

(19) World Intellectual Property Organization
International Bureau



A standard linear barcode is located at the bottom of the page, spanning most of the width. It is used for document tracking and identification.

**(43) International Publication Date
30 April 2009 (30.04.2009)**

PCT

(10) International Publication Number
WO 2009/053117 A2

(51) International Patent Classification:
A61B 18/12 (2006.01)

(81) **Designated States** (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(21) International Application Number: PCT/EP2008/055911

(84) **Designated States** (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

(22) International Filing Date: 14 May 2008 (14.05.2008)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

10 2007 051 097.9 24 October 2007 (24.10.2007) DE

(71) *Applicant (for all designated States except US): CELON AG MEDICAL INSTRUMENTS [DE/DE]; Rheinstrasse 8, 14513 Teltow (DE).*

(72) Inventor; and

(75) **Inventor/Applicant (for US only):** STRAUSS, Timo [DE/DE]; Damaschkestrasse 32, 10711 Berlin (DE).

(74) Agent: EISENFÜHR, SPEISER + PARTNER; Anna-Louisa-Karsch-Strasse 2, 10178 Berlin (DE).

Declaration under Rule 4.17

— *of inventorship (Rule 4.17(iv))*

Published:

- without international search report and to be republished upon receipt of that report

(54) Title: HF-SURGERY DEVICE AND METHOD FOR AN HF-SURGERY DEVICE

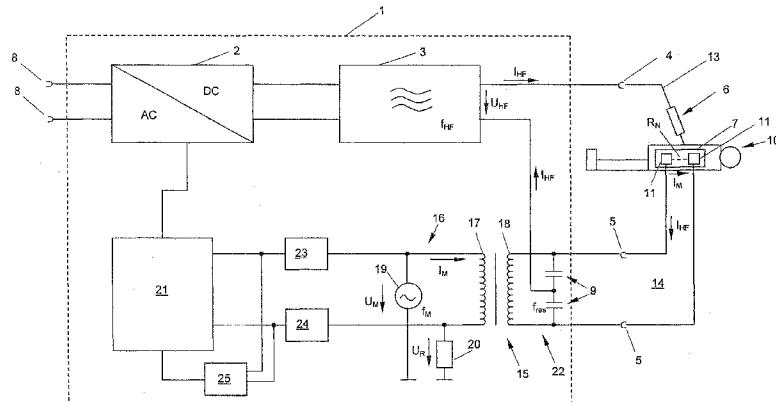


Fig. 1

WO 2009/053117

(57) Abstract: The invention concerns an HF-surgery device for cutting and/or coagulating biological tissue and a method for same, which in operation monitors the patient skin contact of a connected neutral electrode having at least two separate contact surfaces. The HF-surgery device includes at least one parallel resonant circuit arranged in a patient circuit, at least one measurement energy source arranged in a measurement circuit galvanically separated from the patient circuit for producing a measurement voltage/current acting between the contact surfaces of the neutral electrode, and at least one measuring and computing unit which in operation determines by means of the measurement voltage/current a tissue impedance which is representative of the patient skin contact and which acts between the contact surfaces. An HF-current flows in the patient circuit which is closed in the cutting or coagulation operation and the measurement voltage which is independent of the HF-current can be produced in the measurement circuit. To provide an improved HF-surgery device it is provided according to the invention that the frequency of the measurement voltage source is substantially equal to a resonance frequency of the parallel resonant circuit.

HF-surgery device and method for an HF-surgery device

The invention concerns an HF-surgery device for cutting and/or coagulating biological tissue, which in operation monitors the patient skin

5 contact of a connected neutral electrode having at least two separate contact surfaces. The HF-surgery device includes at least one parallel resonant circuit arranged in a patient circuit, at least one measurement energy source arranged in a measurement circuit galvanically separated from the patient circuit for producing a measurement voltage/current acting

10 between the contact surfaces of the neutral electrode, and at least one measuring and computing unit which in operation determines by means of the measurement voltage/current a tissue impedance which is representative of the patient skin contact and which acts between the contact surfaces. An HF-current flows in the patient circuit which is closed

15 in the cutting or coagulation operation and the measurement voltage which is independent of the HF-current can be produced in the measurement circuit.

