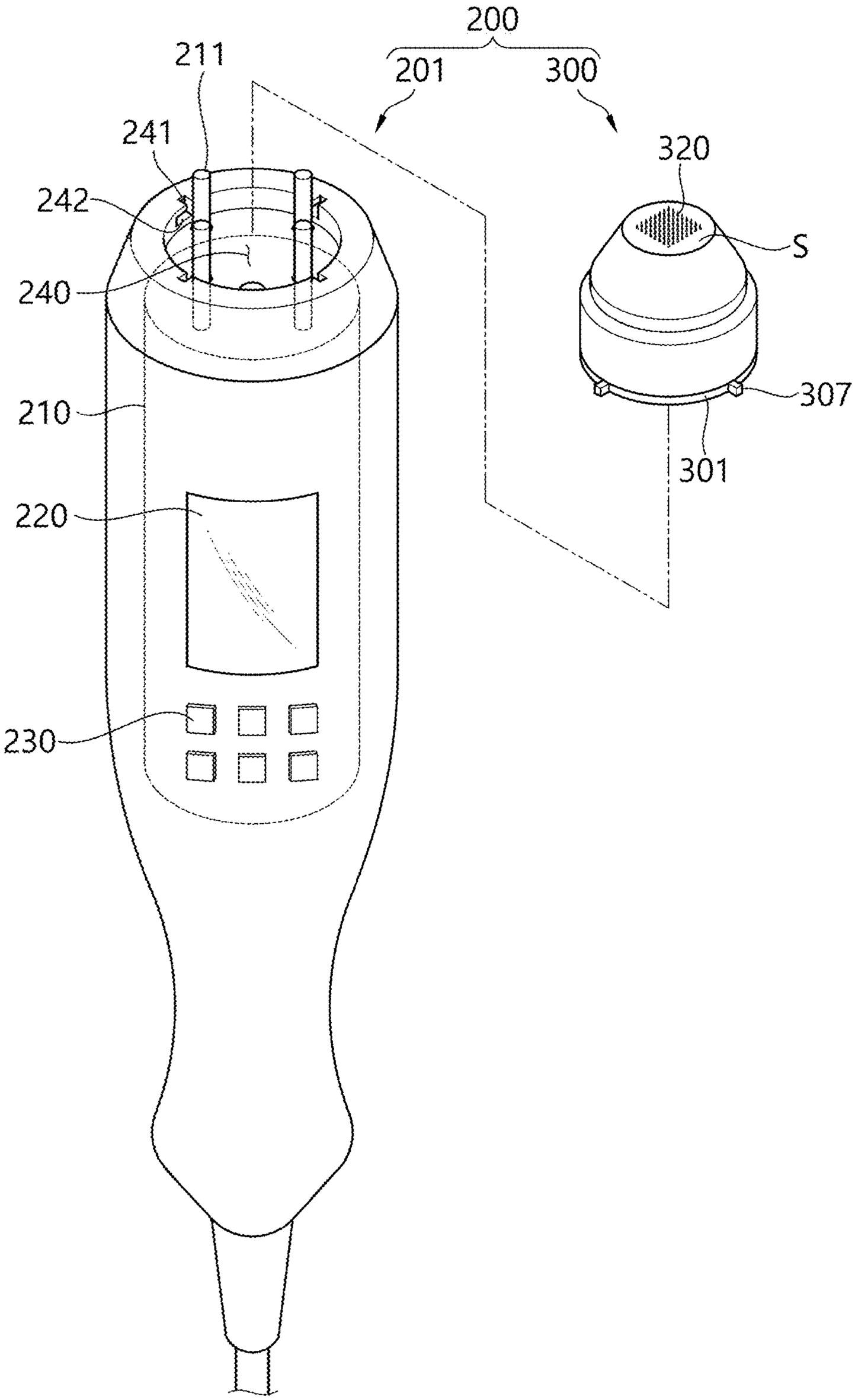


FIG. 14



RF TREATMENT APPARATUS, METHOD OF CONTROLLING RF TREATMENT APPARATUS AND SKIN TREATMENT METHOD USING RF ENERGY

CROSS REFERENCE TO RELATED APPLICATIONS PARAGRAPH

This application is a U.S. National Stage of PCT/KR2018/002436, filed Feb. 28, 2018, which claims the priority benefit of Korean Patent Application No. 10-2017-0041801, filed on Mar. 31, 2017 in the Korean Intellectual Property Office, the disclosures of which are incorporated herein by reference.

TECHNICAL FIELD

The present invention relates to an RF treatment apparatus, a method of controlling the RF treatment apparatus, and a skin treatment method using RF energy and, more particularly, to an RF treatment apparatus controlling RF energy using calculated impedance, a method of controlling the RF treatment apparatus, and a skin treatment method using RF energy.

BACKGROUND ART

A method of treating a tissue may be divided into a method of treating a tissue outside the tissue and an invasive treatment method of treating a tissue by inserting some of or the entire treatment apparatus into the tissue. The invasive treatment method basically uses a treatment apparatus having a thin-necked insertion unit, such as a needle or a catheter. Treatment is performed after the treatment apparatus is inserted into a target location within a tissue.

The invasive treatment method includes various treatment behaviors, such as delivering a treating substance to the inside of a tissue, performing surgical treatment through a mechanical operation in the state in which a predetermined tissue within a tissue is adjacent, or delivering energy to a target location within a tissue. The treatment method has been disclosed in Korean Patent Application Publication No. 10-2011-0000790, and is applied in various methods.

However, the existing RF treatment apparatus has a problem in that a tissue may be damaged because excessive energy is applied when applying high energy within a short time.

DISCLOSURE

Technical Problem

The present invention has been made to solve the aforementioned problem of the conventional RF treatment apparatus, and an object of the present invention is to provide an RF treatment apparatus capable of cutting off RF energy prior to excessive damage to the skin, a method of controlling the RF treatment apparatus, and a skin treatment method using RF energy.

Technical Solution

As means for solving the object, there may be provided an RF treatment apparatus, comprising an RF generator generating RF energy, an electrode applying the RF energy to a target tissue, a sensor unit configured to sense the RF energy and a controller controlling output of the RF generator,

receiving a sensing value from the sensor unit, calculating impedance of the target tissue, and cutting off the RF energy if the impedance is determined to have increased for a specific period.

