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(57) Abstract

An electrosurgical instrument is disclosed for the treatment of tissue in the presence of an electrically–conductive fluid. The instrument comprises an instrument shaft, and a tissue treatment electrode at one end of the shaft, the tissue treatment electrode being constructed to define thermal barriers for limiting thermal conduction therealong, thereby to encourage the formation and maintenance of a layer of vapour over the electrode.

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AN ELECTROSURGICAL INSTRUMENT

This invention relates to an electrosurgical instrument for the treatment of tissue in the presence of an electrically-conductive fluid medium, to electrosurgical apparatus including such an instrument, and to an electrode unit for use in such an instrument.

Endoscopic electrosurgery is useful for treating tissue in cavities of the body, and is normally performed in the presence of a distension medium. When the distension medium is a liquid, this is commonly referred to as underwater electrosurgery, this term denoting electrosurgery in which living tissue is treated using an electrosurgical instrument with a treatment electrode or electrodes immersed in liquid at the operation site. A gaseous medium is commonly employed when endoscopic surgery is performed in a distensible body cavity of larger potential volume in which a liquid medium would be unsuitable, as is often the case in laparoscopic or gastroenterological surgery.

Underwater surgery is commonly performed using endoscopic techniques, in which the endoscope itself may provide a conduit (commonly referred to as a working channel) for the passage of an electrode. Alternatively, the endoscope may be specifically adapted (as a resectoscope) to include means for mounting an electrode, or the electrode may be introduced into a body cavity via a separate access means at an angle with respect to the endoscope - a technique commonly referred to as triangulation. These variations in technique can be subdivided by surgical speciality, where one or other of the techniques has particular advantages given the access route to the specific body cavity. Endoscopes with integral working channels, or those characterised as resectoscopes, are generally employed when the body cavity may be accessed through a natural body opening - such as the cervical canal to access the endometrial cavity of the uterus, or the urethra to access the prostate gland and the bladder. Endoscopes specifically designed for use in the endometrial cavity are referred to as hysterocopes, and those designed for use in the urinary tract include cystoscopes, urethroscopes and resectoscopes. The procedures of transurethal resection or vaporisation of the prostrate gland are known as TURP and EVAP respectively. When there is no natural body opening through which an endoscope may be passed, the technique of triangulation is commonly employed. Triangulation is commonly used during underwater endoscopic surgery on joint cavities such as the knee and the shoulder. The endoscope used in these procedures is commonly referred to as an arthroscope.

Electrosurgery is usually carried out using either a monopolar instrument or a bipolar instrument. With monopolar electrosurgery, an active electrode is used in the operating region, and a conductive return plate is secured to the patient's skin. With this arrangement, current passes from the active electrode through the patient's tissues to the external return plate. Since the patient represents a significant portion of the circuit, input power levels have to be high (typically 150 to 250 watts), to compensate for the resistive current limiting of the patient's tissues and, in the case of underwater electrosurgery, power losses due to the fluid medium which is rendered partially conductive by the presence of blood or other body fluids. Using high power with a monopolar arrangement is also hazardous, due to the tissue heating that occurs at the return plate, which can cause severe skin burns. There is also the risk of capacitive coupling between the instrument and patient tissues at the entry point into the body cavity.

With bipolar electrosurgery, a pair of electrodes (an active electrode and a return electrode) are used together at the tissue application site. This arrangement has advantages from the safety standpoint, due to the relative proximity of the two electrodes so that radio frequency currents are limited to the region between the electrodes. However, the depth of effect is directly related to the distance between the two electrodes; and, in applications requiring very small electrodes, the inter-electrode spacing becomes very small, thereby limiting tissue effect and the output power. Spacing the electrodes further apart would often obscure vision of the application site, and would require a modification in surgical technique to ensure correct contact of both electrodes with the tissue.

There are a number of variations to the basic design of the bipolar probe. For example, U.S. Patent Specification No.4706667 describes one of the fundamentals of the design, namely that the ratio of the contact areas of the return electrode and of the active electrode is greater than 7:1 and smaller than 20:1 for cutting purposes. This range relates only to cutting electrode configurations. When a bipolar instrument is used for desiccation or coagulation, the ratio of the contact areas of the two electrodes may be reduced to approximately 1:1 to avoid differential electrical stresses occurring at the contact between the tissue and the electrodes.

The electrical junction between the return electrode and tissue can be supported by wetting of the tissue by a conductive solution such as normal saline. This ensures that the surgical effect is limited to the needle or active electrode, with the electric circuit between the two electrodes being completed by the tissue. One of the obvious limitations with the design is that the needle must be completely buried in the tissue to enable the return electrode to complete the circuit. Another problem is one of the orientation: even a relatively small change in application angle from the ideal perpendicular contact with respect to the tissue surface, will change the contact area ratio, so that a surgical effect can occur in the tissue in contact with the return electrode.

Cavity distension provides space for gaining access to the operation site, to improve visualisation, and to allow for manipulation of instruments. In low volume body cavities, particularly where it is desirable to distend the cavity under higher pressure, liquid rather than gas is more commonly used due to better optical characteristics, and because it washes blood away from the operative site.

Conventional underwater electrosurgery has been performed using a non-conductive liquid (such as 1.5% glycine) as an irrigant, or as a distension medium to eliminate electrical conduction losses. Glycine is used in isotonic concentrations to prevent osmotic changes in the blood when intra-vascular absorption occurs. In the course of an operation, veins may be severed, with resultant infusion of the liquid into the circulation, which could cause, among other things, a dilution of serum sodium which can lead to a condition known as water intoxication.

The applicants have found that it is possible to use a conductive liquid medium, such as normal saline, in underwater endoscopic electrosurgery in place of non-conductive, electrolyte-free solutions. Normal saline is the preferred distension medium in underwater endoscopic surgery when electrosurgery is not contemplated, or a non-electrical tissue effect such as laser treatment is being used. Although normal saline (0. 9%w/v; 150mmol/l) has an electrical conductivity somewhat greater than that of most body tissue, it has the advantage that displacement by absorption or extravasation from the operative site produces little physiological effect, and the so-called water intoxication effects of non-conductive, electrolyte-free solutions are avoided.

The applicants have developed a bipolar instrument suitable for underwater electrosurgery using a conductive liquid or gaseous medium. This electrosurgical instrument for the treatment of tissue in the presence of a fluid medium, comprises an instrument body having a handpiece and an instrument shaft, and an electrode assembly at one end of the shaft. The electrode assembly comprises a tissue treatment electrode which is exposed at the extreme distal end of the instrument, and a return electrode which is electrically insulated from the tissue treatment electrode and has a fluid contact surface spaced proximally from the exposed part of the tissue treatment electrode. In use of the instrument, the tissue treatment electrode is applied to the tissue to be treated whilst the return electrode, being spaced proximally from the exposed part of the tissue treatment electrode, is normally spaced from the tissue and serves to complete an electrosurgical current loop from the tissue treatment electrode through the tissue and the fluid medium. This electrosurgical instrument is described in the specification of our International Patent Application No. PCT/GB96/01473, the contents of which are incorporated in this application by reference.

The electrode structure of this instrument, in combination with an electrically-conductive fluid medium, largely avoids the problems experienced with monopolar or bipolar electrosurgery. In particular, input power levels are much lower than those generally necessary with a monopolar arrangement (typically 100 watts). Moreover, because of the relatively large spacing between its electrodes, an improved depth of effect is obtained compared with a conventional bipolar arrangement.

Figure 1 illustrates the use of this type of instrument for tissue removal by vaporisation. The electrode assembly 12 of this instrument comprises a tissue treatment (active) electrode 14 which is exposed at the distal end of the instrument, and a return electrode 18 which is spaced from the exposed part of the tissue treatment electrode by an insulation sleeve 16. This electrode assembly is powered to create a sufficiently high energy density at the tissue treatment electrode 14 to vaporise tissue 22, and to create a vapour pocket 24 surrounding the active tip. The formation of the vapour pocket 24 creates about a 10-fold increase in contact impedance, with a consequent increase in output voltage. Arcs 26 are created in the vapour pocket 24 to complete the circuit to the return electrode 18. Tissue 22 which contacts the vapour pocket 24 will represent a path of least electrical resistance to complete the circuit. The closer the tissue 22 comes to the electrode 14 the more energy is concentrated to the tissue, to the extent that the cells explode as they are struck by the arcs 26, because the return path through the conductive fluid (saline in this case) is blocked by the high impedance barrier of the vapour pocket 24. The saline solution also acts to dissolve the solid products of vaporisation.

The power threshold required to reach vaporisation is an important parameter of this type of instrument, and it is the aim of the invention to provide a bipolar electrosurgical instrument having improved vaporisation power threshold properties.

In its broadest aspect, the invention provides an electrosurgical instrument having an electrode which is so constructed as to have a better vaporisation power threshold than known electrodes.

The present invention provides an electrosurgical system for the vaporisation of tissue in the presence of an electrically-conductive medium, the system comprising an electrosurgical generator for generating radio frequency power, and an electrosurgical instrument connectable to the generator, wherein the generator has a radio frequency output stage for delivering radio frequency power to a pair of output connections, which output stage has an open loop output impedance of less than 250 ohms; the electrosurgical instrument comprises an instrument shaft and, situated at a distal end of the shaft, an electrode assembly comprising an active electrode with an exposed treatment portion and a return electrode with an exposed fluid contact surface, the fluid contact surface being set back from the treatment portion so that, when the electrode assembly is brought into an operative position with the treatment portion on, or adjacent to, the surface of the tissue to be treated, the fluid contact surface is further from the tissue surface than the treatment portion; and the ratio of the surface area of the exposed treatment portion to the surface area of the exposed fluid contact surface is greater than or equal to 0.5 to 1; the electrode assembly further comprising means associated with the active electrode for hindering the dissipation of heat from the active electrode to its surroundings, thereby to encourage the formation and maintenance of a layer of vapour over its surface.

In a preferred embodiment, the heat dissipation hindering means comprises a shroud partly covering the active electrode, with a space between the shroud and the active electrode, said space defining a gap which, in use, traps vapour constituting a thermal barrier for hindering the dissipation of heat from the active electrode to its surroundings.

Alternatively, the heat dissipation hindering means comprises a cavity in the active electrode, the cavity being effective to trap vapour, thereby constituting a thermal barrier for hindering the dissipation of heat from the active electrode to its surroundings. In this case, the active electrode may be formed as a tube with at least one open end. Preferably, the active electrode is in the form of a tubular wire coil, gaps between adjacent turns of the coil trapping said vapour, and thereby constituting the thermal barrier.

In another preferred embodiment, the active electrode is formed as a plurality of electrically-interconnected electrode parts, and the heat dissipation hindering means comprises a thermal barrier between said electrode parts to hinder heat conduction between said parts.

Advantageously, the active electrode is in the form of a tubular wire helix, gaps between adjacent turns of the helix being effective to trap vapour, thereby constituting the thermal barrier. Alternatively, the active electrode comprises a metallic body with a ridged, outwardly-directed treatment surface, the active electrode being mechanically fitted to an insulator positioned between, and electrically insulating the return electrode from the active electrode, in such a manner that a gap is defined between the active electrode and the insulator, vapour trapped in the gap constituting the thermal barrier.

In another preferred embodiment, the active electrode comprises a plurality of electrically-common filamentary members arranged side-by-side, gaps between the filamentary members being effective to trap vapour, thereby constituting a thermal barrier for hindering the dissipation of heat from the active electrode to its surroundings. Preferably, a single coiled filament constitutes the filamentary members, the coils of the filament constituting the filamentary members, and gaps between adjacent turns of the coil trapping said vapour, thereby constituting the thermal barrier.

In each case, the vapour trapped can be vaporised tissue and/or water vapour.

The invention also provides an electrosurgical instrument for the treatment of tissue in the presence of an electrically-conductive fluid medium, the instrument comprising an instrument shaft and an electrode assembly at a distal end of the shaft, wherein the electrode assembly comprises:

a single active electrode having an exposed tissue treatment portion;

a return electrode having an exposed fluid contact surface; and

an insulating member positioned between and electrically insulating the active electrode and the return electrode, and serving to space apart the exposed treatment portion of the active electrode and the exposed fluid contact surface of the return electrode, the fluid contact surface of the return electrode being set back in the direction of a treatment axis of the assembly from the active electrode exposed treatment portion; and wherein the ratio of the area of the exposed treatment portion to the area of the exposed fluid contact surface is greater than or equal to 0.5 to 1; and the active electrode is constituted by a singled coiled filament which defines a generally tubular member, adjacent turns of the coiled filament defining indentations in said generally tubular member, said indentations constituting thermal barriers for limiting thermal conduction along said generally tubular member, whereby, in use , application of sufficient radio frequency power to the electrode assembly vaporises the conductive fluid medium adjacent to the tissue treatment portion to create a stable vapour pocket around the tissue treatment portion.

The invention further provides an electrosurgical instrument for the treatment of tissue in the presence of an electrically-conductive fluid medium, the instrument comprising an instrument shaft and an electrode assembly at a distal end of the shaft, wherein the electrode assembly comprises:

a single active electrode having an exposed tissue treatment portion;

a return electrode having an exposed fluid contact surface; and

an insulating member positioned between and electrically insulating the active electrode and the return electrode, and serving to space apart the exposed treatment portion of the active electrode and the exposed fluid contact surface of the return electrode, the fluid contact surface of the return electrode being set back in the direction of a treatment axis of the assembly from the active electrode exposed treatment portion; and wherein the ratio of the area of the exposed treatment portion to the area of the exposed fluid contact surface is greater than or equal to 0.5 to 1; and the active electrode is configured to define thermal barriers for limiting thermal conduction therealong, whereby, in use, application of sufficient radio frequency power to the electrode assembly vaporises the conductive fluid medium adjacent to the tissue treatment portion to create a stable vapour pocket around the tissue treatment portion.

The invention still further provides an electrosurgical system for the vaporisation of tissue in the presence of an electrically-conductive medium, the system comprising an electrosurgical generator for generating radio frequency power, and an electrosurgical instrument connectible to the generator, wherein:

the generator has a radio frequency output stage for delivering radio frequency power to a pair of output connections, which output stage has an open loop output impedance of less than 250 ohms;

the electrosurgical instrument comprises an instrument shaft and, situated at a distal end of the shaft, an electrode assembly comprising an active electrode with an exposed treatment portion and a return electrode with an exposed fluid contact surface, the fluid contact surface being set back from the treatment portion so that, when the electrode assembly is brought into an operative position with the treatment portion on, or adjacent to, the surface of the tissue to be treated, the fluid contact surface is further from the tissue surface than the treatment portion; and

the ratio of the surface area of the exposed treatment portion to the surface area of the exposed fluid contact surface is greater than or equal to 0.5 to 1;

wherein the surface of the active electrode is such that there is a large thermal gradient across said surface, thereby hindering the dissipation of heat from the active electrode to its surroundings, thereby to encourage the formation and maintenance of a layer of vapour across said surface.

This large thermal gradient may be partly due to choosing a relatively poor thermal conductivity metal for the active electrode, and partly by said surface trapping vapour. Thus, the active electrode may be made of a material, such as stainless steel, which has poor thermal conductivity, and the active electrode surface may be such as to trap vapour, thereby constituting a thermal barrier for hindering said heat dissipation.

The electrosurgical instrument of the invention is useful for dissection, resection, vaporisation, desiccation and coagulation of tissue and combinations of these functions with particular application in hysteroscopic surgical procedures. Hysteroscopic operative procedures may include: removal of submucosal fibroids, polyps and malignant neoplasms; resection of congenital uterine anomalys such as a septum or subseptum; division of synechiae (adhesiolysis); ablation of diseased or hypertrophic endometrial tissue; and haemostasis.

The instrument of the invention is also useful for dissection, resection, vaporisation, desiccation and coagulation of tissue and combinations of these functions with particular application in arthroscopic surgery as it pertains to endoscopic and percutaneous procedures performed on joints of the body including, but not limited to, such techniques as they apply to the spine and other non-synovial joints. Arthroscopic operative procedures may include: partial or complete meniscectomy of the knee joint including meniscal cystectomy; lateral retinacular release of the knee joint; removal of anterior and posterior cruciate ligaments or remnants thereof; labral tear resection, acromioplasty, bursectomy and subacromial decompression of the shoulder joint; anterior release of the temperomandibular joint; synovectomy, cartilage debridement, chondroplasty, division of intra-articular adhesions, fracture and tendon debridement as applied to any of the synovial joints of the body; inducing thermal shrinkage of joint capsules as a treatment for recurrent dislocation, subluxation or repetitive stress injury to any articulated joint of the body; discectomy either in the treatment of disc prolapse or as part of a spinal fusion via a posterior or anterior approach to the cervical, thoracic and lumbar spine or any other fibrous joint for similar purposes; excision of diseased tissue; and haemostasis.