The invention further concerns a method for an HF-surgery device for monitoring the skin contact of a neutral electrode which is electrically connected to the HF-surgery device and which has at least two separate contact surfaces. In the method a measurement voltage/current is produced in a measurement circuit, the measurement voltage/current is transferred from the measurement circuit into a galvanically separated patient circuit in which an HF-current flows in operation in the closed condition, the measurement voltage/current in the patient circuit is passed by way of a parallel resonant circuit and the tissue between the contact surfaces and the tissue impedance representative of the patient skin contact is determined by means of the measurement voltage/current.

HF-surgery devices and methods of the above-indicated kind are known from the state of the art. The high frequency (HF)-surgery devices are used for cutting and/or coagulating biological tissue. An active electrode is usually connected to the HF-surgery device. An active electrode has a small current transmission surface in order to achieve a high level of

current density. The active electrode is guided by the physician in the treatment and passes the HF-current into the body of the patient. In addition, one or more neutral electrodes connected to the patient are connected to the HF-surgery device for the return flow of the current.

5 Neutral electrodes are electrodes of relatively large surface area for application to the body of a patient. They serve to form a return flow path for the high frequency current at such a low current density in the body tissue that unwanted physical effects such as burns are avoided. The neutral electrode was intended to be reliably applied with its entire surface
10 area against the body of the patient. In addition care is to be taken to ensure that secure contact of the neutral electrode is ensured for the entire duration of the high frequency use.

Divided neutral electrodes have at least two contact surfaces which are electrically insulated from each other and which are applied to the skin
15 of the patient in mutually juxtaposed relationship and make electrical contact with the skin. Fitted to the patient, the tissue between the contact surfaces represents an electrical connection whose resistance changes with the size of the connecting area. Instead of a divided neutral electrode with separate contact surfaces it will be appreciated that it is also possible to
20 use two or more neutral electrodes.

Various devices are known which are intended to automatically monitor the skin contact of the neutral electrode and, in the event of inadequate contacting with the body of the patient, generate warning signals and/or switch off the high frequency application.

25 It is known for an auxiliary or measurement current to be passed by way of the contact surfaces of the divided neutral electrode and monitored. The measurement circuit into which the measurement current is fed is galvanically separated from the patient circuit in which the HF-current flows by way of the active and neutral electrodes during use. The skin contact of
30 the neutral electrode can be monitored by the tissue impedance between the two electrode portions being ascertained and observed. A measuring and computing unit of the HF-surgery device can implement continuous

checking of the neutral electrode and deliver suitable warning or switch-off signals.

Methods and apparatuses for contact monitoring of neutral electrodes are known for example from DE 32 49 766, DE 35 44 443 or EP 5 0 390 937.

DE 197 14 972 discloses an apparatus for contact monitoring of a neutral electrode comprising a resonant circuit that is activated by alternating voltage of varying frequencies and arrange of a resonant frequency and that provides a peak reading detector, which records a peak 10 reading of the alternating voltage occurring in the resonance frequency.

US 7,160,293 discloses a multiple radio-frequency return pad contact detection system that eliminates or minimizes interference or measurement interaction between a plurality of pad pairs by providing a different signal source frequency for each pad contact pair, but a frequency which matches 15 an associated series resonant network frequency.

DE 10 2004 025 613 discloses an apparatus that determines a transient impedance between two parts of a two part neutral electrode.

The known methods and circuit arrangements suffer from the disadvantage that the quality of skin contact monitoring can fluctuate. In 20 particular it has been found that, from impedances of higher than about 130 ohms, which can be caused for example by an increased proportion of fat in the tissue, detectability of an inadequately arranged neutral electrode deteriorates.

Therefore the object of the present invention is to provide an HF- 25 surgery device and a method for an HF-surgery device, which reliably monitors the skin contact of a connected neutral electrode even when high tissue impedances are involved.

In the HF-surgery device according to the invention that object is attained in that the frequency of the measurement voltage source is 30 substantially equal to a resonance frequency of the parallel resonant circuit.