In this case, the controller determines the impedance to have increased for the specific period when a parameter value exceeds a threshold, and the parameter value is defined as a product of a specific time and the impedance of the tissue.

Furthermore, the parameter is defined as a product of a rising time from a current time to the predetermined time before and impedance for the rising time.

In this case, the rising time is a case where the impedance continues to have increased from the current time to the predetermined time before.

Furthermore, The RF treatment apparatus of claim **2**, wherein the parameter value is defined as a product of the specific time and an average of the impedance for the predetermined time.

Furthermore, the parameter value is defined as a product of the specific time and an average of changes in the impedance for the specific time.

Furthermore, a case where the impedance is determined to have increased for the specific period is a case where a change in the impedance continues to have increased for the specific period.

Meanwhile, the threshold is determined in accordance with a temperature at which the tissue is not ablated when the temperature of the tissue rises as the RF energy is applied.

Furthermore, the threshold is determined to be a value when a temperature of the tissue is 70° C. as the RF energy is applied.

Moreover, the sensor unit measures current, a voltage and power applied to the electrode and the controller calculates the impedance as a root mean square (RMS) when calculating the impedance.

Moreover, wherein the controller controls an output voltage of the RF generator so that the power does not exceed a specific range.

Furthermore, the electrode comprises at least one of a contact type and an insertion type.

In Addition, there may be provided a method of controlling an RF treatment apparatus, comprising steps of applying RF energy to a tissue through an electrode, calculating impedance of the tissue, calculating a parameter defined as a product of a specific period of a time during which the RF energy is applied and impedance calculated in the specific period, and determining whether the parameter exceeds a threshold and cutting off the RF energy when the parameter exceeds the threshold.

Meanwhile, the parameter is defined as a product of a rising time from a current time to the specific time and impedance for the rising time.

Furthermore, the parameter is defined as a product of a rising time from a current time to a specific time and a change in the impedance for the rising time.

Moreover, the parameter is defined as a product of a rising time from a current time to a predetermined time before and an average of changes in the impedance for the rising time.

Furthermore, the step of determining whether the parameter exceeds the threshold is performed after a specific time from a point of time at which the RF energy is applied.

Furthermore, the threshold is determined in accordance with a temperature at which the tissue is not ablated when the temperature of the tissue rises as the RF energy is applied.

Meanwhile, the step of positioning the electrode in the tissue is performed by at least one of a contact and insertion of the electrode on and into the tissue.

In addition, there may be provided a method of controlling an RF treatment apparatus, comprising steps of applying RF energy to a tissue through an electrode, calculating impedance of the tissue, determining whether a parameter defined as an average of impedance of the tissue from a current time to a specific time exceeds a threshold and cutting off the RF energy when the parameter exceeds the threshold.

In Addition, there may be provided a skin treatment method In this case, the comprising steps of positioning an electrode in a tissue, heating the tissue to a treatment temperature by applying RF energy to the electrode, measuring the RF energy applied to the tissue, calculating impedance of the tissue to which the RF energy is applied, comparing a parameter into which impedance from a current time to a predetermined time before has been incorporated with a threshold and determining whether to cut off the RF energy based on a result of the comparison between the parameter and the threshold in order to prevent ablation of the tissue.

In this case, determining whether to cut off the RF energy based on a result of the comparison comprises continuing to apply the RF energy when the parameter is less than the threshold and cutting off the RF energy when the parameter is the threshold or more.

Meanwhile, the parameter is defined as any one of an average of impedance values measured during a time interval from a current time to a specific time, a product of impedance values, a change in the impedance value, and an average of changes in the impedance values.

DESCRIPTION OF DRAWINGS

FIG. **1** is a conceptual diagram of an RF treatment apparatus according to the present invention.

FIG. **2** is a diagram showing an impedance change according to a temperature rise of a tissue.

FIGS. **3***a* and **3***b* are conceptual diagrams when ablation within a tissue occurs.

FIGS. **4***a* and **4***b* are impedance and temperature graphs of a tissue when ablation occurs.

FIGS. **5***a* and **5***b* are graphs of impedance in the ablation prevention mode.

FIG. **6** is a flowchart of a method of controlling an RF treatment apparatus in the ablation prevention mode.

FIGS. **7***a* and **7***b* are impedance and temperature graphs of a tissue when the ablation prevention mode is performed.

FIGS. **8***a*, **8***b* and **8***c* are conceptual diagrams of when coagulation within a tissue occurs.

FIG. **9** is a graph showing RF energy measurement values when RF energy is applied within a tissue.

FIG. **10** is a flowchart of the coagulation mode.

FIG. **11** is a detailed flowchart of an energy control step in FIG. **10**.

FIGS. **12***a* and **12***b* are graphs showing RF energy measurement values when the coagulation mode is performed.

FIG. **13** is a perspective view of an RF treatment apparatus according to the present invention embodiment.

FIG. **14** is an enlarged perspective view of a handpiece of FIG. **13**.

MODE FOR INVENTION

Hereinafter, an RF treatment apparatus, a method of controlling the RF treatment apparatus, and a skin treatment method using RF energy according to embodiments of the present invention are described in detail with reference to the accompanying drawings. Furthermore, in the following description of the embodiments, elements may be named differently in the field to which the present invention pertains. However, if the elements have functional similarity and identity, they may be considered to be equivalent elements although they adopt modified embodiments. Furthermore, reference numerals assigned to respective elements are written for convenience of description. However, contents shown in the drawings in which the reference numerals are written do not restrict respective elements to the ranges in the drawings. Likewise, although the elements in the drawings adopt partially modified embodiments, they may be considered to be equivalent elements if the elements have functional similarity and identity. Furthermore, a description of an element is omitted if the element is recognized as being an element that must be naturally included in view of the level of a person having ordinary skill in the art.

Hereinafter, a "treatment apparatus" includes all apparatuses for treating mammals including people. The treatment apparatus may include may include various treatment apparatuses used to improve a lesion or the state of a tissue. For example, the treatment apparatus includes an apparatus transferring treating substances, such as medicines, anesthetic, and stem cells, an operation apparatus for surgically treating a predetermined tissue, and various treatment apparatuses applying RF energy.

