

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
28 August 2008 (28.08.2008)

PCT

(10) International Publication Number
WO 2008/102154 A2

- (51) International Patent Classification:
A61B 18/12 (2006.01) A61N 1/08 (2006.01)
- (21) International Application Number:
PCT/GB2008/000614
- (22) International Filing Date:
22 February 2008 (22.02.2008)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
0703417.6 22 February 2007 (22.02.2007) GB
- (71) Applicant (for all designated States except US): **ECSH-MANN HOLDINGS LIMITED** [GB/GB]; Peter Road, Lancing, West Sussex BN15 8TJ (GB).

- (74) Agent: **WILSON, Alan, S.**; Barker Brettell LLP, 138 Hagley Road, Edgbaston, Birmingham B16 9PW (GB).
- (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.
- (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).

- (72) Inventors; and
- (75) Inventors/Applicants (for US only): **GONON, Bertrand, Jean, Louis** [FR/FR]; 25 Route Neuve, F-69360 Ternay (FR). **ROGANTI, Luca** [IT/IT]; Via Aldo Moro 16, I-63021 Amandola (IT).

Published:
— without international search report and to be republished upon receipt of that report

(54) Title: ELECTROSURGICAL SYSTEMS

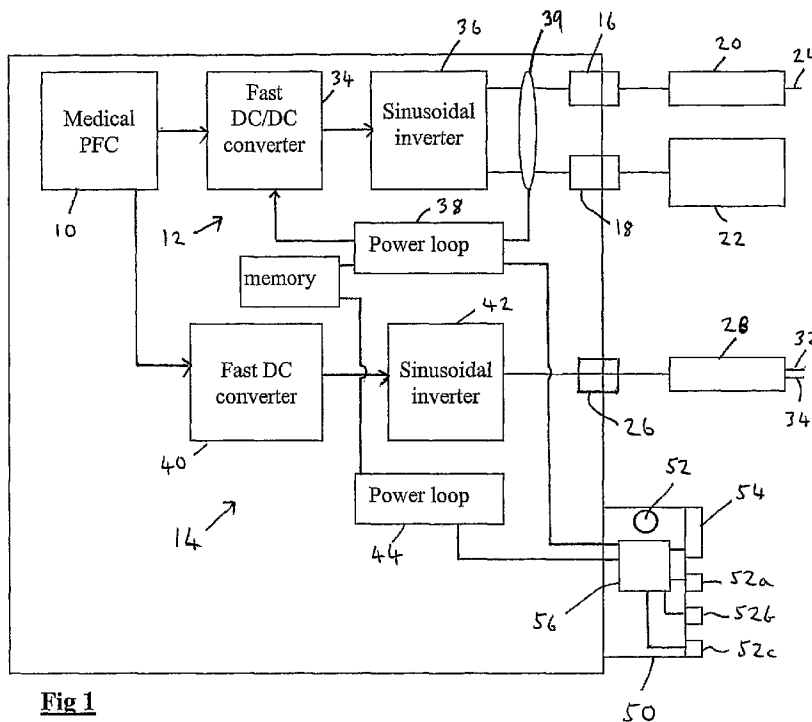


Fig 1

(57) Abstract: An electrosurgical system comprises outputs (16, 18, 26) for connection to respective electrodes (24, 22, 32, 34) and control means arranged to apply an alternating voltage between the outputs (16, 18, 26). The control means includes frequency control means arranged to vary the frequency of the alternating voltage.

WO 2008/102154 A2

ELECTROSURGICAL SYSTEMS

The present invention relates to electrosurgical systems, and in particular
5 to the control of the levels of power and energy generated in such
systems.

Electrosurgical systems generally comprise a hand piece or probe, with
one active electrode arranged to generate electric currents in the tissue to
10 be surgically operated upon and at least one electrode to collect the
current. In a bipolar system the probe has two electrodes arranged close
together to generate a local electric current in a region of tissue to be
surgically operated upon. In a monopolar system the probe has the one
active electrode which is used in conjunction with a separate electrode
15 pad remote from the region surgically operated upon, and these generate
electric currents which are concentrated locally to the active electrode.

Conventionally an oscillating AC voltage is applied to the electrodes, and
the voltage can be controlled to some degree, usually by manual inputs, to
20 control the amount of power that is produced. The amount of power
needed and the manner in which it is delivered depends on the type of
surgical operation on which the system is being used.

When dissecting tissue, the electrosurgery unit typically delivers power in
25 a continuous sine wave at relatively low voltage. The amount of power
needed depends in part on the impedance of the tissue actually being
dissected.

In contrast to dissection, when used for coagulation, an electrosurgery
30 unit typically delivers a pulse wave at high voltage.

During the same operation, the surgeon is likely to operate on tissues of significantly different impedance. Changes in impedance, with a constant voltage applied, will result in changes in the level of surgically effective power delivered to the tissue. Therefore, unless the level of power that is delivered by the electrosurgery unit is changed (either manually or automatically) in response to such changes in tissue impedance, there is a risk of causing damage to the patient by inadvertently delivering too much power, or conversely not achieving the surgical effect because of the application of too little power.

10

Accordingly, in some cases the surgeon needs an electrosurgery unit that offers a reliable means of measuring tissue impedance at the operating site, either before or during an operation, or both.

15 Some embodiments of the present invention offer advantages in this respect. First, it may measure tissue impedance through more than one separate source signal. In some cases, both source signals must identify the same level of impedance before the unit will operate. This is inherently more reliable (and therefore likely to be safer) than a measurement taken from a single source signal, because there is no means of verifying that such single source signal is accurate.

20

Second, in some embodiments, the present invention measures tissue impedance before the surgeon commences an operation by measuring the signal from at least one source through which only very low or negligible power, and no surgically effective power, is applied and at the same time, or subsequently, or previously, measuring the signal from a source through which a low level of power is applied. Since only a low level of power is applied, there can be very little risk to the patient in such measurement. Once the measurements have been taken, the electrosurgery unit may automatically give a warning (or not proceed to

25
30

operate at all, or not at full power) if the operating mode selected is not appropriate for the impedance measured. Thus the patient is protected from the risk of too much power being applied.

