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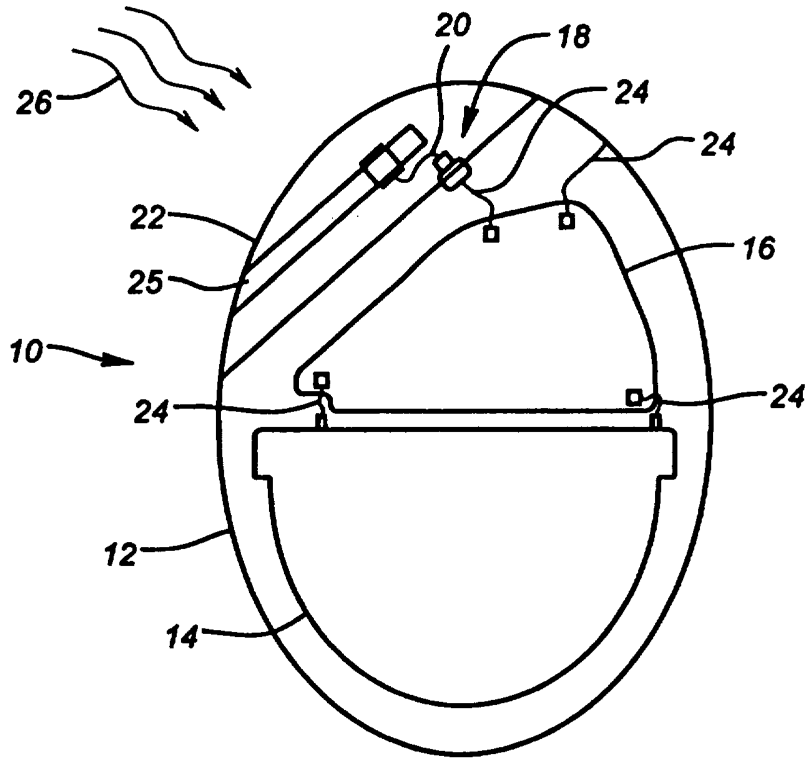
(57) Abstract

A feedthrough filter assembly (18) for performing both transient voltage clamping and EMI filtering within an implantable medical device (10). The feedthrough assembly comprises a terminal pin subassembly (36) having a conductive ferrule (40) and elongated terminal pin (46), and a filter subassembly (38) having a multilayer transient voltage suppressor. The transient voltage suppressor includes a first set of electrode plates (64) electrically connected to the terminal pin, and a second set of electrode plates (68) electrically connected to the ferrule. At lower voltages, the transient voltage suppressor functions to filter EMI, and at higher voltages, the transient voltage suppressor functions as a voltage clamping device. The filter subassembly is positioned remotely from the medical device such that transient voltages and EMI are filtered before such interference reaches the electronic circuitry of the medical device. As such, high currents occuring during voltage clamping are circulated away from the control circuitry.



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Description

Feedthrough Assembly with Transient Voltage Suppressor and EMI Filter for Implantable Medical Devices

Technical Field

The present invention relates to a feedthrough assembly for an implantable medical device such as a pacemaker, defibtillator or other implantable pulse generator having a hermetically sealed housing through which electrical conductors are passed. Still more particularly, the present invention relates to feedthrough assemblies which act as transient voltage suppressors or electro-magnetic interference (EMI) suppressors.

Background Art

Implantable medical devices such as pacemakers, defibrillators, and other implantable pulse generators generally comprise a self-contained power generator and a microprocessor based hybrid circuit encased in a hermetically sealed conductive housing. One or more electrical leads in electrical communication with this circuitry emanate from the housing and typically terminate at a distal location within the patient. The leads transmit electrical signals to and from the device and, as such, are fabricated having a conductor made from a metal alloy to enable good conductivity.

Because of their conductive properties, these leads effectively act as an antenna and thus tend to conduct unwanted electromagnetic interference (EMI) signals. These EMI signals may be transmitted to the medical device and interfere with normal operations. Sources of EMI signals are prevalent and include, for example, radio and TV transmitters, cellular telephones, medical electrosurgical equipment, microwave devices, welding equipment, security and surveillance systems, and other sources of radio frequency interference (RFI).

Two basic approaches are employed to reduce the effects of unwanted EMI on implantable medical device operations. In the first approach, the medical device is enclosed in a metallic housing or shield which is tied to ground with a low resistance connection. In the second approach, a filtering circuit removes potential EMI signals before they reach the circuitry of the medical device.

Presently, multilayer ceramic type capacitors and, in particular, discoidal capacitors are recognized as an effective alternative for filtering EMI. In a typical construction, these discoidal capacitors form part of a feedthrough filter assembly. The feedthrough assembly includes a metallic ferrule connected to the capacitor and a terminal pin hermetically supported from and extending through the ferrule. The metallic ferrule is connected to and hermetically sealed with the medical device. Typically, the discoidal capacitor has two separate electrode plate sets which are embedded within a dielectric substrate. One set of the electrode plates is electrically coupled to the terminal pin. This pin is electrically connected at one end to the medical device circuity and at another end to the leads used to transmit the desired electrical signals to and from the patient. The other set of electrode plates is electrically coupled to a cylindrically shaped ferrule which, in turn, is welded to the housing of the medical device. Generally, the ferrule consists of a conductive material and may have an insulating material disposed along an inner portion of the outer conductive surface. This insulating material is used to support the terminal pin and maintain it in nonconductive relation with the housing of the medical device.

During signal transmission, the discoidal capacitor permits passage of relatively low frequency signals along the lead, through the terminal pin, and to the medical device. Higher frequencies, representing the spectrum of unwanted EMI, however, are shunted to the housing of the medical device by the capacitor and not permitted to pass into the medical device. As a consequence, interfering signals which could otherwise adversely affect the performance of the device are filtered as they enter the medical device.

Discoidal capacitors, as well as other multilayer ceramic capacitors, are formed of multiple layers of alternating ceramic and metallic materials. Generally, the multilayer ceramics are available in several different dielectrics and the choice of material depends on the desired capacitance volume efficiency and the operating temperature range. Ceramic capacitors of this nature, however, primarily serve to filter EMI and not protect against voltage transients and surges. For further information regarding discoidal and multilayer capacitors, reference should be made to U.S. Pat. No. 5,333,095 by Stevenson *et al.*, issued July 26, 1994, entitled "Feedthrough Filter Capacitor Assembly for Human Implant", and Ivan G. Sarda and William H. Payne, "Ceramic EMI Filters - A Review," *Ceramic Bulletin*, Vol. 67, No. 4 (1988), pp. 737-746.

Another important concern with implantable medical devices, aside from protecting them against unwanted EMI, is to protect the devices from exposure to immoderate or unwanted voltage surges and voltage transients. For example, patients requiring implantable heart pacers or defibrillators typically are at higher risk for cardiac complications, such as the pacemaker syndrome involving fatigue, dizziness, syncope, or other cardiac conditions leading to adverse hemodynamics effects. During a cardiopulmonary resuscitation, for example, the patient may undergo cardioversion wherein electrical shocks ranging from about 200 to 360 Joules are externally administered to resuscitate the heart. Such shocks could damage, disrupt, or destroy the complex circuitry of the implantable device. Protection of the device from electrostatic discharge (ESD) during the manufacture and assembly stages are also serious concerns.

In order to protect against voltage surges, implantable devices employ a surge protection circuit. This protection circuit typically comprises a voltage breakdown or voltage clamping device, such as Zener diodes. These clamping devices often are positioned on the hybrid circuit of the implanted device and are connected to the housing of the device and the leads entering the device. As such, unwanted electrical surges are clamped in the control circuitry of the device. For further information regarding surge protection circuits, reference should be made to U.S. Pat. No. 4,745,923 by Winstrom, issued May 24, 1988, entitled "Protection Apparatus For Patient-Implantable Device," and Paul J. Van Lake, Paul A. Levine, and Gabriel A. Mouchawar, "Effect of Implantable Nonthoracotomy Defibrillation System on Permanent Pacemakers: An In Vitro Analysis with Clinical Implications," *PACE*, Vol. 18 (January 1995), pp. 182-187.

One important disadvantage associated with prior surge protection circuits concerns the proximity of the protection circuit to the circuitry of the medical device. In this regard, when voltage clamping occurs, large amounts of current and accompanying energy are generated. This resultant energy may be absorbed or circulated within the control circuitry of the medical device and result in component damage or signal disruption. For example, protection circuits often include back-to-back Zener diodes having a given breakdown voltage point. These diodes have a high resistance when exposed to voltages below their breakdown voltage. However, once the applied voltage is greater than the breakdown voltage, the resistance of the diode sharply decreases. In turn, the electric current through the diodes greatly increases. The control circuit of the medical device may circulate these large currents. Larger currents circulating within the control circuitry may themselves generate additional EMI which, as noted, itself possesses a risk to the medical device.

As another disadvantage, in order for the protection circuit to accommodate the larger currents generated during voltage clamping, the trace lines on the ceramic substrate of the hybrid circuit must be enlarged. These enlarged traces not only require additional space but, as noted, the large currents transmitted through them may generate unwanted EMI.

Another disadvantage associated with implantable medical devices concerns the need for two separate protection circuits. In this regard, a multilayer ceramic capacitor circuit, which may be located in the feedthrough assembly, is needed to filter unwanted EMI. However, a second and separate protection circuit located on the hybrid circuit is needed to clamp voltage transients and surges.

Another disadvantage associated with protection circuits concerns the performance characteristics of the solid state components commonly used in the protection circuit. In particular, single Zener diodes exhibit an asymmetrical current response during forward and reverse biasing (i.e., under forward biasing, the diode's voltage-current characteristics generally follow the Shockley diode equation, whereas under reverse biasing, Zener or avalanche breakdown occurs at a breakdown voltage). Additionally, Zener diodes exhibit current leakage around the p-n junction under reverse biasing before reaching breakdown. Furthermore, the use of Zener diodes may lead to complications caused by the demodulation of RFI.

It therefore would be advantageous to employ a voltage surge protection circuit or transient voltage suppressor within the feedthrough assembly. A protection circuit or clamping device positioned in the feedthrough would be effectively removed from the circuitry of the implantable medical device.

It also would be desirable to provide a single feedthrough assembly which functions both as an EMI filtering circuit and as a protection circuit capable of clamping voltage transients and surges. It further would be advantageous if this feedthrough assembly did not require separate components for filtering and separate components for voltage clamping. Such an assembly would reduce circuit structure and the total number of electrical components.

It further would be desirable to provide a surge protection circuit removed from the circuitry of the implanted device such that current and energy generated during voltage clamping would not result in component damage, signal disruption, or additional EMI generation.

It also would be desirable to offer a feedthrough assembly that effectively dissipates heat resulting from excess current and energy during a voltage surge.

In addition to the above, it would be desirable to provide a feedthrough assembly that did not require enlarged circuit substrate traces to accommodate currents during voltage clamping.

It further would be desirable to provide a feedthrough assembly that exhibited highly symmetrical, balanced voltage-current response characteristics during forward and reverse biasing so as to reduce RFI demodulation.

Additionally, it would be advantageous if such an assembly did not exhibit excessive current leakage.

Furthermore, it would be desirable to provide a feedthrough assembly having good voltage surge absorbing characteristics.

A significant need exists, therefore, for a feedthrough assembly of the type used, for example, in implantable medical devices wherein transient voltage suppression and EMI filtration occur within a single assembly isolated from the control circuitry of the medical device and wherein both voltage suppression and filtration do not each require separate components or circuitry. The present invention fulfills these needs and provides further related advantages.

Disclosure of Invention

The present invention is addressed to a feedthrough assembly having a single filtering device which performs both transient voltage protection and EMI filtration. The filtering device is remotely positioned away from the control circuitry housed within the medical device. As such, high or excessive currents occurring during voltage clamping or EMI filtering are effectively circulated within the conductive housing of the medical device and not circulated inside the housing or otherwise in the control circuitry. The feedthrough assembly thus configured is structured to substantially eliminate unwanted transient voltage and EMI before such interference reaches the control circuitry of the medical device.