Hereinafter, a "tissue" means a set of cells forming various body organs of an animal including people, and includes various tissues forming various organs within the body, including a skin tissue.

FIG. **1** is a conceptual diagram of an RF treatment apparatus according to the present invention. The RF treatment apparatus is configured to treat a tissue by applying RF energy to the inside of the tissue to denaturize the tissue. As shown, the RF treatment apparatus according to the present invention may include an electrode **2**, an RF generator **3**, a power supply **4**, a sensor unit **7**, a controller **5** and a reference unit.

The electrode **2** is configured to apply RF energy from the RF treatment apparatus to the skin. A plurality of electrodes **2** may be configured to apply energy to a plurality of points. The electrode **2** has a bipolar type, and may be configured so that RF energy is concentrated on a lesion portion positioned between each of pairs of the electrodes **2**. Furthermore, a plurality of pairs of electrodes **2** is provided, and may be configured to generate fractional damage within a tissue. The plurality of electrodes **2** may be configured in an insertion and/or contact type. If the electrodes are configured in the insertion type, a plurality of micro needles may be configured to be inserted into a skin tissue and to generate heat in a deep part. Furthermore, if the electrodes are configured in the contact type, they may come into contact with the skin and generate deep part heat. In this case, an insulating part may be applied to each electrode **2** so that an RF energy transmission condition is changed. In this case, the configuration of the electrode **2** may be modified and applied in various manners, and thus a further detailed description thereof is omitted.

The RF generator **3** is configured to be supplied with power from the power supply **4** and to generate RF energy. The RF generator **3** generates RF energy used for treatment through the electrode **2**. In this case, the RF generator **3** is configured to change the frequency, voltage, etc. of the RF energy, if necessary.

The sensor unit **7** is configured to measure an output value of RF energy. The sensor unit **7** may be provided on an electrical path between the electrodes **2** from the RF generator **3**, and is configured to measure current, a voltage and power applied to the electrodes **2**. An impedance value of a tissue can be calculated based on the current, a voltage and power.

The controller **5** is configured to receive a sensing value from the sensor unit **7** and to control the RF generator **3**. Furthermore, the controller **5** is configured to control the RF generator **3** and other elements when operating in various modes in response to a user input. The controller **5** may function to determine the state within a tissue while RF energy is applied and to control the applied RF energy or block the RF energy based on the state of the tissue. In this case, the controller **5** may determine the state within the tissue or output of the RF energy based on data stored in the reference unit. Meanwhile, although the reference unit is not provided, the controller **5** may perform control using a predetermined setting value.

Hereinafter, RF energy applied to the inside of a tissue, a temperature of the tissue, and a change in the state of the tissue are described with reference to FIG. **2**.

FIG. **2** is a diagram showing an impedance change according to a temperature rise of a tissue. When RF energy is applied, a tissue is denaturized. Such denaturalization may be divided into a heat phase, a coagulation occurrence phase, a desiccation occurrence phase and a vaporization occurrence phase. The heat phase corresponds to the section in which a tissue rises up to a treatment temperature as RF energy is applied. In this case, when the temperature of the tissue reaches about 44° C., tissue necrosis begins. Thereafter, when the temperature of the tissue reaches about 70° C., coagulation of the tissue starts. Thereafter, when the temperature of the tissue reaches about 90° C., desiccation occurs. In this case, cells lose moisture, but the ultrastructure of the tissue may remain intact. Thereafter, when the temperature of the tissue reaches 100° C., moisture starts to be vaporized. When the tissue is further heated, carbonization occurs about 200° C.

Impedance of the tissue at this time is described. When RF energy of the same power is applied, the tissue is denaturized and an impedance value is greatly changed depending on a temperature rise of the tissue. That is, in the heat phase, after a sudden rise of the impedance, a stabilization phase in which a change (AZ) in the impedance is reduced appears. This corresponds to the coagulation occurrence phase. Thereafter, a phase in which a sudden rise of the impedance occurs corresponds to the desiccation occurrence phase. In contrast, the current state of a tissue may be estimated by measuring impedance of the tissue and checking a variation tendency. Predeterminedally, it may be seen that after the RF energy is applied, if an impedance value is stabilized within a predetermined range after a lapse of a predetermined time, temperature of the tissue is about 70° C. and coagulation occurs. Thereafter, it may be seen that when a sudden rise of the impedance occurs, the impedance becomes the desiccation occurrence phase in which ablation occurs.

In other words, an important factor in the aspect of control of a temperature of a tissue and energy based on the temperature is impedance of the tissue. The impedance of the tissue tends to be generally similar according to a temperature change (as a treatment time elapses). An increment phase and a sudden increment phase appear after the phase in which impedance of a tissue is gradually decreased.

The controller performs control based on a calculated impedance value so that RF energy is optimized and applied depending on treatment purposes. For example, the controller may perform control so that a local portion is denaturized until right before ablation for the purposes of removal of a scar, removal of a tissue, etc., or coagulation occurs in a wide volume for the retightening of the skin.

Hereinafter, two treatment modes of the functions of the controller are described. An ablation prevention mode is described with reference to FIGS. **4** to **7**, and a coagulation mode is described with reference to FIGS. **8** to **12**. In this case, each mode may be optionally applied by a user.

I. Ablation Prevention Mode

FIGS. **3***a* and **3***b* are conceptual diagrams when ablation within a tissue occurs. FIGS. **4***a* and **4***b* are impedance and temperature graphs of a tissue when ablation occurs. FIGS. **5***a* and **5***b* are graphs of impedance in the ablation prevention mode. FIG. **6** is a flowchart of a method of controlling an RF treatment apparatus in the ablation prevention mode. FIGS. **7***a* and **7***b* are impedance and temperature graphs of a tissue when the ablation prevention mode is performed.

Referring to FIG. **3***a*, there are shown a region denaturized because coagulation has occurred in a tissue (i) and a region in which ablation has occurred (ii) thereafter. This corresponds to a case where the ablation region is expanded because a temperature of a tissue around the electrode rises rapidly compared to the speed at which the region where coagulation has occurred is expanded. Accordingly, the ablation prevention mode is applied to prevent ablation in the tissue and to denaturize a proper region.