The instrument of the invention is also useful for dissection, resection, vaporisation, desiccation and coagulation of tissue and combinations of these functions with particular application in urological endoscopic (urethroscopy, cystoscopy, ureteroscopy and nephroscopy) and percutaneous surgery. Urological procedures may include: electro-vaporisation of the prostrate gland (EVAP) and other variants of the procedure commonly referred to as transurethral resection of the prostate (TURP) including, but not limited to, interstitial ablation of the prostate gland by a percutaneous or perurethral route whether performed for benign or malignant disease; transurethral or percutaneous resection of urinary tract tumours as they may arise as primary or secondary neoplasms, and further as they may arise anywhere in the urological tract from the calyces of the kidney to the external urethral meatus; division of strictures as they may arise at the pelviureteric junction (PUJ), ureter, ureteral orifice, bladder neck or urethra; correction of ureterocoele shrinkage of bladder diverticular, cystoplasty procedures as they pertain to corrections of voiding dysfunction; thermally induced shrinkage of the pelvic floor as a corrective treatment for bladder neck descent; excision of diseased tissue; and haemostasis.

Surgical procedures using the instrument of the invention include introducing the electrode assembly to the surgical site whether through an artificial conduit (a cannula), or through a natural conduit which may be in an anatomical body cavity or space or one created surgically. The cavity or space may be distended during the procedure using a fluid, or may be naturally held open by anatomical structures. The surgical site may be bathed in a continuous flow of conductive fluid such as saline solution to fill and distend the cavity. The procedures may include simultaneous viewing of the site via an endoscope or using an indirect visualisation means.

The invention also provides an electrode unit for an electrosurgical instrument for the treatment of tissue in the presence of an electrically-conductive fluid medium, the electrode unit comprising a shaft having at one end means for connection to an instrument handpiece, and, mounted on the other end of the shaft, a tissue treatment electrode, the tissue treatment electrode being constructed to define pockets for trapping electrically-conductive fluid and vapour.

The invention further provides an electrode unit for an electrosurgical instrument for the treatment of tissue in the presence of an electrically-conductive fluid medium, the electrode unit comprising a shaft having at one end means for connection to an instrument handpiece, and, mounted on the other end of the shaft, a tissue treatment electrode, the tissue treatment electrode being made from an electrically-conductive material and being coated with a resistive inert material which is effective to increase the local power density within the tissue treatment electrode.

The invention still further provides electrosurgical apparatus comprising a radio frequency generator and an electrosurgical instrument for the treatment of tissue in the pressure of an electrically-conductive fluid medium, the instrument comprising an instrument shaft, and an electrode assembly at one end of the shaft, the electrode assembly comprising a tissue treatment electrode and a return electrode which is electrically insulated from the tissue treatment electrode by means of an insulation member, the tissue treatment electrode being exposed at the distal end portion of the instrument, the return electrode having a fluid contact surface spaced proximally from the exposed end of the tissue treatment electrode by the insulation member, and the radio frequency generator having a bipolar output connected to the electrodes, wherein the exposed end of the tissue treatment electrode is constructed to define a plurality of pockets for trapping electrically-conductive fluid and vapour.

The invention also provides electrosurgical apparatus comprising a radio frequency generator and an electrosurgical instrument for the treatment of tissue in the presence of an electrically-conductive fluid medium, the instrument comprising an instrument shaft, and an electrode assembly at one end of the shaft, the electrode assembly comprising a tissue treatment electrode and a return electrode which is electrically insulated from the tissue treatment electrode by means of an insulation member, the tissue treatment electrode being exposed at the distal end portion of the instrument, the return electrode having a fluid contact surface spaced proximally from the exposed end of the tissue treatment electrode by the insulation member, and the radio frequency generator having a bipolar output connected to the electrodes, wherein the exposed end of the tissue treatment electrode is made from an electrically-conductive material and is coated with a resistive inert material which is effective to increase the local power density within the tissue treatment electrode.

Advantageously, the radio frequency generator includes control means for varying the output power delivered to the electrodes. Preferably, the control means is such as to provide output power in first and second output ranges, the first output range being for powering the electrosurgical instrument for tissue desiccation, and the second output range being for powering the electrosurgical instrument for tissue removal by vaporisation. Conveniently, the first output range is from about 150 volts to 200 volts, and the second output range is from about 250 volts to 600 volts, the voltages being peak voltages.

The invention further provides a method of operating an electrosurgical apparatus having at least a tissue desiccation mode and a tissue vaporisation mode, the apparatus having a radio frequency generator coupled to an electrode assembly for the treatment of tissue in the presence of an electrically-conductive fluid medium, the electrode assembly comprising a tissue treatment electrode and a return electrode which is electrically insulated from the tissue treatment electrode by means of an insulation member, the tissue treatment electrode being exposed at the distal end portion of the assembly, and the return electrode having a fluid contact surface spaced proximally from the exposed end of the tissue electrode by the insulation member, the method comprising the steps of: controlling the output power of the radio frequency generator to lie within a first output range for the tissue desiccation mode, and to lie within a second output range for the tissue vaporisation mode, the first output range being such that the power supplied to the electrode assembly maintains the conductive fluid adjacent to the tissue treatment electrode substantially at boiling point for tissue desiccation without creating a vapour pocket surrounding the tissue treatment electrode, and the second output range is such that the output power supplied to the electrode assembly for vaporisation of tissue is such as to maintain a vapour pocket surrounding the tissue treatment electrode; and reducing the power threshold for vaporisation at the tissue treatment electrode when the output power of the radio frequency generator is in the second output range.

The invention still further provides an electrosurgical method comprising the steps of: providing an electrosurgical apparatus comprising a radio frequency generator coupled to an electrode assembly comprising a tissue treatment electrode and a return electrode, the tissue treatment electrode being exposed at the distal end portion of the assembly; the method comprising the steps of introducing the electrode assembly into a selected operation site with the tissue treatment electrode adjacent to the tissue to be treated, and with the tissue and the tissue electrode assembly immersed in a conductive liquid; activating the generator; applying sufficient radio frequency power to the electrode assembly to vaporise the conductive liquid surrounding the tissue treatment electrode to maintain a vapour pocket surrounding the tissue treatment electrode; and reducing the power threshold for vaporisation at the tissue treatment electrode.

The invention will now be described in greater detail, by way of example, with reference to the drawings, in which:-

Figure 1 is a diagrammatic side elevation of an electrode unit, showing the use of such a unit for tissue removal by vaporisation;

Figure 2 is a diagram showing an electrosurgical apparatus constructed in accordance with the invention;

Figure 3 is a perspective view of the distal end of a first form of electrode unit constructed in accordance with the invention;

Figure 4 is an exploded perspective view of the tip assembly of the first form of electrode unit;

Figure 5 is a diagram showing the tip assembly of Figure 4 in side elevation;

Figure 6 is a diagrammatic side elevation of the electrode assembly of a second form of electrode unit constructed in accordance with the invention;

Figure 7 is a diagrammatic side elevation of the electrode assembly of a third form of electrode unit constructed in accordance with the invention;

Figure 8 is a diagrammatic side elevation of the electrode assembly of a fourth form of electrode unit constructed in accordance with the invention;

Figure 9 is a diagrammatic side elevation of the electrode assembly of a fifth form of electrode unit constructed in accordance with the invention;

Figures 10 and 11 are schematic side elevations of the distal end portion of an electrode assembly similar to that of Figure 7, showing different stages in the formation of a vapour pocket around conductive electrode filaments;

Figure 12 is a perspective view of a modified form of the electrode assembly of Figure 8;

Figure 13 is a perspective view of part of the assembly of Figure 12;

Figure 14 is a cross-section taken on the line A-A of Figure 12;

Figure 15 is a graph illustrating the hysteresis of the electrical load impedance and dissipated radio frequency power which occurs during use of an instrument in accordance with the invention in desiccating and vaporising modes;

Figure 16 is a block diagram of an electrosurgical generator in accordance with the invention;

Figure 17 is a block diagram of part of the control circuitry of Figure 16;

Figure 18 is a waveform diagram showing a typical RF output voltage variation pattern obtained with the generator of Figures 16 and 17, the voltage being shown varying with time according to variations in load impedance and generator output stage supply voltage;

Figure 19 is a graph showing the variation of output power produced by the generator as a function of the load impedance presented to it by the electrode assembly, the output power variation being shown in two operation modes of the generator; and

Figure 20 is a graph showing the variation of output power produced by the generator as a function of load impedance after modification of the generator characteristics in response to the output voltage sensing.

Each of the electrode units described below is intended to be used with an electrically-conductive fluid medium such as normal saline, and each instrument has a dual-electrode structure, with the conductive medium acting as a conductor between the tissue being treated and one of the electrodes, hereinafter called the return electrode.

The other electrode is applied directly to the tissue, and is hereinafter called the tissue treatment active) electrode.

Referring to the drawings, Figure 2 shows electrosurgical apparatus including a generator 1 having an output socket 2 providing a radio frequency (RF) output for an instrument in the form of a handpiece 3 via a connection cord 4. Activation of the generator 1 may be performed from the handpiece 3 via a control connection in the cord 4, or by means of a foot switch unit 5, as shown, connected separately to the rear of the generator 1 by a foot switch connection cord 6. In the illustrated embodiment, the foot switch unit 5 has two foot switches 5a and 5b. for selecting a desiccation mode and a vaporisation mode of the generator 1 respectively. The generator front panel has push buttons 7a and 7b for respectively setting desiccation and vaporisation power levels, which are indicated in a display 8. The handpiece 3 mounts a detachable electrode unit E, such as the electrode units El to E6 to be described below.

Figure 3 shows the distal end of the first form of electrode unit El for detachable fastening to the electrosurgical instrument handpiece 3. The electrode unit El is formed with an electrode assembly at the distal end thereof, the electrode assembly comprising a tissue treatment (active) electrode 31 and a return electrode 32. The electrode assembly is supported by a pair of laterally-spaced conductor arms 33 which are attached to the handpiece 3 by a shaft 34. The arms 33 are kinked at the point where they meet the shaft 34, so as to lie on opposite sides of the axis of the instrument; and, just distally of the end of the shaft, they are bent downwardly to support the electrode assembly at a position in alignment with the axis of the instrument. Except for their extreme distal end portions, the conductors forming the arms 33 are sleeved with a heat shrink material throughout their length.

The electrode assembly is a bipolar instrument working tip with a comparatively large area tissue treatment electrode 31 designed for removing large volumes of tissue by tissue vaporisation. An example of such tissue is that associated with a condition known as benign prostatic hypertrophy (BPH). BPH produces an enlargement of the prostate which restricts the flow of urine from the bladder through the urethra, which it surrounds. The procedure entails the removal of all the tissue within a walnut-shaped capsule, which restores normal urine flow. A typical weight of tissue removed is 30 to 40 grams.

Referring to Figures 3 and 4 together, the electrode assembly comprises a ceramic insulator body 35 of generally cylindrical configuration, extending transversely between the extreme distal end portions of the conductor arms 33. The active electrode 31 is a thin, part-cylindrical stainless steel tissue treatment electrode which covers a lower surface portion of the insulator body 35. The return electrode 32 is made of stainless steel, and covers an upwardly-directed surface of the insulator body 35. The return electrode 32 thus lies on the opposite side of the insulator body 35 from the active electrode 31. The return electrode 32 is, therefore, directly above the active electrode 31, and at substantially the same position in the longitudinal direction of the electrode assembly. Both electrodes 31 and 32 extend transversely between the extreme distal ends of the arms 33, and each is secured directly to the ceramic insulator 35 without the use of adhesive, so that there is no intimate contact between the electrodes 31, 32 and the insulator body 35.

As shown clearly in Figure 4, the active electrode 31 has, in addition to a part-cylindrical base lamina 31a, a plurality of tranversely-extending, parallel, outwardly-projecting integral ribs 31b. These serve to lower the power threshold of the vaporisation of the electrode assembly by hindering heat convection away from the electrode 31, and by trapping small pockets of saline vapour, particularly when the active electrode is placed near the surface of the tissue to be treated. The function of the ribs 31b is enhanced by arranging for the exposed surface of the electrode 31 to be microscopically roughened. This roughening can be engineered or designed to occur during use as a result of the spark erosion which occurs on the exposed surface.

The active electrode 31 is constructed of stainless steel which has relatively poor thermal conductivity. This, in conjunction with the low thermal mass yielded by the small thickness of the base lamina 31a (the thickness being in the region of from 0.15mm to 0.5mm), hinders the transfer of heat from one portion of the active electrode 31 to another, so that, should a portion of the active electrode be wetted by the conductive liquid, heat is not quickly dissipated to the wetted portion from other portions of the electrode. Supporting the tip of the electrode assembly on wires also reduces heat dissipation to the remainder of the assembly. These measures all help to promote vaporisation of the conductive liquid over the surface of the active electrode 31.

As will be seen also from Figure 4, the active electrode 31 has an integral undercut inner rib 31c running parallel to the transverse ribs 31b. This allows the active electrode 31 to interlock positively in a complementary undercut groove 35a in the ceramic insulator body 35. The groove 35a extends transversely of the insulator body 35, and is open at one lateral end of the insulator body, but closed at the other. Consequently, the active electrode 31 may be mounted to the insulator body 35 by sliding the inner rib 31c transversely into the open end of the groove 35a until it is pushed completely home with the rib 31c abutting the closed end.

A similar undercut groove 35b is cut into the upper surface of the insulator body 35 to receive a corresponding inner rib 32a of the return electrode 32, also shown in Figure 4. In this case, however, the upper groove 35b opens to the opposite lateral end of the insulator body 35 from the open end of the lower groove 35a. Like the lower groove 35a, it is closed at its other end. As a result, the return electrode 32 can be mounted to the insulator body 35 in the same manner as the active electrode 31, by sliding from one side, but in this case from the other side.

Adjacent to the open ends of their respective grooves 35a, 35b, each electrode 31, 32 is welded to a respective one of the conductor arms 33. Proximally, the arms 33 are fastened together. This, together with the resilience of the arms 33 and a spring bias towards each other, acts to retain each electrode 31, 32 against the closed end of its respective groove 35a, 35b, whereby the distal tip assembly remains assembled without the use of adhesive material.

The return electrode 32 has no outer ribs, but acts as an oppositely-directed, generally part-cylindrical shell portion 32b with a smooth outer surface 32c. In practice, the return electrode 32, like the active electrode 31, is made of stainless steel. However, it can be made of material of higher thermal conductivity to supplement the effect of the smooth surface 32c in hindering vaporisation at the return electrode 32.

The insulator body 35 separates the electrodes 31, 32 in such a way that conduction through the tissue to be treated is the path of least electrical resistance, and so that direct arcing between active and return electrodes is largely prevented. The applicants have found that the minimum conductive path length between the electrodes for achieving this in most circumstances is 1.5mm. The manner in which this clearance is obtained is best seen in the diagrammatic side elevation of Figure 5. In this embodiment of the electrode assembly, the insulator body 35 is shaped to reduce as far as possible the degree to which it and the electrodes 31, 32 block the surgeon's view of the tissue being treated.

The insulator body 35 is shaped and mounted so as to define a separation plane between the electrodes 31, 32, which plane lies substantially parallel to the support structure 33, 34, and with the distal edges of the electrodes closer together than their proximal edges. To achieve a conductive path length of at least 1.5 mm between pairs of edges (i.e. between the distal edges and the proximal edges respectively), the insulator body 35 has a distal rib 35d which projects well beyond the distal edges 31d, 32d of the electrodes 31, 32. Consequently, the conductive path length between these distal electrode edges 31d, 32d is considerably greater than their geometric separation. On the proximal side, the insulator body 35 has a proximal separating rib 35e which is wider than the distal rib 35d, and projects beyond the main cylindrical mass of the insulator body to a relatively small degree. In this way, the overall size of the distal tip assembly in the field of the surgeon is reduced, whilst maintaining the ability to remove tissue at different angles of attack, due to the semicircular cross-section of the active electrode 31. At the same time, the short projecting rib 35c on the proximal side has the benefit of making the active electrode 31 visible so that the surgeon can see when a vapour pocket is formed.

The proximal-distal circumferential extent and the width of the active electrode 31 are respectively about 1.8 mm and 4mm, giving a geometrical area of the lamina of about 7 7 mm^2. In the general sense, a part-cylindrical or outer area greater than 5 mm^2 is preferred. The actual exposed surface area of the active electrode 31 when mounted on the assembly is typically in the region of 15 mm^2 upwards, due to the surface projections and lateral edge surfaces. This figure is preferably in the range of from 15 to 35 mm^2, but can be as high as 50 or 60 mm^2.

It will be understood that the larger the area of the active electrode 31, the greater is the rate at which tissue can be removed, providing sufficient power can be dissipated at the electrode and a vapour layer maintained over its entire exposed surface.

Although the electrode unit E1 is described as being for direct attachment to the handpiece 3, it will be apparent that it could form part of an endoscopic electrosurgical instrument. In this case, the shaft 34 would be provided with clip for attaching the electrode assembly to the telescope of the endoscope. In either case, saline is fed to the tip assembly to provide a saline flow in the region of the active electrode 31. In the endoscopic embodiment saline will be fed through the endoscope. Otherwise, saline can be fed in any suitable manner known per se.

