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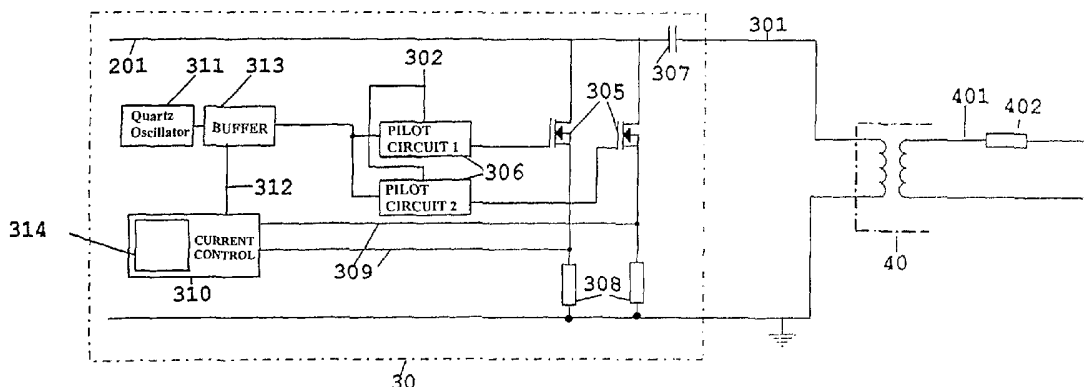
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(54) Title: ELECTRONIC SCALPEL TO CUT ORGANIC TISSUES



(57) Abstract: The invention relates a method of regulating the power available at the manipulator of an electronic scalpel to make said manipulator adapted to carry out the cutting operation of an organic tissue, said electronic scalpel being of the kind comprising: at least a rectifying circuit of the mains voltage supplying a rectified and direct voltage to at least a radio frequency circuit adapted to emit an output of a current signal at a substantially constant frequency feeding said manipulator through a radio frequency transformer, said radio frequency circuit comprising at least an electronic switch controlled by a circuit provided with an oscillator, wherein said method consists in applying to the manipulator a wave form having such a power that the energy due to the wave form of the resonance frequency and the harmonics transferred to the manipulator is substantially equal to the sum of the energies required to break the bonds of the molecules of the tissue to be cut. The invention relates also to the electronic scalpel carrying out said method.

ELECTRONIC SCALPEL TO CUT ORGANIC TISSUES.

The present invention relates to an electronic scalpel to cut organic tissues, adapted for surgical applications.

More particularly, as it will be better pointed out hereinafter, the invention
5 relates to an electronic scalpel adapted to transfer to the manipulator an electric power and therefore energy adapted to break the bonds of the molecules forming the organic tissue to be cut, without raising sensibly the temperature of the adjacent tissues.

European patent EP 1087691 discloses an electronic scalpel operating at a
10 frequency of 4 MHz which is particularly adapted to avoid necrotic effects on the cells adjacent to the area to be cut.

The wave form available at the manipulator according to the disclosure of said patent, has no harmonics, as this wave signal derives from a radio frequency circuit closed on a resonant load essentially consisting of the eddy capacity of
15 one or more MOSFETs and the inductance of the radio frequency transformer. Tests effected on cuts made with such a kind of electronic scalpel still highlighted the presence of some necrotic cells around the cut due to cell heating.

Additional studies carried out highlighted that the cells undergoing the cutting
20 operation, are not subject to necrotic degenerations when the energy transferred to break the molecular bond of these cells is substantially equal to the energy holding together said molecular bond.

As a matter of fact whenever energy is transferred to a cellular tissue, this causes the tissue molecules to vibrate and the increase of kinetic energy is
25 transformed into a temperature increase of said tissue.

When temperature of the cells goes around 50°C or over, the cells necrotize and die.

Therefore it is extremely important to operate in such a way that the electronic scalpel carries out the cutting operation without producing heat in the
30 surrounding tissue.

As pointed out above, the phenomenon of temperature increase does not occur when and only when the energy transferred to the tissue molecules is equal to the molecule bonding energy.

Indeed in this case the delivered energy is not used to increase the molecule
35 kinetic energy, but only to break the bond joining the molecules to each other.