Referring to FIGS. **4***a* and **4***b*, there are shown temperatures and impedance when RF energy is applied to different persons. As shown, although the RF energy is applied with the same power for the same application time, points of time at which the temperature rises suddenly are different in the persons. Accordingly, if the RF energy is not controlled, unwanted damages may occur. For example, if RF energy having power of 20 W is applied for 0.5 second, unlike in FIG. **4***a*, ablation occurs in the case of FIG. **4***b* and thus damage to a tissue occurs. Accordingly, the controller blocks power in a step prior to the occurrence of ablation at a predetermined point of time in order to prevent such damage.

The function of the controller **5** is described below based on a sampling time T. The controller **5** controls the RF generator **3** so that power of RF energy is controlled or the RF energy is blocked. Power control of the RF generator **3** is first described below.

To constantly maintain power of RF energy applied to a tissue during treatment is preferred in terms of the prevention of damage to the tissue attributable to the sudden application of energy, the treatment range of the tissue, and accuracy of a treatment effect. In this case, if a method of measuring a temperature within the tissue is used, time delay occurs due to the temperature measurement, and thus control of the output of the RF energy is not properly incorporated. Accordingly, it is preferred to measure and incorporate impedance of the tissue, but a fine change in the volume occurs if fractional damage occurs. Furthermore, since treatment is performed within a short time, an impedance value, that is, an electrical characteristic of the tissue, may be sensitively changed. Accordingly, temperature measurement is used for control through a predetermined step.

Accordingly, an impedance effective value (i.e., root-mean-square (RMS)) of a tissue may be obtained based on values obtained by measuring a voltage, current and power continuously (at T intervals) using the sensor unit **7** while RF energy is applied.

Detailed contents are described below.

At a point of time T that is an initial step 1, an R1 value may be derived as the RMS of a voltage V1, current I1 and power P1.

Thereafter, at a point of time 2T that is step 2, R2 may be derived as the RMS of a voltage V2, current I2 and power P2.

In this case, referring to a power relation in step 1 and step 2, a power loss occurs due to a change in the reactance. At this time, a power factor may be defined as follows.

$$\varphi=PRMS(t)/PRMS(t-1)$$

In this case, the power factor becomes a reactance value in step 2. Accordingly, the reactance value in step 2 can be obtained although the impedance value of the tissue is not measured.

An example of detailed numerical values is shown in Table 1.

TABLE 1

STEP	1	2	3	4
V [V]	1	1	1	1
I [A]	1	2	2	1
P [W]	1	2	2	1
Power factor	—	2	1	1.5
Resistance [Ω]	1	0.5	0.5	1
Reactance	—	2	1	1.5

As described above, the impedance value of the tissue is calculated in each step. Power suitable for a corresponding tissue based on an impedance value is determined by matching the impedance value with data stored in the reference unit **6**. Thereafter, the tissue can be properly treated within a short time by controlling an output voltage of the RF generator **3** so that RF energy of a determined power value is applied.

The cutting off of RF energy, that is, a function of the controller **5**, is described below.

The controller **5** may be configured to block applied RF energy if it determines that impedance has suddenly increased for a predetermined period. This is for preventing ablation occurring due to a sudden rise of a tissue temperature.

The controller **5** may determine that impedance has increased for a predetermined period based on a parameter value defined as the product of a rising time "Trising", that is, a predetermined period during which impedance has increased, and the mean (Zvalue) of impedance corresponding to the rising time "Trising" as follows.

$$Parameter=Trising\times Zvalue$$

A determination of whether impedance has increased for a predetermined period is described based on a sampling period T. Whether impedance has increased is determined for a time interval from the present point of time to a predetermined time. In this case, if the rising time, that is, the time from the current time to the predetermined time, is too large, rapid handling is difficult. If the rising time is too small, it may be sensitive to low noise. Accordingly, it is preferred to properly determine the rising time.

FIGS. **5***a* and **5***b* are graphs of impedance in the ablation prevention mode. As shown, whether a parameter exceeds a first threshold is determined every step after a predetermined time. A case where a predetermined time interval is three sampling time intervals is described as an example with reference to FIG. **5***a*. In the case of ti at present, an impedance value calculated during a time interval until ti−3, ti−2, ti−1, and ti may be applied to a parameter value. Meanwhile, impedance is reduced at ti. At this time, energy is not blocked. Predeterminedally, referring to FIG. **5***b* showing an enlarged rising phase, in the case of tj, during time up to tj−3, tj−2, tj−1, and tj, impedance rise up to Zj−3, Zj−2, Zj−1, and Zj. At this time, a change (ΔZ) in the impedance continues to rise. This corresponds to a case where the parameter value exceeds the first threshold or becomes the first threshold or more. Accordingly, the RF energy may be blocked. When the RF energy will be blocked at any point of time during the period in which the impedance rises may be different according to circumstances. Predeterminedally, a location is different depending on a set first threshold. If a high first threshold is set, the RF energy may be blocked at a higher temperature. If a low first threshold is set, the RF energy may be blocked at a low temperature.

That is, the controller blocks RF energy if the following condition is satisfied.

$$Parameter>first\ threshold$$

Furthermore, impedance may be determined to have increased for a predetermined period if any one value of the mean (Zave) of impedance values during a period from the current to a predetermined time before, the product of an impedance value, a change (ΔZ) in the impedance value, and a change in the mean (ΔZave) of an impedance value is the first threshold or more. In this case, the parameter may be defined as any one of the followings.

$$Parameter=Zave$$

$$Parameter=Z_t\times Z_{t-1}\times Z_{t-2}\times \ldots \times Z_{t-k}$$

$$Parameter=\Delta Z$$

$$Parameter=\Delta Zave$$

In this case, t is the current time, and k is a set time interval. In this case, a determination of a parameter value after a predetermined time interval when RF energy is applied may be determined so that handling can be performed in the ablation phase without handling a change in the initial impedance value.

A method of controlling the RF treatment apparatus when the ablation mode is applied is described below. FIG. **6** is a flowchart of the method of controlling the RF treatment apparatus in the ablation prevention mode.