It will be appreciated that both the return and the active electrodes 32 and 31 have the potential to form a vapour pocket. In conventional bipolar electrodes, vaporisation of the liquid is confined largely to the active electrode by providing higher energy densities at the active electrode than at the return electrode, by arranging for the exposed surface area of the active electrode to be substantially smaller than that of the return electrode. Typically, known bipolar instruments cannot vaporise a surrounding electrically-conductive fluid such as saline if the ratio of the fluid contacting areas of the active and return electrodes approaches 0.5 to 1. In contrast, the electrode assembly described above with reference to Figures 3 to 5 typically has an active to return electrode surface area ratio exceeding 1:1, and more typically is in the range of from 1.25:1 to 3:1. Here, the surface area is that area which is in contact with the conductive liquid when completely immersed, before activation by the electrosurgical generator 1. This electrode assembly has been designed such that the configuration of the return electrode 32 discourages vapour pocket entrapment and formation on its surface, whilst such entrapment is provided by the features of the active electrode 31 so that, once vapour bubbles begin to form, they are trapped in the cavities between the tips and in the microscopic indentations provided by the surface roughness, so as then to reduce the effective contact area of the electrode with the conductive liquid. This promotes rapid formation of a vapour pocket completely covering the active electrode 31. Placing the active electrode 31 adjacent to the tissue surface reduces the cooling effect of convection currents in the liquid, allowing the trapped saline to absorb the electrosurgical power, and to rapidly reach and maintain the boiling point of the liquid. Once boiling commences, the grooves between the ribs 31b slow down the migration of the emerging vapour bubbles away from the surface of the active electrode 31 so as to encourage them to coalesce into a vapour pocket. The return electrode 32, being located directly above the active tip, is positioned to avoid contact with tissue, thereby, ensuring that it is constantly surrounded by conductive liquid which cools its surface, thereby dissipating energy throughout a large volume of liquid.

Once a vapour has formed, the tips 31b of the active electrode 31 promote arc propagation because they form natural areas of high ion concentration. The ribs 31b are rounded to avoid accidentally tearing the tissue to be treated. The ribs 31b are oriented at 90° to the direction of travel of the electrode 31 over the tissue surface. It has been found that this arrangement causes the best axial retention of vapour, while the sides of the vaporised trench in the tissue limit the amount lost from the lateral sides of the electrode assembly. A secondary benefit of retaining the vapour in this way is that the migration of bubbles away from the tip is reduced, thereby improving the surgeon's view of the operative site. This orientation of the active electrode 31 also produces the most even tissue removal across the width of the assembly.

To further facilitate even tissue removal, as the active electrode 31 is moved over the tissue, it is swung through an arc, intended to match the curvature of the tissue to be removed. For this reason, the active tip has a semicircular cross-section to provide the maximum surface area for tissue removal at all stages of both the forward and return strokes.

The above-described electrode assembly is intended particularly for electro-vaporisation of the prostate gland (EVAP) and other variants of the procedure commonly referred to as transurethral resection of the prostate (TURP), typically by interstitial ablation of the prostate gland by a perurethal route, whether performed for benign or malignant disease; transurethral removal of urinary tract tumours as they may arise as primary or secondary neoplasms, and further as they may arise anywhere in the urological tract from the calyces of the kidney to the external urethral meatus.

This electrode unit E1 has further additional applications for vaporisation of tissue in general laparoscopic, endoscopic gastroenterological surgery, hysteroscopic, thoracoscopic, an neurosurgical procedures being particularly useful in the removal of diseased tissue and neoplastic disease whether benign or malignant.

The power threshold for vaporisation is not well defined. If the instrument were operating in a static conductive medium, then the vaporisation threshold would be well defined by an impedance switching point where the electrode impedance suddenly rises as a result of vapour pockets forming around the active electrode 31. The threshold is normally dependent upon the dissipation mechanism of the saline. In a static environment, the dissipation mechanism is predominantly by convection currents within the saline. Under these circumstances, the power threshold is defined by the input power into the electrode active region being in excess of the dissipation from the saline. However, in the embodiment described above, the saline around the active electrode 31 is continually refreshed. If it were not, then the only dissipation mechanism would be by latent heat of vaporisation, and the saline would quickly evaporate. By providing a flow, the threshold power level is increased. However, the threshold power level is dependent on the saline refresh rate at the very periphery of the active electrode 31. The refresh rate at this boundary layer can be modified by altering the surface finish of the active electrode 31. For example, if the active electrode 31 had a smooth surface, then saline would be rapidly refreshed, as a rapid flow rate would be established. However. as the active electrode 31 has an irregular finish, the refresh rate of pockets within the irregular surface is diminished. Thus, the irregular surface traps saline (or at least delays the refresh) and vapour, and so absorbs more power before being replaced. In other words, the power threshold is decreased by the irregular active electrode surface. This is a highly desirable property, as the electrode power requirement drops substantially without adversely effecting tissue performance. The threshold power is further reduced because the active electrode 31 is constructed so as to provide a capillary action. Thus, even in the vaporised state, the active electrode 31 is intermittently wetted. By ensuring that this wetting wets the entire active electrode 31 by capillary action, there is a continual source of vapour which minimises the intermittent wetting, and so further reduces the power demand.

The return electrode 32 has a smooth polished surface which has no impediment to convection currents. Consequently, the return electrode 32 does have a constantly changing saline boundary layer which is replaced at a high rate, and the return electrode has a high power threshold. Indeed, the power threshold of the return electrode 32 is increased in this way so that it is considerably in excess of the maximum available power. This ensures that, even if the return electrode 32 is partially obscured, or the flow of saline impeded, the power threshold at the return electrode will never be reached. As the power threshold for vaporisation at the return electrode 32 cannot be reached. there is no risk of tissue being vaporised by the return electrode. Collateral tissue damage is, therefore, avoided.

By varying the output of the generator 1, the electrode unit El can also be used for desiccation (coagulation). In this case, the generator 1 is controlled so that small vapour bubbles form on the surface of the active electrode 31, but insufficient vapour is produced to provide a vapour bubble (pocket) surrounding the active tip of the electrode, the vapour bubble being essential for tissue removal by vaporisation.

The generator 1 is controlled in such a manner that it has respective output ranges for tissue desiccation and for tissue removal by vaporisation. The former range is from 150 volts to 200 volts, and the latter range is from 250 volts to 600 volts. the voltages being peak voltages. In the vaporisation mode, the generator 1 is controlled in such a manner as to prevent the active electrode 31 overheating. This requires a reduction in the output voltage of the generator 1 once a vapour pocket has been established. The generator 1 and its control means are described in greater detail in the specification of our European Patent Application 96304558.8

The coagulation from this electrode is vastly superior to any conventional bipolar electrode. The reasons are twofold. Firstly, the coagulation mechanism is not merely by electrical current in the tissue, but is also due to the heated saline. Secondly, under normal circumstances, the weakest link in providing electrical power to the tissue is the electrode interface, as this is the point of highest power density, and so imposes a power limit. If too high a power level is attempted, the tissue at the interface quickly desiccates far faster than the larger cross-section of tissue forming the remaining circuit. If a lower power is selected, the interface can dissipate the temperature rise by mechanisms other than vaporisation. Consequently, the interface remains intact longer, and so a greater depth of effect can be achieved. In this embodiment, the electrical interface is much stronger by virtue of the saline, and it is not possible completely to desiccate the target tissue. Thus, power can be delivered at a higher rate and for a longer period, resulting in a depth of effect which is purely time and power related.

Vaporisation threshold control is an important aspect of such a multi-functional active electrode, the active electrode area being maximised for desiccation, whilst still being capable of vaporisation or cutting functions by retaining the vapour pocket and heated saline in the interstices of the active electrode.

As mentioned above, a fundamental feature of the design of a bipolar electrosurgical instrument is the ratio of the contact areas of the return electrode and of the active electrode. This ratio should be high for vaporisation and low for desiccation. A balance must, therefore, be struck for multi-functional electrodes. The electrode unit El achieves this balance by minimising the ratio to ensure efficient desiccation, and by providing vaporisation threshold control to ensure efficient vaporisation.

Figure 6 shows the electrode assembly of the second form of electrode unit E2. This unit E2 has a shaft (not shown) for detachably fastening the unit to the electrosurgical instrument handpiece 3. The electrode assembly is positioned at the distal end of the shaft, means (not shown) being provided at the other end of the shaft for connecting the electrode assembly to the handpiece 3 both mechanically and electrically.

The electrode assembly includes a central, tissue treatment (active) electrode 41 which is exposed at the extreme distal end of the instrument. The active electrode 41 is a helical coil made of a refractory metal such tungsten or tantalum, or a noble metal such as platinum, or a platinum alloy such as platinum cobalt, platinum/iridium or platinum/tungsten. The active electrode 41 is electrically connected to the RF generator 1 by a central conductor (not shown). An insulating sleeve 42 surrounds the active electrode 41 and the inner conductor, the distal end of the insulating sleeve being exposed proximally of the exposed part of the electrode 41. The sleeve 42 is made of a ceramic material, silicone rubber or glass. A return electrode 43 surrounds the sleeve 41, the return electrode being in the form of a stainless steel tube. The return electrode 43 is constituted by the distal end portion of the shaft of the instrument, and is electrically connected to the RF generator 1. An outer insulating polyamide coating (not shown) surrounds that portion of the shaft adjacent to the return electrode 43.

The electrode unit E2 of Figure 4 is intended for tissue removal by a vaporisation within a distension medium in the form of an electrically-conductive liquid such as saline. In this case, the power threshold required to reach vaporisation is dependent on the power dissipation capability of the active electrode 41 and the flow characteristics around it. As the electrode assembly is immersed in saline, power dissipation is by electrical conversion to heat. The heated saline rises as a plume from the active electrode 41 by the action of convection. Under these circumstances, the power threshold of vaporisation is dependent on the maximum rate of convection from the active electrode.

The highest power density exists at the surface boundary of the active electrode 41. Power density falls off at a rate proportional to $1/d^2$ where d is the distance away from the active electrode 41. Therefore, it is the saline at the surface of the electrode 41 which defines the power threshold. The rate of saline replacement by convection and conduction losses at this point defines the power threshold. As soon as this boundary layer vaporises, then the electrode 41 becomes stable in vaporisation with a lower power level.

The adjacent turns of the active electrode 41 constitute an irregular surface which traps saline, and so absorbs more power before being replaced. A highly polished active electrode would have a constantly changing saline boundary layer, due to the convection currents "washing" its surface. In this case, the boundary layer would be replaced at a high rate, so there would be a high power threshold. The irregular surface of the active electrode 41, however, results in the trapping of saline (and vapour) so that the saline boundary layer changes at a low rate. Thus, the irregular surface of the active electrode 41 defines a number of peaks and troughs. The saline at the boundary layer of the peaks will be replaced readily by the convection currents. However, the convection of saline in the troughs will be impeded. Thus, the saline in the troughs will not be replaced as quickly, and so will absorb more power before being replaced. In other words, the power threshold is decreased by the irregular surface of the active electrode 41. Saline is also trapped within the coil itself, thereby leading to a further reduction in the replacement rate of saline at the boundary layer, and a consequent further reduction in the power threshold. As with the embodiment of Figures 3 to 5, this is desirable as the electrode power requirement drops substantially without adversely affecting tissue performance. The threshold power is further reduced because the active electrode 41 is constructed so as to provide a capillary action. Thus, even in a vaporised state, the active electrode 41 is intermittently wetted. By ensuring that this wetting wets the entire active electrode 41 by capillary action, there is a continual source of vapour which minimises the intermittent wetting, and so further reduces the power demand.

The electrode unit E1 of Figure 6 has an active electrode 41 having a fluid-contacting surface that is 1.1 times the fluid-contacting surface of the return electrode 43.

Figure 7 shows an electrode unit E3 having an active electrode 61 in the form of a brush constituted by a plurality of filaments made of a refractory metal such as tungsten or tantalum, a noble metal such as platinum, or a platinum alloy such as platinum/iridium, platinum/cobalt or platinum/tungsten. In use, saline is trapped within the strands of the filaments, once again leading to a reduction in the replacement of saline at the boundary layer, and a reduction in the power threshold. The filaments of the brush electrode 61 also provide a capillary action, further reducing the power threshold.

The electrode unit E3 also has an active electrode 61 having a fluid-contacting surface that is 1.1 times the fluid-contacting surface of the return electrode 43.

The electrode unit E4 of the embodiment of Figure 8 is similar to that of Figure 6, having an active electrode 41 in the form of a coil made of a refractory metal such as tungsten or tantalum, a noble metal such as platinum, or a platinum alloy such as platinum/iridium, platinum/cobalt or platinum/tungsten. In this embodiment, however, the insulating sleeve 42 is formed with an arcuate extension 42a which constitutes a shroud. The inner surface of the shroud 42a closely overlies the turns of the coil electrode 41 over about half its circumference. The shroud 42a does, therefore, impede convection current flow, thereby increasing the ability of the electrode assembly to trap saline, and so leads to a further decrease in the power threshold. This electrode assembly benefits from a secondary mechanism. Thus, when in the vaporising state, tissue destruction yields gaseous products. The shroud 42a captures these gaseous products, and so excludes conduction by virtue of the insulating properties of these gaseous products.

Here again, the active electrode 41 has a fluid-contacting surface that is 1.1 times the fluid-contacting surface of the return electrode 43.

Figure 9 shows a further form of electrode unit E5 having an active electrode 71 in the form of a roller ball. The roller ball electrode 71 is made of stainless steel, and is rotatably supported on an arm 72 made of an electrically-conductive material such as copper. A generally hemispherical shroud 73 is fixed to the arm 72 so as to closely surround about half of the area of the ball electrode 71. The shroud 73 is made of an insulating material such as a ceramic material, silicone rubber or glass. A return electrode 74 made of stainless steel is mounted on that side of the shroud 73 remote from the ball electrode 71. Here again, the shroud 73 traps saline between its inner surface and the outer surface of the roller ball electrode 71, so the power threshold of the active electrode is reduced. The shroud 73 also traps the products of vaporisation to reduce the effective size of the large active electrode 71. Moreover, by excluding a direct return path through the saline, the return : active area ratio is effectively increased. This feature reduces the amount of power required to support vaporisation, and enables the use of a much larger active electrode 71 than would otherwise be possible. Another advantage of the shroud 73 is that it preserves the environment in the immediate region of the active electrode 71 from disturbances which otherwise would be created by the flow of saline.

The active electrode 71 has a fluid-contacting surface that is 2.0 times the fluid-contacting surface of the return electrode 74.

The return electrode of each of the embodiments of Figures 6 to 9 has a smooth polished surface which has no impediment to convection currents. As with the embodiment of Figures 3 to 5, therefore, each of these return electrodes has a high power threshold for vaporisation, so that there is no risk of tissue being vaporised by the return electrode, and no risk of collateral tissue damage. The electrode assembly of each of these embodiments could be positioned adjacent to the saline supply port of an endoscope so that saline will flow over the return electrode to provide a turbulent flow of saline along that electrode. This would result in the boundary layer replacement at the return electrode being very rapid, and further increase the power threshold of the return electrode.

As mentioned above, multifunctional electrode units require vaporisation threshold control, and a minimum for the ratio of the contact areas of the return electrode and the active electrode. The minimum ratio depends on four important criteria, namely:

1. The intrinsic impedance of the target tissue;

2. The volume of the body cavity;
3. The configuration of the active electrode.
4. The maximum output power from RF generator.

The configuration of the active electrode obviously influences the ratio, with cylindrical forms representing the lowest ratio for a given length, but the other factors relate to the ability of the electrode to retain the vapour bubble. The filaments of the brush-type electrodes retain vapour bubbles, which helps maintain the vaporisation condition. As a result, the ratio for this type of electrode can be lowest of the multifunctional electrodes; and, when combined with application to tissue with high impedance, the ratio is similar to that for desiccate functions, that is in the region of 1:1 to 2:1. With solid electrode forms, however, the transition and maintenance of the vaporisation condition at similar ratios requires very high power levels (greater than 150w at 1.5mm diameter) for a given electrode size. As a result, the ratio must be elevated for these forms to the region of 2:1 to 3:1. Changing the exterior surface with a variety of grooves or cuts, or by using coiled wire to produce a similar form, assists vaporisation performance by stimulating the vapour pocket retention of the brush-type electrodes, thereby allowing a reduction in the ratio.

An arthroscopic electrode may be characterised as short (100-140mm), rigid, and having a working diameter up to 4mm. If can be introduced through a stab incision into a joint cavity (with or without a cannula) using the triangulation technique. It is operated with a motion which commonly moves the electrode between the 9 o'clock and 3 o'clock positions on the arthroscopic image. As a result, the tissue to be treated is commonly approached at a shallow working angle with respect to the axis of the electrode. The active electrode, therefore, needs to include a range of end-effect to side-effect properties. In certain circumstances, an end-effect is desirable, particularly as an end-effect is very difficult to obtaining using a shaver device wherein the centre of rotation represents the desired point of application. The tissue to be treated (such as meniscal cartilage) is commonly dense and of a high electrical impedance with a free edge of the cartilage representing the common site of injury where treatment is required. The electrode units E2 and E3 are end-effect electrode units suitable for arthroscopic use.