In the present invention, the feedthrough assembly is hermetically sealed to the implantable medical device and comprises a terminal pin subassembly and a filter subassembly. The terminal pin subassembly includes an elongated terminal pin and a conductive ferrule enclosing an inner insulating portion. The terminal pin extends through the insulating portion and has a first end in electrical communication with the control circuitry of the medical device and a second end extending outwardly from the feedthrough assembly. The filter subassembly is connected with the terminal pin subassembly and preferably includes a multilayer transient voltage suppressor. The transient voltage suppressor has a zinc oxide ceramic base and an opening for receiving the first end of the terminal pin. A plurality of parallel electrode plates are embedded within the ceramic base. A first set of plates is electrically connected to the terminal pin, and a second set is electrically connected to the ferrule.

The feedthrough assembly of the present invention is particularly advantageous because the filter subassembly functions both as an EMI filtering circuit and as a protection circuit capable of clamping high voltage transients and surges. In this regard, the use of a transient voltage suppressor presents a non-linear behavior as a function of the voltage between the terminal pin and the ferrule. At low voltages, the zinc oxide ceramic semiconductor behaves as a dielectric material. Since the ceramic is disposed between parallel conductive electrode plates, the transient voltage suppressor functions as a parasitic capacitor at these lower voltages. As such, when high frequency EMI transmits through the terminal pin from the exterior of the medical device, EMI shunts to the ferrule and is filtered from the device. At higher voltages, for example those due to voltage transients such as ESD or defibrillation shock, the transient voltage suppressor behaves as a voltage clamping device. In this regard, transient voltage suppressors possess the ability to function as surge absorbers in much the same way back-to-back Zener diodes clamp voltage. Thus, separate electrical components for filtering and separate electrical components for voltage clamping are not required, effectively decreasing the overall number of electrical components.

As another advantage, although zinc oxide transient voltage suppressors behave similarly to back-to-back Zener diodes, these transient voltage suppressors possess much greater current and energy handling capabilities inasmuch as the construction of the device increases the dissipation of energy. This increase in energy dissipation, in turn, increases the rating of the transient voltage suppressor as compared to a discrete device, such as a Zener diode, of the same kind and size mounted on the hybrid circuit.

Additionally, unlike Zener diodes, transient voltage suppressors exhibit symmetrical voltage-current response characteristics during forward and reverse biasing. This response symmetry reduces the possibility of demodulating RFI, such as RFI produced by monopolar and bipolar electrosurgical cutting instruments powered by an electrosurgical generator. As such, compliance with regulations governing implantable medical devices and design of the control circuitry are facilitated.

As another aspect, transient voltage suppressors generally do not exhibit excessive current leakage under reverse biasing or lead to complications caused by the demodulation of RFI when used as filters or voltage clamping devices in implantable medical devices.

As another advantage, the feedthrough assembly of the present invention may include a zinc oxide transient voltage suppressor having a multilayer discoidal configuration. The transient voltage suppressor includes a ceramic base having an annular cross-section and a plurality of electrodes in the form of annular disks embedded therein.

The invention, accordingly, comprises the apparatus and method possessing the construction, combination of elements, and arrangement of parts which are exemplified in the following detailed description.

Brief Description of Drawings

Other objects and advantages of the invention will become apparent upon reading the following detailed descriptionand upon reference to the accompanying drawings in which:

FIG. 1 is a sectional view of an implantable medical device employing the feedthrough assembly of the present invention;

FIG. 2 is an enlarged sectional view illustrating a feedthrough assembly according to the invention;

FIG. 3 is a circuit model illustrating the electromagnetic interference filtering characteristics of the invention;

FIG. 4 is a waveform illustrating an unfiltered input signal having electromagnetic interference;

FIG. 5 is a waveform illustrating a filtered input signal of FIG. 4;

FIG. 6 is a circuit model illustrating the voltage clamping characteristics of the invention;

FIG. 7 is a waveform illustrating an unfiltered and unclamped input signal having electromagnetic interference and voltage surges;

FIG. 8 is a waveform illustrating a clamped and filtered input signal of FIG. 7;

FIG. 9 is a graph of the voltage-current characteristics for a multilayer transient voltage suppressor and back-to-back Zener diodes;

FIG. 10 is an exploded perspective view of a discoidal zinc oxide transient voltage suppressor;

FIG. 11 is a partial perspective view of the discoidal transient voltage suppressor of FIG. 10;

FIG. 12 is an exploded perspective view showing an embodiment of the invention;

FIG. 13 is an enlarged sectional view taken along the line 13-13 of FIG. 12;

FIG. 14 is an enlarged sectional view taken along the line 14-14 of FIG. 13;

FIG. 15 is an enlarged sectional view taken along the line 15-15 of FIG. 14;

FIG. 16 is an alternative preferred embodiment of a feedthrough assembly array;

FIG. 17 is a circuit diagram illustrating two stacked filter and voltage clamping assemblies;

FIG. 18 is a schematic representation of two stacked filter and voltage clamping assemblies;

FIG. 19 is an exploded view showing an alternative stacking arrangement for a plurality of filter assemblies;

FIG. 20A is a first alternative distribution of a plurality of voltage clamping devices;

FIG. 20B is a second alternative distribution of a plurality of voltage clamping devices;

FIG. 20C is a third alternative distribution of a plurality of voltage clamping devices;

FIG. 21 is a cross sectional top view of a feedthrough assembly according to the invention;

FIG. 22 is an enlarged sectional view illustrating a multilayer transient voltage suppressor according to the invention;

FIG. 23 is a cross sectional view of a feedthrough assembly according to the invention;

FIG. 24 is a cross sectional view of an alternative feedthrough assembly according to the invention;

FIG. 25 is a logarithmic plot of frequency versus impedance between one lead of a feedthrough assembly and a ferrule according to the invention;

FIG. 26 is a logarithmic plot of frequency versus phase angle between one lead of a feedthrough assembly and a ferrule according to the invention; and

FIG. 27 is a graph of the voltage-current characteristics between one lead of a feedthrough assembly and a ferrule according to the invention.

<u>Best Mode for Carrying Out the Invention</u>

FIG. 1 illustrates an implantable medical device 10 such as a cardiac pacemaker, defibrillator, pulse generator, or the like. Implantable devices of this type typically have an outer conductive housing 12 formed of a metallic alloy. A source for generating electrical energy 14, such as a lithium battery for example, and electronic control circuitry 16 are encased within housing 12. Control circuitry 16 typically is formed as a microprocessor based hybrid circuit and is shown connected via a feedthrough assembly 18 to an electrical lead 20 encased in a biocompatible header 22. Lead 20 connects to an electrical terminal 23 disposed within a lead cavity 25 in header 22. For a further description of connector couplings within the header, reference should be made to U.S. Pat. No. 4,860.750 by Frey *et al.*, issued August 29, 1989, entitled "Sidelock Pacer Lead Connector." An additional lead or electrode (not shown) may be inserted in terminal 23 and connected to lead 20 within header 22 and terminated at a desired stimulation or sensing location in the patient, such as the heart. Electrical communication between battery 14, control circuit 16, and feedthrough filter assembly 18 is established through conductors 24. Medical device 10 is illustrated having a single lead 20 for conventional unipolar single-chamber stimulation. Bipolar and other multiple lead arrangements also may be employed.

Implantable medical device 10 may be exposed to unwanted electromagnetic interference (EMI) signals and excessive voltages surges or transients shown generally as radiation 26. Radiation 26 may be conducted or radiated to medical device 10 and interfere with electronic operations or damage control circuitry 16. For example, if radiation 26 is not filtered, EMI and voltage transients could pass along lead 20, through feedthrough assembly 18, and enter housing 12 and control circuitry 16. Feedthrough assembly 18 of the present invention provides in a single device protection against both EMI and voltage surges.

Turning to FIG. 2, feedthrough assembly 18 is illustrated in more detail and shown to include a terminal pin subassembly 36 and a filter subassembly 38. Together, these two subassemblies both filter EMI and absorb or clamp voltage surges and transients. Terminal pin subassembly 36 includes a cylindrically shaped ferrule 40 having an outer conductive housing 42 forming a central region 43. Ferrule 40 is formed from a suitable biocompatible conductive material, such as titanium or titanium alloy. An inner insulating portion or ring 44 is provided within central region 43 and encased within housing 42 of ferrule 40. Insulator ring 44 establishes a hermetic seal to prevent the passage of fluids through terminal pin subassembly 36 and feedthrough assembly 38. Additionally, the ring may be formed from a polymer, such as teflon or from a glass-fired or ceramic-based material, such as polycrystaline alumina or sapphire crystal. An adhesive or sealing layer (not shown) may be disposed between insulator ring 44 and ferrule 40 to provide a hermetic seal.

Lead 20 of FIG. 1 extends through ferrule 40, central region 43, and insulating ring 44 and is shown as an elongated terminal pin 46. In particular, first end 48 of terminal pin 46 extends through feedthrough assembly 38 and is electrically connected with control circuitry 16 (FIG. 1). A second end 50 extends outwardly from terminal pin subassembly 36 and is electrically connected with electrical terminal 23 (FIG. 1). Insulator ring 44 provides support and mechanical rigidity, as well as electrical insulation from ferrule 40, for terminal pin 46. Terminal pin 46 may be formed from a biocompatible metal, such as platinum, tantalum, niobium wire, or the like.

Filter subassembly 38 is shown adjacent to and connected with terminal pin subassembly 36. Preferably, filter subassembly 38 includes a zinc oxide transient voltage suppressor 56. Transient voltage suppressor 56 may be formed having various geometrical configurations, such as a rectangular, cylindrical, or discoidal shape, and may be single or multi-layered. FIG. 2 depicts a multi-layered transient voltage suppressor having a plurality of parallel electrode plates 58 embedded within a ceramic base 60. Electrode plates 58 include a first electrode set 62 having at least one first electrode 64 of a first polarity and a second electrode set 66 having at least one second electrode 68 of opposite polarity to first electrode 64. First electrode set 62 is electrically connected to an inner termination 65 which provides electrical communication to terminal pin 48. Second electrode set 66 is electrically connected to an outer termination 67 which provides electrical communication to ferrule 40. These terminations 65 and 67 are formed from a metallic or conductive material. Transient voltage suppressor 56 is shown cylindrically shaped to define periphery 70. As illustrated, second electrode set 66 extends within ceramic base 60 to periphery 70. Ferrule 40 extends downwardly and surrounds periphery 70 in order to be in electrical communication with electrode set 66. Ferrule 40 also extends upwardly to surround insulating portion 44 and to provide a seal with it. Ceramic base 60 is disposed between each of the first and second electrodes 64 and 68, respectively, and has an opening 72 extending through each of the first and second electrodes and dimensioned to receive terminal pin 48. This ceramic preferably is formed from a zinc oxide base. Construction of transient voltage suppressor 56 is conventional or done in accordance with methods known in the art. For example, multilayer transient voltage suppressors may be manufactured by mixing a ceramic powder in an organic binder. Thereafter, this mixture or slurry is cast into thin layers, and metallic electrodes are deposited onto the layers. The device then undergoes a sintering process at which time an array of zinc oxide grains are surrounded by electrically insulating barriers. The breakdown voltage of the device may be predetermined in accordance with the established number of grain boundary interfaces between electrodes. Further, transient voltage suppressors also may be constructed, for example, as described in U.S. Pat. No. 5,134,540 by Rutt, issued July 28, 1992, entitled "Varistor or Capacitor and Method of Making Same" or described in U.S. Pat. No. 5,235,310 by Cowman *et al.*, issued August 10, 1993, entitled "Varistor Having Interleaved Electrodes" or as a commercially available multi-layer ceramic transient voltage suppressor sold, for example, under the trademark "TRANSGUARD" manufactured by AVX Corporation.