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On the other hand the molecules forming a kind of organic tissue on which the surgical cut should be effected are not all of the same nature and therefore some of them, even in a lower quantity, are characterized by having a bonding energy different from the molecules of the main tissue.

5 The main object of the invention is to propose a method of regulating a device transmitting the wave form to the manipulator of the electronic scalpel, and to provide such an electronic scalpel that transfers to the tissue an energy generally equally to the bonding energy of the different molecules of the tissue. Consequently the purpose is to obtain that the molecules of the tissue
10 undergoing the cutting operation are not subject to such a heating to compromise the functionality of the cells close to the cutting point.

Another object is to restrict as much as possible the bleeding phenomena connected with the tissue cutting operation.

A further object is to reduce as much as possible the oedematous tissue and
15 the possibility of cheloid formation and post operative troubles.

The foregoing objects and others that will be better highlighted hereinafter, are attained by the electronic scalpel of the invention that according to the contents of the main claim is of the kind comprising:

- a manipulator to cut organic tissues;
- 20 - a rectifying circuit fed by the mains voltage to feed rectified and direct voltage to a radio frequency circuit;
- a radio frequency circuit comprising at least an electronic switch fed by said rectified and direct voltage and controlled by a pilot circuit emitting a generally square current wave of predetermined amplitude and frequency;
- 25 - at least an electrode in contact with the body having organic tissues to be cut, wherein said scalpel is characterized in that said circuit is a wide pass-band resonant circuit adapted to transfer to the manipulator a sinusoidal voltage distorted by the presence of a plurality of harmonics.

The invention concerns also the method of regulating the power available at
30 the manipulator of an electronic scalpel of the above mentioned kind, characterized by applying to said manipulator a wave form having such a power that the energy due to the wave form of the resonant frequency and the harmonics transferred to the manipulator, is equal to the sum of the energies required to break the bonds of the molecules forming the tissue to be cut.

35 Advantageously according to the invention the presence at the manipulator of

a plurality of harmonics belonging at least to the second and the third order even if dampened, allows to supply energy of a different quantity and quality in addition to the energy of the fundamental wave so that to the various kinds of molecules of the tissue to be cut, a different energy is supplied which is equal
5 to the bonding energy for each type of molecule.

It is clear that in this way, by supplying to each molecule its own bonding energy, the bond joining the molecules to each other is broken without causing molecule degradation due to heating and therefore avoiding that the tissue cells undergo a considerable heating.

10 As a matter of fact the cell temperature remains under 50°C so that their functionality is kept unaltered.

The advantage arising from this absolute limitation of the molecular and therefore cellular heating involves a number of very interesting and unexpected benefits.

15 Indeed use of the electronic scalpel according to the invention, in addition to avoid necrosis of the cells adjacent to the cut, attains a very quick recovery, a tissue resuturation without problems, a patient's pain surprisingly under the normal pain threshold, a reduced bleeding and a dramatic reduction of all the post operative troubles.

20 Moreover no stimulation was observed when operations were effected close to nerves or nerve endings.

With this method of supplying only the bond energy of the tissue molecules to the cutting area and therefore to the tissue to be cut, it was observed that it is possible to obtain very quick biopsies of high quality because the taken
25 samples are not damaged and consequently the analysis carried out are totally reliable.

The temperature of the tissue involved in the action carried out by the electronic scalpel of the present invention was always kept below 50°C which is recognized to be the limit temperature under which the cells do not
30 necrotize.

Further characteristics and features of the invention will be better highlighted in the following description of a particular embodiment of the invention given as an illustrative but not limiting example and shown in the accompanying sheets of drawings in which:

35 - Fig. 1 is block diagram of the electronic scalpel of the invention;

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- Fig. 2 is a detailed illustration of the radio frequency circuit of the electronic scalpel of Fig. 1; and
- Fig. 3 shows the wave form of the power available at the manipulator of the electronic scalpel referred to the various frequencies.

5 With references now to the figures of the drawings and more particularly to Fig. 1, one can see that the circuit of the electronic scalpel is fed by the mains voltage and is provided with an input filter **10** as a protection against the possible radio frequency noise existing on the mains or that could enter the mains from the electronic scalpel.