The method of controlling the RF treatment apparatus when the ablation mode is applied may include a step S**100** of positioning an electrode in a tissue, a step S**200** of applying RF energy, a sensing step S**300**, a step S**400** of calculating impedance, a step S**500** of determining whether a parameter exceeds a first threshold, and a step S**600** of cutting off the RF energy.

The step S**100** of positioning an electrode in a tissue corresponds to the step of positioning the electrode close to a tissue that is a target of treatment. When the skin is treated, the electrode may be brought in contact with the skin or the electrode including a plurality of micro needles may be inserted through the skin and positioned.

The step S**200** of applying RF energy corresponds to the step of applying RF energy in order to treat the tissue. In this case, the RF energy is controlled and applied depending on the state of the tissue through feedback control.

The sensing step S**300** corresponds to the step of measuring a voltage, current and power applied to the electrode and a load including the tissue while the RF energy is

applied. In this case, a unique impedance value may vary because the RF energy is applied to the tissue. A corresponding voltage, current and power is measured in real time.

In the step S**400** of calculating impedance, impedance is calculated using the result values measured in the sensing step S**300**. In this case, the calculation is performed as an RMS.

The step S**500** of determining whether a parameter exceeds a first threshold corresponds to the step of determining whether cut-off is necessary in order to prevent excessive energy from being transferred to the tissue. The application of the RF energy is cut off right before ablation of the tissue in order to prevent the ablation from occurring because excessive RF energy is applied within a short time.

If a temperature is measured at this time, there is a difficulty in using the temperature for feedback because time delay occurs. Accordingly, a point of time of cut-off is determined based on a parameter into which a change in the impedance (ΔZ) of the tissue has been incorporated. In this case, the parameter may be determined as described above with reference to the aforementioned function of the controller.

In other words, a parameter determined based on the "phase in which a change (ΔZ) in the impedance rises (impedance increment rising phase)" and "a value of the impedance during the risen phase (rising phase)". When the parameter is the first threshold or more, the RF energy may be automatically cut off. Furthermore, the parameter may be determined by incorporating the mean of impedance values during the rising phase in order to reduce an error attributable to noise.

As a result, whether a step is a step right before ablation may be determined by sensing an electrical predetermined value of the tissue over time in the state right before the ablation, and thus ablation is prevented.

The step S**600** of cutting off RF energy corresponds to the step of cutting off the RF energy in order to prevent ablation if the parameter value is determined to be higher than the first threshold.

FIG. **7** is an impedance and temperature graph of a tissue when the ablation prevention mode is performed in the RF treatment apparatus. As shown, when a parameter into which a sudden rise of impedance has been incorporated reaches a first threshold when the impedance rises suddenly, RF energy is cut off so that a temperature of a tissue does not become a predetermined temperature or more. Accordingly, if a tissue has different electrical characteristics depending on a person although the tissue is located in the same portion, RF energy is cut off at a different point of time, thereby being capable of preventing ablation from occurring.

II. Coagulation Mode

Hereinafter, the coagulation mode that may be optionally applied by the controller is described in detail with reference to FIGS. **8***a* to **12***b*.

FIGS. **8***a* and **8***b* are conceptual diagrams when coagulation within a tissue occurs. As shown, a treatment lesion within a tissue when the electrode that is an invasive type and a bipolar type is used occurs around the electrode and on the path along which RF energy between the electrodes is transferred. In this case, a temperature of the tissue rises as the RF energy is applied to the tissue, so the tissue becomes a coagulation state when the temperature is about 70 to 80° C. Thereafter, if the temperature further rises, the coagulation state changes into an ablation state. It has been known that in treatment for purposes, such as wrinkle improvement and a skin elasticity increase as in the skin, ablation is not preferred and it is helpful to treat a tissue in the coagulation state.

FIG. **8***a* shows a treatment volume (i) in which coagulation occurs when RF energy is applied. If the RF energy is suddenly applied from this point of time, ablation rapidly occurs (ii) in the treatment volume of the tissue compared to an increase of the coagulation region (i), as in FIG. **8***b*. In order to prevent such ablation and also increase the treatment volume in which coagulation occurs, as shown in FIG. **8***c*, a method of repeatedly applying RF energy to a neighboring region through insertion/reinsertion or a method using a large electrode is used. However, such a method is not appropriate for rapid treatment and a reduction of pain because a patient's pain increases due to the repetitive insertion and an insertion location needs to be precisely controlled.

FIG. **9** is a graph showing RF energy measurement values when RF energy is applied within a tissue. As shown, when RF energy of a constant voltage is applied, RF power applied to a tissue has an initial peak value. Thereafter, the RF power tends to suddenly rise from a predetermined point of time. Meanwhile, a temperature of the target tissue gradually rises, and the temperature tends to gradually rise from a predetermined point of time. At this time, when the temperature of the tissue rises, an impedance value of the tissue also rises. As a result, RF energy is suddenly applied to the tissue. In such a case, as described above with reference to FIGS. **8***a* to **8***c*, ablation in some regions rapidly occurs compared to an increase of the treatment volume in which coagulation occurs. This occurs when the transfer of energy according to RF energy is faster than the transfer of heat toward surroundings within a target tissue.

The controller controls RF power so that a temperature of a tissue becomes constant. In this case, the temperature of the tissue may be estimated based on a change in the impedance of the tissue. If the impedance of the tissue is maintained within a constant range, the temperature can also be maintained to a predetermined level.

The controller performs control of RF energy from a point of time after a predetermined point of time, that is, from a point of time at which coagulation occurs after RF energy is applied. In this case, the sensor unit measures a voltage, current and power, and the controller calculates an impedance value based on the voltage, current and power. Such calculation may be performed as an RMS.

The controller continues to monitor a change (ΔZ) in the impedance after a predetermined point of time, that is, a first application time, for example, after 50 ms (heat phase). Control may be performed when an instant impedance change exceeds a predetermined range. That is, when a change in the accumulated impedance exceeds a predetermined numerical value for a predetermined time interval up to the current time, the controller applies RF energy by increasing or decreasing RF power so that the impedance of a tissue can be maintained to a proper level. In this case, control of the RF power may be performed for a third application time.