5 Third, during the course of a surgical operation, each time the electrosurgery unit is operated, for a fraction of a second prior to applying full power, the tissue impedance may be measured by reference to at least one signal source delivered at very low power, for example from a low current power source, and at least one signal source delivered
10 at low power, for example from a main surgical power source at less than full operating power. Again, the unit may issue a warning (or not proceed to operate at all or not at full power) if the measurements of each signal source do not agree one with another, and/or if the power setting, together with the measured impedance, are not appropriate and might
15 result in unwanted tissue damage. This can ensure both that impedance is reliably measured and that the operating mode selected is appropriate for the tissue on which the surgeon is operating at that time.

In some embodiments, during the course of a surgical operation, while
20 the electrosurgery unit is operated, the unit will continue to measure tissue impedance several hundred times per second. This may be using just the signal at full operating power, or may be by means of at least one signal delivered at low power from a separate source, and at least one signal delivered at the full operating power from the main surgical power
25 source, or one of the surgical power sources if the system has more than one. In this way, reliable tissue impedance measurement and protection of the patient from excessive power is continuous throughout the operation regardless of the differing impedance of the various types of tissue on which the surgeon operates.

30

It is a further advantage of some embodiments of the present invention

that the measurement of tissue impedance by means of at least two source signals enables the electrosurgery unit to determine whether there is a fault in the system and/or whether the patient is only partially or not at all connected to the patient return plate and patient return circuit, or whether
5 the patient is touching an alternative return path that might lead to burning the patient.

Electrosurgery units are designed so that either manually or automatically it is possible to adjust current, voltage or power. It is an advantage of
10 some embodiments of the present invention that in addition to these parameters it is also possible, manually or automatically, to adjust the frequency of the signal. This offers considerable clinical advantages in that, by matching the frequency to the tissue type, the impedance can be controlled so that the minimum amount of power is delivered to the
15 patient to accomplish the operation that the surgeon requires. This in turn minimises any damage to tissue adjacent to the operation site. In some embodiments, this can allow the unit to adjust or control the power delivered to the subject automatically as surgery is in progress, by adjusting the frequency and optionally one or more other parameters as
20 well, such as the power of the power source or other parameters of the voltage. This can enable the surgically effective power to be limited to a desired level (which may be variable) so as to prevent damage to the subject, but may also enable the power to be kept at a sufficient level to ensure that a desired surgical result is achieved. Control of the frequency
25 can allow the power delivered to the tissue, i.e. the surgically effective power, to be controlled in response to changes in the nature of the subject, for example tissue type, at the site of operation. This can allow the surgically effective power to be maintained at a desired or predetermined level during changes of tissue type, or tissue impedance.
30 The desired or predetermined level may be constant, or may vary either in a predetermined way over time or in a predetermined way in response

to one or more other changing parameters.

Thus the present invention provides in one aspect an electrosurgical system comprising at least one output for connection to an electrode and
5 control means arranged to apply an alternating voltage to the output, wherein the control means includes frequency control means arranged to vary the frequency of the alternating voltage. The control means may be arranged to vary the frequency before and/or during use of the system.

10 The control means may be arranged to receive at least one input and to control the frequency of the alternating voltage in response to the at least one input. The input may be generated by a user interface or user input so that a user can control the frequency, or it may be generated by a sensing means which may, for example, be arranged to monitor or measure the
15 value of one or more parameters and produce the input in response. For example the parameter may be the impedance of the tissue.

The control means may be arranged to define a target value for a controlled parameter of the system and the control means may be
20 arranged to control the frequency so that the controlled parameter approaches the target. For example the controlled parameter may be the power delivered, for example to tissue being operated on. The target value may be set automatically by the system, or manually by an operator of the system.

25

The present invention further provides an electrosurgical system for surgical operation on a subject, the system comprising outputs for connection to respective electrodes and control means arranged to apply an alternating voltage between the outputs, wherein the control means is
30 arranged to monitor the impedance of the subject either before or during an operation, and to provide an indicator indicative of the impedance.

Such impedance measurement may be carried out with negligible power, with low or minimal power, or with high power. The control means may be arranged to monitor the impedance of the subject by monitoring an impedance between the outputs. This can enable the system to monitor the impedance of the part of the subject that is being operated on. In a bipolar system the measured impedance is clearly dependent on the nature of the part of the subject being operated on. In a monopolar system, changes in measured impedance are also generally largely related to changes in the nature of the part of the subject being operated on or contacted by the probe.

The indicator may be, for example, a signal of a level or format which indicates the impedance, or it may be a value, for example calculated by software, that is stored in memory.

The control means may be arranged to control a parameter of the alternating voltage in response to the signal. The system may further comprise a display means arranged to produce a display that varies with the signal.

Preferred embodiments of the present invention will now be described by way of example only with reference to the accompanying drawings in which:

Figure 1 is a schematic diagram of an electrosurgery unit according to an embodiment of the present invention;

Figure 2 is a diagram of the unit of **Figure 1** in use;

Figures 3 to 5 are examples of voltage waveforms that can be used in the unit of **Figure 1**;

Figure 6 is a graph of heating power of a known unit as a function of tissue impedance;

5 **Figure 7** shows the impedance of various tissue types;

Figure 8 is a diagram showing how the depth of heating by the unit of **Figure 1** depends on waveform frequency;

10 **Figure 9** is a schematic diagram of an electrosurgery unit according to a second embodiment of the invention;

Figure 10 is a diagram of part of the unit of **Figure 9**;

15 **Figure 11** is a diagram of the unit of **Figure 9** in a different operating mode; and

Figure 12 is a diagram of part of the electrical circuit in the unit of **Figure 9**.

20

Referring to **Figure 1** an electrosurgical unit (ESU) according to a first embodiment of the present invention comprises a DC power supply 10, which includes medical power factor correction (PFC), providing power to a monopolar AC power supply 12 and a bipolar AC power supply 14.