Either extensions or side-effect configurations of the insulator material assist with engagement, and prevent unwanted effects occurring in adjacent structures - usually the articular surfaces of the femur and tibia. In addition, the extension or side-effect electrode forms (of Figures 8 and 9) also assist in retaining the vapour pocket, and prevent cooling of the saline in the immediate vicinity of the active electrode by the flow of saline irrigant commonly from the endoscope.

The risk of heating distension fluid within the joint cavity occurs primarily during power application to reach the vaporisation threshold. Once the threshold has been reached, power requirements typically fall by 30-50%. Reducing the ratio increases the power requirement to reach the threshold so that, despite the high impedance of the target tissue, it is undesirable to reduce the ratio to the lowest value capable of supporting vaporisation. The feature of vaporisation threshold control retains vapour pockets and heated saline in the interstices of the electrode, and configures the insulator to reduce the effect of irrigant flow, thereby assisting in reducing the power required to establish vaporisation and hence the risk of unwanted heating.

By way of example, the coiled wire-form electrode of Figure 6 entraps vapour products, as does the electrode of Figure 8 (a side-effect form with the added feature of the insulator shrouding the non-contact region of the active electrode). The addition of the insulator shrouding feature can halve the power required to reach the vaporisation threshold.

Typically, in arthroscopic use, the primary function comprises rapid debulking of dense, a vascular tissue. The volume of tissue removed can be increased for a given size of electrode by a combination of the vaporisation threshold control feature and by increasing the output voltage from the RF generator 1. Figure 10 shows a schematic of the brush-type electrode of Figure 8, wherein the vapour threshold is exceeded, and a vapour pocket, indicated by the reference P, is established around each of the filaments.

When applied to tissue, particularly firm, dense tissue such as that comprising meniscal cartilage, the result will be vaporisation of a series of grooves in the tissue corresponding each of the filaments. Increasing the RF output voltage will increase the size of the vapour pockets around each of the filaments which, because of the retention will reach the stage, shown in Figure 11, where they merge to form a contiguous vapour pocket, indicated by the reference P', so that tissue which may otherwise have passed between the filaments is also vaporised.

Our European Patent Application No. 96304558.8 discloses discrimination between desiccation and vaporisation output functions. It also discloses that a blended function can be created by constantly alternating between these output states. Vaporisation threshold control is particularly advantageous in these circumstances, as the hot saline created by the desiccate output phase is retained in proximity to the active electrode such that the vaporisation threshold is rapidly exceeded during the vaporisation cycle. This is useful as a method to achieve simultaneous desiccation when detaching muscle from bony attachments, such as is performed in an acromioplasty of the shoulder joint, or when debulking diseased tissue with a vascular component such as synovium.

The embodiment of Figure 9 is particularly useful with a resectoscope to perform electrosurgical vaporisation of the prostate (EVAP). This particular configuration comprises a roller bar (cylindrical) active electrode 71, typically 2.4 to 3mm in diameter by 3 to 4 mm in width. It is evident that the return electrode 74 could be mounted in an axially-separated arrangement on the shaft 72. Under these circumstances, however, the size of the active electrode 71, and the exposure of the complete surface area to the conductive environment as well as the cooling effect of irrigant flow over the electrode, would require a very high power to reach the vaporisation threshold.

It will be appreciated that the electrode 71 can be grooved or ridged so as to further reduce the vaporisation threshold. Similarly, the side-effect active electrode of Figure 8 which could be axially or transversely mounted with respect to the axis of the resectoscope), could be substituted for the electrode assembly of Figure 9. In this case, the active electrode would not provide a mechanical rolling function.

This instrument can also be used to perform electrosurgical vaporisation of soft tissue tumours, such as a prostatic adenoma, without use of a dispersive return plate in a conductive fluid environment. It can also be applied to fibroids using a resectoscope in the uterine cavity.

Figures 12 to 14 show a modified form of the electrode unit E4 of Figure 8. This electrode unit E6 has an active electrode 91 in the form of a coiled-spring electrode mounted within a cut-out $92a^1$ formed in an arcuatic extension 92a of an insulation member 92, the arcuate extension forming a shroud for the active electrode. The coiled-spring electrode 91 is made of a refractory metal such as tungsten or tantalum, or an alloy of tungsten or platinum, and its proximal end is connected to the RF generator 1 by an insulated central copper conductor (not shown). As shown in Figure 13, the insulation member 92 is formed with a recess 92b which receives a return electrode 93 having an extension 93a (see Figure 14) which overlies the active electrode 91.

As shown in Figure 14, the active electrode 91 has a distal end portion which is exposed at the distal end of the instrument for tissue contact. This embodiment has advantages over the earlier embodiments, particularly where access is needed to remote areas of a joint cavity.

Figure 14 illustrates the way in which the insulation member 92 projects laterally in the region between the active electrode 91 and the extension 93a of the return electrode 93. This laterally-projecting part of the insulation member 92 increases the conductive fluid path length from the active electrode 91 to the return electrode 93, and forces the electric field outwardly, thereby preventing preferential arcing between the return electrode and the nearest part of the active electrode, and promoting arcing between the active electrode and the neighbouring tissue. The return electrode 93 is spaced from the active electrode 91 so that, in use, it does not contact the tissue to be treated, and so that the electrical circuit is always completed by the saline, and not simply arcing between the electrodes. Indeed, the arrangement is such that arcing between adjacent parts of the electrode assembly is avoided, thereby ensuring that the active electrode 91 can become enveloped in a vapour pocket, so that tissue entering the vapour pocket becomes the preferred path for current to flow back to the return electrode 93 via the conductive fluid.

To consider the operation of the electrode unit E6 in more detail, when it operates in a tissue cutting or vaporising mode, a vapour bubble is formed around the tip 91a of the active electrode 91. This tip 91a constitutes an active electrode treatment portion. This bubble is sustained by arcing within it. The greater the applied voltage, the greater is the size of the bubble. The energy dissipated by each arc is impedance-limited by the remaining fluid in the conduction path, and by the source impedance of the generator. However, an arc behaves as a negative impedance in that, if the energy in the arc is sufficiently high, an ionised path of very low impedance is formed. This can lead to an unstable condition of ever-decreasing ionised path impedance, unless the impedance of the fluid between the bubble and the return electrode 93 is sufficient to act as a limit on dissipated power. It is also possible for the vapour pocket around the active electrode treatment portion 91a to encroach the return electrode 93. In these circumstances, the arc energy is limited only by generator source impedance, but such power limitation is poor and cannot be adjusted according to electrode size. For these reasons, the dimensions and configuration of the insulation member 92 should be such as to define a minimum conduction path length of 1mm between the active electrode treatment portion 91a and the fluid contact surface of the return electrode 93. This minimum path length is, in the case of the embodiment shown in Figure 14, the arc length a of the insulation member 92 plus the step dimension c of the laterally-projecting part of the insulation member.

A further consideration is the possibility of a vapour pocket forming only over part of the exposed treatment portion 91a of the active electrode 91. When the applied voltage and power are sufficiently high, a vapour pocket will form around the active electrode exposed treatment portion 91a. Preferably, the pocket is formed uniformly over the entire length of the treatment portion 91a. In such a situation, the load impedance presented to the generator 1 can change by as much as a factor of 20. However, when there are significant differences in the conduction path length between the return electrode fluid contact surface 93a and different parts of the exposed active electrode treatment portion 91a, a voltage gradient is established over the length of each electrode. With some insulation member and active electrode configurations, the voltage gradient can be sufficiently large to enable vapour pocket formation only over that part of the exposed treatment portion closest to the fluid contact surface, leaving the extreme distal end of the exposed treatment portion still in contact with the conductive fluid. Thus, the voltage gradient is established within the conductive fluid where the edge of the vapour pocket intersects the surface of the active electrode treatment portion 91a. The electrical behaviour of such a partially-enveloped active electrode treatment portion 91a is very different from that of a fully-enveloped treatment portion. In terms of controlling generator output by sensing peak voltage, the behaviour of the electrode assembly is no longer bistable. However, the power demand is considerably higher as a result of the vaporisation voltage presented across the low impedance wetted region of the active electrode treatment portion 91a. The clinical effect is not only the required vaporisation, but also a potentially undesirable thermal damaging effect resulting from the increased power dissipation.

Partial enveloping of the active electrode treatment portion 91a can be largely avoided by ensuring that the ratio of the length (b) of the conductive path between the furthermost point of the active electrode treatment portion and the length of the shortest conductive path between the active electrode treatment portion and the fluid contact surface is at most 2:1 i.e. b/ (a+c) 2. The laterally-projecting portion of the insulation member 92 defines an insulation barrier to direct electrical current flow through the fluid medium, thereby increasing the shortest conductive path between the fluid contact surface 93a and the active electrode 91.

It will be noted, from Figure 14, that the downward extent of the exposed active electrode treatment portion, i.e. the distance d by which the active electrode projects beyond the shrouding parts of the insulation member 92 on each side, is at least one half of the width of the exposed treatment portion in a transverse plane. This allows the instrument to be rotated about the axis of its shaft to some extend without losing the required surgical effect.

Figure 14 also shows that the active electrode 91 has an exposed end (the tip 91a) which extends laterally through the cut-out 92a[1] in a first direction which is opposite to the direction in which the fluid contact surface 93a faces. This first direction defines a treatment axis which lies in a common plane with the two shortest conductive paths referred to above.

By varying the output of the generator 1, each of the electrode units E1 to E6 can be used for tissue removal by vaporisation, or for desiccation. Figure 15 illustrates how the RF generator 1 can be controlled to take advantage of the hysteresis which exists between the desiccation and the vaporising modes of an electrode unit. Thus, assuming the electrode assembly of the electrode unit is immersed in a conductive fluid medium such as saline, there is an initial impedance "r" at point "O", the magnitude of which is defined by the geometry of the electrode assembly and the electrical conductivity of the fluid medium. The value of "r" will change when the active electrode contacts tissue, the higher the value of "r", the greater the propensity of the electrode assembly to enter the vaporisation mode. When RF power is applied to the electrode assembly, the fluid medium heats up. Assuming the fluid medium is normal saline (0.9% w/v), the temperature coefficient of the fluid medium is positive, so that the corresponding impedance coefficient is negative. Thus, as power is applied, the impedance initially falls and continues to fall with increasing power dissipation to point "B", at which point the saline in intimate contact with the electrode assembly reaches boiling point. Small vapour bubbles form on the surface of the active electrode and the impedance then starts to rise. After point "B", as power is increased further, the positive power coefficient of impedance is dominant, so that small increases in power now bring about large increases in impedance.

As a vapour pocket forms from the vapour bubbles, there is an increase in the power density at the residual electrode/saline interface. There is, however, an exposed area of the active electrode not covered by vapour bubbles, and this further stresses the interface, producing more vapour bubbles and thus even higher power density. This is a run-away condition, with an equilibrium point only occurring once the electrode is completely enveloped in vapour. The only means of preventing the run-away condition is to limit applied voltage, thereby preventing power dissipation into higher impedance loads. For given set of variables, there is a power threshold before this new equilibrium can be reached (point "C").

The region of the graph between the points "B" and "C", therefore represents the upper limit of the desiccation mode. The transition from point "C" to the vaporise equilibrium state will follow the power impedance curve for the RF stage of the generator (shown as a dotted line in Figure 15). Once in the vaporisation equilibrium state, the impedance rapidly increases to around 1000 ohms, with the absolute value depending on the system variables. The vapour pocket is then sustained by discharges across the vapour pocket between the active electrode and the vapour/saline interface. The majority of power dissipation occurs within this pocket, with consequent heating of the active electrode The amount of energy dissipation, and the size of the pocket, depends on the output voltage. If this is too low, the pocket will not be sustained, and if it is too high the electrode assembly will be destroyed. It should be noted that, if power were delivered at the same level as point "C", the resulting voltages would cause electrode destruction. The normal operating point for an electrode used for vaporisation is illustrated by point "D". This point is defined uniquely by the combination of the impedance power characteristic for the electrode in conjunction with the vaporise voltage limit.

The dotted line E indicates the power level above which electrode destruction is inevitable. As the power is reduced, the impedance falls until, at point "A", the vapour pocket collapses and the electrode assembly reverts to the desiccation mode. At this point, power dissipation within the vapour pocket is insufficient to sustain it, so that direct contact between the active electrode and the saline is re-established, and the impedance falls dramatically. The power density at the active electrode also falls, so that the temperature of the saline falls below boiling point. The electrode assembly is then in a stable desiccation mode.

It will be apparent that each of the electrode units E1 to E6 can be used for desiccation by operating the unit in the region of the graph between the point "O" and a point in the region between the points "B" and "C". In this case, the electrode assembly would be introduced into a selected operation site with the active electrode and the return electrode immersed in the saline. The RF generator 1 would then be activated (and cyclically controlled as described below) to supply sufficient power to the electrode assembly to maintain the saline adjacent to the active electrode at, or just below, its boiling point without creating a layer of vapour around the active tip. The electrode assembly would then be manipulated to cause heating and desiccation of the tissue in a required region adjacent to the active electrode. The electrode unit can be used for vaporisation in the region between the point "D" and the dotted line F which constitutes the level below which vaporisation cannot occur. The upper part of this curve is used for tissue removal by vaporisation. It should also be appreciated that each of the electrode units could be used for cutting tissue. In the cutting mode, the electrode unit still operates with a vapour pocket, but this pocket is much smaller than that used for vaporisation, so that there is the least amount of tissue damage commensurate with cutting. Typically, the generator 1 operates at about 270 volts peak for cutting.

The generator 1 will now be described in greater detail, this generator being such as to allow both desiccation electrosurgery substantially without unwanted cell disruption, and electrosurgical cutting or vaporisation substantially without electrode burning. Although intended primarily for operation in a conductive liquid distension medium such as saline, it has application in other electrosurgical procedures, e.g. in the presence of a gaseous distension medium, or wherever rapid load impedance changes can occur.

Referring to Figure 16, the generator 1 comprises a radio frequency (RF) power oscillator 160 having a pair output connections 160C for coupling via output terminals 162 to the load impedance 164 represented by the electrode assembly when in use. Power is supplied to the oscillator 160 by a switched mode power supply 166.

In the preferred embodiment, the RF oscillator 160 operates at about 400 kHz, with any frequency from 300 kHz upwards into the HF range being feasible. The switched mode power supply typically operates at a frequency in the range of from 25 to 50 kHz. Coupled across the output connections 160C is a voltage threshold detector 168 having a first output 168A coupled to the switched mode power supply 166, and a second output 168A coupled to an "on" time control circuit 170. A microprocessor controller 172 coupled to the operator controls the display 8 (shown in Figure 2), and is connected to a control input 166A of the power supply 166 for adjusting the generator output power by supply voltage variation, and to a threshold-set-input 168C of the voltage threshold detector 168 for setting peak RF output voltage limits.

In operation, the microprocessor controller 172 causes power to be applied to the switched mode power supply 166 when electrosurgical power is demanded by the surgeon operating an activation switch arrangement which may be provided on the handpiece 3 or on the footswitch unit 5 (see Figure 2). A constant output voltage threshold is set via the input 168C according to control settings on the front panel of the generator 1 (see Figure 2). Typically, for desiccation or coagulation, the threshold is set at a desiccation threshold value between 150 volts and 200 volts. When a cutting or vaporisation output is required, the threshold is set to a value in the range of from 250 or 300 volts to 600 volts. These voltage values are peak values. Their being peak values means that, for desiccation at least, it is preferable to have an output RF waveform of low crest factor to give maximum power before the voltage is clamped at the values given. Typically a crest factor of 1.5 or less is achieved.

When the generator 1 is first activated, the status of the control input 160I of the RF oscillator 160 (which is connected to the "on" time control circuit 170) is "on", such that the power switching device which forms the oscillating element of the oscillator 160 is switched on for a maximum conduction period during each oscillation cycle. The power delivered to the load 164 depends partly on the supply voltage applied to the RF oscillator 160 from the switched mode power supply 166, and partly on the load impedance 164. If the supply voltage is sufficiently high, the temperature of the liquid medium surrounding the electrodes of the electrosurgical instrument may rise to such an extent that the liquid medium vaporises, leading to a rapid increase in load impedance and a consequent rapid increase in the applied output voltage across the terminals. This is an undesirable state of affairs if a desiccation output is required. For this reason, the voltage threshold for a desiccation output is set to cause trigger signals to be sent to the "on" time control circuit 170 and to the switched mode power supply 166 when the threshold is reached. The "on" time control circuit 170 has the effect of virtually instantaneously reducing the "on" time of the RF oscillator switching device. Simultaneously, the switched mode power supply is disabled so that the voltage supplied to oscillator 160 begins to fall.