A determination of whether the accumulated impedance exceeds the predetermined numerical value may be made by comparing a parameter value into which a change in the impedance has been incorporated with a second threshold. In this case, the comparison of the parameter includes calculating impedance from the current to a predetermined time before every sampling time cycle. For example, impedance values, such as the average of impedance, the average of impedance changes, the product of impedance, the prod-

uct of the impedance mean, and the absolute value of an impedance change, may be incorporated into the parameter.

Predeterminedally, if control is performed using the mean (Zave) of impedance values, the sensor unit senses RF energy, the mean of target impedance of a tissue from the current to a predetermined time before may be calculated, and whether the second threshold is exceeded may be determined. For example, if the current time is t and the predetermined time interval is 3T, the average of impedance may be defined as "Zave=(Z(t)+Z(t−T)+Z(t−2T)+Z(t−3T))/4." Furthermore, if a treatment temperature is to be maintained, the controller may control RF energy so that the mean is maintained within a predetermined range using the mean (Zave) of the impedance for the predetermined time interval. That is, if the mean (Zave) of the impedance is lower than the second threshold, the controller can maintain the average of the impedance within the predetermined range by increasing RF power. In contrast, if the mean (Zave) of the impedance is higher than the second threshold, the controller can maintain the average of the impedance within the predetermined range by decreasing RF power.

FIG. **10** is a flowchart of the coagulation mode, and FIG. **11** is a detailed flowchart of the energy control step of FIG. **10**.

As shown, a method of controlling the RF treatment apparatus when the coagulation mode is performed according to the present invention may include a step S**1100** of positioning an electrode, a step S**1200** of applying RF energy, a step S**1300** of determining whether a target tissue has reached a treatment temperature, and a step S**1400** of controlling the RF energy.

The step S**1100** of positioning an electrode corresponds to the step of preparing treatment by positioning the electrode in a target tissue, and may be performed by bringing the electrode in contact with a surface of the target tissue, inserting the electrode into the target tissue or performing a contact and insertion at the same time.

The step S**1200** of applying RF energy corresponds to the step of applying RF energy with predetermined power. In this case, the predetermined power may be a value previously set based on the size of the electrode, an array of the electrodes, the characteristics of the tissue, etc. The predetermined power may be determined based on an impedance value through the step of initially calculating an impedance value of the tissue.

The step S**1300** of determining whether the target tissue has reached a treatment temperature corresponds to the step of determining whether the target tissue has reached the treatment temperature by measuring the RF power. RF power when it is applied to the tissue is monitored. If a change (ΔZ) in the impedance corresponds to a range within a predetermined range, it may be determined that the target tissue has entered a stabilization step and has reached a coagulation temperature.

Furthermore, the step S**1300** of determining whether the target tissue has reached the treatment temperature may be started from a first application time after the RF energy is applied. The reason for this is that in the heat phase, an impedance value of the tissue is suddenly changed and separate control of the RF power is not necessary.

The step S**1400** of controlling the RF energy corresponds to the step of controlling the RF power so that a volume corresponding to the treatment temperature is maximized for a predetermined time if the target tissue has reached the treatment temperature.

Referring to FIG. **11**, the step S**1400** of controlling the RF energy may include a step S**1410** of determining whether the first application time has elapsed, a step S**1420** of determining a change in the impedance of the tissue, steps S**1430** S**1440** of controlling the voltage of the RF generator, and a step S**1450** of determining whether a third application has elapsed.

The step S**1410** of determining whether the first application time has elapsed corresponds to the step of applying energy of preset RF power without determining whether the target tissue has reached a treatment temperature during the time corresponding to the heat phase. In this phase, impedance of the tissue may change suddenly, and thus the step is performed because separate control is not necessary.

The step S**1420** of determining a change in the impedance of the tissue corresponds to the step of determining whether impedance of the tissue has changed by deriving the impedance of the tissue. The impedance of the tissue may be derived by measuring a voltage, current and power value of the RF energy applied to the electrode. In this case, an impedance value of the tissue and a change in the impedance value may be derived every moment and used for control.

The step S**1430**, S**1440** of controlling the voltage of the RF generator corresponds to the step of controlling the RF power by controlling the voltage based on the impedance change derived in the step S**1420** of determining a change in the impedance of the tissue. That is, the RF power is decreased (S**1430**) when the impedance value increases, and the RF power is increased (S**1430**) when the impedance value decreases. In the step of controlling the voltage of the RF generator, the RF power is controlled so that the transfer rate of heat toward surrounding tissues has the same level as the transfer rate of the RF energy transferred from the electrode in a local volume in which the treatment temperature has been reached. The target tissue that has reached the treatment temperature maintains the temperature, and the volume in which the target tissue has reached the treatment temperature is gradually increased. Furthermore, in control of the RF energy, the RF power may be controlled using an accumulated value of the change (ΔZ) in the impedance.

In the step S**1450** of determining whether the third application has elapsed, whether the step S**1430**, S**1440** of controlling the RF power has been performed for a preset time is determined. If a preset third application time has elapsed, the RF energy is cut off and a corresponding cycle is terminated. A detailed numerical value of the third application time is omitted because the third application time may be different depending on the characteristics of a target tissue, the configuration of an electrode, etc.

FIGS. **12***a* and **12***b* are graphs showing RF energy measurement values when the coagulation mode is performed. FIG. **12***a* shows a graph before the coagulation mode is performed, and FIG. **12***b* shows a graph after the coagulation mode is performed.

As shown, although RF power is constant after a predetermined point of time, the phase in which an impedance value of a tissue suddenly rises occurs. In this case, ablation occurs as described above. In this case, if the RF power is controlled so that the impedance maintains a constant range, the impedance can maintain a proper level as in FIG. **12**(*b*). In this case, if control is performed based on a change (ΔZ) in the impedance, an impedance change converges within a predetermined range. In such a case, if the impedance corresponds to the predetermined range, this means that a temperature of a target tissue is also maintained within the predetermined range. Accordingly, a change (ΔZ) in the impedance is monitored from a point of time at which coagulation occurs. The impedance may be maintained

within a predetermined numerical value by lowering the voltage of the RF power at a point of time at which the change suddenly changes.

As a result, the volume in which coagulation occurs can be expanded because a tissue can be prevented from rising to a temperature or more at which ablation occurs and the tissue can also be maintained to a treatment temperature.

Hereinafter, a detailed configuration of the RF treatment apparatus according to the present invention is described with reference to FIGS. **13** and **14**.