25 The monopolar power supply 12 controls the voltages applied to two output connectors 16, 18 to which a monopolar probe 20 and an electrode pad 22 respectively are connected. This enables it to control the voltages of the electrode 24 of the monopolar probe 20 and the electrode pad 22. The bipolar power supply 14 controls the voltages applied to two
30 terminals in a bipolar connector 26 to which a bipolar probe 28 is connected. This enables it to control the voltages of the two electrodes

30, 32 of the bipolar probe 28.

The monopolar power supply 12 comprises a DC/DC converter 34 and a sinusoidal inverter 36 which are arranged to control, in a continuously variable manner, the amplitude and frequency respectively of the AC voltage applied across the monopolar probe 20 and the electrode pad 22. In this case, the frequency is variable from 300kHz to 1MHz, but other values can be used.

10 The unit also includes a power control loop 38 which is arranged to measure, using appropriate sensors 39, the voltage at, and current through, the active electrode and pad of the monopolar circuit by sampling those parameters at a sampling frequency, in this case 1.0 to 1.4 kHz, but other values can be used. From these measurements it is arranged to determine the instantaneous impedance of the tissue between the two electrodes 22, 24, and to control the voltage and current output of the DC/DC converter 34 and the frequency of the inverter 36 in response. The power control loop 38 is also arranged to determine the heating power of the probe from these measurements, and also to determine whether the pad 22 is well connected to the patient, and whether the patient is well isolated from earth, as will be described in more detail below.

25 The bipolar power supply 14 also comprises a DC/DC converter 40 and a sinusoidal inverter 42 which are arranged to control, in a continuously variable manner, the amplitude and frequency respectively of the AC voltage applied across the electrodes of the bipolar probe 28. It also includes a power control loop 44 which is arranged to measure the voltage at and current through each of the electrodes 30 32 in the bipolar circuit by sampling those parameters. From these measurements it is arranged to determine the instantaneous impedance of the tissue between

the two electrodes 30, 32, the heating power of the bipolar probe 28, and to control the voltage output of the DC/DC converter 40 and the frequency of the inverter 42.

5 The ESU further comprises a user interface 50 which includes a user input 52. In this example the user input is in the form of a rotary knob which can be rotated to any of a number of positions. This allows manual selection of any of a number of operating modes for the system, and further inputs 52a, 52b, 52c that can be used to select the desired voltage,
10 power output and frequency of the AC supply. While these parameters cannot all be controlled independently of each other, each of them can be selected in at least some modes of operation of the system as will be described in more detail below. The ESU further comprises a display 54 which is arranged to display graphically information relating to a number
15 of operating parameters of the system, and in particular the supply frequency, the heating power, and the measured impedance of the tissue, as will be described in more detail below. The user interface 50 includes an interface processor 56 which controls the display 54 and sends signals to the power control loops 38, 44 identifying the mode that the power
20 control loops 38, 44 are to operate in. The interface processor 56 also receives from the power control loops 38, 44 signals indicating the measured values of the operating parameters that are to be displayed on the display 54.

25 Referring to Figure 2, when the monopolar probe 20 is being used the pad electrode 22 is placed in contact with the patient 60, typically by being placed under the patient, and the electrode 24 of the probe 20 is placed in contact with the tissue to be operated on. Electric current flows through the patient between the electrodes 22, 24, with by far the highest current
30 density, and therefore power density, in the region close to the point of contact with the probe electrode 24. The monopolar power supply 12

controls the frequency and amplitude of the AC voltage applied between the electrodes 22, 24, which controls the level of heating of the tissue in the region close to the point of contact of the probe electrode 24.

- 5 The heating effect of the probe is determined by a number of factors, as is well known. The heating power W is governed by the basic law

$$W = I^2 (Z + R) \quad (1)$$

10 where I is the current flowing between the electrodes, Z is the impedance of the tissue through which the current is flowing, and R is resistance in the rest of the circuit and is a constant. Because the power dissipated in the tissue, and hence the heating of the tissue, is dependent on the impedance of the tissue and therefore on the type of tissue, if the voltage
15 and frequency of the power supply is kept constant the temperature to which the tissue is heated will vary depending on the type of tissue. The variation of power with tissue impedance for a typical system operating at constant frequency is shown in Figure 6.

20 For each of the probes 20, 26 the voltage can be set to a number of predetermined waveforms. Referring to Figure 3, a first waveform used for cutting comprises a continuous sine-wave AC voltage. Referring to Figure 4, a second waveform used for coagulation comprises a series of pulses, each comprising a single sine-wave, separated by periods of zero
25 voltage. The pulse spacing, i.e. the length of the zero voltage periods can be used to control the heating power of the current. This gives a further parameter, in addition to the frequency and amplitude of the sinusoidal AC waveform, for controlling the heating power of the probe. Referring to Figure 5, a blend waveform can be used in which periods of sine-wave
30 voltage are alternated with periods of zero voltage, and the relative lengths of the sine-wave and zero voltage periods determine the heating

power. For example a 40% blend where the AC pulses take up 40% of the time provide less heating than a 60% blend where the AC pulses take up 60% of the time. Each of these waveforms can be selected, and the amplitude, frequency, pulse spacing and blend ratio set by the operator via the user interface. However, more complex waveforms can also be set up by the operator. Specifically waveforms that vary in a predetermined way with time can be programmed into the power control loop via the user interface. The frequency and amplitude of the voltage waveforms, as well as the pulse spacing and blend ratio, or any one or more of those parameters, can be programmed to vary in a specific way with time to produce a waveform specifically suited to a particular operation. These waveforms can be stored in memory and later selected for use. For example to perform a 'cut and coagulate' operation the waveform may be designed which produces a period of high power for cutting followed by a period of lower power for coagulation.

Alternatively, rather than being fixed, time-dependent, or purely time-dependent, one or more of the frequency, amplitude, pulse spacing and blend ratio of the waveform can be arranged to vary in a predetermined way in response to changes in one or more other parameters, which may be measured parameters such as the instantaneous measured impedance of the part of the subject being tested or operated on. This can be used, for example, to control the power applied to the tissue, for example to maintain a constant power, and therefore a constant level of heating, as the nature of the tissue in contact with the electrodes changes. Alternatively it can be used to provide an applied power that varies in a predetermined way with time to provide a desired operational sequence.