Feedthrough assembly 18 of FIG. 2 may additionally include a ferrite bead 74 surrounding terminal pin 46 and generally disposed between insulating ring 44 and transient voltage suppressor 56. At the location where ferrite bead 74 surrounds terminal pin 46, the electrical impedance of terminal pin 46 varies as a function of the frequency. As such, the general equivalent of an "L," "Pi," or the like low-pass filter configuration may be achieved while ferrite bead 74 is in combination with one or more voltage clamping devices acting as parasitic capacitors. Ferrites of this nature are formed from a ceramic compound consisting of iron oxide and another metal or metals depending upon the frequency of signal sought to be suppressed. In the present configuration, the ferrite contributes to a greater attenuation (in dB/octave) of high frequency components of EMI, as compared with a configuration in which a capacitor alone is employed. The performance of the feedthrough assembly may be enhanced or tailored to design parameters with the addition of ferrite bead 74; however, the addition of the ferrite is optional, rather than an integral part of the feedthrough assembly.

FIG. 2 further illustrates that terminal pin 46 is hermetically sealed at 76 with a sealant. Additionally, two oppositely disposed shoulders 77 circumferentially extend around the outer periphery of ferrule 40. Shoulders 77 form a recess into which housing 12 of medical device 10 fits and, as such, establish electrical and heat transfer contact. Ferrule 40 is laser welded at 78 to outer housing 12 of medical device 10 (FIG. 1). For a fuller description regarding the assembly and mounting of feedthrough assemblies, reference should be made to U.S. Pat. No. 5,333,095 by Stevenson *et al.* Transient voltage suppressors may have alternative embodiments similar to the geometry of a discoidal capacitor as described in U.S. Pat. No. 5,117,663 by Ingleson *et al.*, issued January 5, 1993, entitled "Multilayer Discoidal Capacitor" and U.S. Pat. No. 4,247,881 by Coleman, issued January 27, 1981, entitled "Discoidal Monolithic Ceramic Capacitor."

In transient voltage suppressor 56, electrodes plates 58 may be formed of a number of metallic alloys which ensure that conductive ion leakage will not occur during the assembly and operational life of medical device 10. A suitable alloy is platinum-enhanced palladium silver (PdPtAg). Electrical connection between these electrodes and terminal pin 46 or ferrule 42 may be achieved by means of solder or conductive adhesives, such as a curable polyamide adhesive loaded with colloidal conductive particles.

Transient voltage suppressor 56 exhibits non-linear behavior as a function of the voltage between, for example, terminal pin 46 and ferrule 44. At lower voltages, i.e., those under the breakdown voltage threshold of the ZnO ceramic semiconductor, the ZnO ceramic semiconductor behaves as a dielectric material. Since the ceramic is disposed between parallel conductive plate electrodes, the transient voltage suppressor behaves as a parasitic capacitor at these lower voltages. For instance, when transient voltage suppressor 56 has a multilayer configuration in the shape of a geometric disk, the transient voltage suppressor acts as a discoidal capacitor and effectively shunts to ground. For example, a large portion of high-frequency EMI or transient voltage conducted by terminal pin 46 from the exterior of the implantable medical device would be shunted to ferrule 44. Ferrule 44, in turn, is connected to outer housing 12 which, itself, is connected to ground. As such, shunting occurs to ferrule 44, to outer housing 12, and to ground.

At higher voltages, *i.e.*, those above the breakdown voltage of the ZnO ceramic semiconductor, such as those added to the signal conveyed by terminal pin 46 due to high-amplitude voltage transients such as ESD, defibrillation shocks, etc., transient voltage suppressor 56 acts as a voltage-clamping device in which the threshold barrier has been exceeded. In this instance, transient voltage suppressor 56 behaves somewhat similarly to back-to-back Zener diodes and clamps the incoming signal. For a fuller description of transient voltage suppressor operations see U.S. Pat. No. 5,369,390 by Lin *et al.*, issued November 29, 1994, entitled "Multilayer ZnO Varistor."

One important feature of the present invention is that the feedthrough assembly may be positioned remotely from the control circuitry of the implantable medical device to perform both transient voltage clamping and EMI filtering. FIG. 2 reveals that filter subassembly 38 forms part of feedthrough assembly 18. FIG. 1 further reveals that the feedthrough assembly is positioned away from control circuitry 16. As such, high currents occurring during voltage clamping are effectively conducted within the feedthrough assembly and not circulated in the housing or otherwise within or in close proximity to the control circuitry. In this regard, when large voltages appear across the feedthrough assembly, the voltages are clamped to a cutoff value. As a result, high currents may be generated. In the feedthrough assembly of the present invention, the energy resulting from these currents is dissipated or shunted to the ferrule and to ground. FIG. 2 shows ferrule 40 in electrical conductive and thermal transfer relations with outer housing 12 of the implantable medical device which, itself, is grounded. Thus, the total effective area for dissipating and shunting excess current and energy is greatly increased.

Another important feature of the present invention is that a single feedthrough assembly 18 performs both transient voltage suppression and EMI filtering. Looking to FIG. 3, a circuit model 84 is shown to illustrate the EMI filtering characteristics of feedthrough assembly 18. Circuit model 84 consists of a capacitor 86, an optional ferrite bead represented as an inductor symbol 88, and an alternating current signal source 90, with V_{in} representing the input voltage, Zin representing the impedance of the signal source, and V_{out} representing the output voltage. FIG. 4 depicts an a.c. waveform 92 at V_{in}, with the x-axis being time and the y-axis being the magnitude of the input voltage. EMI or electrical noise 94 is shown to be present in waveform 92 in the form of a high frequency signal superimposed on a low frequency stronger signal. If not filtered, EMI, radio frequency, and other electrical noise disturbances may be transmitted into an implantable medical device and interfere with operations. FIG. 5 graphically illustrates (with the x-axis being time and the y-axis being the magnitude of the output voltage) waveform 92 at V_{out}. As shown in FIG. 5, much of the EMI 94 present in the input signal is filtered.

Looking now to FIG. 6, a circuit model 96 is shown to illustrate the transient voltage suppression characteristics of the feedthrough assembly of the invention. Circuit model 96 consists of a capacitor 98 representing the parasitic capacitance of a transient voltage suppressor, an optional ferrite bead shown as an inductor symbol 100, a symmetrical voltage clamping device 102 in parallel with capacitor 98 and representing the voltage-clamping behavior of a transient voltage suppressor, and an a.c. signal source 104, with V_{in} representing the input voltage and V_{out} representing the output voltage. FIG. 7 depicts an a.c. waveform 106 at V_{in}. In the figure, the x-axis represents time; the y-axis represents the magnitude of the input voltage; and $V_{Breakdown}$ represents the breakdown voltage threshold of the ZnO ceramic based transient voltage suppressor 56 (FIG. 2). This breakdown threshold voltage varies depending on circuit and design parameters; however, transient voltage suppressors may be manufactured having predetermined breakdown voltages, for example, as disclosed in U.S. Pat. No. 5,134,530 by Rutt.

As shown in FIG. 7, waveform 106 has two locations 108 and 109, respectively, wherein the absolute value of the magnitude of V_{in} is greater than the absolute value of $V_{Breakdown}$. FIG. 8 illustrates waveform 106 at V_{out}, with the x-axis again being time and the y-axis being the magnitude of the output voltage. As shown, the magnitude of V_{out} is clamped or cutoff at 108 and 109. In this regard, the magnitude of V_{out} is limited to the absolute value of $V_{Breakdown}$ or the breakdown voltage of the transient voltage suppressor used in the feedthrough assembly. As such, the maximum magnitude of voltage which can pass through the feedthrough assembly into the implantable medical device is limited to the absolute magnitude of $V_{Breakdown}$.

The process for filtering input signals is explained with reference to FIGS. 1 and 2. Input signals originating outside implantable medical device 10 initially are transmitted along lead 20 to terminal pin 46. These signals, as shown in FIGS. 4 and 7, may include EMI and voltage transients. The signals then transmit into feedthrough assembly 18, and more particularly to terminal pin subassembly 36 and then to filter subassembly 38. Thereafter, the EMI portion of the input signals is removed, as shown in FIG. 5. Additionally, input signals exhibiting a voltage greater than the breakdown voltage of the transient voltage suppressor are clamped, as shown in FIG. 8. Both clamping and EMI filtering occur in the feedthrough assembly. As such, the input signal is free from

EMI and voltage surges and spikes as it enters within the housing of the implantable medical device and, thus, ultimately before transmitting to the control circuitry.

Another aspect of the present invention concerns the symmetrical behavior of the filter subassembly. In this regard, transient voltage suppressors exhibit symmetrical voltage-current response characteristics during forward and reverse biasing, unlike back-to-back Zener diodes which, if not perfectly matched with a process of sorting, exhibit more asymmetrical characteristics. In a symmetrical device, EMI signals are less likely to become demodulated. FIG. 9 illustrates this distinction in a graph having current (I) as a y-axis and voltage (V) as an x-axis, with V_{BV} representing the breakdown points of a transient voltage suppressor and V_{BZ} representing the breakdown points of back-to-back Zener diodes. Curves 110 and 112 are the voltage-current responses for a typical multilayered transient voltage suppressor and typical back-to-back Zener diodes. As shown, curve 110 exhibits complete symmetry about the x-axis and y-axis. In fact, breakdown along the x-axis during forward and reverse biasing occurs at identical locations, specifically at the absolute value V_{BV}. The response characteristics for curve 112 are asymmetrical. Back-to-back Zener diodes exhibit asymmetry, in part, due to the fact that individual diodes are not completely identical and thus are not perfectly matched. Zener diodes can provide good symmetry in a back-to-back configuration if the individual diodes are matched; matching, however, requires precision components and sorting which is expensive. Additionally, curve 110 exhibits little current leakage during forward and reverse biasing prior to reaching one of the breakdown points.

The filter subassembly of the present invention may be formed as a multilayer device having various geometric configurations known to those skilled in the art. FIGS. 10 and 11 illustrate a transient voltage suppressor formed with a discoidal stack of electrodes 120 having a central opening 121 for receiving terminal pin (not shown). This type of multilayer ceramic transient voltage suppressor, or discoidal transient voltage suppressor, is in the geometric configuration of a plurality of stacked disks. This discoidal configuration has considerable volumetric efficiency and reliability as other multilayer ceramic devices, such as discoidal capacitors. Furthermore, the discoidal configuration enhances the EMI filtering capabilities of the parasitic capacitance due to negligible parasitic inductance, as compared with other geometries. A first set of electrodes 122 is configured to make electrical connection to an inner circumferential metallized edge 124 disposed along central opening 121. A second set of electrodes 126 of opposite polarity is configured to make electrical connection to an outer circumferential metallized edge 128. Electrodes 122 extend outwardly from inner edge 124 a distance adjacent to but separated from outer edge 128. Electrodes 126 extend inwardly from outer edge 128 a distance adjacent to but separated from inner edge 124. Cover layers 130 may be provided on the top and bottom of electrode stack 120 to further enclose and seal the filter assembly. As shown in FIG. 11, a ZnO ceramic 132 separates electrode sets 122 and 126 to form an alternating discoidal electrode array. Electrical connection with a ferrule (not shown) may be provided along outer edge 128, and electrical connection with a terminal pin (not shown) may be provided along inner edge 124. Inner edge 124 and outer edge 126 may be formed, for example, by deposition of conductive PdPtAg electrode paste.

In addition to the multilayer single pin structures shown in FIGS. 2 and 11, various multilayer multiple pin configurations also are known to those skilled in the art, for example, as illustrated in U.S. Pat. No. 5,333,095, by Stevenson *et al.* FIG. 12 exemplifies one multiple pin configuration for a feedthrough assembly 139 in which four generally parallel terminal pins 140 are supported in and separated by an insulative spacer 142. Spacer 142 may be made, for example, from glass based or ceramic based insulation material. Pins 140 are aligned to fit within four corresponding receiving apertures 144 formed within a multilayer discoidal transient voltage suppressor 146. A conductive ferrule 148 surrounds the outer periphery of transient voltage suppressor 146. Outer housing 150 of the medical device connects to ferrule 148 and is in electrical conductive relation therewith.