10 The circuit is also provided with a transformer indicated with **11**, whose input is a voltage **101** for instance of 230 V, and having a voltage output **102** reduced to about 140 or 160 V.

This voltage enters the rectifying circuit **20** which is a normal rectifying diode circuit with double half wave transforming the alternated current into a
15 pulsating rectified current which is then filtered so that at the output there is a rather high direct voltage **201** for instance of 220 V, constituting the feed of the radio frequency circuit **30**.

According to an executive embodiment of the invention, instead of the transformer **11** and the rectifying circuit with filter **20** a stabilized switching
20 AC/DC converter can be used, or a transformer coupled with a rectifying circuit with filter having a stabilized switching DC/DC converter in output.

In any case, the voltage **201** outgoing from these rectifying circuits should be direct and stabilized, with a prefixed value preferably comprised for instance between 50 V and 200 V, where the chosen voltage value depends on the
25 utilization of the operating equipment.

Alternatively, for the same intended use of the equipment, the voltage can be different for different functions.

For instance, the feeding voltage can come from two feeders with two different voltage values for the scalpel bipolar function, or its single-polar function
30 present on the same equipment.

This radio frequency circuit is better shown in Fig. 2.

The circuit in this example uses two electronic switches MOSFET.

However, if an electronic scalpel requires higher cutting powers, it is possible to use three or more MOSFET components.

35 Each MOSFET **305** is controlled by a pilot circuit **306** fed by the voltage **302**

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supplied by a direct voltage stabilized power supply of know type not shown in the drawings, in which it is possible to regulate the output voltage, which can be also of switching type, to obtain a better efficiency.

The pilot circuit **306** is also regulated by a current control **310** comprising among others a microprocessor **314**.

More particularly the radiofrequency circuit **30** provides that each MOSFET **305** acts as a switch breaking the direct current coming from the output voltage **201** of the rectifying circuit **20** and applied to the collector of each MOSFET. Each pilot circuit **306** emits a unidirectional pulsating not alternated square wave **304** that drives the base of each MOSFET.

The frequency of the pilot circuit **306** is kept constant through a quartz oscillator **311** having an oscillation frequency of 4 MHz connected to a BUFFER **313**.

The basic oscillation frequency of 4 MHz, and the higher frequencies too, can be also obtained by a circuit or a specific electronic device, like for instance a frequency synthesizer.

The control of MOSFET **305** occurs through a signal having an oscillation frequency equal to that of the quartz, or of the proper circuit or device, that in case of this example is 4 MHz.

The MOSFET **305** when closed interrupts the current on the leg **301** and when is open it lets the current to pass to the leg **301**.

The width of the current wave form at **301** depends on the regulation of the signal **302** connected to the pilot circuit **306**.

The regulation of the signal at **302**, performed by a potentiometer **303**, or for example by a regulator of touch screen type, allows to choose the width of the output wave so as to obtain the power intended for the manipulator **41** of the electronic scalpel according to the operation to be carried out.

The following table shows the maximum powers employed in some application fields, using the scalpel of the invention in cutting operations according to the surgical intervention fields.

TABLE 1

FIELD	POWER OF SCALPEL
Plastic Surgery	Max 160 W
Maxillo Facial	Max 160 W
Dermatology	50-120 W
ENT	Max 160 W
Gynaecology	Max 160 W
Neurosurgery	Max 90 W
Urology	Max 200 W

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From table 1 one can see that the maximum power employed can range from 50 Watts, for small dermatologic interventions, up to a maximum of 200 Watts, generally employed in urologic field.

To obtain a power adjustment method which is different from the one described in the example, providing for the power adjustment by the variation of the feeding voltage **302** of the drivers piloting the power MOSFETs gates, a still direct and stabilized (by AC/DC converter or by DC/DC converter), but variable for instance from 0 V to 200 V, voltage **201** can be used, while the voltage **302** is maintained steady.

Another possibility is that of using the direct and stabilized voltage **201**, variable for instance from 0 V to 200 V, and the variable voltage **302** too to obtain in this case a power adjustment of mixed type.