Referring to Figure 7, the impedance between the electrodes 22, 24 of the monopolar probe can vary very significantly, in some cases by a factor of ten, from low impedance tissues such as muscle and kidney to

the highest impedance tissues such as fat, scar tissues and adhesions. This can obviously greatly affect the temperatures to which the different tissues will be heated by the same applied voltage.

- 5 The effects on the tissue vary critically with temperature. From 40°C to 48°C reversible cell damage results. From 49°C to 70°C irreversible cell damage, or denaturation, results. From 70°C to 100°C coagulation, when collagen in the cells is converted to gelatin, occurs. From 100°C to 200°C desiccation, in which the gelatin becomes sticky, occurs. At
10 temperatures above 200°C carbonization occurs.

Therefore it will be appreciated that the impedance of the tissue is a significant factor in controlling the amount of heating produced by the probe, and therefore in controlling the surgery that is being performed.

15

Another factor which is taken into account by the system of Figure 1, is that the impedance, as well as being a function of the tissue that is in contact with the probe 20, is also a function of the frequency of the AC voltage applied to it. The exact nature of this dependence does not follow
20 a simple pattern, but it can be measured for various tissue types, and the information obtained recorded as a frequency profile for different tissues. These profiles can then be used to control the heating power of the probe by varying the frequency of the AC power supply. The voltage of the power supply can also be used to control the heating power.

25

Referring to Figure 8, the frequency of the AC power supply also affects the depth, from the point of contact of the probe electrode 24, to which the tissue is heated by the probe. Generally, the higher the frequency, the shallower will be the volume of tissue in which the heating is
30 concentrated. For example, with a frequency of 1MHz, the heating will be concentrated within a shallow region 100, with a frequency of 500kHz,

the heating will be spread through a larger and deeper region 102, and with a frequency of 300kHz the heating will be concentrated through a still larger and deeper region 104. Therefore the variable frequency supply of the unit of Figure 1 allows the depth and volume of the treated area to be controlled.

It will be appreciated that, provided the frequency and at least one other parameter affecting power can be controlled independently, the frequency can be selected to control the depth of heating required, and then the other parameter, e.g. Voltage amplitude, blend ratio or pulse spacing, selected to control the heating power. This allows the heating depth and heating power to be controlled independently of each other.

When the bipolar probe 28 is used, the factors affecting the system are very similar to when the monopolar probe 20 is being used. The impedance values are significantly lower, as the electrodes 30, 32 are much closer together, but vary in a similar manner with the type of tissue.

The ESU can be operated in a number of different modes that use different degrees of automation of control of the operating parameters. These will be described for the monopolar probe 20, but can be used equally with the bipolar probe 28. In a simple manual mode, the operator sets the voltage and frequency of the power supply manually using the user inputs 52a, 52c. The power loop 38 monitors the voltage and current and determines the instantaneous impedance of the tissue being operated on, and displays the impedance, for example graphically or numerically, on the display 54. This allows the operator to adjust either one or both of the voltage and frequency to compensate for changes in the impedance, and obtain the degree of heating required. In order to allow the operator to control the inputs before applying a significant current to the tissue,

the system can be arranged to generate a low current between the electrodes 22, 24 during a calibration period to enable the operator to determine the tissue impedance before setting the voltage and frequency to a suitable level for performing the operation. Alternatively the display
5 can be arranged to indicate the level of heating power, as determined by the power control loop, and the frequency and voltage amplitude controlled manually to control the heating power to the desired level.

In a power control mode, the power loop 38 is arranged to monitor the
10 instantaneous heating power, as determined from the measured current and voltage, and control the frequency as well as the voltage of the power supply to maintain the heating power at a constant target level, as selected by the operator by means of the user input 52b. In a modification to this the voltage can be maintained at a constant level, and the frequency alone
15 used to maintain the power at a desired level. Normally the desired power will be constant over time, but in some cases it is desired to vary the power over time. In this case one or more power profiles, defining values of delivered power as a function of time over a period of time, can be stored and selected, and used to control the power in a predetermined
20 time-varying manner.

The display of impedance can also be used to monitor the progress of an operation, such as the sealing of an artery. This operation requires coagulation of the blood in the artery, and the voltage and frequency can
25 be set to appropriate levels to achieve this. Then as the heating is applied to the appropriate location, the impedance, as indicated on the display 54 is monitored. As the impedance varies with the degree of coagulation of the tissue being operated on, the point at which the sealing is completed can be determined from the way in which the impedance varies with time.
30 This allows the operator to stop heating the artery at the correct time and thereby prevents both over-heating of the tissue, and premature stopping

the operation before sealing is complete.

Similarly, in an automated version of this process, the power control loop 38 is arranged to monitor the instantaneous impedance as the operation, such as the sealing of an artery, progresses. When it detects that the impedance reaches a predetermined level, the operation is deemed to be completed and the power to the probe is cut off. The selection of the cut-off value for the impedance can be set directly by the operator via the user input, or selected from a number of predetermined values each of which is identified by a tissue type or type of operation, or a combination of the two, which can be selected by the operator via the user input, for example from a menu. In a modification to this version, the power or other parameters of the applied voltage, can be varied either in a predetermined pattern, or in response to measured impedance, as the surgical process progresses towards its end where power is cut off.

In a further mode the power loop 38 is arranged to control a total amount of energy applied to the tissue. In order to do this it is arranged to monitor the power and also includes a clock so that it can measure time. From the power and the time the total amount of energy delivered can be monitored. Then, for example, the power loop 38 can be arranged to cut off the power or change the power to a different level, or to change any parameter of the applied voltage, once a predetermined amount of energy has been delivered.

The unit can also operate in a record mode in which parameters are monitored and recorded over time as it is being used. This results in a record stored in memory of those parameters and how they varied during a particular operation. For example, in the artery sealing operation referred to above, the impedance can be recorded throughout the operation and stored, for example as a sequence of time-stamped values

of impedance, and this will provide a record of the operation, which can be used to check that an operation was performed correctly, or to analyse the effect that various parameters have on the operation. Clearly other parameters, such as the waveform frequency, amplitude, blending ratio
5 and pulse spacing, and the power can also be stored in the same way to provide a more complete record of the operation. The recorded data can then subsequently be retrieved from memory and printed out or displayed on the screen 54 for review.