FIGS. 13-15 reveal transient voltage suppressor 146 in more detail. A plurality of parallel electrode plates 152 are embedded within a zinc oxide ceramic base 154. Electrode plates 152 include a first electrode set 156 having four electrodes 158 of a first polarity and a second electrode set 160 having a second electrode 162 of opposite polarity. Each of the four electrodes 158 is in electrical communication with one of the terminal pins 140, and the second electrode plate 162 is in electrical communication with ferrule 148. Ceramic base 154 is disposed between each of the first and second electrode sets 156 and 160, respectively.

FIG. 16 reveals another multilayered stacking array in which four parallel electrical input and output lines are being filtered for both EMI and transient voltage surges. A conductive ground plate or ferrule 166 is provided with four feedthrough assemblies 168. Each of the discrete feedthroughs 168 may be connected, for example by soldering or conductive adhesive, into holes 170 bore through ground plate 166. Feedthrough assembly 168 may include a discoidal type transient voltage suppressor as described in connection with FIGS. 10 and 11.

The feedthrough assemblies described in connection with FIGS. 12 and 16 provide each terminal pin with a separate voltage clamping array and EMI filtering array. Additionally, a single voltage clamping ground reference, provided through the ferrule, is common to each of the feedthrough assemblies. It will be appreciated that other configurations are known in the art as well.

FIGS. 17 and 18 reveal an alternative embodiment for a multilayer array in which a plurality of filter and voltage clamping assemblies are arranged in a stack. FIG. 17 shows a circuit model 180 of a dual stacking arrangement having two filter assemblies 182 and 184. Each filter assembly includes a transient voltage suppressor or a transient protection device 186, a capacitor 188 representing the parasitic capacitance of the transient protection device and in series with it, and an optional ferrite bead 190 modeled as an inductor symbol. In FIG. 18, each filter assembly 182 and 184 is configured similarly to the filter assembly described in connection with FIG. 2. In this regard, each assembly includes first and second electrode sets 192 and 194, respectively, and a ferrite bead array 196. A terminal pin 198 is in electrical communication with first electrode set 192. Common leads 200 extend from second electrode set 194.

FIG. 18 shows a single pin, multilayer array; however, various different multiple pin arrays also are available. FIG. 19 depicts one such multiple pin array in which two discoidal filter assemblies 204 and 206 are vertically stacked. Each filter assembly includes a discoidal transient voltage suppressor 208 and a ferrite bead array 210. Two terminal pins 212 extends through and are supported by filter assemblies 204 and 206. Ferrite bead 210 surrounds terminal pins 212 in order to vary the impedance as a function of the frequency. A common connection to second electrode set 194 may be established through connection with the metallic ferrule (not shown).

FIGS. 20A-20C further illustrate alternative embodiments for arranging transient voltage suppressors within a feedthrough assembly in order to provide EMI filtering and transient protection. Each of the figures shows a quadropole arrangement having four terminal pins 219, a plurality of transient voltage suppressors 220, and ferrules 222. The transient voltage suppressors may be connected such that they clamp transient voltage surges between a terminal pin and the ferrule, between multiple terminal pins, or a combination of these alternatives. Various design configurations and transient voltage suppressor stacking arrays exist and depend largely on the design of the implantable medical device and type of circuit protection desired. In this regard, FIG. 20A illustrates a common mode connection between each transient voltage suppressor 220a and ferrule 222a. FIG. 20B depicts a connection between differential pairs of terminal pins 219b. FIG. 20c shows a combination of the connections illustrated in FIGS. 20A and 20B in order to provide either common mode protection, differential mode protection, or combined mode protection. The transient voltage suppressors shown in FIGS. 20A-20C may be built as individual, discrete components (such as shown in FIG. 21) or built having a multi-layer, multi-electrode configuration (such as shown in FIG. 19). The electrical characteristics of each transient voltage suppressor may be independently selected to achieve a specific breakdown voltage for common mode protection which may be different than that used for differential mode protection.

Turning now to FIG. 21, a cross sectional top view of feedthrough assembly 230 is shown having a plurality of transient voltage suppressors 232, a conductive ferrule 234, and a plurality of terminal pins 236. Transient voltage suppressors 232 may be connected between ferrule 234 and terminal pins 236 in a variety of configurations, such as shown in FIGS. 20A - 20C. In FIG. 21, each transient voltage suppressor 232 has a first end connected to conductive ferrule 234 and a second end connected to a respective terminal pin 236. Ferrule 234 circumvents an insulating portion 238 used to support and electrically isolate terminal pins 236.

FIG. 22 shows a detailed cross sectional view of one transient voltage suppressor 232. As shown, each transient voltage suppressor is formed having a multilayer configuration and includes a zinc oxide ceramic base 260 having first and second terminations 262 and 264, respectively. Each termination 262 and 264 is formed from a conductive or metallic material, such as conductive PdPtAg electrode paste. A plurality of electrodes 268 are embedded within ceramic base 260. Electrodes 268 consist of a first electrode set 270 of at least one electrode plate having a first polarity and a second electrode set 272 of at least one electrode plate having a second polarity opposite the first polarity. The first and second electrode sets 270 and 272, respectively, preferably are evenly spaced apart and parallel. As shown, first electrode set 270 is in electrical contact with termination 262, and second electrode set 272 is in electrical contact with termination 264. When terminations 262 and 264, respectively, are oppositely polarized, opposing charges develop on the electrodes and charge is distributed over the area of overlap. Transient voltage suppressor 232 may be cylindrically or rectangularly configured or the like.

FIG. 23 shows a cross sectional view of one embodiment of feedthrough assembly 230 of FIG. 21 in which transient voltage suppressors 232 are oriented in a substantially horizontal position adjacent insulating portion 238. Each transient voltage suppressor 232 has one end connected to ferrule 234 and a second end connected to one terminal pin 236 using a conductive adhesive compound or soldering, shown at 276. A nonconductive potting compound 278 surrounds transient voltage suppressors 232. Potting compound 278 protects transient voltage suppressors 232 and terminal pins 236 and helps maintain mechanical rigidity. An example of one such potting compound is a nonconductive epoxy (type number 84-3) manufactured by Ablestick Laboratories. As an example, compound 276 may be an epoxy sold under the trademark "EPO-TEK H2OE" manufactured by Epoxy Technology, Inc.

A FIG. 24 shows an alternate embodiment of FIG. 23. In FIG. 24, transient voltage suppressors 232 are oriented in a substantially canted position. In this regard, one end of each transient voltage suppressor 232 connects to ferrule 234 and a second end is disposed vertically lower and connects to one of the respective terminal pins 236. Transient voltage suppressors 232 may be provided having a monolithic, multi-layer construction, such as the transient voltage suppressor manufactured under the trademark "TRANSGUARD" by AVX Corporation.

A prototype of the feedthrough assembly and transient voltage suppressor described in connection with FIGS. 21, 22, and 24 was built and tested using four "TRANSGUARD" transient voltage suppressors (part number VC060309A200) manufactured by AVX Corporation which were mounted to a quad feedthrough (Intermedics Incorporated part number 35-0002-8301/7). Manufactured specifications for each transient voltage suppressor included:

maximum working voltage = 9.0 volts,
breakdown voltage = 11.0 - 14.0 volts,
maximum clamping voltage = 20 volts,
maximum peak current = 30 amperes,
maximum transient energy = 0.1 joules,
a typical capacitance = 650 pF, and
a typical inductance < 1.0 nH.

The capacitance between each of the four terminal pins and the ferrule was measured using a Sencore LC102 capacitor/inductor analyzer. The following results were obtained:

lead 1 - ferrule = 832 pF
lead 2 - ferrule = 826 pF
lead 3 - ferrule = 735 pF
lead 4 - ferrule = 705 pF

Lead 1 was further tested using a Hewlett Packard 4396A Network Analyzer. Test results are presented in FIGS. 25, 26, and 27. FIG. 25 is a logarithmic graph of the frequency (shown along the x-axis in Hertz) versus impedance (shown along the y-axis in ohms) for Lead 1. As shown in this figure, the impedance at high frequencies, for example 100 mega-Hertz, is relatively low, approximately 2 ohms. As such, the feedthrough assembly provides a very effective shunt for noise. At even higher frequencies, for example 1.0 giga-Hertz, the impedance is approximately 17 ohms. As such, the feedthrough assembly provides very effective protection against high frequency EMI.

FIG. 26 is a phase plot on a logarithmic graph of the frequency (shown along the x-axis in hertz) versus the phase angle (shown along the y-axis in degrees). As shown in this figure, the first resonance is indicated by a reversal of phase angle and occurs at approximately 145 MHz. At the resonant frequency, the impedance dropped to approximately 0.6 Ohms.

FIG. 27 is a graphic plot of the voltage to current characteristics for Lead 1 measured against the ferrule and using a Hewlett-Packard 4145 Semiconductor Parameter Analyzer. The x-axis represents voltage with 2.6 volts per division, and the y-axis represents current with 200 micro-amperes per division. As shown, the voltage to current characteristics for the transient voltage suppressor are completely symmetrical about the x and y axes. Breakdown for the transient voltage suppressor begins to occur at approximately 10.1 volts.

WHAT IS CLAIMED IS:

1. An implantable medical device (10), comprising:

a conductive outer housing (12) enclosing control circuitry (16) and a source (14) for generating electrical energy; and

a feedthrough (12) assembly hermetically sealed to said outer housing and including:

a conductive ferrule (40) defining an open central region,

a terminal pin (46) extending through said central region, electrically insulated from said ferrule, and in electrical communication with said control circuitry, and characterized by

a combination transient voltage suppressor and electromagnetic interference filter (38) in said feedthrough assembly and in electrical communication with said terminal pin.

2. The implantable medical device of claim 1 in which said transient voltage suppressor includes a zinc oxide base, and first and second sets of electrode plates embedded within said base, wherein said first set of electrode plates is in electrical communication with said terminal pin and said second set of electrode plates is in electrical communication with ground.

3. The implantable medical device of claim 2 in which said ferrule is electrically connected to said ground.

4. The implantable medical device of claim 1 in which:

said feedthrough assembly includes a plurality of terminal pins generally parallel, extending through said central region, and electrically insulated from said ferrule; and

said transient voltage suppressor includes first and second sets of electrode plates embedded within said base, wherein said first set of electrode plates is in electrical communication with said terminal pins and said second set of electrode plates is in electrical communication with ground.

5. The implantable medical device of claim 1 in which said transient voltage suppressor both clamps voltage surges and filters high frequency electromagnetic interference transmitted to said feedthrough assembly.

6. The implantable medical device of claim 5 in which:

said ferrule is in electrically conductive relation with said ground and with said outer housing;and

excess current generated during clamping of said voltage surges is circulated to said ferrule and to said outer housing.

7. The implantable medical device of claim 1 in which said transient voltage suppressor has a multilayered discoidal configuration.

8. The implantable medical device of claim 1 in which said feedthrough assembly is removed from said control circuitry such that said filtering of electromagnetic interference and said transient voltage supression occur before said incoming signals transmit to said control circuitry.

9. The implantable medical device of claim 1 in which said filtering of electromagnetic interference and said transient voltage supression occur before said incoming signals transmit into said housing of said implantable medical device.

10. The implantable medical device of claim 1 in which excess current generated during said supression of transient voltage is circulated to said ferrule.

11. The implantable medical device of claim 10 in which:

said ferrule is in electrical communication and thermal transfer communication with said housing of said implantable medical device; and

said excess current is further circulated to said housing.

12. The implantable medical device of claim 1 in which said cmbination transient voltage suppressor and electromagnetic interference filter exhibits symmetrical voltage to current response characteristics during forward and reverse biasing of said incoming signals.

13. The implantable medical device of claim 1 in which voltage surges are clamped between said ferrule and said terminal pin.