FIG. **13** is a perspective view of the RF treatment apparatus according to the present invention embodiment. FIG. **14** is an enlarged perspective view of a handpiece of FIG. **13**. The RF treatment apparatus according to the present embodiment is an apparatus in which an insertion unit **10** is inserted into a skin tissue of the human body, for transferring energy into the inside of the skin tissue. The insertion unit **10** of the present embodiment includes a plurality of needles and may transfer energy to the inside of a skin tissue through the end of the needles.

The treatment apparatus according to the present embodiment is described in detail includes a main body **100**, a handpiece **200** that a user can grasp and perform treatment, and a connection unit **400** connecting the main body and the handpiece.

The RF generator and the controller (not shown) may be provided within the main body **100**. As described above, the controller generates a control input to control the RF generator based on a sensing value received from the sensor unit. In this case, the frequency of RF energy may be controlled depending on a patient's physical constitution, treatment purposes, a treatment portion, etc. For example, RF energy used for skin treatment may be controlled within a range of 0.1 to 10 MHz.

An on/off switch **110** of power, a frequency control lever **120** capable of controlling the frequency of RF energy generated by the RF generator, and a touch screen **130** on which a variety of types of information including operating contents of the treatment apparatus are displayed and treatment information is displayed and in which a user can input a command may be positioned on an external surface of the main body **100**.

Meanwhile, the handpiece **200** is connected to the main body by the connection unit **400**. The connection unit **400** may transfer RF energy, generated by the RF generator of the main body, to a plurality of needles **320** corresponding to the insertion unit **10** of the aforementioned embodiment, and may transfer power from the main body, which is necessary for various elements on the handpiece side to operate. The connection unit **400** is configured in a cable form and may use a cable including a plurality of metal lines covered with insulating coating.

A driving unit **210** and a cooling unit **40** are positioned within the housing of the handpiece **200**. The driving unit **210** is configured to linearly move output terminals **211** provided at one end of the driving unit in the length direction. As the output terminals **211** move linearly, the plurality of needles **320** disposed at the end of the output terminals may appear and disappear to an external surface of a contact surface of the handpiece. Accordingly, when the driving unit **210** is driven, the plurality of needles **320** may be inserted into a patient's tissue or may be drawn out from the tissue. The driving unit **210** may be formed of a linear actuator using a solenoid or a hydraulic/pneumatic cylinder.

A handpiece manipulation unit **230** and a handpiece display unit **220** may be provided on an external surface of the handpiece **200**. The handpiece manipulation unit **230** is configured to manipulate the on/off of the handpiece, control the insertion depth of the insertion unit **10** or control the amount of energy applied through the insertion unit **10**. The handpiece display unit **220** may display a variety of types of information for a user during a setting mode or treatment. Accordingly, the user can easily control treatment contents during treatment through the handpiece manipulation unit **230** in the state in which the user has grasped the handpiece, and can easily check treatment contents through the handpiece display unit **220**.

A tip module **300** is provided at the end of the handpiece. The tip module includes the plurality of needles **320** and may be detachably positioned in the main body **201** of the handpiece. Predeterminedally, a base **301** forms the bottom of the tip module. Outward protruded detachment protrusions **307** are formed in the outside wall of the base. A hollow through which a cooling wind from the cooling unit **40** can pass may be formed in a portion that belongs to the base **301** and that neighbors the protruded parts of the needles. Furthermore, a plurality of through holes may be formed in an outside portion that does not neighbor the protruded parts of the needles other than the protruded parts of the needles so that a cooling wind can be discharged. Guide grooves **241** guiding the detachment protrusions and anti-separation grooves **242** for preventing the detachment of the detachment protrusions **307** guided along the guide grooves **241** are formed in a recess part **240** to which the tip module is coupled on the handpiece side. Furthermore, the detachment protrusions **307** of the tip module are installed on the handpiece in such a manner that they are guided along the guide grooves **241** and coupled to the anti-separation grooves **242**. Meanwhile, the tip module may be configured to cool the needles **320** by the driving of the cooling unit **40**, but to seal the inside and outside of the handpiece in order to prevent an externally drained cooling wind from affecting a surface of the skin. In this case, the sealing means that a gap is formed between the handpiece and the tip module to the extent that a surface of the skin is not influenced by an externally drained cooling wind.

In this case, what the tip module is detachably positioned in the handpiece as in the present embodiment is an example. The tip module may be integrated with the handpiece.

Predeterminedally, the electrode **11** may be formed of a micro electrode **11** having a diameter of about 5 to 500 μm. The electrode **11** is made of a conductive material so that it can deliver RF energy. A portion that belongs to a surface of each electrode **11** and that excludes the front part is made of an insulating material **321** so that RF energy is not transferred to a tissue. Accordingly, part of the front part of each needle functions as the electrode **11**. RF energy is applied to the tissue through the front part. Accordingly, RF energy can be selectively transferred to a portion where the end of the electrode **11** is positioned during treatment.

The front S of the tip module may form a portion that neighbors or comes into contact with the skin of a patient during treatment. The plurality of through holes **302** through the plurality of electrodes **11** appears and disappears is formed in the front.

At least one hole **303** through which the output terminals **211** can pass is provided at the bottom of the tip module. When the driving unit **210** operates, the output terminals **211** pressurize a board **13** while linearly moving along the hole **303**. The back of the board **13** is seated in a support **304** within the tip module, and the front thereof is pressurized by an elastic member **330** positioned within the tip module. When the output terminals **211** moves and pressurizes the

board **13**, the board **13** advances while being separated from the support **304**, and the plurality of electrodes **11** is inserted into a skin tissue while being protruded toward the front of the through hole **302**. Furthermore, when the output terminals **211** retreat by the driving of the driving unit **210**, the board **13** retreats by restoring force of the elastic member **330** and the plurality of electrodes **11** also returns to the inside of the tip module. Although not separately shown, a separate guide member for guiding the path along which the board moves may be further provided.

Although not shown in the drawing predeterminedally, the circuit of the board **13** may be configured to be electrically connected to the RF generator of the main body when the tip module is positioned in the handpiece. Alternatively, the circuit of the board may be configured to be selectively electrically connected to the RF generator when the board is pressurized by the output terminals **211** (e.g., the electrode **11** is formed at the end of the output terminal and electrically connected to the board when the electrodes is pressurized).