10 Referring to Figure 9, in a second embodiment of the invention an electrosurgery unit also includes bipolar and monopolar power outputs controlled by a safety monitoring system 102, which provides all of the functionality of the first embodiment described above, as well as further features which will be described here. Only the monopolar power output
15 is shown for simplicity. The ESU comprises a high frequency AC power generator 104 with active and return outputs 106, 108, and also further comprises an active terminal 116 connection to the active probe electrode 124 and two return terminals 118 for connection to two separate parts of a split pad electrode 122. The split pad electrode 122 allows the two parts
20 of the pad to be connected to different parts of the patient. These two parts 122a, 122b are shown in more detail in Figure 10. The safety monitoring system comprises a low voltage AC power source 110 and a pair of control switches 112, 114. The control switches can be switched between a first state, which is an operational state in which the system
25 can be used for surgery, and a test state. In the operational state the control switches connect the HF supply outputs 106, 108 directly to the output terminals 116 118. In the test state, the switches connect the lower voltage power source 110 between the output terminals 116, 118. This allows a low test voltage to be applied between the output terminals 116,
30 118 to allow the impedance between the electrodes 122, 124 to be checked. The safety monitoring system (SMS) 102 also comprises a

further switch 120 between the low voltage supply 110 and the second control switch 114 which can be switched to disconnect one of the outputs of the low voltage supply 110 from the output terminal 118 and connect it to earth so that the lower voltage supply 110 is connected between the active output terminal 116 and earth. This allows the SMS 102 to check the insulation between the patient and earth. The ESU further includes sensors 130 arranged to sense the voltage V2 and current A3 at the active electrode 124 and sensors 132 arranged to measure the voltage V1 at the pad electrode 122 and the current A1, A2 through each pad 122a, 122b of the split pad electrode 122.

The SMS 102 further includes a user interface which is similar to that of the first embodiment but is not shown in Figure 9, which includes user inputs and a display.

15

In this embodiment the ESU operates in a number of different modes. These modes can generally equally be used in systems with other arrangements of electrodes. The first of these is an impedance test mode which is entered on power up and used before any significant power is supplied to the electrodes 122, 124. In the impedance test mode the user interface outputs a prompt to the surgeon to touch the subject with the active electrode 124 at, or as close as possible to, the point on the subject where the operation is to be carried out. The SMS 102 then connects the low voltage supply 110 to the electrodes 122, 124, with the current clamped to a fixed value, and monitors the voltage at each of the electrodes 122, 124. From the fixed current value and the measured voltage drop across the load, the SMS 102 derives a measure of the impedance of the tissue being touched. The current from the low voltage supply may be, for example, of the order of a few micro-Amps which will have no significant heating effect on the subject. If the measured impedance is within a predetermined safe range, then this is indicated by

the SMS 102 via the user interface to the surgeon to indicate that he can proceed. If it is not within the predetermined range, then this is indicated to the surgeon, and optionally the SMS 102 may be arranged to prevent connection of the main power supply to the electrodes 122, 124 until a
5 successful test is carried out. Provided it determines that this first impedance test is passed, the SMS 102 switches to an earth connection test mode by switching the switch 120 to connect the power supply 110 between the active electrode 124 and earth, and monitoring the current A3 in the active electrode 124. If this is above a predetermined threshold this
10 indicates that the patient is not sufficiently insulated from earth and a warning is generated by the SMS 102 at the user interface. If the current is below the threshold then an indication is given at the user interface that it is safe to proceed. The SMS 102 then proceeds to a surgery mode, in which the surgeon can request operational power at the electrodes.

15

In the surgery mode, the SMS 102 waits for a request for power from the surgeon, input via the user interface. On receipt of the request for power, the SMS 102 first reverts to the test configuration for a brief period, in this case 30ms. In this period the tissue impedance and earth connection
20 are again tested using the low voltage power supply 110. Provided the impedance and the current to earth are within predetermined ranges, the SMS operates the control switches 112 114 to connect the main power supply 104 to the electrodes 122, 124. This full power arrangement is shown in Figure 11. Before applying the full power requested by the surgeon, the SMS 102 controls the main power supply 104 to produce a
25 signal at a level significantly below full power, for example at 30% of full power, for a further short period of, in this case, 35ms. This power level and time are chosen so that even if the impedance is very different from what is expected, not enough heating energy will be applied to the
30 subject to produce any significant heating effect. The SMS 102 again measures the impedance and compares this measured impedance with that

measured in the impedance test mode. If there is sufficient agreement between these two measurements, then this suggests that the measurements are reliable, and the SMS 102 controls the main power supply 104 to provide the full requested power. If there is significant
5 disagreement between the two measurements, then this indicates that the measurements are not reliable. This may be because of a fault in the system, of a result of current leakage which becomes more significant at higher currents. In this case the SMS 102 is arranged either to prevent any further application of power until a subsequent test provides reliable
10 measurements, or to limit the power which can be provided to a level, which may be significantly below the full requested power.

When the full requested power is applied, the SMS 102 again measures the impedance. The measurement can be made in a similar time period, of
15 the order of 30ms. If this measurement agrees with both of the previous measurements, then this further confirms that the impedance measurement is reliable, and the surgery proceeds with the power applied as requested. If at any stage in this initial procedure there is disagreement between any two of the three impedance measurements, then a warning signal can be
20 generated by the SMS to warn the surgeon, and the power supplies turned off to prevent the continued generation of power.