The output signal of the radio frequency circuit therefore is a current pulsating wave **301** at the frequency of 4 MHz with a width regulated by the power regulator **303** which modifies the voltage **302**.

As the output of the radio frequency circuit **30** is connected to the primary of the radio frequency transformer **40**, a circulating current **301** is established passing through a resonant circuit at the frequency of 4 MHz, where the capacity and inductance of the resonant circuit are given by the eddy capacity of the MOSFET **305**, the capacitor **307**, of negligible reactance, but acting as lock of the direct component of a voltage **201** and the inductance of the primary circuit of the transformer **40**, respectively.

According to the invention, the resonant circuit is of the wide pass-band type so as to let pass even if dampened, at least the second and the third harmonic of the carrier wave relative to the signal **301**.

Preferably it is desired that the signal **301** has at least the second, the third and the fourth harmonic.

To obtain a wide pass-band resonant circuit in the embodiment of Fig. 2 a high frequency transformer was used, having a number of turns of the secondary circuit which is equal or greater than the number of turns of the primary circuit.

In this way, the dosage in decreasing and particular way of the harmonics greater than 4 MHz is obtained, also as a consequence of the kind of scalpel, or the device controlling it, which changes depending on the different surgical utilization fields.

As it is known, for a resonant circuit the resonance coefficient Q is given by the

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formula:

$$Q = \omega C_R R_E = 2\pi f C_R R_E =$$

where f is the resonance frequency, C_R is the capacity of the resonant circuit, R_E is the equivalent Resistance of the primary circuit when to the secondary circuit a load is applied consisting for instance of the patient's body to be operated with the electronic scalpel.

As the equivalent Resistance may be expressed by the formula:

$$R_E = R_C \left(\frac{N_1}{N_2} \right)^2$$

where R_C is the load resistance and N_1 and N_2 is the number of turns of the primary and secondary respectively, one can see that the resonance factor Q may be expressed by the formula:

$$Q = 2\pi f C_R R_C \left(\frac{N_1}{N_2} \right)^2$$

The formula points out that the resonance coefficient decreases when the number of the secondary turns increases relative to that of the primary turns.

The resonance coefficient may also be expressed with the formula:

$$Q = \frac{F_R}{B}$$

where F_R is the resonance frequency and B is the pass-band.

In the case of the invention, when it is desired to widen the pass-band of 4 MHz to 8 MHz, 12 MHz and 16 MHz, in the resonant circuit a transformer is inserted with a suitable number of turns so that the resonance coefficient be lower than 1, preferably between 0,6 and 0,7.

With these characteristics of wide pass-band of the resonant circuit, the secondary current signal of the transformer at **401** takes the form shown in Fig. 3.

Checking the wave form of Fig. 3, one can see that at 4, 8, 12 and 16 MHz there are power peaks that are the interesting ones and are transferred to the scalpel manipulator with the above mentioned effects.

One can see that the current of signal **401**, once the power regulator **303** is set, is controlled through a current control coming from a current sensor **308** arranged after the MOSFET **305**.

The voltage signal **309** coming from the current sensor **308** drives the current control **310** providing to limit, through quick comparators controlled by the microprocessor **314**, the maximum current **401** acting with the signal **312** on the pilot circuit of the MOSFET, or acting with the supplying voltage **201**.

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The current controller **310** can be a circuit or a specific electronic device, or the same microprocessor **314**, which controls the entire system.

The current control can be also performed by the microprocessor **314**, which controls the entire system, without employing fast comparators.

5 In case of low impedance, as the current would rise to very high values, in the circuit there is a current limiter consisting of the inductance **402** limiting the current to the manipulator and hindering the circuit to exceed the maximum admissible current value.

10 The electric circuit is closed through the patient's ohmic load between two electrodes which are the manipulator **41** and a plate electrode **42**.

The plate **42** is preferably covered by a light insulating layer to avoid plate burns to the patient, which are typical of the electronic scalpel.

One can see that the electrode assembly constituted by manipulator **41** and plate **42** may also take the different form of pincers with bipolar operation.