The method according to the invention attains that object in that the frequency of the measurement voltage/current is set substantially to a resonance frequency of the parallel resonant circuit.

The invention has the advantage that the influence of the components in the parallel resonant circuit on the measurement current or the measurement voltage is minimised. The resistance of the parallel resonant circuit becomes at a maximum at its resonance frequency. In 5 operation, when the neutral electrode is connected to the HF-surgery device, the transition or tissue resistance between the contact surfaces of the neutral electrode and the parallel resonant circuit form a parallel circuit. In a parallel circuit, the reciprocal value of the total resistance is formed by the sum of the reciprocal values of the individual resistances. At maximum 10 resistance of the parallel resonant circuit therefore the influence of the components of the parallel resonant circuit on the measurement current tends towards zero or is negligibly low. It has been found that skin contact of the neutral electrode can be accurately detected by means of the invention even with tissue impedances of greater than 130 ohms.

15 The invention can be further developed by various advantageous configurations. Such configurations are described hereinafter.

Thus the HF-surgery device can have a transformer galvanically separating the measurement circuit from the patient circuit. At the same time the parallel resonant circuit can include a secondary side of the 20 transformer, that is associated with the patient circuit, and at least one anti-faradisation capacitor. More specifically anti-faradisation capacitors are provided for avoiding direct currents in the patient current, which are dangerous to the patient. This advantageous embodiment has the advantage that an influence of the anti-faradisation capacitors, which 25 causes disturbance in terms of measuring procedure, is minimised, and at the same time this affords a simple structure with few individual components.

According to the invention the tissue impedance can be determined at the transformer which separates the measurement circuit from the 30 patient circuit. In order to be able to easily calculate that impedance at the transformer side arranged in the measurement circuit, the HF-surgery device can have in the measurement circuit at least one measurement resistor connected in series with the transformer. The measuring and

computing device which is connected to the measurement circuit in regard to the signal aspect measures for example the voltage across the voltage source and the voltage at the measurement resistor. The impedance at the transformer representing the tissue impedance can be easily calculated
5 from the two voltage values and the known resistance of the measurement resistor.

In addition the HF-surgery device can include a phase angle measurement unit which measures a phase shift angle between the measurement current and the measurement voltage or between
10 proportional values of the measurement current and the measurement voltage. At the same time the measuring and computing unit can be adapted to determine the effective tissue resistance representative of the patient skin contact between the contact surfaces by means of the phase shift angle. Thus the effective tissue resistance which is more informative
15 can be calculated from the tissue impedance of the neutral electrode. The impedance comprises the real effective resistance and the imaginary reactive impedance. The reactive impedance is not significant regarding the risk of burning at the neutral electrode, but is increased for example due to the capacitive action of the neutral electrode bearing against the skin.
20 Therefore the tissue impedance is falsified by the reactive resistance, in relation to the patient skin contact to be determined. Values proportional to the measurement current and the measurement voltage are for example the voltage drop across the measurement current source and the voltage drop across a measurement resistor. That is advantageous because voltage
25 measurement is easier to implement than current measurement.

In order to eliminate disturbances in the measurement current or the measurement voltage due to the HF-current of the patient circuit, the HF-surgery device can have at least one filter unit for filtering the measurement current and/or the measurement voltage. The filter unit is
30 preferably arranged in the measurement circuit, upstream of the measurement and computing unit in relation to the signals involved. The filter unit limits the measurement signal to frequencies around the measurement current frequency, that is to say the resonance frequency of

the parallel resonant circuit. The filter unit thus acts in addition to the parallel resonant circuit which also already has a filtering action in the region of the resonance frequency.

5 The invention is described hereinafter with reference to the accompanying drawings by way of example. The different features can be combined as desired, like the above-described configurations.

In the drawings:

10 Figure 1 shows a simplified schematic block circuit diagram of an HF-surgery device according to the invention with connected active and neutral electrodes.

An HF-surgery device 1 for cutting and/or coagulating biological tissue has a mains unit 2, a frequency generator 3 and connecting contacts 4, 5 for an active electrode 6 and a neutral electrode 7.