In the full power mode the power is controlled according to the requirements set by the surgeon using the user interface, together with
25 any additional control provided by the SMS as required by the particular mode of operation. During full power operation the SMS is arranged to monitor the voltage and current at each of the electrodes and electrode parts 124, 122a, 122b. From these it can continuously monitor the impedance, at a sampling rate of, for example, 400 times a second,
30 enabling it to control the power as described above. In the split pad electrode system specifically shown, the SMS 102 is also arranged to

continuously compare the currents A1, A2 through the two parts 122a, 122b of the pad electrode 122. If these differ by more than a predetermined amount, or if the difference between them is outside a predetermined initial range, this indicates that one of them has lost proper
5 contact with the patient, and the SMS is arranged to issue a warning via the user interface and/or switch off the power supply.

Referring to Figure 12, the SMS 102 is also arranged to monitor RF leakage during operation of this system. To do this it is arranged to
10 monitor the current or voltage V2 at the active electrode 124 and the current or voltage V1 at the pad electrode or plate 122. The difference in voltage would be expected to have a certain value depending on the impedance, which is measured as described above. If RF leakage is occurring, then the voltage at the pad electrode 122 will be lower than
15 expected. Therefore the difference between the expected pad voltage, based on the known impedance, and the measured pad voltage, is monitored and if it exceeds a predetermined limit this is taken as an indication that leakage is occurring and a warning is generated at the user interface.

20

Also referring to Figure 12, the SMS 102 includes a current sensor 140 in the inlet earth connection, which enables the SMS to measure the current flowing to earth via the ESU. The SMS 102 is arranged to measure this earth current with the main power on and with the main power off. If the
25 difference between these exceeds a predetermined limit this indicates that a leakage to earth due to the power supply is occurring, and this is indicated to the surgeon by issuing a warning via the user interface.

The SMS 102 may be arranged to perform other checks. For example
30 prior to entering the impedance test mode, the SMS may switch a fixed resistance across each of the power supplies 104, 110 and measure the

current produced thereby to calibrate the power supplies 104, 110.

CLAIMS

1. An electrosurgical system comprising outputs for connection to respective electrodes and control means arranged to apply an alternating
5 voltage between the outputs, wherein the control means includes frequency control means arranged to vary the frequency of the alternating voltage.
2. A system according to claim 1 wherein the control means is
10 arranged to vary the frequency to the appropriate setting prior to a surgical operation.
3. A system according to claim 1 wherein the control means is arranged to vary the frequency during a surgical operation.
15
4. A system according to any foregoing claim , wherein the control means is arranged to receive at least one input and control the frequency of the alternating voltage in response to the at least one input.
- 20 5. A system according to claim 4 wherein the control means is arranged to define a target value for a controlled parameter of the system and the control means is arranged to control the frequency so that the controlled parameter approaches the target.
- 25 6. A system according to claim 5 wherein the control means is arranged also to control at least one controlling parameter of the voltage thereby to control the controlled parameter.
- 30 7. A system according to claim 6 wherein the controlling parameter is an amplitude, pulse spacing, or blending ratio.

8. A system according to any of claims 5 to 7 wherein the target value of the controlled parameter is arranged to vary with time.
9. A system according to any of claims 5 to 8 wherein the controlled
5 parameter is power.
10. A system according to any of claims 5 to 8 wherein the controlled parameter is heating depth.
- 10 11. A system according to any foregoing claim wherein the control means is arranged to monitor a measured parameter and to control the frequency of the alternating voltage in response to changes in the measured parameter.
- 15 12. A system according to claim 10 wherein the measured parameter is a parameter of the subject.
13. A system according to claim 11 or claim 12 comprising a further electrode wherein the measured parameter is the impedance in the
20 electrical path between the electrodes.
14. A system according to any foregoing claim wherein the frequency control means is arranged to control the frequency so that it varies in a predetermined way over time.
- 25
15. An electrosurgical system for surgical operation on a subject, the system comprising outputs for connection to respective electrodes and control means arranged to apply an alternating voltage between the outputs, wherein the control means is arranged to monitor the impedance
30 of the subject and to provide an impedance indicator indicative of the impedance.

16. A system according to claim 15, the system comprising two power supplies, wherein the control means is arranged to connect each of the power supplies to the electrodes and, for each power supply, to monitor
5 the impedance of the subject and to provide an impedance indicator indicative of the impedance.

17. A system according to claim 16 wherein one of the power supplies is a main power supply arranged to supply power for performing surgery,
10 and one of the power supplies is a test power supply.

18. A system according to claim 16 or claim 17 wherein one of the power supplies is arranged to generate power at higher voltages than the other.
15

19. A system according to claim 15, wherein the control means is arranged to apply alternating voltages of two different amplitudes between the outputs and, for each voltage amplitude, to monitor the impedance of the subject and to provide an impedance indicator indicative of the
20 impedance.

20. A system according to claims 18 or claim 19 wherein the control means is arranged to apply the higher voltage only if the impedance measured with the lower voltage is within a predetermined range.
25

21. A system according to any of claims 18 to 20 wherein the control means is arranged to apply a full power surgery voltage only if the impedances measured with the higher and lower voltages meet
30 predetermined conditions.

22. A system according to claim 18 wherein the control means is arranged to limit the current generated by the lower voltage supply.
23. A system according to any of claims 15 to 22 wherein the control
5 means is arranged to connect a power supply between one of the outputs and earth and to measure the current produced thereby to check for current leakage between the subject and earth.
24. A system according to claim 23 wherein the control means is
10 arranged to measure leakage using a first voltage, and to apply the second higher voltage only if the measured current leakage is within a predetermined range.
25. A system according to claim 21 wherein the control means is
15 arranged to measure the impedance during application of the full power surgery voltage.
26. A system according to any of claims 15 to 25 wherein the control
20 means is arranged to output a warning signal and/or to prevent operation of the electrosurgery unit, or limit the systems power, if the measured impedance is outside a predetermined range.
27. A system according to any of claims 15 to 26 wherein the outputs
25 include two plate outputs for connection to respective parts of a split plate electrode, and the control means is arranged to monitor the difference between the currents through the two plate outputs, and to generate a warning indicator if the difference exceeds a predetermined limit.
28. A system according to any of claims 15 to 27 wherein the control
30 means is arranged to control a parameter of the alternating voltage in response to the impedance indicator or indicators.

29. A system according to claim 28 wherein the parameter is a frequency, an amplitude, a pulse spacing or a blending ratio of the alternating voltage.