15 With the adjustment method for regulating the electronic scalpel of the invention, the dosage of the energy transmitted to the cells cut by the scalpel is thus obtained, by the choice of a proper resonance frequency, of 4 MHz in the case of the invention, of the impulsive wave combined with the presence of harmonics.

20 Moreover, the dosage of the output power available at the manipulator of the electronic scalpel allows to provide for a power adapted to the nature of the intervention to be performed.

25 As a consequence of said kind of dosage, the advantages obtained are mainly a cold cut without tissue necrosis and with cheloids reduction, a sterile cut with fewer haemorrhages and fewer problems in the post-operating stage.

Furthermore, a very significant decrease of the pains felt by the patient in post-operating stage is obtained, and consequently a reduced stay time in hospital after surgery.

There is also the possibility to perform biopsies without any related necrosis.

30 It has to be noted that the surgery time is also reduced to a minimum.

It is possible to use as well the scalpel of the invention also on patients having pace-makers, because the frequencies chosen for said scalpel utilization do not interfere with pace-maker working.

35 As a consequence, a considerable cost reduction of the patients operations is obtained.

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CLAIMS

1) A method of regulating the power available at the manipulator of an electronic scalpel to make said manipulator adapted to carry out cutting of an organic tissue, said electronic scalpel being of the kind comprising:

- 5 - at least a rectifying circuit of the mains voltage supplying a rectified and direct voltage to
- at least a radio frequency circuit adapted to emit as output a current signal with substantially constant frequency feeding said manipulator through a radio frequency transformer, said radio frequency circuit comprising
- 10 - at least an electronic switch controlled by a circuit provided with an oscillator,

characterized by applying to said manipulator a wave form having such a power that the energy due to the wave form of the resonant frequency and the harmonics transferred to the manipulator, is substantially equal to the sum of
15 the energies required to break the bonds of the molecules constituting the tissue to be cut.

2) The method according to claim 1) **characterized by** applying to said manipulator a distorted sinusoidal wave form.

3) An electronic scalpel carrying out the method of claim 1) of the
20 kind comprising:

- a manipulator (41) to cut organic tissues and at least an electrode to close the electric circuit;
- a rectifying circuit (20) fed by the mains voltage, supplying a voltage (201) rectified and direct to a radio frequency circuit (30);
- 25 - a radio frequency circuit (30) comprising at least an electronic switch (305) fed by said rectified and direct voltage (201) and controlled by a pilot circuit (306) emitting a generally square current wave (301) of predetermined amplitude and frequency, said radio frequency circuit having an output consisting of a current pulsating wave circulating in a resonant circuit
- 30 feeding said manipulator,

characterized in that said resonant circuit is a wide pass-band circuit adapted to transfer to the manipulator a distorted sinusoidal voltage due to the presence of harmonics at least of the second and third order, **and in that** said manipulator supplies to the tissue a wave form whose frequencies give an
35 energy substantially equal to the sum of the energies required to open the

bond of the molecules belonging to the tissue to be cut.

4) The electronic scalpel according to claim 3) **characterized in that** said resonant circuit comprises at least the parasitic capacity of said electronic switch (305) and the inductance of the primary circuit of a radiofrequency transformer (40).

5) The electronic scalpel according to claim 3) **characterized in that** the wave form amplitude at the manipulator (41) is variable by means of a regulator (303) which modifies the voltage (302) of the pilot circuit (306).

6) The electronic scalpel according to claim 3) **characterized in that** the wave form amplitude at the manipulator (41) is variable by the modification of the rectified and direct voltage (201) which feeds said radiofrequency circuit (30), being maintained constant the voltage (302) feeding the pilot circuit (306) of said at least an electronic switch (305).

7) The electronic scalpel according to claim 3) **characterized in that** the wave form amplitude at the manipulator (41) is variable by the modification of the rectified and direct voltage (201) which feeds said radiofrequency circuit (30) and by means of a regulator (303) which modifies the voltage (302) of the pilot circuit (306).

8) The electronic scalpel according to claim 3) **characterized in that** the radio frequency circuit (30) emits a generally square wave at the frequency of 4 MHz.