15 The mains unit 2 can be connected to a mains voltage source (not shown) by way of mains contacts 8. The frequency generator 3 is coupled at its input side to the mains unit 2. At the output side the frequency generator 3 is connected on the one hand to the connecting contact 4 for the active electrode 6 and on the other hand to the connecting contacts 5 for the neutral electrode 7. A respective anti-faradisation capacitor 9 is 20 arranged between the frequency generator 3 and the two connecting contacts 5 for the divided neutral electrode 7.

25 As shown in Figure 1, connected to the connecting contact 4 is an active electrode 6, for example a cutting or coagulation electrode. The neutral electrode 7 is applied to the skin of the patient 10 in known manner. The neutral electrode 7 is in the form of a divided neutral electrode 7 and has two contact surfaces 11 which are electrically separated from each other and which are each in electrical contact with the skin of the patient. The contact surfaces 11 are therefore connected together only by way of the electrically conductive tissue of the patient 10.

30 In operation of the HF-surgery device 1 the alternating current which is fed in by way of the mains contacts 8 is converted into a direct current which then flows to the frequency generator 3. The direct current is converted by the frequency generator 3 into a high-frequency alternating

current I_{HF} which is usual for high-frequency surgery, at a frequency f_{HF} of about 300 to 450 kHz.

The frequency generator 3 is part of a patient circuit 12 in which the HF-current I_{HF} flows in an active path 13 from the frequency generator 3 to the active electrode 6. The active path 13 is the part, disposed upstream of the patient 10 in Figure 1, of the patient circuit 12 which extends from the frequency generator 3 to the active electrode 6. Upstream of the active electrode 6 the HF-current I_{HF} flows by way of the patient 10 to the contact surfaces 11 of the neutral electrode 7. When passing into or passing from the active electrode 6 to the biological tissue of the patient 10 the HF-current produces the desired surgical effect such as cutting and/or coagulation.

A passive path 14 of the patient circuit 12 extends from the neutral electrode 7 to the frequency generator 3 and is downstream of the patient in Figure 1. In operation the HF-current I_{HF} flows in the passive path 14 from the contact surfaces 11 of the neutral electrode 7 back to the frequency generator 3 by way of one of the two anti-faradisation capacitors 9. The anti-faradisation capacitors 9 minimise direct currents and currents of low frequency, which are dangerous to the patient, and are for example of a size of about 50 to 100 nF.

Defective or inadequate application and thus inadequate electrical contact of the neutral electrode 7 against the patient 10 can lead to burns at the contact surfaces. A transition resistance or tissue resistance R_N between the contact surfaces 11 of the neutral electrode 7 is representative of the contact between the neutral electrode 7 and the skin of the patient. For determining the tissue resistance R_N , a measurement voltage U_M or a measurement current I_M , acting between the contact surfaces 11, is fed into the passive path 14 of the patient circuit 12. The smaller the contact between the contact surfaces 11 and the skin, the lower the tissue resistance R_N also is. In that respect the measurement current I_M flows from the one contact surface 11 by way of the tissue of the patient 10 to the other contact surface 11.

A measurement voltage source 19 for generating the measurement current I_M is arranged in a measurement circuit 16. In order to galvanically separate the measurement circuit 16 from the patient circuit 12, a transformer 15 is provided in the HF-surgery device 1. Thus, the 5 measurement voltage source 19 is arranged at an intermediate circuit level which is decoupled from the patient. The transformer 15 has a primary side 17 arranged in the measurement circuit 16 and a secondary side 18 arranged in the patient circuit 12. In the embodiment in Figure 1 the number of turns on the primary and secondary sides 17, 18 is the same. In 10 addition, a series-connected measurement resistor 20 is provided in the measurement circuit 16, beside the transformer 15 and the measurement voltage source 19.

The inductance of the secondary side 18 of the transformer 15 forms a parallel resonant circuit 22 together with the capacitance of the two anti- 15 faradisation capacitors 9 which are connected in parallel. In that case the anti-faradisation capacitors 9 are arranged in parallel with the tissue resistance R_N of the neutral electrode 7.