Subsequent control of the "on" time of individual cycles of the oscillator 160 will be understood by considering the internal configuration of the "on" time control circuit which is shown in Figure 17. The circuit comprises an RF sawtooth generator 174 (synchronised at the RF oscillation frequency by a synchronisation signal derived from the oscillator and applied to a synchronisation input 174I), and a ramp generator 176 which is reset by a reset pulse from the output 168B of the voltage threshold detector 168 (see Figure 16) produced when the set threshold voltage is reached. This reset pulse is the trigger signal referred to above. The "on" time control circuit 170 further comprises a comparator 178 for comparing the sawtooth and ramp voltages produced by the sawtooth and ramp generators 174 and 176 to yield a square wave control signal for application to the input 160I of the RF oscillator 160. As shown by the waveform diagrams in Figure 17, the nature of the sawtooth and ramp waveforms is such that the mark-to-space ratio of the square wave signal applied to the oscillator 160 progressively increases after each reset pulse. As a result, after a virtually instantaneous reduction in "on" time on detection of the output voltage reaching the set voltage threshold, the "on" time of the RF oscillator 160 is progressively increased back to the original maximum value. This cycle is repeated until the supply voltage for the oscillator 160 from the power supply 166 (Figure 16) has reduced to a level at which the oscillator can operate with the maximum conduction period without the output voltage breaching the set voltage threshold as sensed by the detector 168.

The output voltage of the generator 1 is important to the mode of operation. In fact, the output modes are defined purely by output voltage, specifically the peak output voltage. The absolute measure of output voltage is only necessary for multiple term control. However, a simple term control (i.e. using one control variable) can be used in this generator 1 in order to confine the output voltage to predetermined limit voltages. Thus, the voltage threshold detector 168 shown in Figure 16 compares the RF peak output voltage with a preset DC threshold level, and has a sufficiently fast response time to produce a reset pulse for the "on" time control circuit 170 within one RF half cycle.

Before considering the operation of the generator 1 further, it is appropriate to refer back to the impedance power characteristic of Figure 15. It will be appreciated that the most critical control threshold is that applicable during desiccation. Since vapour bubbles forming at the active electrode are non-conducting, the saline remaining in contact with the electrode has a higher power density and consequently an even greater propensity to form vapour. This degree of instability brings about a transition to a vaporisation mode with the same power level due to the runaway increase in power density at the active electrode. As a result, the impedance local to the active electrode rises Maximum absorbed power coincides with the electrode condition existing immediately before formation of vapour bubbles, since this coincides with maximum power dissipation and the greatest wetted electrode area. It is, therefore, desirable that the electrode remains in its wetted state for the maximum desiccation power. Use of voltage limit detection brings about a power reduction, which allows the vapour bubbles to collapse which, in turn, increases the ability of the active electrode to absorb power. For this reason, the generator 1 includes a control loop having a large overshoot, in that the feedback stimulus of the peak voltage reaching the predefined threshold causes a large instantaneous reduction in power. This control overshoot ensures a return to the required wetted state.

In the generator 1 described above with reference to Figures 16 and 17, power reduction in response to voltage threshold detection takes place in two ways:-

(a) an instantaneous reduction in RF energy supplied to the resonant output circuit of the oscillator 160, and

(b) a shut down of DC power to the oscillator 160 for one or more complete cycles of the switched mode power supply (i.e. typically for a minimum period of 20 to 40μs).

In the preferred embodiment, the instantaneous power reduction is by at least three quarters of available power (or at least half voltage) from the DC power supply, but continuous voltage threshold feedback continually causes a reduction in delivered power from the DC power supply. Thus, a high speed response is obtained in the RF stage itself, with the DC supply voltage tracking the reduction to enable the RF stage to return to a full duty cycle or mark-to-space ratio, thereby enabling further rapid power reductions when the voltage threshold is again breached.

The effect of this process on the RF output voltage is shown in the waveform diagram of Figure 18, containing traces representative of the output voltage, the oscillator supply voltage, and the load impedance during a typical desiccation episode over a 1 ms period.

Starting on the left-hand side of the diagram with the supply voltage approximately constant, the output voltage increases with increasing load impedance to a point at which the output voltage threshold is reached, whereupon the above-described instantaneous reduction in oscillator "on" time occurs. This produces a rapid decrease in the RF output voltage, as shown, followed by a progressive increase, again as described above. When the output voltage reaches the threshold voltage, the voltage threshold detector 168 (shown in Figure 16) also disables the power supply, leading to a gradual decrease in the supply voltage. As a result, when the "on" time of the oscillator device has once again reached its maximum value, illustrated by point a in Figure 18, the threshold voltage has not been reached. However, the load impedance begins rising again, cause a further, albeit slower, increase in the output voltage until, once again, the threshold voltage is reached (point b). Once more, the "on" time of the oscillator is instantly reduced and then progressively increased, so that the output voltage waveform repeats its previous pattern. Yet again, the threshold voltage is reached, again the output voltage is instantly reduced (at point c), and again the "on" time is allowed to increase. On this occasion, however, due to the supply voltage having further reduced (the power supply still being disabled), the output voltage does not reach the threshold level (at point d) until a considerably longer time period has elapsed. Indeed, the length of the period is such that the output voltage has failed to reach the threshold voltage over a complete switching cycle of the power supply, so that it has in the meantime been enabled (at point e).

The generator output impedance is set to about 160 ohms. The effect of this choice will be evident from the following description with reference to Figures 19 and 20 which are graphs showing the variation of output power which can be produced by the generator into different load impedances.

Referring to Figure 19, the power delivered to the load is here shown as a function of load impedance for two different oscillator supply voltage settings. In both cases, it will be seen that, to the left of the power/impedance peak, an increase in load impedance leads to an increase in output power and, hence, an increase in output voltage. At higher impedances, to the right of the peaks, the voltage continues to increase, albeit less aggressively, as impedance increases.

One of the features of the preferred generator in accordance with the invention is that the output stage operates as an open loop oscillator with an output impedance (corresponding to the peaks in Figure 19) of about 160 ohms. This is considerably lower than the output impedance of conventional generators used for underwater electrosurgery, and contributes to the ability to prevent runaway arcing behaviour and consequent excessive tissue damage and electrode burn-out.

It should be understood that, for desiccation, steam envelope generation to the electrode and arcing should be prevented. Conversely, for cutting or vaporisation, steam envelope generation and arcing are required, but to a level consistent with achieving the required tissue effect and the avoidance of electrode burn-out. Operating points for low and high power desiccation and cutting or vaporisation are shown in Figure 19.

A feature of the combination of the generator in accordance with the invention and an electrode assembly having two adjacent electrodes is that the output is virtually bistable. When operating in desiccation mode, the entire electrode surface is in contact with an electrically-conductive medium and, therefore, the load impedance is comparatively low, consequently inhibiting the rise in output voltage to a level sufficient for arcing. Conversely, when in cutting or tissue vaporisation mode, the entire active electrode surface is covered with a layer of vapour which is of much higher impedance, and the vapour pocket is sustained by arcing within it so that nearly all of the power dissipation occurs within the vapour envelope. In order to traverse from a desiccation mode to the cutting mode, a high power burst is required, hence the positioning of the power/load curve peak between the desiccation and cutting operation points on the curve. By allowing the output power to increase with impedance in this way, a high power burst of sufficient energy to create arcing is achieved despite the lower impedance presented by the electrodes. As the supply voltage to the oscillator is increased, it has a greater propensity to flip into the cut mode, whilst, at lower supply voltage levels, the bistable nature of the output, although more pronounced, tends towards the desiccation state.

The bistable properties arise not only from the electrode impedance behaviour, but also from the shape of the power/load impedance curve. The flatter the load curve, the more constant the output power across a band of impedances, and the less pronounced the effect.

Referring to Figure 19, it will be appreciated that, in the cut or tissue vaporisation mode, a power equilibrium point is achieved by virtue of the decreasing output power as impedance increases. In the desiccation mode, the equilibrium is less straightforward, because there are two impedance change mechanisms. The first mechanism is the heating of the conductive medium and/or tissue which, due its positive coefficient of conductivity, results in a fall in impedance initially, so that, when power is first applied, the operating point moves towards the left-hand side of the diagram in Figure 19. Consequently, there is a well-defined equilibrium point defined by the reduction in impedance with increasing power supply voltage, and the consequent reduction in delivered output power. However, when the saline medium or tissue fluids in contact with the active electrode start to boil, small water vapour bubbles begin to form which increase the impedance. When the generator 1 is about to flip into the cutting mode, impedance rise due to steam formation is dominant. The impedance change, therefore, becomes positive with increasing supply voltage, and the operating point moves towards the right-hand side of the diagram, which allows greater input power as a result of the shape of the load curve, causing a rapid change to cutting or vaporisation mode. As steam formation continues to increase, the increasing impedance causes a fall-off in delivered output power.

The applicants have found that the inherent equilibria described above may be insufficient to maintain a stable coagulation (or desiccation) state or a stable cutting (or vaporisation) state. It is for this reason, that the RF output voltage from the RF oscillator 160 (Figure 16) is limited, the limiting occurring extremely rapidly, typically with a response time of 20μs or less. Excessive RF interference is avoided by linear variation of the oscillator switching device "on" time in response to a feedback signal from the voltage threshold detector. This technique is used in conjunction with the RF oscillator having a comparatively low output Q when matched to the load, this Q being sufficient to suppress switching noise without inordinately damping the response to output threshold detection.

By way of example, the effect of voltage threshold control for a particular electrode configuration is shown in Figure 20. The heavy lines 200 and 202 indicate the modified power/load impedance characteristics. For desiccation, shown by line 200, the switched mode power supply is set to produce a peak (matched) open loop output power of between 75 watts and 100 watts, with the actual peak power in this case being about 90 watts. For cutting and vaporisation (shown by line 202), the peak power can be between 120 watts and 175 watts. In this case it is 150 watts. As examples, the voltage thresholds are set at 180 volts peak for desiccation and 300 volts peak for cutting, as illustrated by the hyperbolic constant voltage lines 204 and 206 respectively. The power/impedance curves follow the respective constant voltage threshold lines to the right of their intersection with the unmodified open loop curves 208 and 210. Thus, it will be understood that the desiccation threshold line represents the maximum voltage that can be achieved in the desiccation mode before arcing is produced, whilst the cut threshold line limits the cutting or tissue vaporisation performance to achieve the desired tissue effect and, in the extreme, to avoid electrode burn-out. The desiccation threshold line also represents a voltage insufficient to achieve arcing for cutting or vaporising tissue.

A significant feature of the generator characteristic for electrosurgical cutting or tissue vaporisation is that, at peak power (matched impedance), the load impedance lies between the impedances corresponding to the threshold voltages at that power level. In contrast, in the desiccation mode, the power/load impedance characteristic has a power peak at an impedance lying below the desiccation threshold line at that power level.

In practice, the output power in the desiccation mode will be higher than in the cutting or tissue vaporisation mode. The reason for this statement (despite the apparent contradiction with the load curves in Figure 20) is that the equilibrium points described above lie at different points on the respective curves. To ensure cutting, the high peak power of the higher curve is required to reach the cut threshold line (corresponding to 300 volts peak). The cutting mode then follows the cutting or vaporisation threshold line. The cutting operating point is defined by the load impedance created when a suitable level of arcing is occurring. Typically, the load impedance in these circumstances is greater than 1000 ohms. Thus, although a full 150 watt peak power is available to ensure that vapour pockets are formed to promote arcing for cutting, the actual power drawn during cutting or tissue vaporisation for this particular electrode example may be between 30 watts and 40 watts. This situation is more easily understood if reference is also made to Figure 15.

In the desiccation mode, the operating point is determined by the positive power coefficient of impedance arising from steam generation. Consequently, the equilibrium naturally occurs in the region of the peak of the desiccation mode power/load impedance curve.

The electrode unit E6 of Figures 12 to 14 has an active electrode 91 having a fluid-contacting surface area that is 1.1 times the fluid-contacting surface area of the return electrode 93. Known bipolar instruments cannot vaporise a surrounding electrically-conductive fluid such as saline if the ratio of these areas approaches 0.5 to 1. The electrode unit E6 can, however, vaporise surrounding saline. This is because of special properties of the active electrode 91 and the generator 1, to be described below.

The active electrode of known instruments is such that the vapour pocket is established as an equilibrium between vapour creation and vapour condensation. However, in order to reach this condition, the active electrode itself must have a temperature in excess of 100°C. Thermal conduction away from the active electrode before the pocket is created will, therefore, increase the power demand. It is important to realise that this thermal conduction may be along the active electrode itself, or to an adjacent component such as an insulator. During use, the active electrode may be intermittently wetted. This wetting is random, and does not necessarily wet the ensure surface of the active electrode. If a large area active electrode were constructed of thermally-conductive material, this occasional wetting could reduce the overall temperature of the active electrode so that vaporisation collapses or is quenched. Thermal conduction away from the active electrode can, however, be the only thermal dissipation mechanism for the active electrode, and so can be important. For optimum vaporisation performance, the active electrode, needs to be between the lower limit of 100°C and the destructive limit defined by its melting point.

The active electrode 91 of the electrode unit E6, though made of a material that is normally considered to be a good thermal conductor, actually has poor thermal conductivity across its surface because of the inbuilt thermal barriers constituted by vapour trapped in the gaps formed between the adjacent turns of the coil. The poor thermal conductivity across its surface prevents the thermal dissipation referred to above, and ensures that this unit E6 can be used in the vaporisation mode.

Similar considerations apply to each of the other electrode units E1 to E5. Thus, as the active electrode 31 of the electrode unit E1 is not bonded to the ceramic insulator body 35, contact between these two items is by isolated points only. Consequently, a thin gap is present between the active electrode 31 and the insulator body 35, and this gap traps vapour, thereby constituting a thermal barrier which prevents the thermal dissipation referred to above, and ensures that the unit E1 can be used in the vaporisation mode. Moreover, the active electrode 31 is made of stainless steel which has a relatively poor thermal conductivity, and this (together with the vapour trapping) allows a large thermal gradient across its surface.

The coil active electrodes 41 of the electrode units E2 and E4 are similar to the coil active electrode 91 of the electrode unit E6, the gaps between adjacent turns trapping vapour, thereby constituting thermal barriers. Similarly, the gaps between the adjacent filaments of the active electrode 61 of the electrode unit E3 trap vapour, and so constitute thermal barriers. Finally, the gap between the spherical active electrode 71 and the shroud 73 of the electrode unit E5 defines a gap which traps vapour, thereby constituting a thermal barrier. In each case, the vapour trapped can be vaporised tissue and/or water vapour.

The other factor ensuring that the vaporisation mode can be maintained with each of the electrode units E1 to E6 is that, as described above with reference to Figures 16 to 20, the generator 1 has a low source impedance of 160 ohms, and is capable of rapid voltage-dependent power reduction upon formation of a vapour pocket around the active electrode 91, thus permitting the control of high-rate vaporisation of tissue.

The electrosurgical instruments described above also have irrigated electrode applications. Thus, each utilises a method of creating a localised saline working environment as a means of completing the electrical circuit of axially separated active and return electrodes to perform tissue vaporisation, cutting and desiccation in a gas or air filled body cavity whether of natural origin or created surgically, or at a tissue surface of the body whether of natural origin or created surgically.

More specifically, each such instrument utilises a method of removing tissue by vaporisation wherein the products of vaporisation are aspirated from the site of application by suction through, or adjacent to, the active electrode assembly. Diseased tissue can be also removed by vaporisation from natural body cavities such as sinuses, nasal cavities and the oropharynx. Similarly, diseased tissue can be removed by vaporisation from the abdominal cavity under gaseous distension.

Such an instrument can also be used to create the surgical access to an interstitial site where the tissue to be treated is lying deep to the tissue surface.

It will be apparent that the invention permits power consumption during vaporisation of the conductive liquid to be reduced by hindering the dissipation of heat from the active electrode to the surroundings (particularly to the body of the instrument shaft and to the surrounding saline), so as to lower the power threshold of vaporisation. This can be achieved by limiting convection by hindering the flow of saline around the electrode, by providing recesses or spaces in and around the electrode to trap vapour, and by limiting cross-electrode thermal conduction by, for instance, forming the electrode in parts with thermal barriers between them. This latter measure reduces the possibility of vapour pocket collapse by part of the electrode being wetted and heat then being conducted away from other parts of the electrode to the wetted part.