14. The implantable medical device of claim 1 further comprises a plurality of terminal pins, and in which voltage surges are clamped between said terminal pins.

15. A feedthrough filter assembly (18) for use with an implantable medical device having a ground, comprising:

a terminal pin subassembly (36) including a conductive ferrule (40) defining an open central region, and an elongated terminal pin (46) extending through said central region; and characterized by

a combined transient voltage suppressor and electromagnetic interference filter (38) connected to said terminal pin subassembly.

16. The feedthrough filter assembly of claim 15 in which said combination transient voltage suppressor and electromagnetic interference filter comprises a ceramic semiconductor base having first and second sets of electrode plates embedded within said ceramic base, wherein said first set of electrode plates is in electrical communication with said terminal pin and said second set of electrode plates is in electrical communication with said ground.

17. The feedthrough filter assembly of claim 16 in which said ceramic semiconductor base is formed from at least zinc oxide.

18. The feedthrough filter assembly of claim 16 in which said transient voltage

suppressor has a multi-layer configuration.

19. The feedthrough filter assembly of claim 18 in which said transient voltage suppressor is in a geometric configuration of a disk.

20. The feedthrough filter assembly of claim 15 in which:

said transient voltage suppressor defines an outer periphery; and

said ferrule extends downwardly and substantially surrounds said periphery in order to be in electrical communication with said second set of electrode plates.

21. The feedthrough filter assembly of claim 15 in which said implantable medical device has an outer conductive housing in electrical communication with said ferrule which is in electrical communication with said ground.

22. The feedthrough filter assembly of claim 15 in which:

said terminal pin subassembly includes an insulating portion formed around said terminal pin and adjacent said transient voltage suppressor; and

said ferrule extends upwardly to surround said insulating portion.

23. The feedthrough filter assembly of claim 15 in which said terminal pin subassembly further includes a ferrite bead disposed around said terminal pin and adjacent said transient voltage suppressor.

24. The feedthrough assembly of claim 15 in which said transient voltage suppressor has a first end electrically connected to said ferrule and a second end electrically connected to said terminal pin.

25. The feedthrough assembly of claim 15 in which said transient voltage suppressor is horizontally disposed within said feedthrough assembly with one end electrically connected to said terminal pin.

26. The feedthrough assembly of claim 15 in which said voltage surges are clamped between said terminal pin and said ferrule.

27. The feedthrough assembly of claim 15 further comprising a plurality of terminal pins in which said voltage surges are clamped between said terminal pins.

28. The feedthrough assembly of claim 15 further comprising a plurality of discrete transient voltage suppressors and a plurality of terminal pins, in which each said transient voltage suppressor has one end electrically connected to one of said terminal pins.

29. The feedthrough assembly of claim 28 in which said transient voltage suppressors are electrically connected to said terminal pins in one or more of a common mode protection or differential mode protection.

30. The feedthrough assembly of claim 15 in which:

said transient voltage suppressor has a ceramic base and a multilayer configuration; and

a plurality of terminal pins pass through said ceramic base.

31. The feedthrough assembly of claim 15 further comprising a plurality of transient voltage suppressors each having a multilayer configuration and electrically connected to form a vertical stacking arrangement.

32. The feedthrough assembly of claim 15 in which said combination transient voltage suppressor and electromagnetic interference suppressor comprises

a zinc oxide ceramic base of annular cross-section having coaxial inner and outer electrically conductive terminations; and

first and second sets of annular electrode plates embedded within said ceramic base and being spaced apart and parallel, wherein said first set of electrode plates is in electrical communication with said inner termination, and said second set of electrode plates is in electrical communication with said outer termination.