9) The electronic scalpel according to claim 8) **characterized in that** said resonant circuit transforms the square wave into a distorted sinusoidal wave.

10) The electronic scalpel according to claim 3) **characterized in that** said at least one electronic switch (305) is a MOSFET component.

11) The electronic scalpel according to claim 3) **characterized in that** the voltage at the manipulator has harmonics of the second, third and fourth order.

12) The electronic scalpel according to claim 3) **characterized in that** the radio frequency transformer (40) has a number of turns (N_2) of the secondary which is equal or greater than the number (N_1) of the primary turns, so that the resonance coefficient (Q) of the resonant circuit is lower than 1.

13) The electronic scalpel according to claim 12) **characterized in that** the resonance coefficient of the resonant circuit is between 0,6 and 0,7.

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14) The electronic scalpel according to claim 3) **characterized in that** the frequency of said pilot circuit (306) of said at least an electronic switch (305) is kept constant by a quartz oscillator (311).

15) The electronic scalpel according to claim 3) **characterized in**
5 **that** the frequency of said pilot circuit (306) of said at least an electronic switch (305) is kept constant by a frequency synthesizer.

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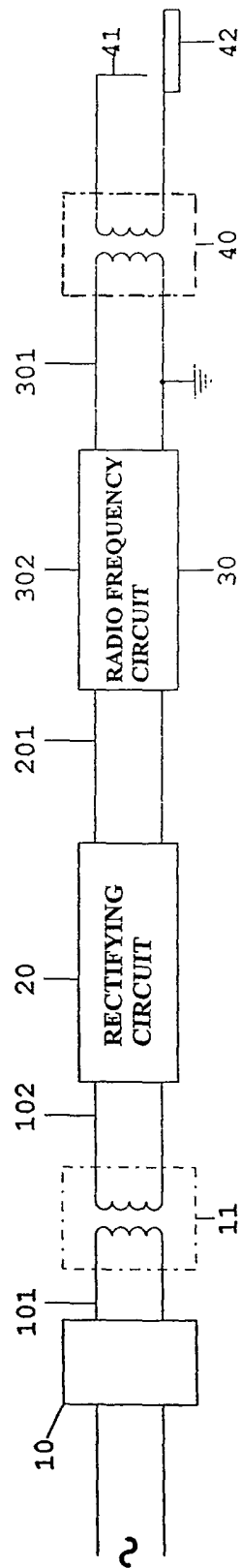