Claims

1. An electrosurgical system for the vaporisation of tissue in the presence of an electrically-conductive medium, the system comprising an electrosurgical generator for generating radio frequency power, and an electrosurgical instrument connectible to the generator, wherein:

the generator has a radio frequency output stage for delivering radio frequency power to a pair of output connections, which output stage has an open loop output impedance of less than 250 ohms;

the electrosurgical instrument comprises an instrument shaft and, situated at a distal end of the shaft, an electrode assembly comprising an active electrode with an exposed treatment portion and a return electrode with an exposed fluid contact surface, the fluid contact surface being set back from the treatment portion so that, when the electrode assembly is brought into an operative position with the treatment portion on, or adjacent to, the surface of the tissue to be treated, the fluid contact surface is further from the tissue surface than the treatment portion; and

the ratio of the surface area of the exposed treatment portion to the surface area of the exposed fluid contact surface is greater than or equal to 0.5 to 1;

the electrode assembly further comprising means associated with the active electrode for hindering the dissipation of heat from the active electrode to its surroundings, thereby to encourage the formation and maintenance of a layer of vapour over its surface.

2. A system according to claim 1, wherein the heat dissipation hindering means comprises a shroud partly covering the active electrode, with a space between the shroud and the active electrode, said space defining a gap which, in use, traps vapour thereby constituting a thermal barrier for hindering the dissipation of heat from the active electrode to its surroundings.

3. A system according to claim 1, wherein the heat dissipation hindering means comprises a cavity in the active electrode, the cavity being effective to trap vapour

thereby constituting a thermal barrier for hindering the dissipation of heat from the active electrode to its surroundings.

4. A system according to claim 3, wherein the active electrode is formed as a tube with at least one open end.

5. A system according to claim 4, wherein the active electrode is in the form of a tubular wire coil, gaps between adjacent turns of the coil trapping said vapour, and thereby constituting the thermal barrier.

6. A system according to claim 1, wherein the active electrode is formed as a plurality of electrically-interconnected electrode parts, and the heat dissipation hindering means comprises a thermal barrier between said electrode parts to hinder heat conduction between said parts.

7. A system according to claim 6, wherein the active electrode is in the form of a tubular wire helix, gaps between adjacent turns of the helix being effective to trap vapour, thereby constituting the thermal barrier.

8. A system according to claim 6, wherein the active electrode comprises a metallic body with a ridged, outwardly-directed treatment surface, the active electrode being mechanically fitted to an insulator positioned between, and electrically insulating, the return electrode from the active electrode, in such a manner that a gap is defined between the active electrode and the insulator, vapour trapped in the gap constituting the thermal barrier.

9. A system according to claim 1, wherein the active electrode comprises a plurality of electrically-common filamentary members arranged side-by-side, gaps between the filamentary members being effective to trap vapour, thereby constituting a thermal barrier for hindering the dissipation of heat from the active electrode to its surroundings.

10. A system according to claim 9, wherein a single coiled filament constitutes the filamentary members, the coils of the filament constituting the filamentary members, and gaps between adjacent turns of the coil trapping said vapour, thereby constituting the thermal barrier.

11. A system according to claim 1, wherein the generator includes means for limiting the peak radio frequency output voltage at said output connections to a threshold voltage in the range of from 250v to 600v peak.

12. A system according to claim 11, wherein the output range includes a radio frequency power switching device which is arranged to switch on and off repeatedly at the radio frequency of the radio-frequency output signal of the generator, and the voltage limiting means comprises a peak voltage sensor and a feedback circuit connected to the sensor and to the switching device, and arranged to reduce the conductive periods of the switching device when the peak output voltage reaches said threshold.

13. A system according to claim 12, wherein the sensor and the feedback circuit are operable in conjunction to reduce the radio frequency power delivered from the switching device to the output connections by at least 50% in less than 100 μs in response to the voltage across said output connections reaching said threshold.

14. A system according to claim 1, wherein said output impedance is in the range of from 50 ohms to 250 ohms.

15. A system according to claim 14, wherein said output impedance is in the range of from 130 ohms to 190 ohms.

16. A system according to claim 15, wherein said output impedance is 160 ohms.

17. An electrosurgical instrument for the treatment of tissue in the presence of an electrically-conductive fluid medium, the instrument comprising an instrument shaft

and an electrode assembly at a distal end of the shaft, wherein the electrode assembly comprises:

a single active electrode having an exposed tissue treatment portion;

a return electrode having an exposed fluid contact surface; and

an insulating member positioned between and electrically insulating the active electrode and the return electrode, and serving to space apart the exposed treatment portion of the active electrode and the exposed fluid contact surface of the return electrode, the fluid contact surface of the return electrode being set back in the direction of a treatment axis of the assembly from the active electrode exposed treatment portion;

and wherein the ratio of the area of the exposed treatment portion to the area of the exposed fluid contact surface is greater than or equal to 0.5 to 1; and

the active electrode is constituted by a singled coiled filament which defines a generally tubular member, adjacent turns of the coiled filament defining indentations in said generally tubular member, said indentations constituting thermal barriers for limiting thermal conduction along said generally tubular member, whereby, in use , application of sufficient radio frequency power to the electrode assembly vaporises the conductive fluid medium adjacent to the tissue treatment portion to create a stable vapour pocket around the tissue treatment portion.

18. An electrosurgical instrument for the treatment of tissue in the presence of an electrically-conductive fluid medium, the instrument comprising an instrument shaft and an electrode assembly at a distal end of the shaft, wherein the electrode assembly comprises:

a single active electrode having an exposed tissue treatment portion;

a return electrode having an exposed fluid contact surface; and

an insulating member positioned between and electrically insulating the active electrode and the return electrode, and serving to space apart the exposed treatment portion of the active electrode and the exposed fluid contact surface of the return electrode, the fluid contact surface of the return electrode being set back in the direction of a treatment axis of the assembly from the active electrode exposed treatment portion;

and wherein the ratio of the area of the exposed treatment portion to the area of the exposed fluid contact surface is greater than or equal to 0.5 to 1; and the active electrode is configured to define thermal barriers for limiting thermal conduction therealong, whereby, in use, application of sufficient radio frequency power to the electrode assembly vaporises the conductive fluid medium adjacent to the tissue treatment portion to create a stable vapour pocket around the tissue treatment portion.

19. An electrosurgical system for the vaporisation of tissue in the presence of an electrically-conductive medium, the system comprising an electrosurgical generator for generating radio frequency power, and an electrosurgical instrument connectible to the generator, wherein:

the generator has a radio frequency output stage for delivering radio frequency power to a pair of output connections, which output stage has an open loop output impedance of less than 250 ohms;

the electrosurgical instrument comprises an instrument shaft and, situated at a distal end of the shaft, an electrode assembly comprising an active electrode with an exposed treatment portion and a return electrode with an exposed fluid contact surface, the fluid contact surface being set back from the treatment portion so that, when the electrode assembly is brought into an operative position with the treatment portion on, or adjacent to, the surface of the tissue to be treated, the fluid contact surface is further from the tissue surface than the treatment portion; and

the ratio of the surface area of the exposed treatment portion to the surface area of the exposed fluid contact surface is greater than or equal to 0.5 to 1;

wherein the surface of the active electrode is such that there is a large thermal gradient across said surface, thereby hindering the dissipation of heat from the active electrode to its surroundings, thereby to encourage the formation and maintenance of a layer of vapour across said surface.

20. A system according to claim 19, wherein the active electrode is made of a material, such as stainless steel, which has poor thermal conductivity.

21. A system according to claim 19 or claim 20, wherein the active electrode surface is such as to trap vapour, thereby constituting a thermal barrier for hindering said heat dissipation.

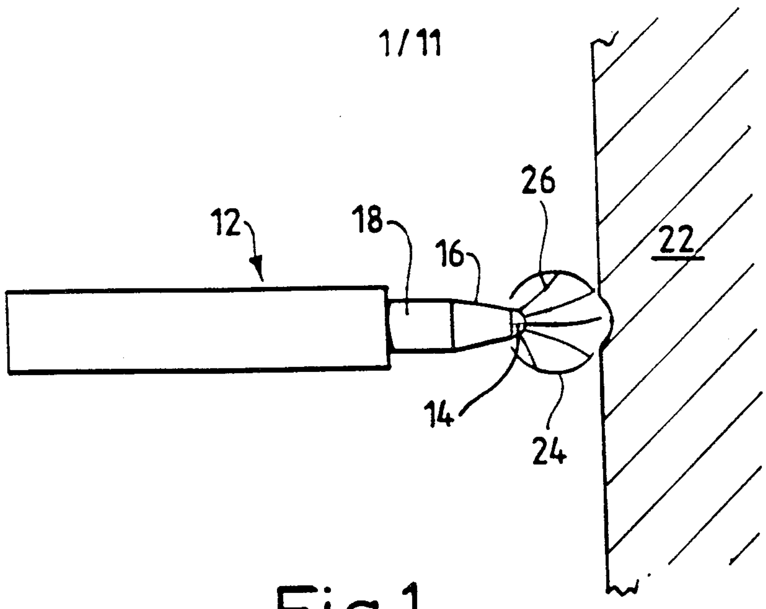


Fig.1.

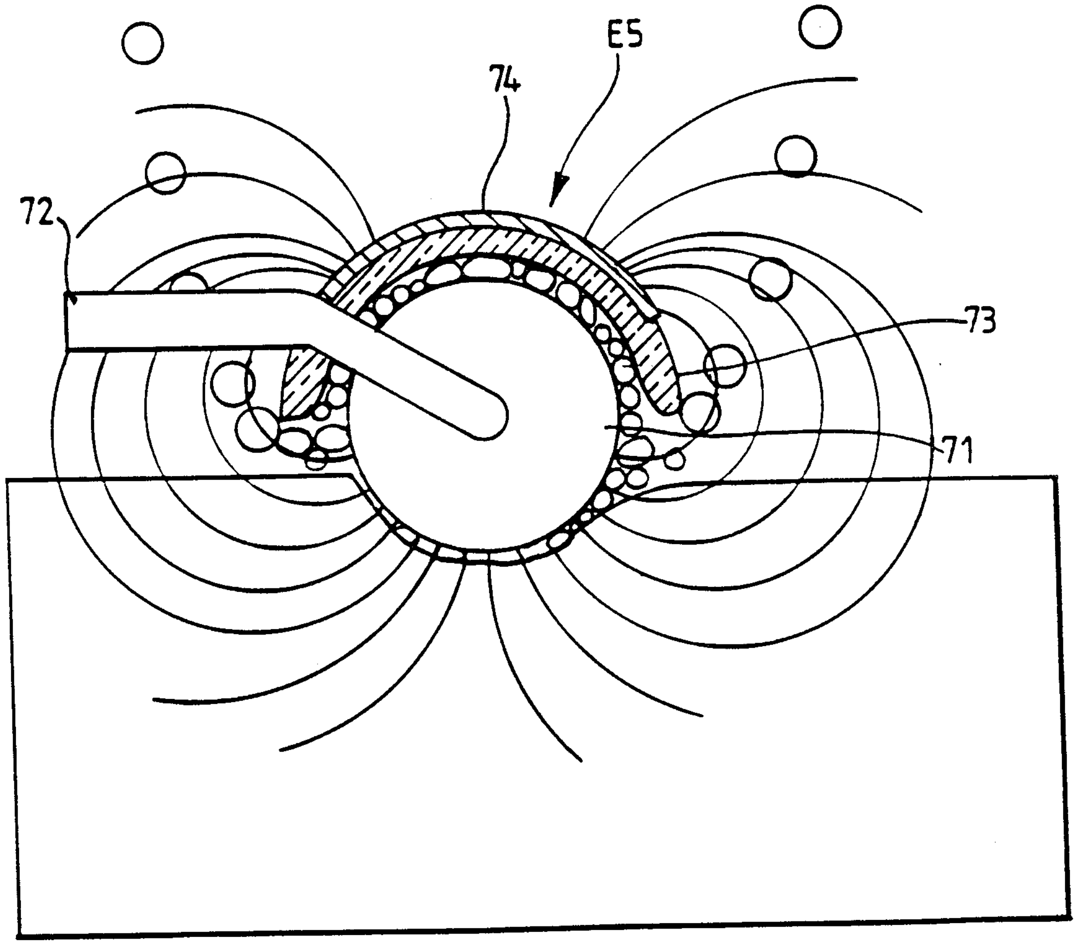


Fig.9.

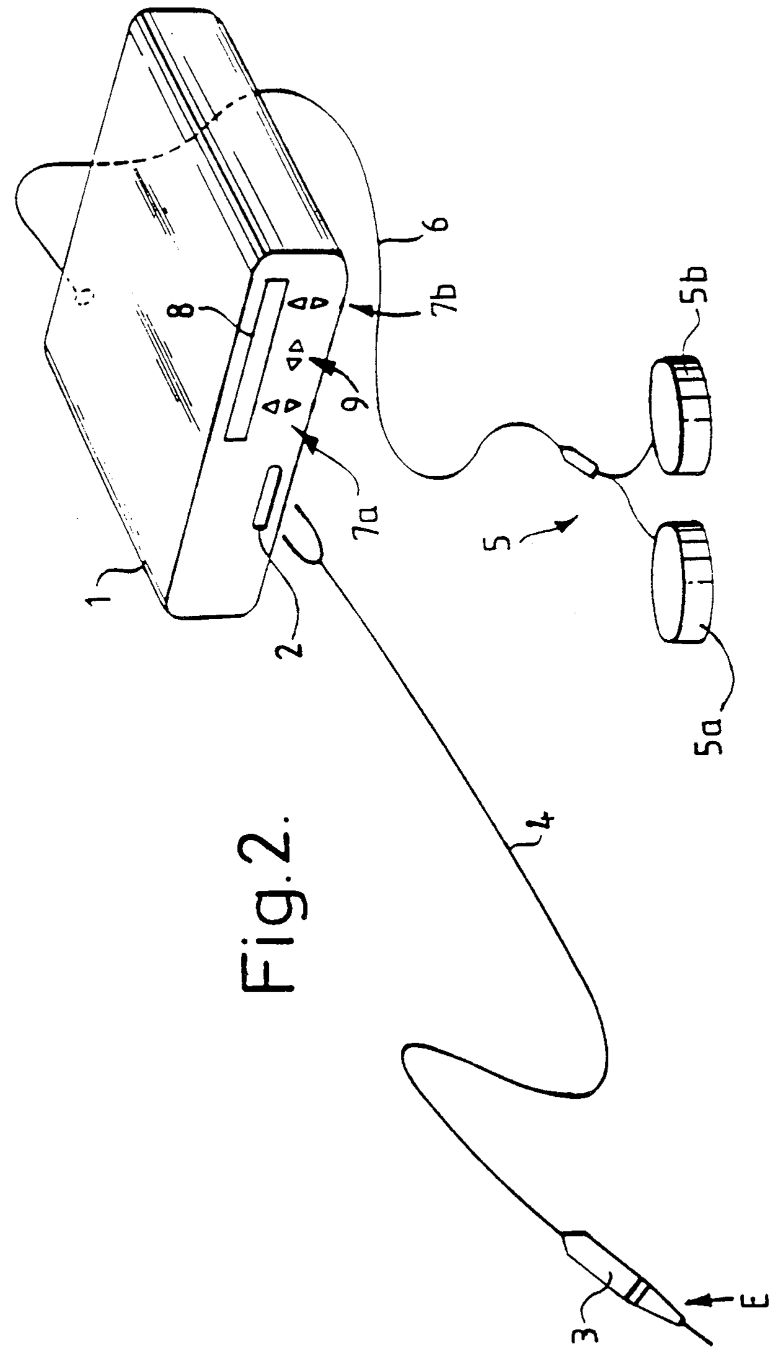


Fig.2.

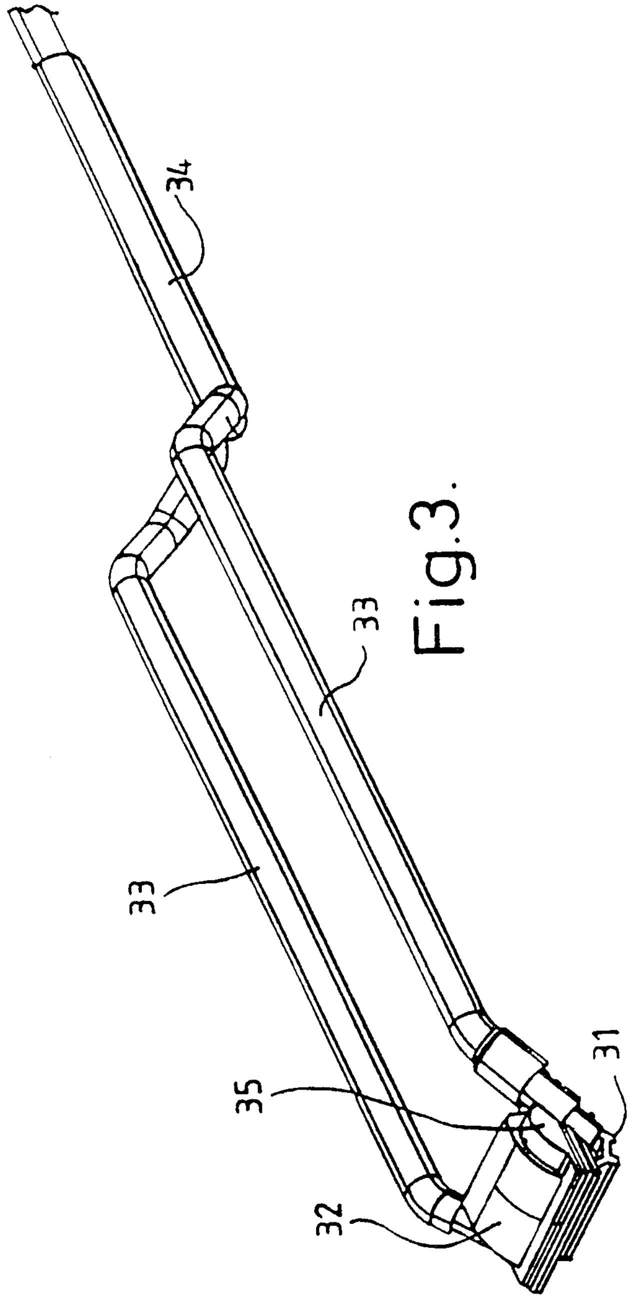


Fig.3.