The HF-surgery device 1 also has a measuring and computing unit 21 which is connected to the measurement circuit 16 in respect of the signals involved. In the case of the HF-surgery device in Figure 1 the measuring 20 and computing unit 21 takes off signals at two locations, between the measurement energy source 19 and the primary side 17 as well as between the primary side 17 and the measurement resistor 20. The measuring and computing unit 21 is additionally coupled in respect of the signals involved 25 to the mains unit 2. Two band pass filters 23, 24 are disposed between the measuring and computing unit 21 and the measurement circuit 16. A phase angle measurement unit 25 for measuring the phase shift angle between the above-mentioned signals is also connected in respect of the signals involved to the measuring and computing unit 21.

30 In operation of the HF-surgery device 1 the measurement voltage source 19 produces the measurement current I_M at a measurement frequency F_M , independently of the HF-current in the patient circuit 12. The measurement frequency f_M of the measurement voltage source 19 is so set

that it is substantially equal to a resonance frequency f_{res} of the parallel resonant circuit 22.

The resonance frequency f_{res} in the parallel resonant circuit 22 is determined by the magnitudes of its inductance and capacitance. As is 5 known the following applies:

$$f_{res} = \frac{1}{2\pi\sqrt{LC}},$$

wherein L is the magnitude of the inductance and C that of the capacitance.

In the HF-surgery device 1 shown by way of example in Figure 1 the measurement frequency f_M and the resonance frequency f_{res} are for 10 example about 75 kHz. In the ideal case, in the steady-state condition, the impedance of the parallel resonant circuit 22 is infinitely large at the resonance frequency f_{res} . In practice the impedance is at least negligibly large. The parallel resonant circuit 22 is connected in parallel with the tissue resistance R_N of the neutral electrode 7. As the reciprocal value of 15 the total impedance of a parallel circuit is determined by the sum of the reciprocal values of the individual impedances, the reciprocal value of the impedance of the parallel resonant circuit 22 becomes very low and as a result is of no significance. Consequently the joint impedance of the tissue resistor R_N , the parallel resonant circuit 22 and the lines therebetween is 20 substantially equal to the tissue resistance R_N .

The action of the transformer 15 provides that that joint impedance is transferred from the secondary side 18 to the primary side 17. It follows therefrom that the complex resistance – the impedance – at the primary side 17 of the transformer 15 substantially corresponds to the tissue resistance R_N representative of the skin contact. The impedance at the primary side 17 can be determined as described hereinafter.

To determine the impedance at the primary side 17 of the transformer 15 the measuring and computing unit 21 measures both the voltage drop U_M at the measurement voltage source 19 and also the 30 voltage drop U_R at the measurement resistor 20. For that purpose the measuring and computing unit 21 takes off the voltage U_M between the

voltage source 19 and the primary side 17. A second voltage U_R is taken off between the primary side 17 and the measurement resistor 20.

As the measurement current I_M oscillates with the resonance frequency f_{res} of the parallel resonant circuit 22 the parallel resonant circuit 5 22 has an advantageous filtering action on the measurement current and measurement voltage. In order to avoid permanent disturbances in the measurement current and the measurement voltage due to the HF-current I_{HF} the signals which are taken off by the measuring and computing unit 21 are additionally filtered. The two band pass filters 23, 24 are provided for 10 that purpose.

The measuring and computing unit 21 can calculate the impedance at the primary side 17, that corresponds to the tissue impedance, from the measured voltages U_M and U_R .

As is known, impedance, that is to say apparent resistance, is 15 composed of the reactance and effective resistance. The risk of burning to the patient at the neutral electrode 7 is represented in particular by the effective resistance and less by the reactance. The reactance in contrast is increased by the capacitive action of the contact surfaces 11 of the neutral electrode 7 on the skin of the patient 10. An advantage of the HF-surgery 20 device 1 shown in Figure 1 lies in evaluation of the effective tissue resistance which more reliably reflects the skin contact than only the tissue impedance.