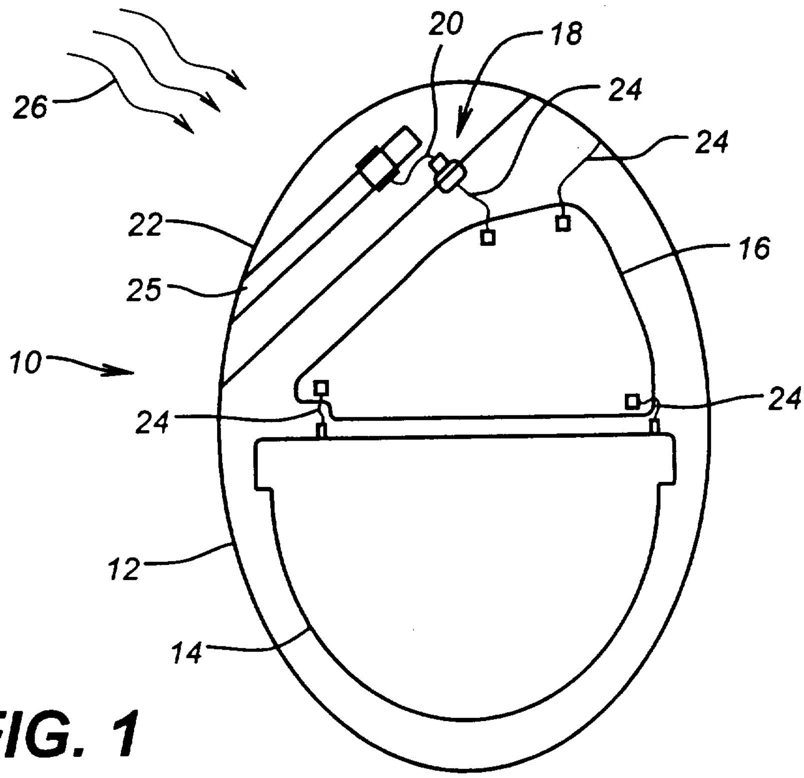

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FIG. 1

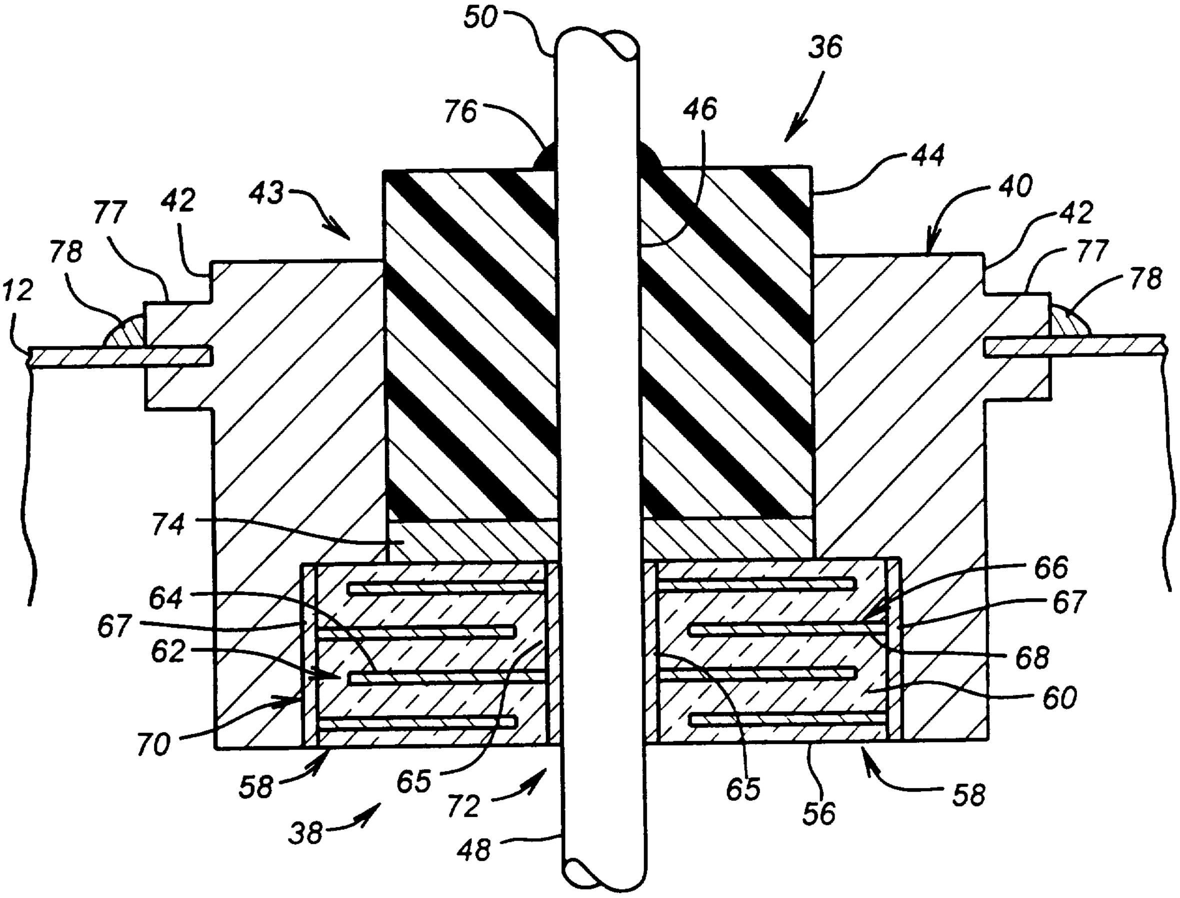

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FIG. 2

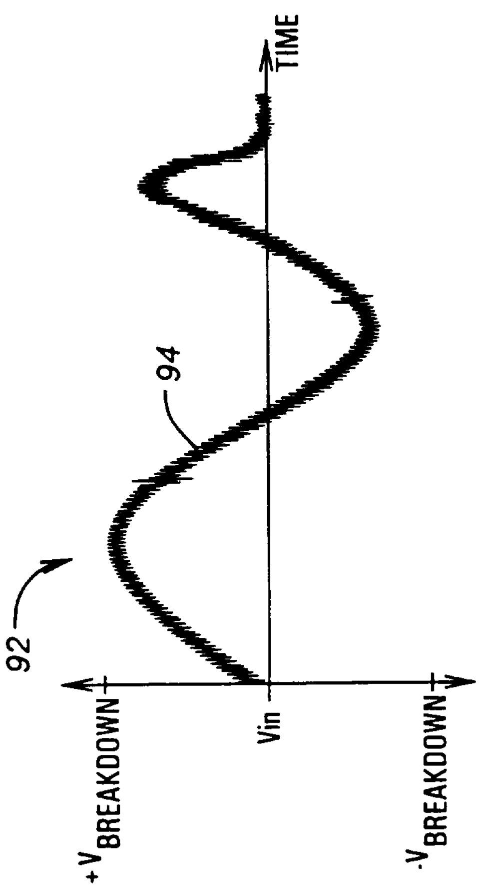


FIG. 4

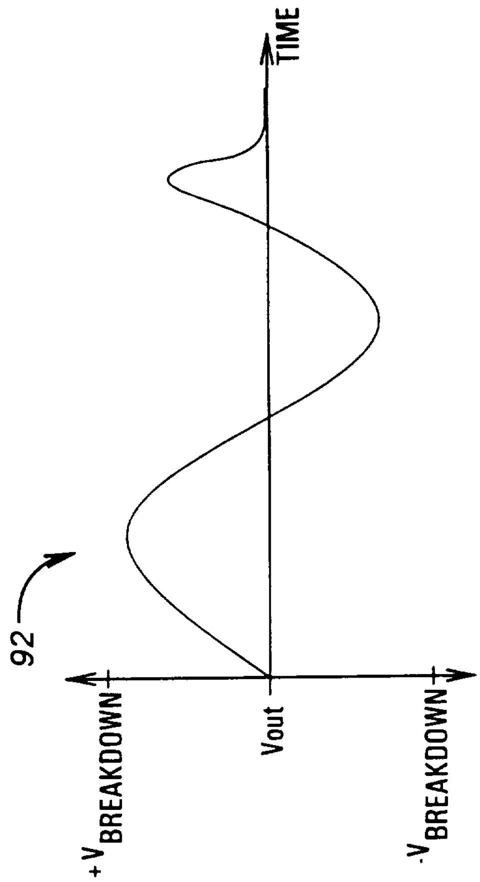


FIG. 5

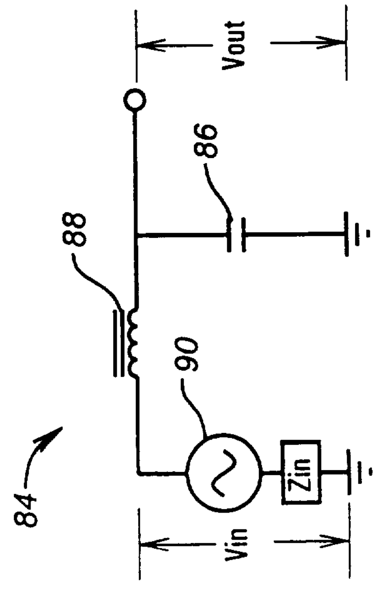


FIG. 3

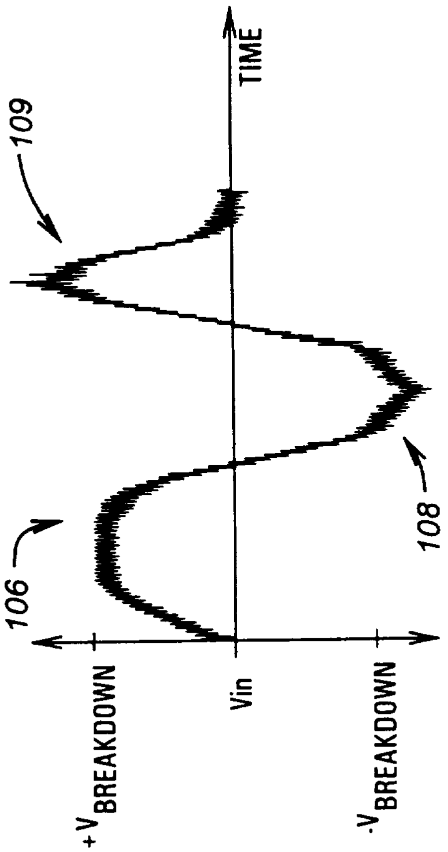


FIG. 7

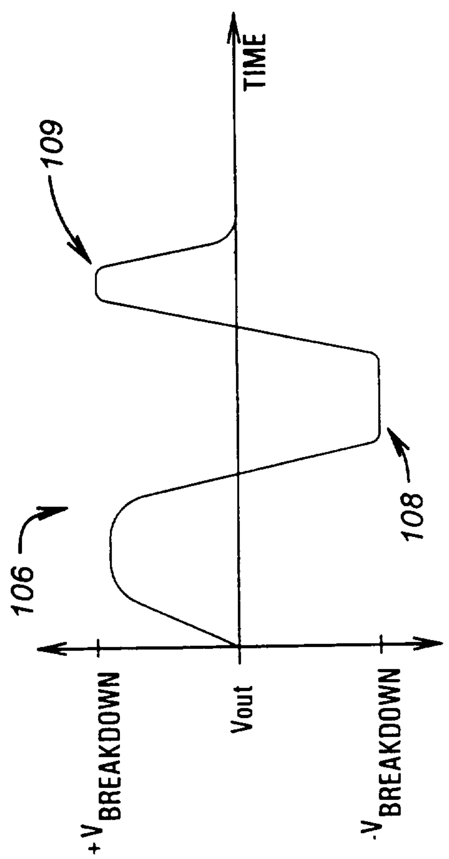


FIG. 8

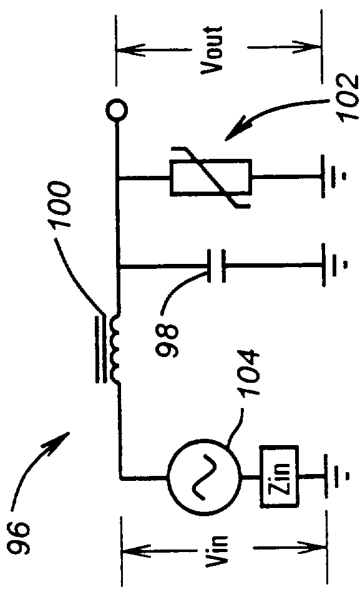


FIG. 6

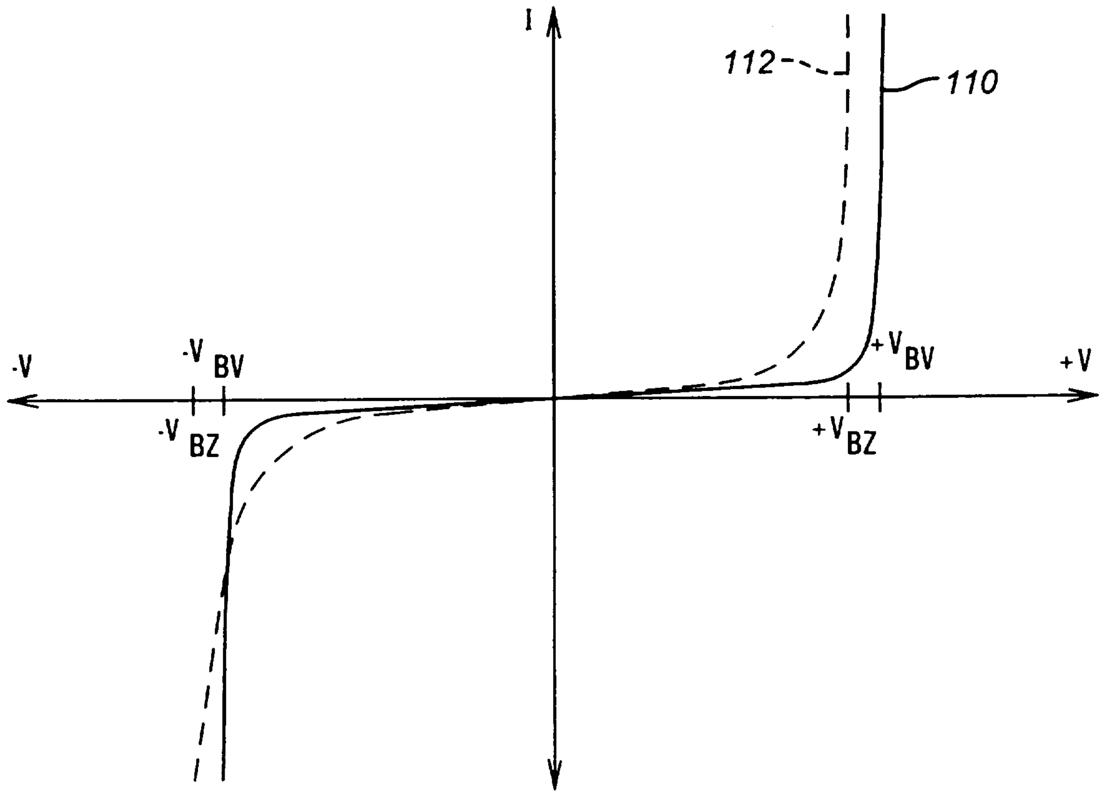


FIG. 9

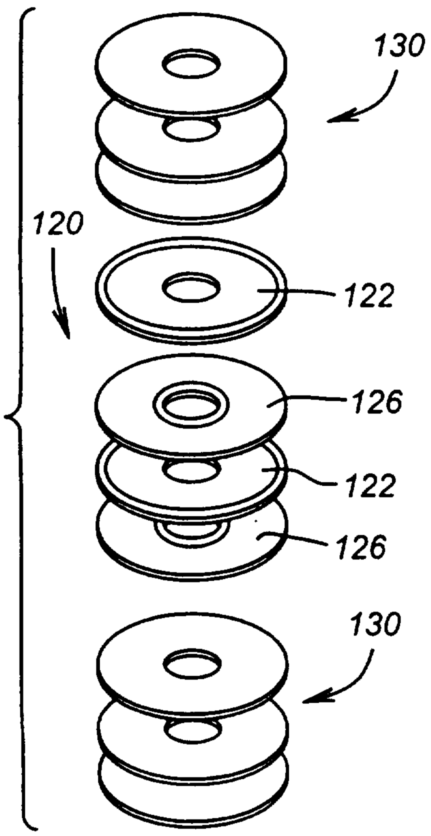


FIG. 10