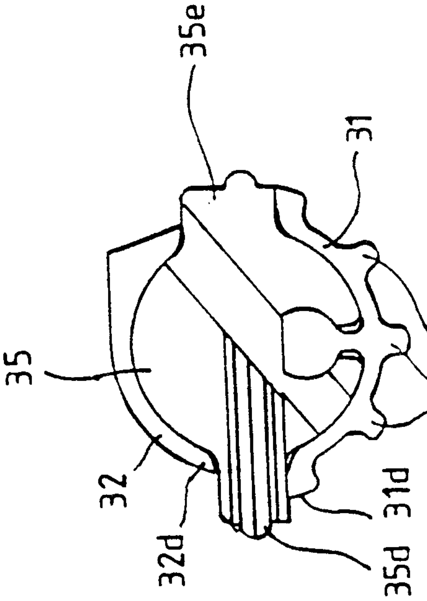


Fig.5.

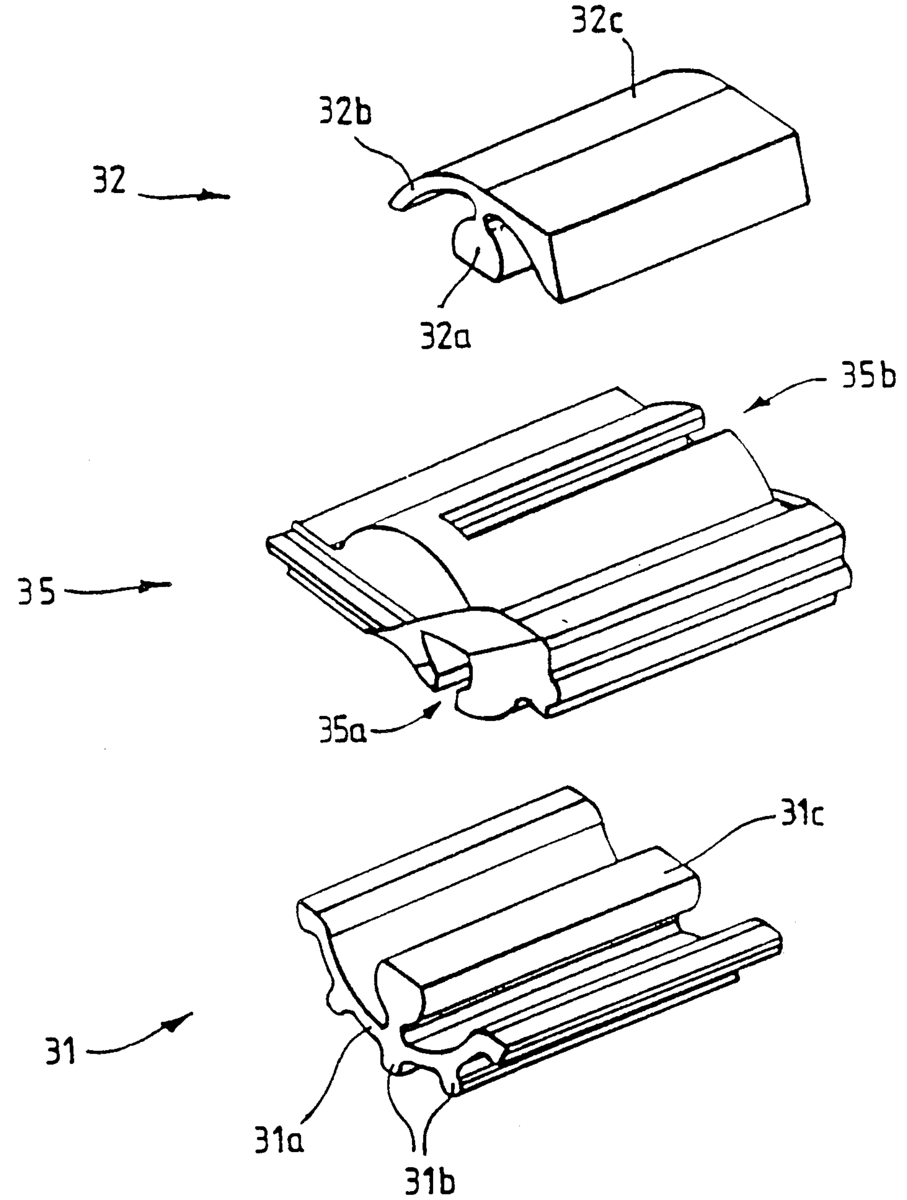


Fig.4.

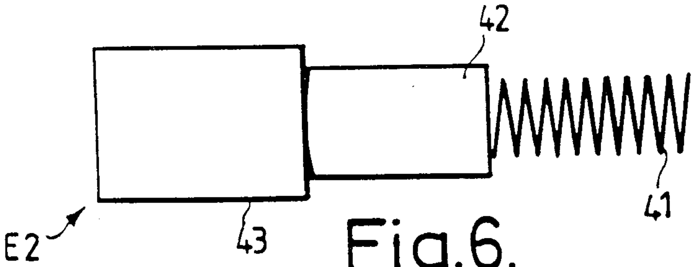


Fig.6.

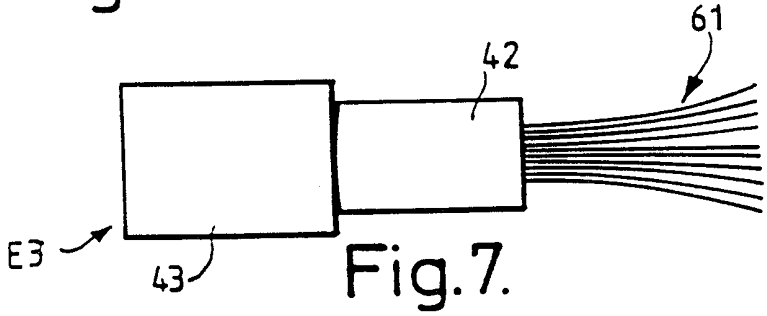


Fig.7.

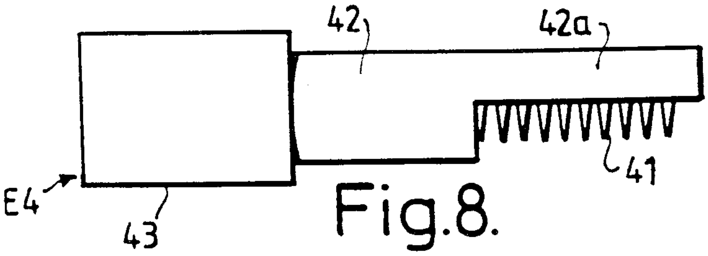


Fig.8.

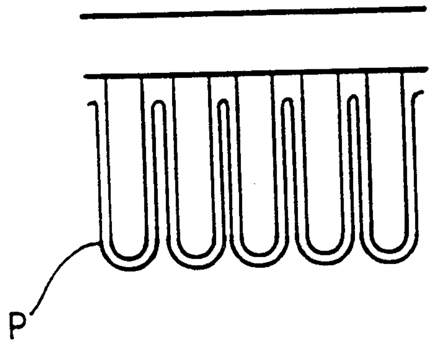


Fig.10.

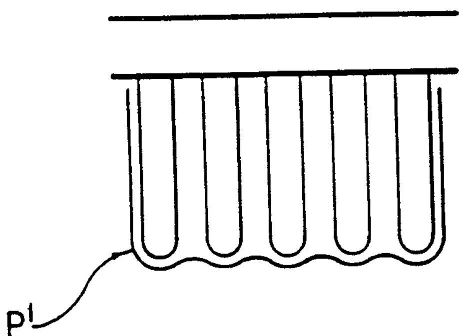


Fig.11.

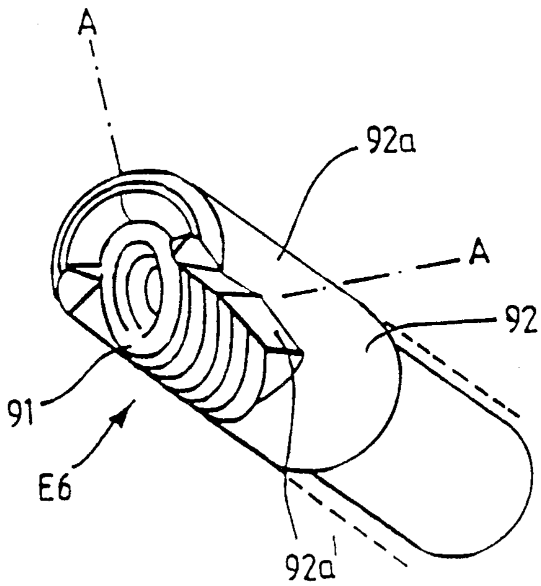


Fig.12.

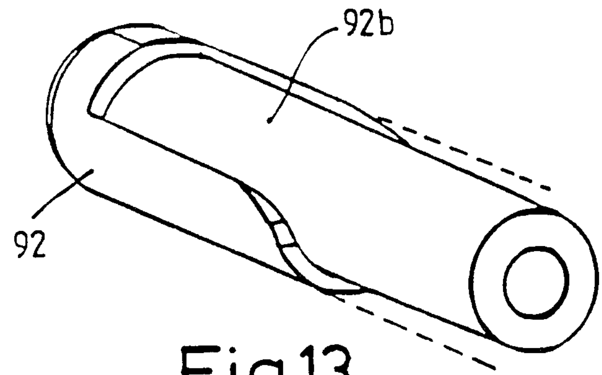


Fig.13.

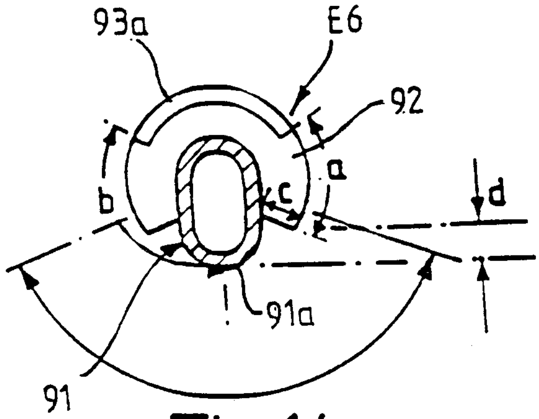


Fig.14.

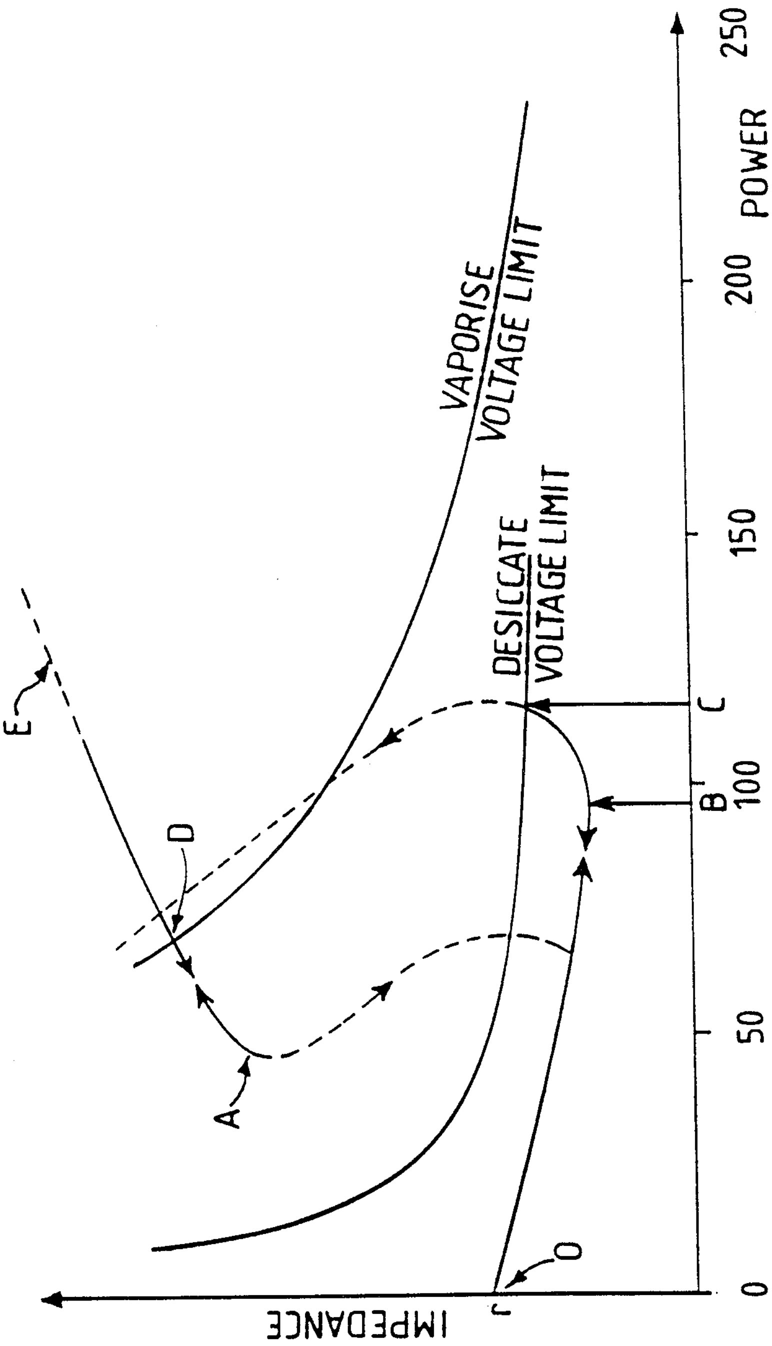
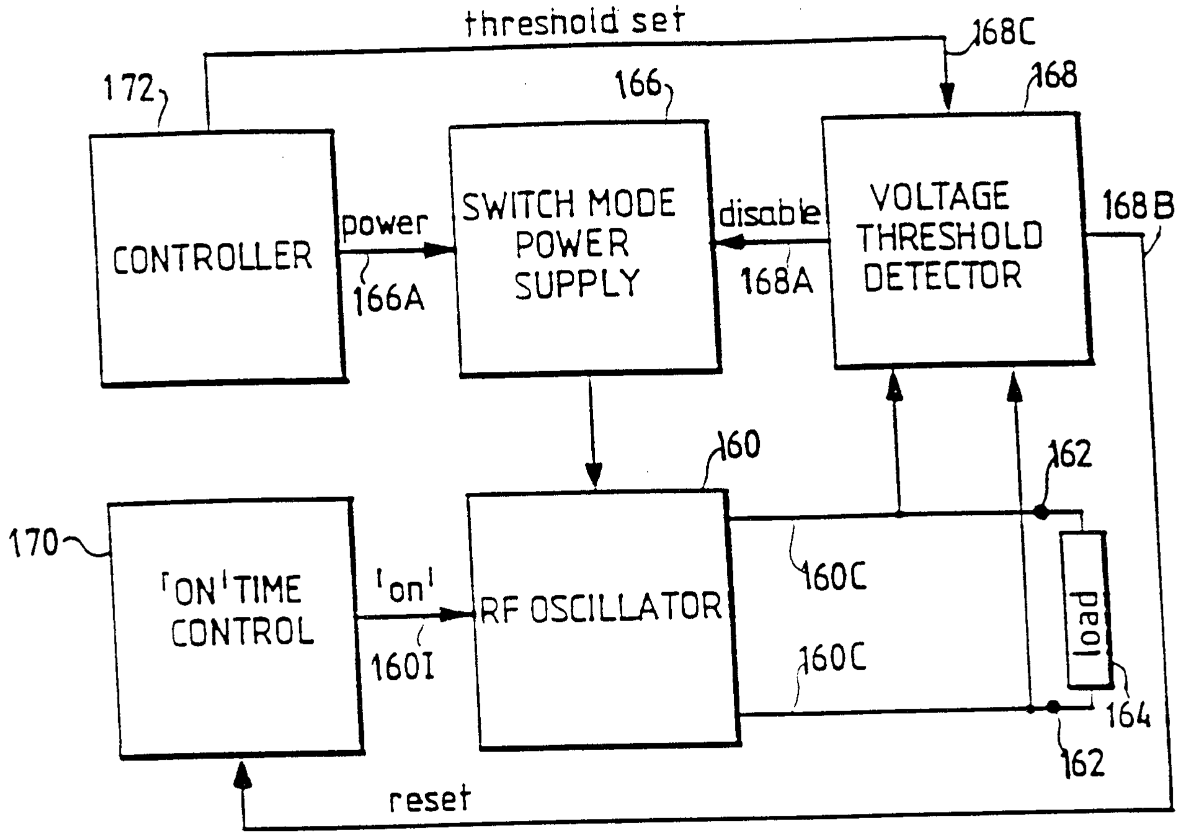