The HF-surgery device shown in Figure 1 and in particular the measuring and computing unit 21 calculates the effective resistance by 25 means of the phase shift angle between the voltages U_M and U_R measured in the measurement circuit 16. The phase shift angle is determined by the phase angle measurement unit 25 and passed to the measuring and computing unit 21. The phase angle measurement unit 25 is connected in respect of the signals involved to the output of the two band pass filters 23, 30 24 to take off the filtered voltages U_M and U_R .

If the tissue impedance or effective tissue resistance ascertained by the measuring and computing unit 21 exceeds a predetermined limit value the measuring and computing unit 21 can send a switching signal to the

mains unit 2. The switching signal can switch off the mains unit 2 and/or the frequency generator 3 or reduce the power output thereof. Thus no or only very little HF-current can flow in the patient circuit 12 and possible burns at the neutral electrode 7 are prevented. Additionally or alternatively 5 the ascertained tissue impedance representative of patient skin contact, or effective resistance, can trigger an operational and/or warning signal, depending on whether the value in question exceeds or falls below the limit value. The operational and warning signal can be for example signal lamps or acoustic signals actuated by the measuring and computing unit 21.

CLAIMS

1. An HF-surgery device for cutting and/or coagulating biological tissue, which in operation monitors the patient skin contact of a connected neutral electrode having at least two separate contact surfaces, including at least one parallel resonant circuit arranged in a patient circuit, at least one measurement energy source arranged in a measurement circuit galvanically separated from the patient circuit for producing a measurement voltage/current acting between the contact surfaces of the neutral electrode, and at least one measuring and computing unit which in operation determines by means of the measurement voltage/current a tissue impedance which is representative of the patient skin contact and which acts between the contact surfaces, wherein an HF-current flows in the patient circuit which is closed in the cutting or coagulation operation and the measurement voltage which is independent of the HF-current can be produced in the measurement circuit, characterised in that the frequency of the measurement voltage source is substantially equal to a resonance frequency of the parallel resonant circuit.
2. An HF-surgery device according to claim 1 characterised in that the HF-surgery device has a transformer galvanically separating the measurement circuit from the patient circuit and the parallel resonant circuit includes a secondary side of the transformer, that is associated with the patient circuit, and at least one anti-faradisation capacitor.
3. An HF-surgery device according to claim 1 or claim 2 characterised in that the HF-surgery device has in the measurement circuit at least one measurement resistor connected in series with the transformer.
4. An HF-surgery device according to one of the preceding claims characterised in that the HF-surgery device includes a phase angle measurement unit which measures a phase shift angle between the measurement current and the measurement voltage or between values

proportional to the measurement current and the measurement voltage and the measuring and calculating unit is adapted to determine the effective resistance representative of the patient skin contact between the contact surfaces by means of the phase shift angle.

5. An HF-surgery device according to one of the preceding claims characterised in that the HF-surgery device has at least one filter unit for filtering the measurement current and/or the measurement voltage.

6. An method for an HF-surgery device for monitoring the skin contact of a neutral electrode which is electrically connected to the HF-surgery device and which has at least two separate contact surfaces, in which a measurement voltage/current is produced in a measurement circuit, the measurement voltage/current is transferred from the measurement circuit into a galvanically separated patient circuit in which an HF-current flows in operation in the closed condition, the measurement voltage/current in the patient circuit is passed by way of a parallel resonant circuit and the tissue between the contact surfaces and the tissue impedance representative of the patient skin contact is determined by means of the measurement voltage/current, characterised in that the frequency of the measurement voltage/current is set substantially to a resonance frequency of the parallel resonant circuit.