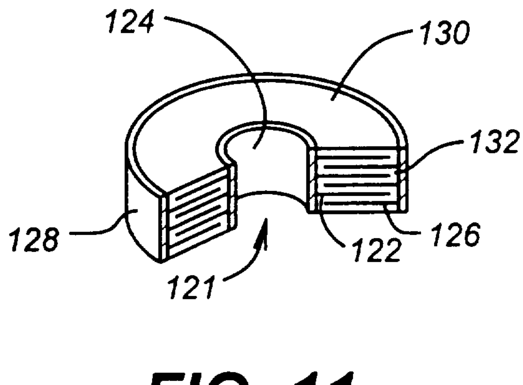


FIG. 11

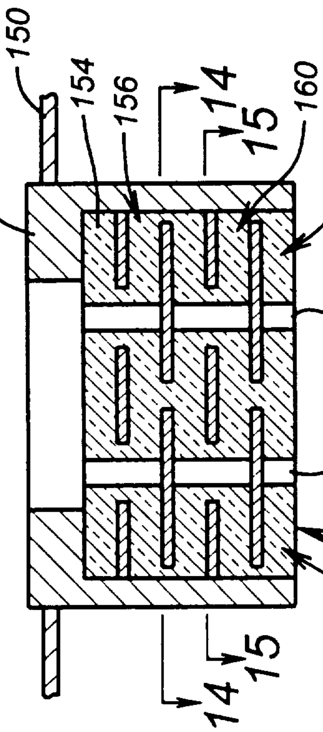


FIG. 13

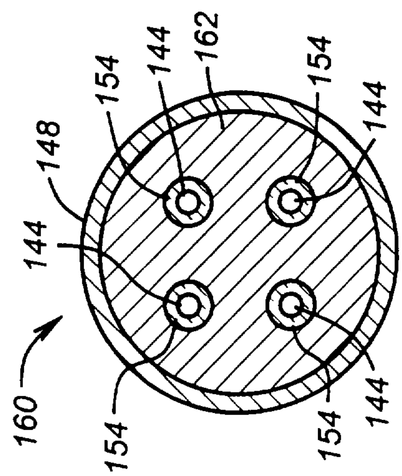


FIG. 15

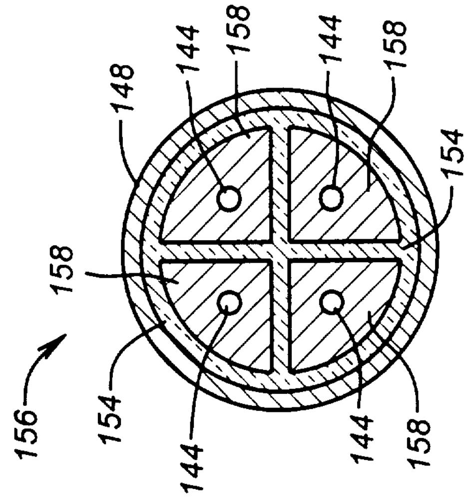


FIG. 14

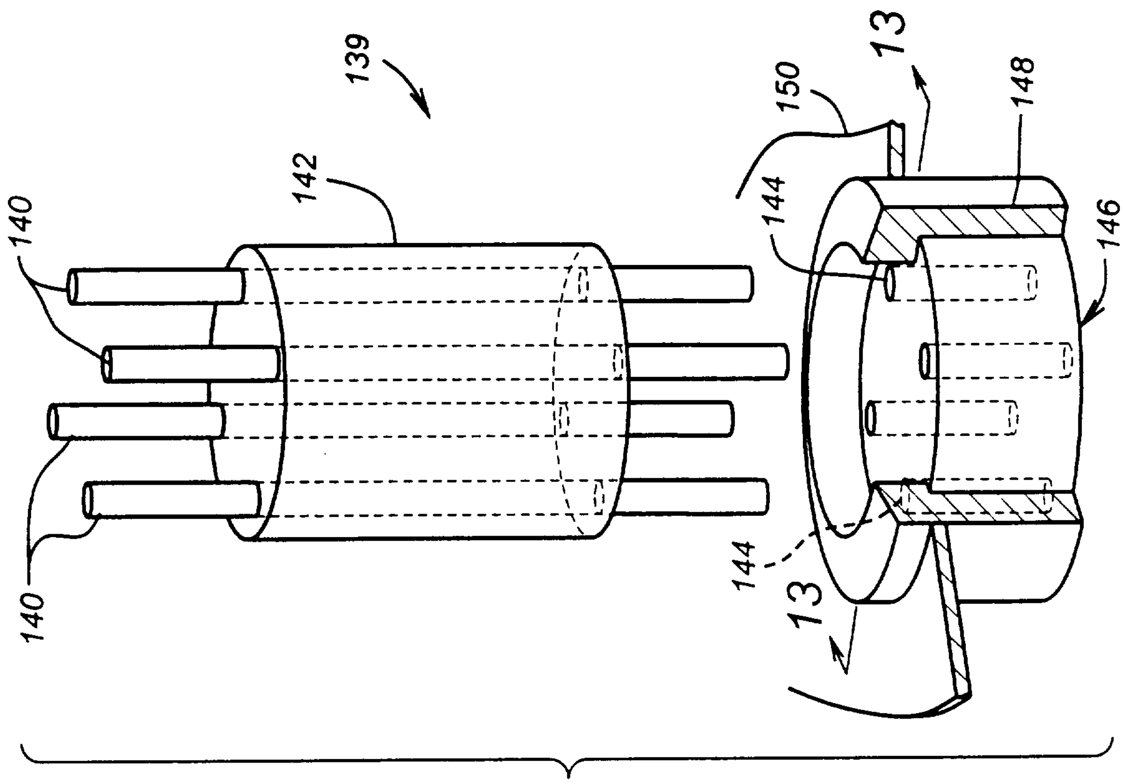


FIG. 12

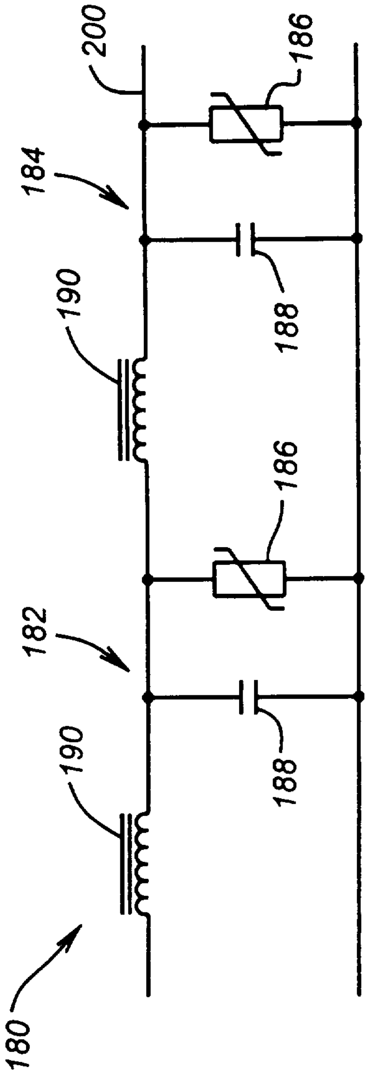


FIG. 17

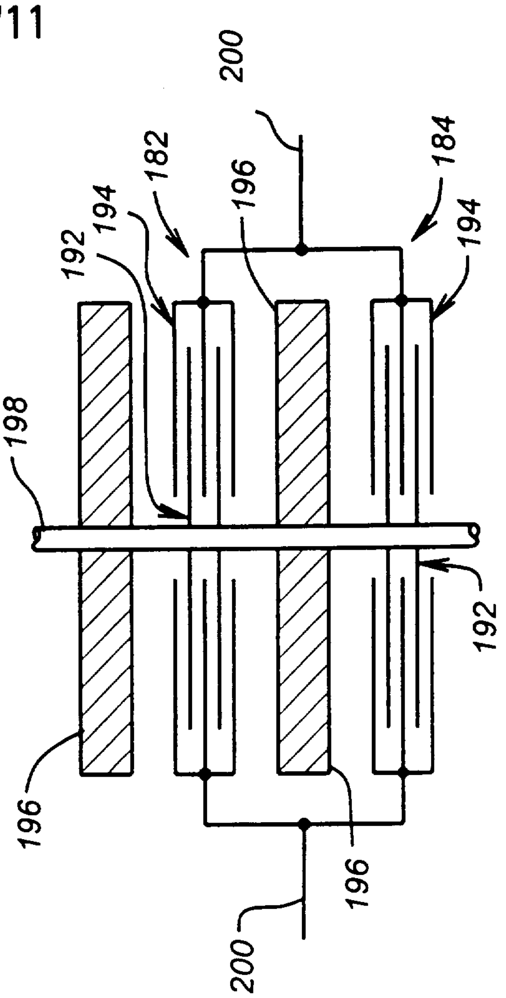


FIG. 18

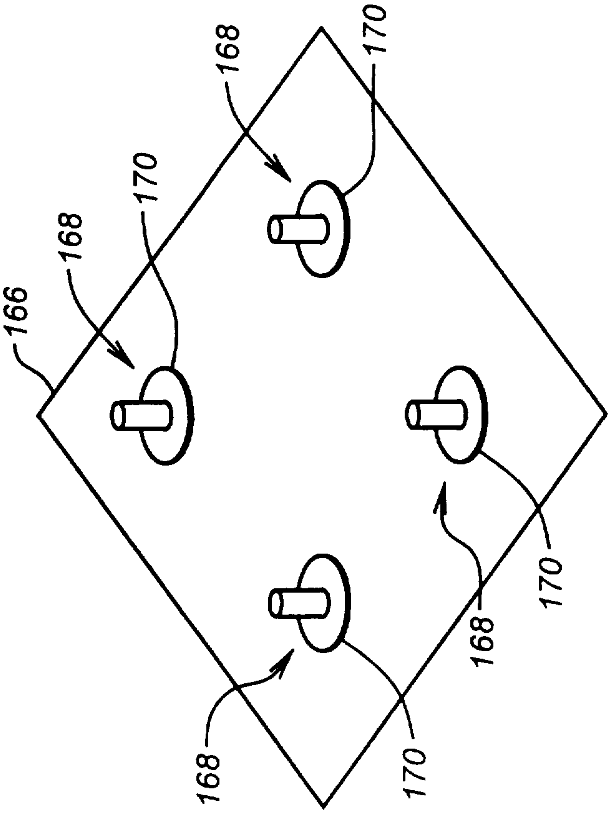


FIG. 16

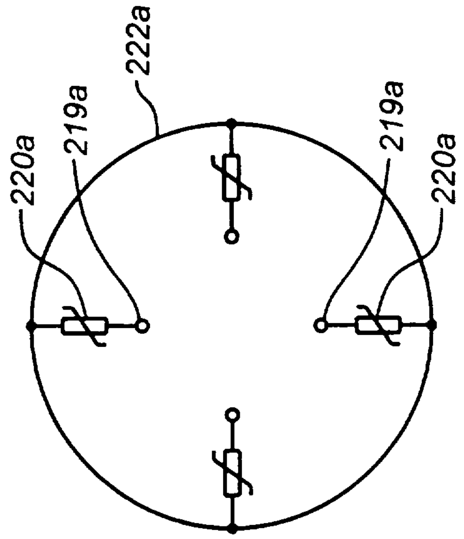


FIG. 20A

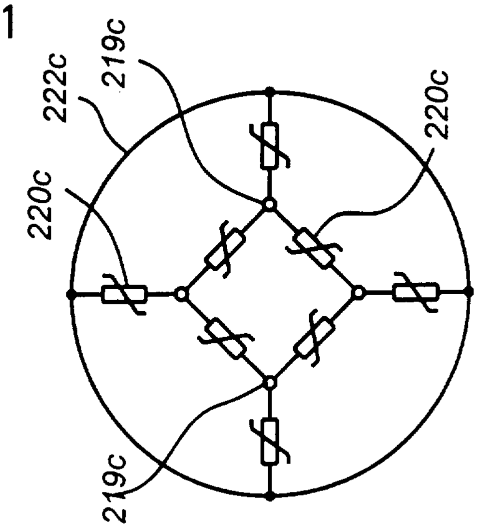


FIG. 20C

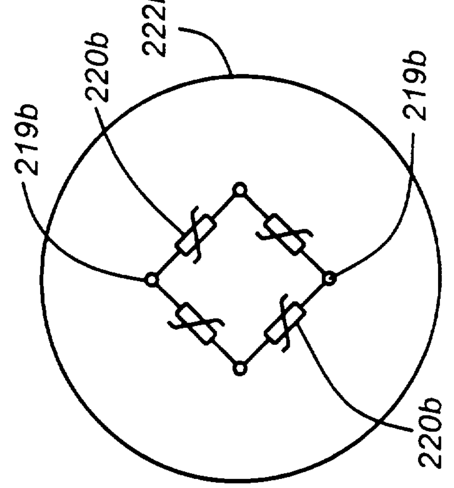


FIG. 20B

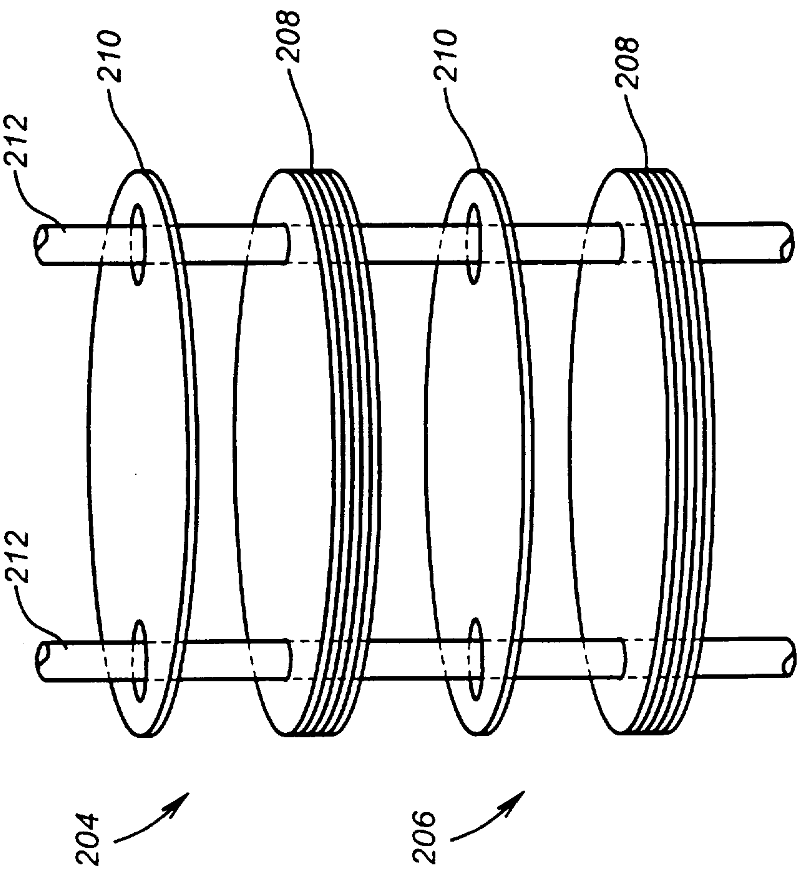


FIG. 19