5

30. An electrosurgical system in which means is provided of measuring the impedance of a subject prior to commencing a surgical operation by means of measurements from at least two signal sources prior to commencing an operation with at least one source able to operate at negligible power and at least one source able to operate at low or minimal power.

10

31. An electrosurgical system in which means is provided of measuring the impedance of a subject during a surgical operation by means of measurements from at least two signal sources during an operation with at least one source capable of operating at low power and at least one source capable of operating at high power.

15

32. A system as in claims 30 or 31 above, in which the electrosurgical system issues a warning if there is a difference between the said impedance measurements made with different power settings.

20

33. A system as in 30 or 32 above, in which the electrosurgical system automatically reduces or switches off power or varies frequency of voltage in order to prevent inappropriate levels of power being applied to a patient.

25

34. A system according to any of claims 3 to 14 wherein the control means is arranged to vary the frequency to maintain the surgically effective power at a predetermined level during changes in the nature of the subject.

30

35. A system according to claim 34 wherein the control means is further arranged to vary the power of the power source providing the voltage to maintain the predetermined level of surgically effective power.
- 5 36. A method of operating on a subject comprising providing a system according to any foregoing claim, connecting respective electrodes to the outputs, apply an alternating voltage between the outputs, and varying the frequency of the alternating voltage.
- 10 37. A method of operating on a subject comprising providing a system according to any of claims 15 to 35, connecting respective electrodes to the outputs, apply an alternating voltage between the outputs, monitoring the impedance of the subject and providing an impedance indicator indicative of the impedance.
- 15 38. An electrosurgical system substantially as hereinbefore described with reference to any one or more of the accompanying drawings.

Fig 1

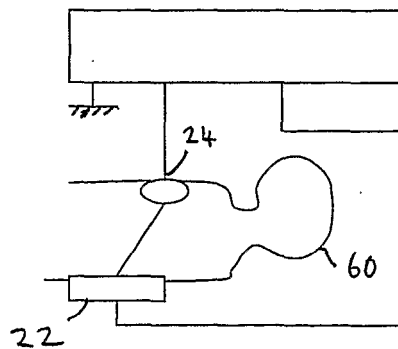
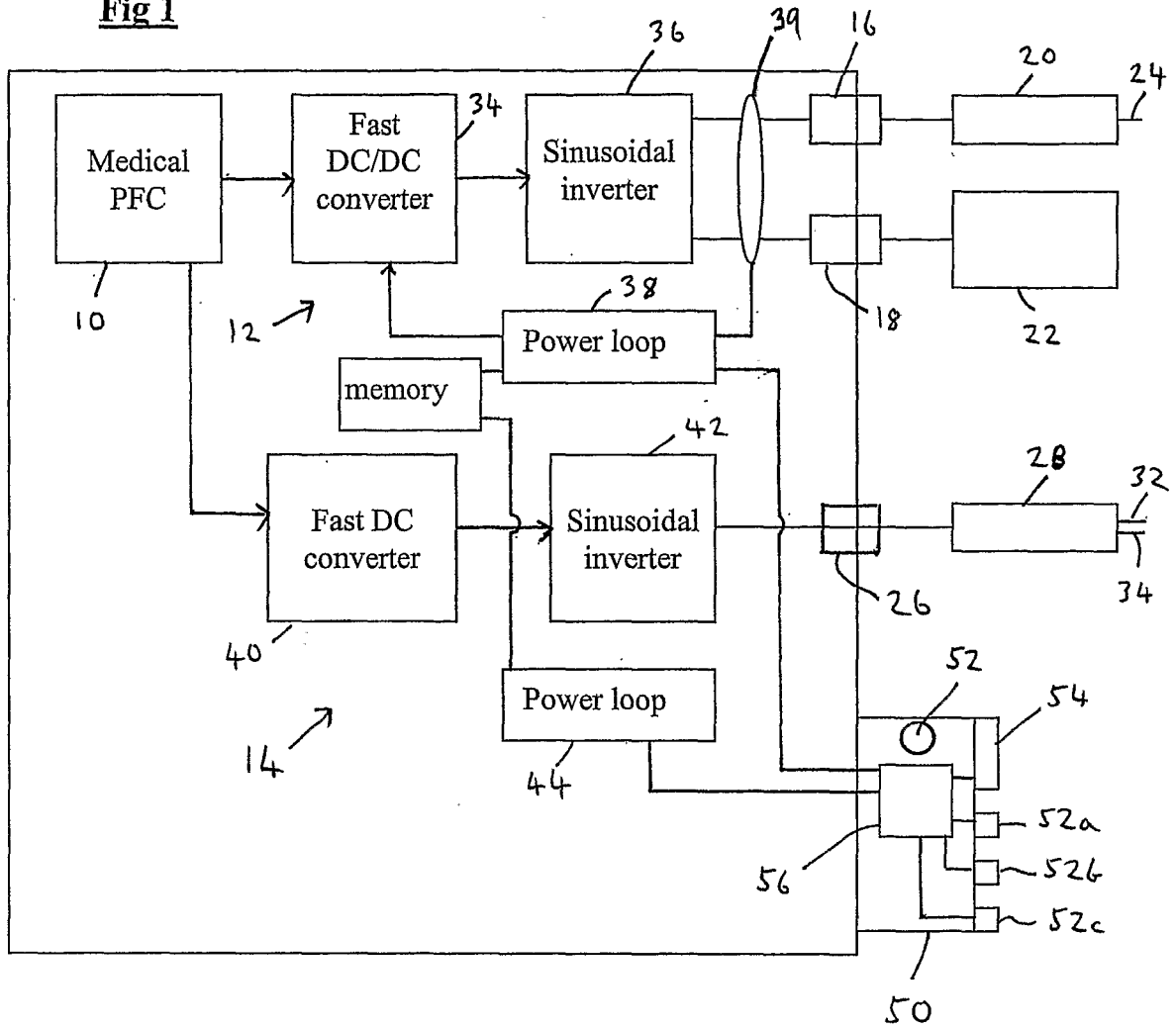