VAPORISE
VOLTAGE LIMIT
DESICCATE
VOLTAGE LIMIT
POWER
IMPEDANCE
0
50
100
150
200
250
A
B
C
D
E
O

Fig.15.


threshold set
168C
172
166
168
CONTROLLER
power
166A
SWITCH MODE
POWER
SUPPLY
disable
168A
VOLTAGE
THRESHOLD
DETECTOR
168B
160
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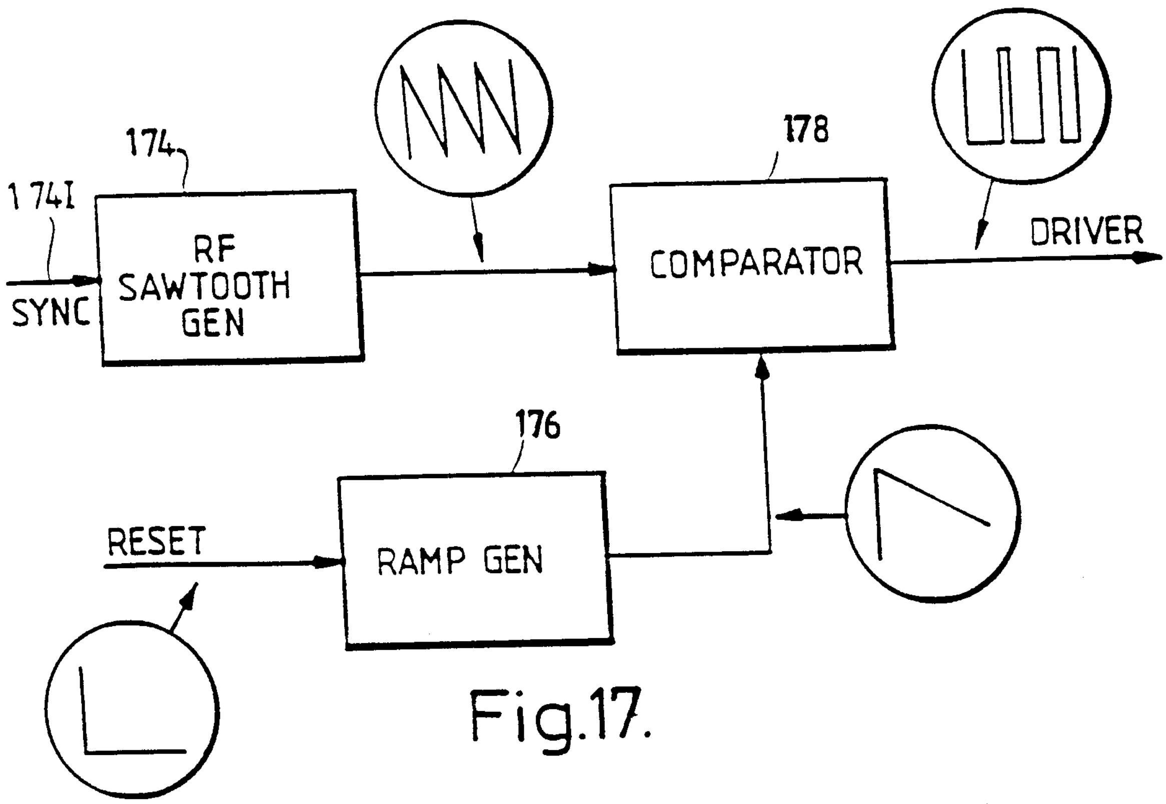
CONTROL
'on'
160I
RF OSCILLATOR
160C
160C
load
164
162
reset

Fig.16.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174I
RF
SAWTOOTH
GEN
SYNC
178
COMPARATOR
DRIVER
176
RESET
RAMP GEN

Fig.17.

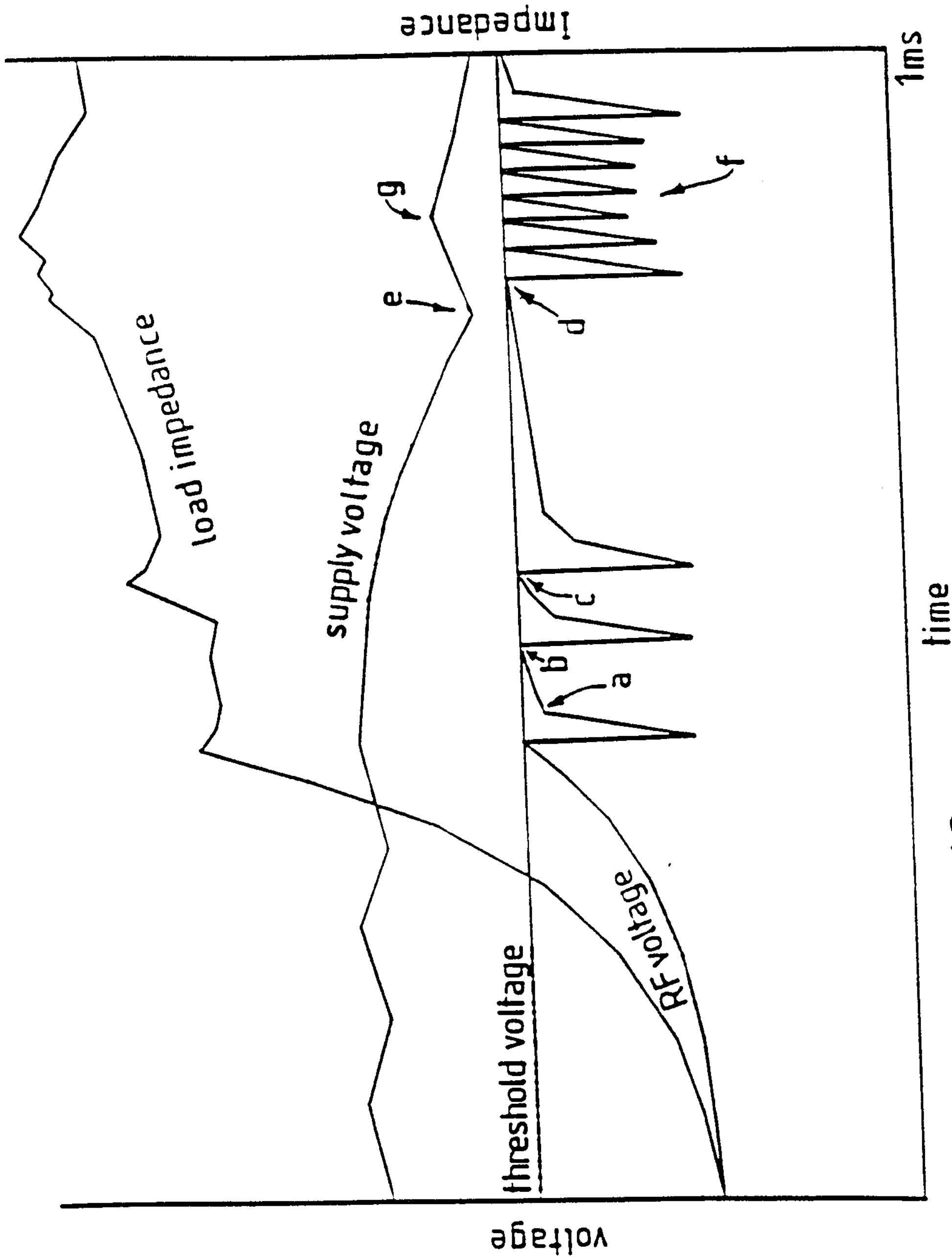
Impedance
load impedance
supply voltage
threshold voltage
RF voltage
voltage
time
1ms
a
b
c
d
e
f
g

Fig.18.

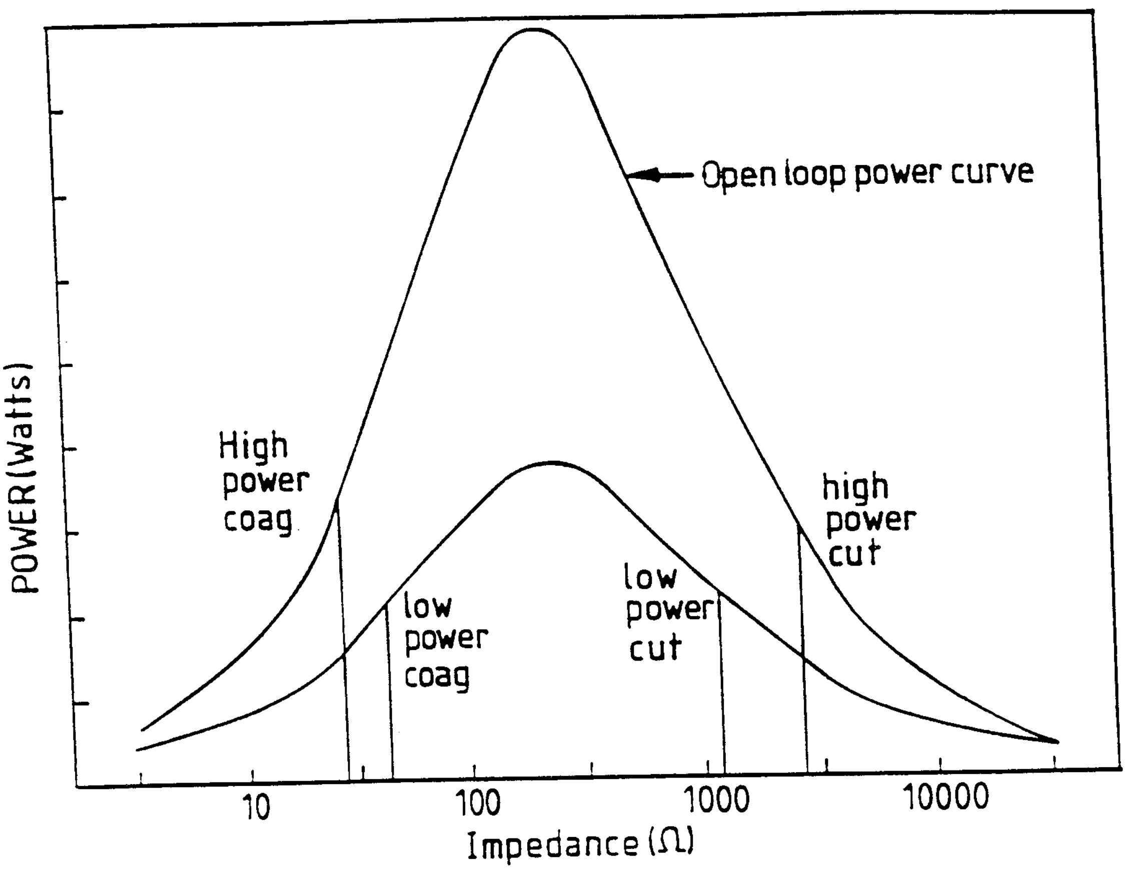
Open loop power curve
POWER (Watts)
High power coag
low power coag
low power cut
high power cut
10
100
1000
10000
Impedance (Ω)

Fig.19.

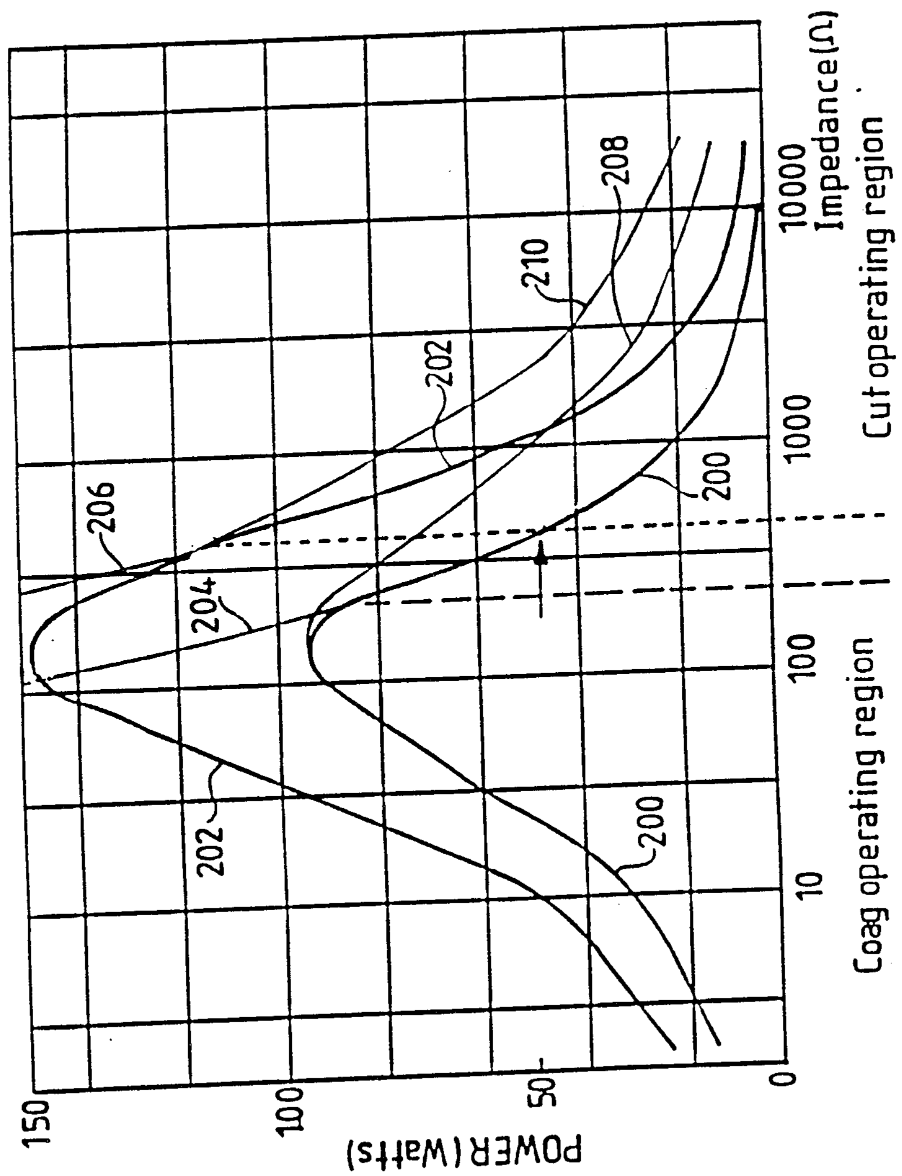
150
100
50
0
POWER (Watts)
10
100
1000
10000
Impedance (Ω)
Coag operating region
Cut operating region
200
202
204
206
208
210

Fig.20.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB 99/00952

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/39

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 6 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)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 97 24993 A (GYRUS MEDICAL LTD ;GOBLE COLIN CHARLES OWEN (GB); GOBLE NIGEL MARK) 17 July 1997 (1997-07-17) cited in the application the whole document ---	1-21
Y	US 4 706 667 A (ROOS EBERHARD) 17 November 1987 (1987-11-17) cited in the application column 2, line 10 - line 26 column 6, line 49 - line 56; figure 1 ---	1-11, 17-21
Y	EP 0 754 437 A (GYRUS MEDICAL LTD) 22 January 1997 (1997-01-22) cited in the application	12-16
A	column 21, line 6 - line 23; claims 2,4,24; figure 9 ---	1,17-19
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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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"A" document defining the general state of the art which is not considered to be of particular relevance

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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
24 August 1999	01/09/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Hansen, S

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	WO 97 00647 A (GYRUS MEDICAL LTD ;GOBLE COLIN CHARLES OWEN (GB); GOBLE NIGEL MARK) 9 January 1997 (1997-01-09) cited in the application page 13, paragraph 2; figure 3 ---	1,17-19
A	US 4 202 337 A (CLARK DAVID E ET AL) 13 May 1980 (1980-05-13) abstract; figure 3 ---	1,17-19
A	DE 196 50 797 A (NORTHGATE TECHNOLOGIES INC) 12 June 1997 (1997-06-12) column 4, line 64 - column 5, line 12; figure 2 ---	1,17-21
A	WO 97 24994 A (GYRUS MEDICAL LTD ;GOBLE COLIN CHARLES OWEN (GB); GOBLE NIGEL MARK) 17 July 1997 (1997-07-17) page 17, line 23 - line 28; figure 1 -----	1,17-19

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/GB 99/00952

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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