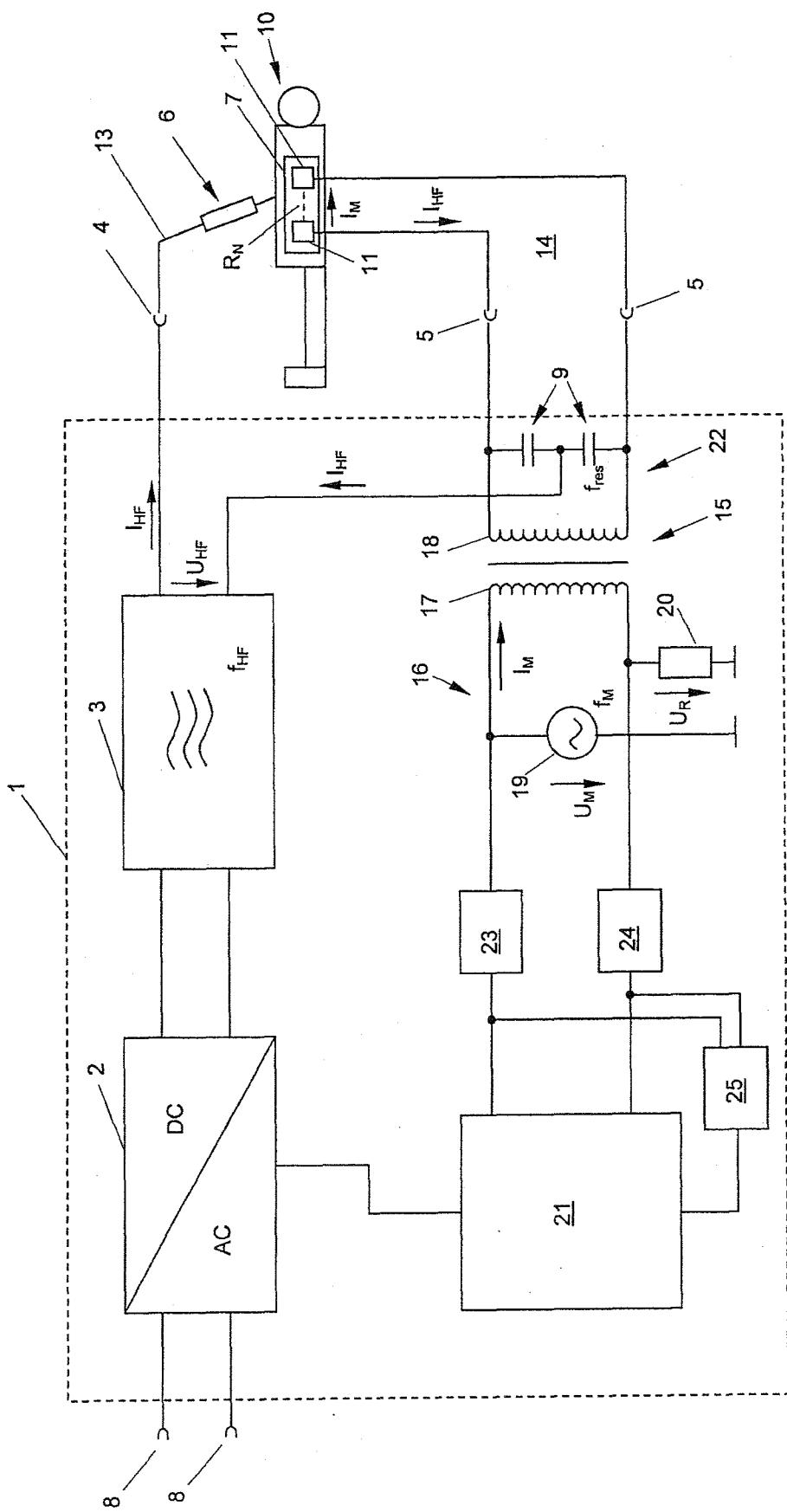
7. A method according to claim 6 characterised in that a total voltage across a measurement energy source and a partial voltage across a series-connected measurement resistor are measured to determine the tissue impedance in the measurement circuit.

8. A method according to claim 7 characterised in that the total voltage and/or the partial voltage are filtered prior to the measurement operation.

9. A method according to one of claims 6 to 8 characterised in that a phase shift angle between the measurement current and the measurement voltage or between proportional values to the measurement current and the measurement voltage is determined.

10. A method according to claim 6, claim 7 or claim 8 and claim 9 characterised in that an effective resistance of the tissue between the contact surfaces, representative of the patient skin contact of the neutral electrode, is determined from the impedance and the phase shift angle.

11. A method according to claim 10 characterised in that, in dependence on the value of the effective resistance, an operational signal or a warning signal is delivered and/or the patient circuit of the HF-surgery device is interrupted.



३८