Fig 2

Fig 3

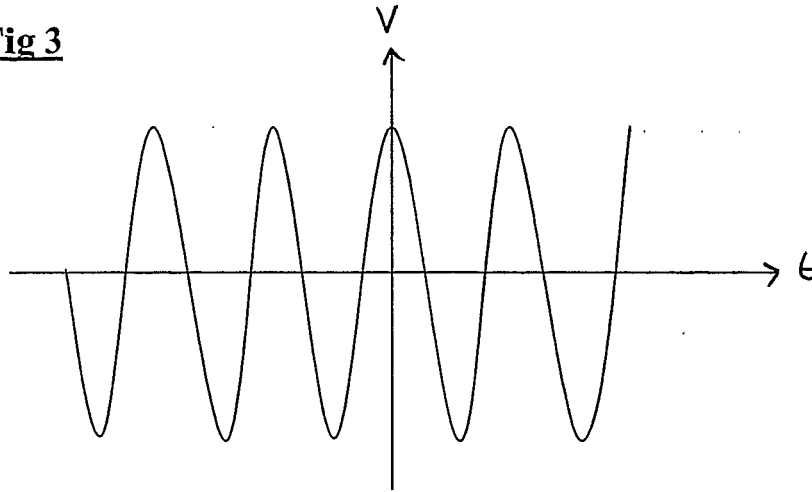


Fig 4

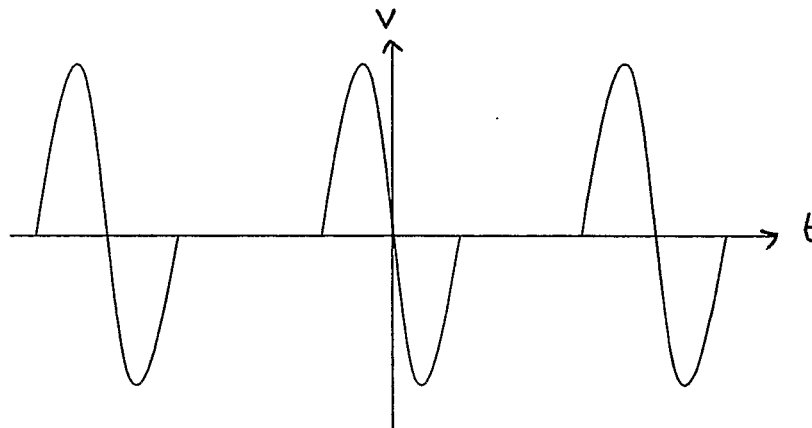
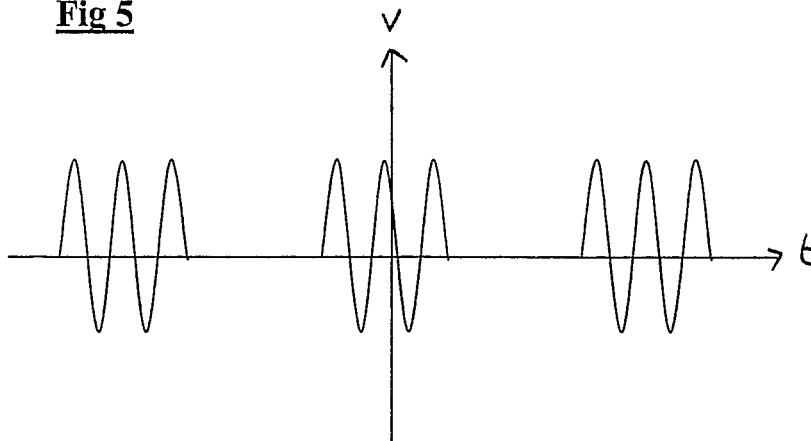


Fig 5



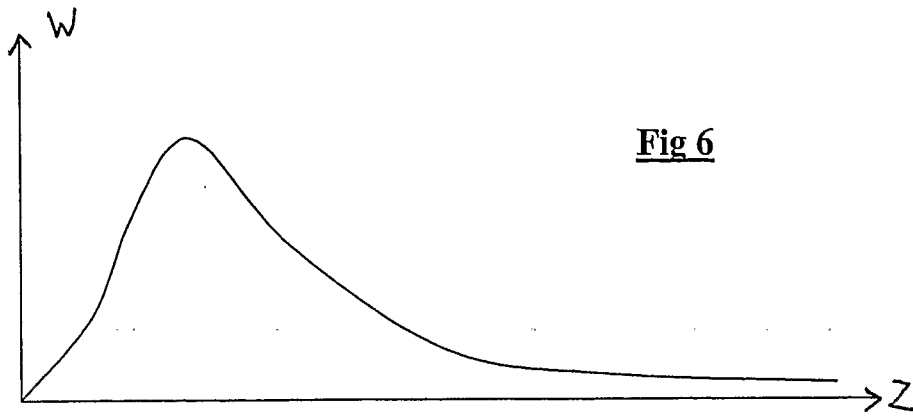


Fig 6

Fig 7

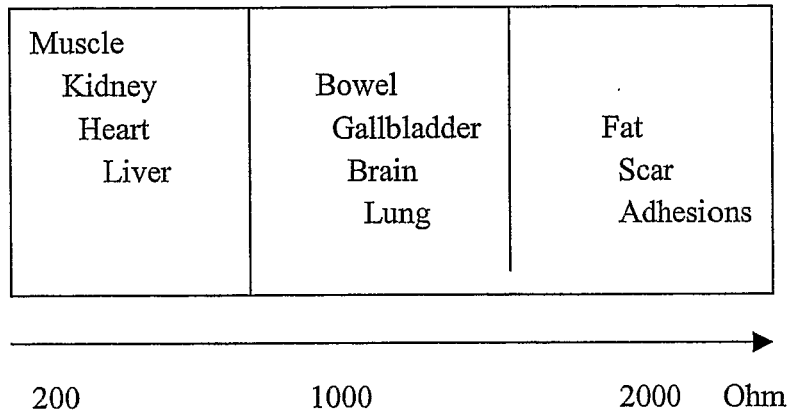


Fig 8