In addition, the present invention may provide a treatment method using RF energy. In the skin treatment method using RF energy, the electrode is positioned in a tissue, the tissue is heated by applying RF energy, the RF energy applied to the tissue is measured, impedance of the tissue to which the RF energy is applied is calculated, a parameter into which the impedance has been incorporated is compared with a threshold, whether to cut off the RF energy is determined based on the threshold, and the skin is treated.

A voltage, a potential and power are measured from the RF energy applied to the tissue. The RMS of impedance of the tissue may be calculated based on the voltage, potential and power. While the RF energy is applied, the RF energy is periodically measured according to a sampling time, impedance is calculated, and control is performed using impedance calculated from the current to a predetermined time before.

In this case, a curer may perform treatment selectively using one of the ablation prevention mode and the coagulation mode as follows. In this case, in the two modes, RF energy may be applied based on the parameter described in the method of controlling the RF treatment apparatus.

In the ablation prevention mode, if impedance suddenly rises and a parameter value is a first threshold or more, RF energy is cut off before ablation of a tissue occurs based on a symptom that the ablation may occur, thereby preventing a temperature of the tissue from rising. Thereafter, a skin treatment method using RF energy by changing the position of an electrode may be repeatedly performed.

In the coagulation mode, RF energy is controlled so that the period during which a tissue is maintained to a treatment temperature can be extended. A temperature of the tissue is estimated and RF energy is controlled based on a parameter into which an impedance value has been incorporated. Accordingly, the tissue does not rise up to a temperature at which ablation occurs and is maintained to a temperature at which coagulation occurs, so the region in which coagulation occurs is increased.

The aforementioned RF treatment apparatus, method of controlling the RF treatment apparatus, and skin treatment method using RF energy according to the present invention can be used to control power of RF energy by deriving an impedance value of a tissue without measuring the temperature and impedance of the tissue when the RF energy is applied. Accordingly, rapid and accurate control can be performed. Furthermore, there are effects in that unnecessary damage to a tissue can be prevented, stability can be improved, and the recovering of a patient can be increased by cutting off RF energy before ablation of the tissue occurs based on a parameter. Furthermore, there is an effect in that a treatment effect can be maximized because a treatment volume is expanded by maintaining a tissue to a coagulation temperature for a long time.

The invention claimed is:

1. An RF treatment apparatus, comprising:
an RF generator generating RF energy;
an electrode applying the RF energy for a target tissue;
a sensor unit configured to sense the RF energy; and
a controller that is configured to:
control output of the RF generator,
receive a sensing value from the sensor unit,
calculate impedance of the target tissue,
determine when the target tissue that is denatured by the RF energy is in a coagulation phase, and determine that a transition from the coagulation phase to an ablation phase is occurring for a specific period after an initial period, and
cut off the RF energy before the tissue enters the ablation phase, wherein the controller determines whether the tissue transition is occurring based on a rate of change of impedance, and the rate of change of impedance is determined using a product or average of impedance values measured in three consecutive time periods.

2. The RF treatment apparatus of claim **1**, wherein:
the controller determines that the transition from the coagulation phase to the ablation phase is occurring when a parameter exceeds a threshold, and
wherein the parameter is based on the rate of change of impedance.

3. The RF treatment apparatus of claim **2**, wherein the parameter is defined as a product of a rising time in which impedance increases for the three consecutive time periods and the rate of change of impedance for the rising time.

4. The RF treatment apparatus of claim **2**, wherein the parameter is defined as a product of a specific time and an average of rate of change of impedance up to the specific time.

5. The RF treatment apparatus of claim **2**, wherein:
the sensor unit measures current, a voltage and power applied to the electrode, and
the controller calculates the rate of change of impedance as a root mean square (RMS) when calculating the impedance.

6. The RF treatment apparatus of claim **5**, wherein the controller controls an output voltage of the RF generator so that the power does not exceed a specific range.

7. The RF treatment apparatus of claim **2**, wherein the electrode comprises at least one of a contact type and an insertion type.

8. The RF treatment apparatus of claim **1**, wherein the controller is further configured to perform in a coagulation mode in which the controller is configured to determine that the transition from the coagulation phase to an ablation phase is occurring for a specific period after an initial period, and reduce the amount of RF energy applied by the electrode at a predetermined time to maintain the coagulation phase without entering the ablation phase.

9. A method of controlling an RF treatment apparatus, comprising steps of:
applying RF energy to a tissue through an electrode;
calculating impedance of the tissue for a plurality of time periods;
calculating a parameter based on a rate of change of impedance using impedance values or changes for at

least three consecutive time periods of the plurality of time periods during which RF energy is applied;

determining that a transition from a coagulation phase to an ablation phase is occurring after an initial period by comparing the parameter to a threshold; and

cutting off the RF energy when the parameter exceeds the threshold.

10. The method of claim **9**, wherein the parameter is defined as a product of a rising time from a current time to a specific time and the rate of change of impedance for the rising time.

11. The method of claim **9**, wherein the parameter is defined as a product of a rising time from a current time to a predetermined time before and an average of rate of change of impedance for the rising time.

12. The method of claim **9**, wherein the step of determining whether the parameter exceeds the threshold is performed after a specific time from a point of time at which the RF energy is applied.

13. The method of claim **9**, wherein the step of positioning the electrode in the tissue is performed by at least one of a contact and insertion of the electrode on and into the tissue.

14. A skin treatment method using RF energy, comprising steps of:

positioning an electrode in a tissue;

heating the tissue to a treatment temperature by applying RF energy to the electrode;

measuring the RF energy applied to the tissue for a plurality of time periods;

calculating a rate of change of impedance of the tissue to which the RF energy is applied using a product or average of impedance changes for at least three consecutive time periods of the plurality of time periods;

comparing a parameter based on the rate of change in the impedance of the tissue to a threshold;

determining that a transition from a coagulation phase to an ablation phase is occurring after an initial period when the parameter exceeds a threshold; and

cutting off the RF energy when the transition occurs in the tissue based on a result of the comparison between the parameter and the threshold in order to prevent ablation of the tissue.

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