Fig. 1

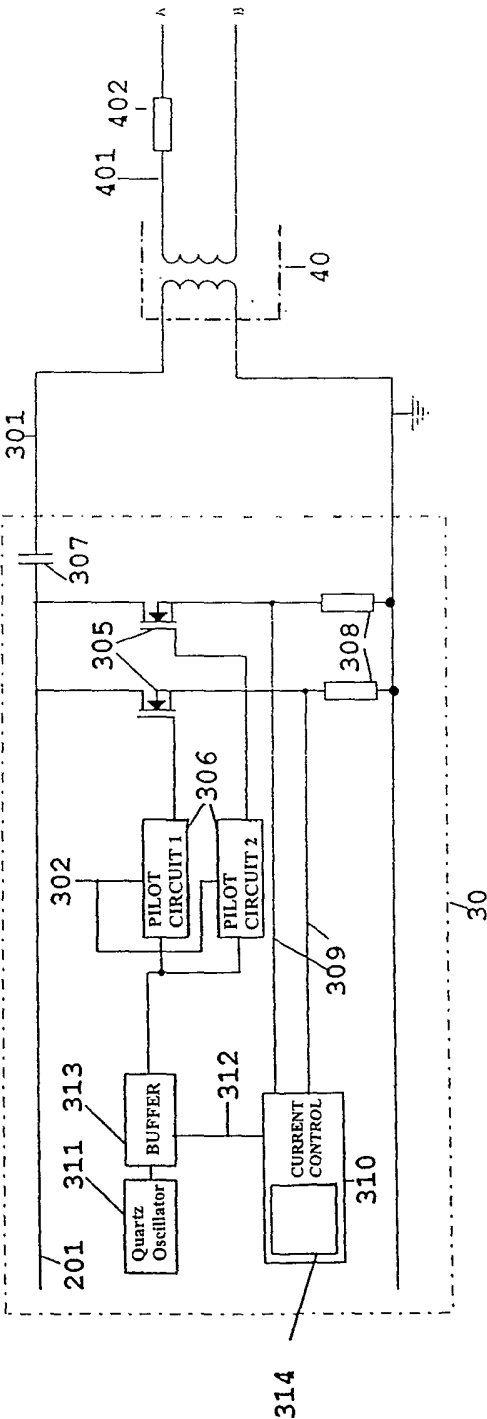


Fig. 2

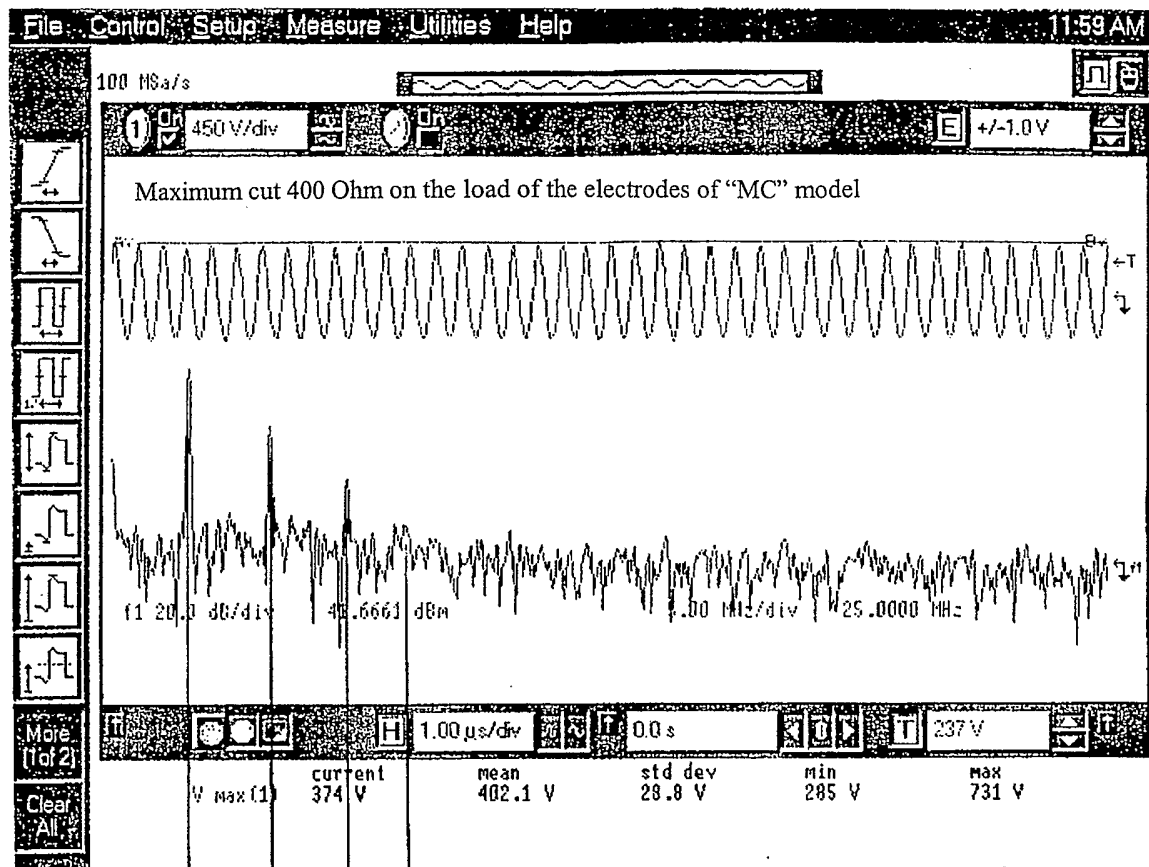


Fig. 3

8 MHz 16 MHz
12 MHz
4 MHz

INTERNATIONAL SEARCH REPORT

International Application No

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A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61B18/12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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INTERNATIONAL SEARCH REPORT

International Application No
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
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Information on patent family members

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