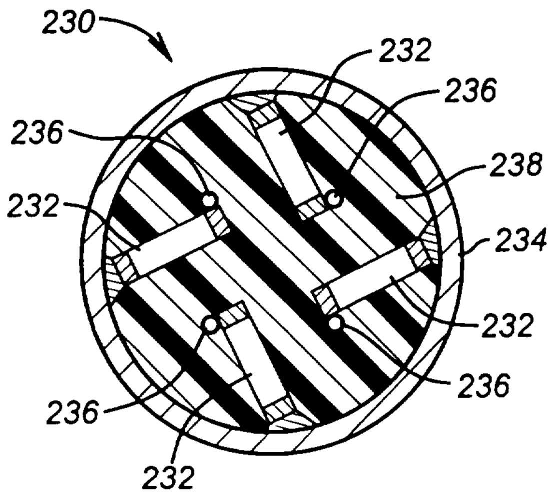


FIG. 21

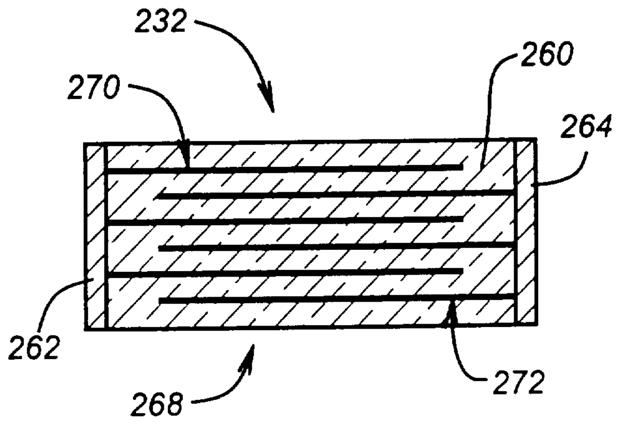


FIG. 22

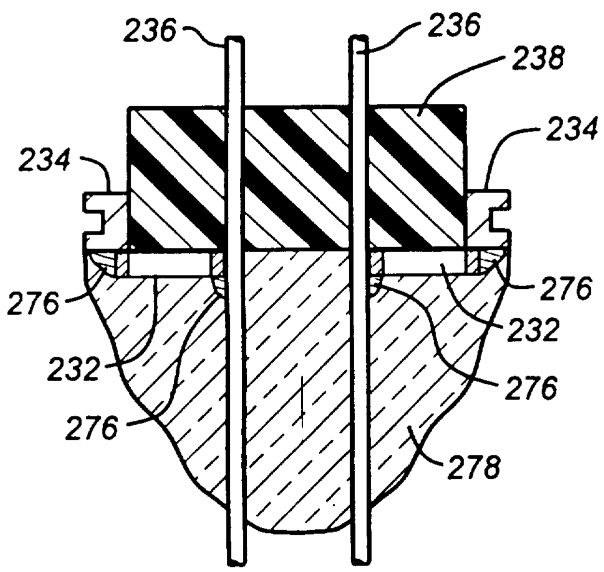


FIG. 23

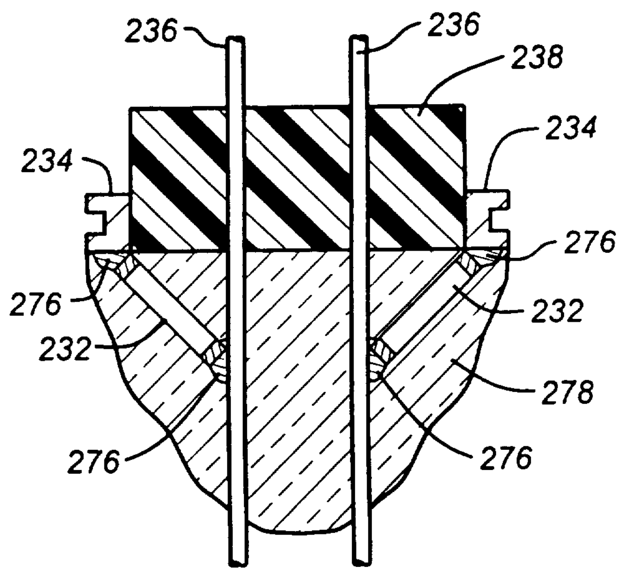
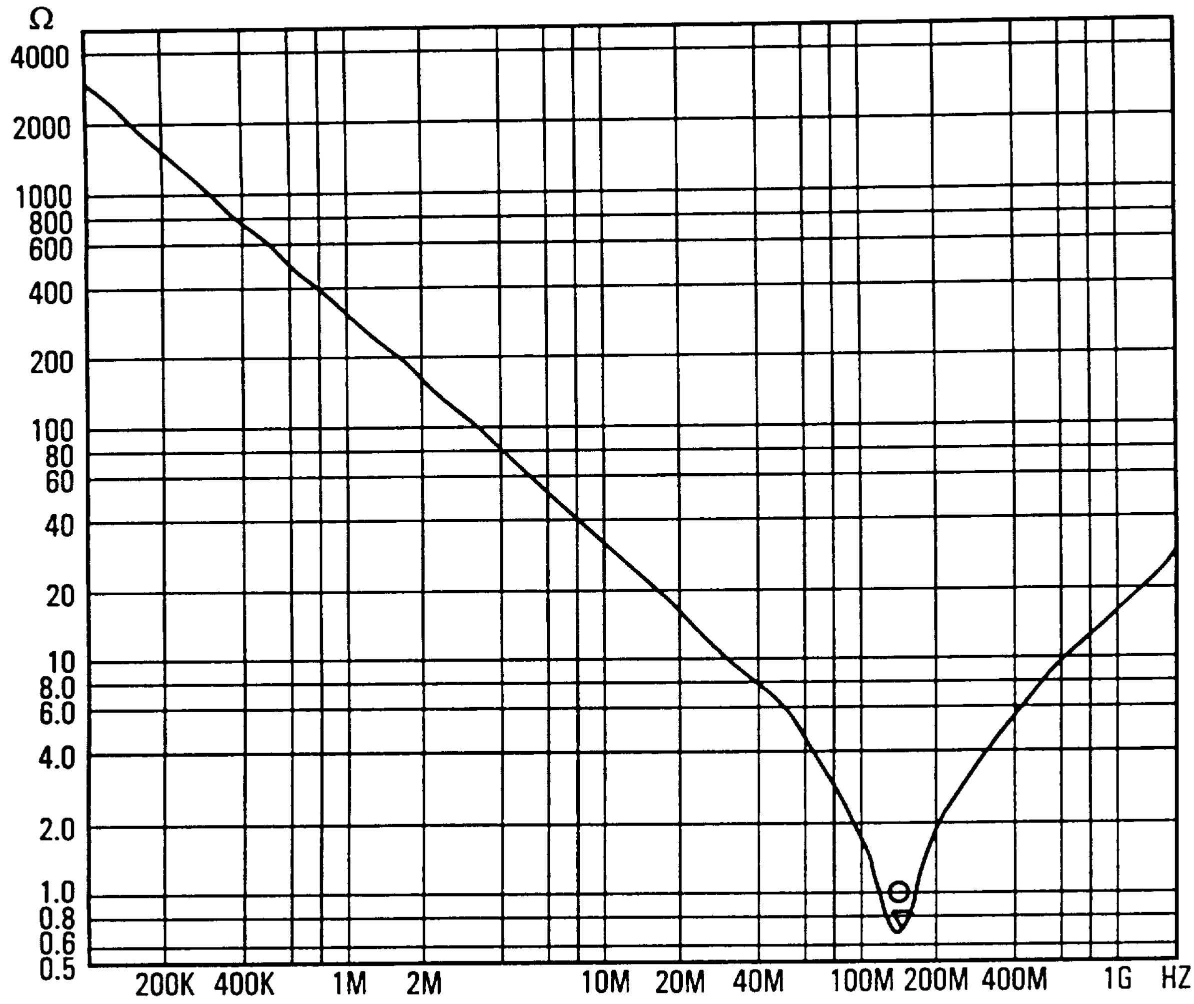


FIG. 24


Ω
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400
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60
40
20
10
8.0
6.0
4.0
2.0
1.0
0.8
0.6
0.5
200K 400K 1M 2M 10M 20M 40M 100M 200M 400M 1G HZ

FIG. 25

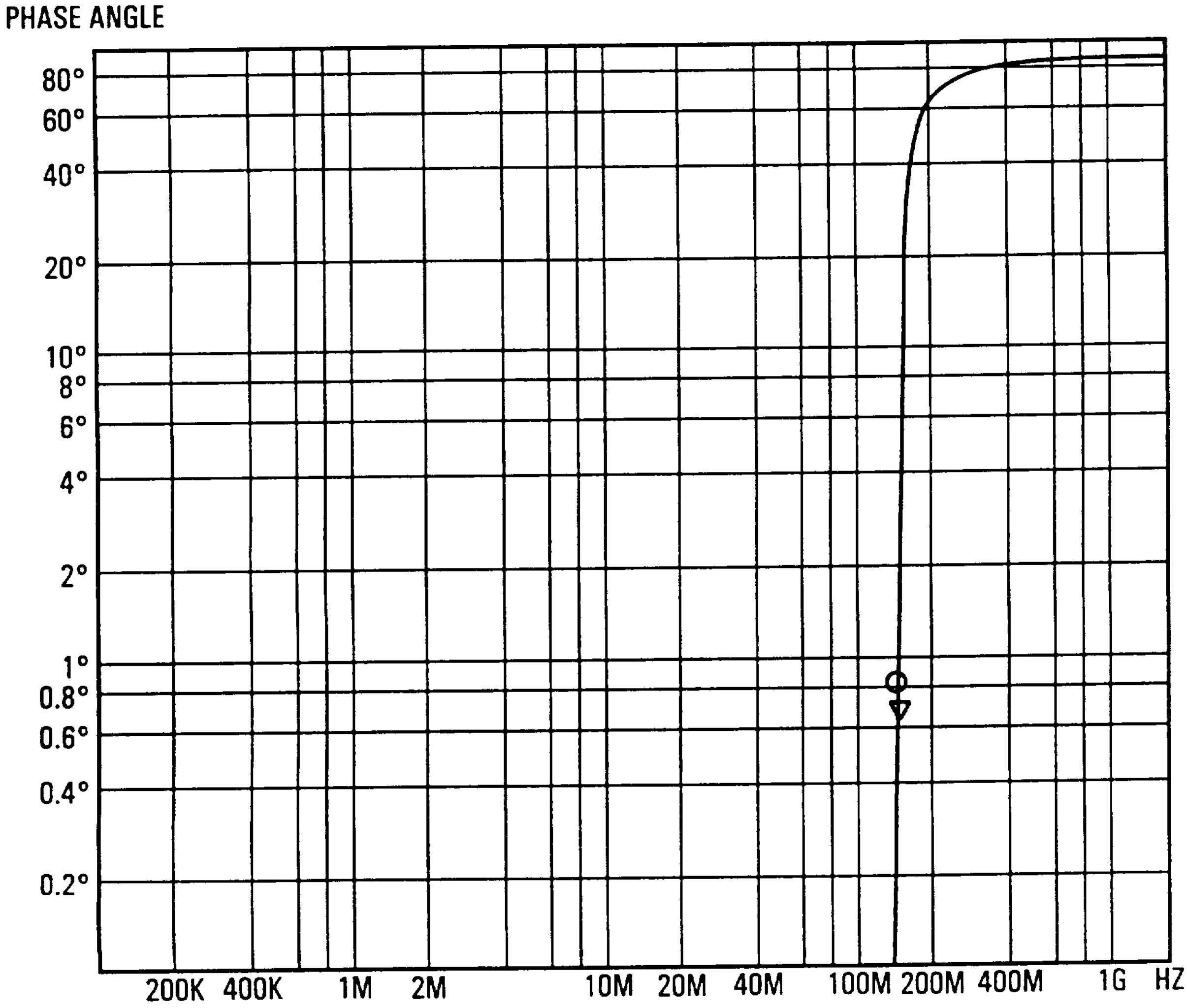
PHASE ANGLE
80°
60°
40°
20°
10°
8°
6°
4°
2°
1°
0.8°
0.6°
0.4°
0.2°
200K 400K 1M 2M 10M 20M 40M 100M 200M 400M 1G HZ

FIG. 26

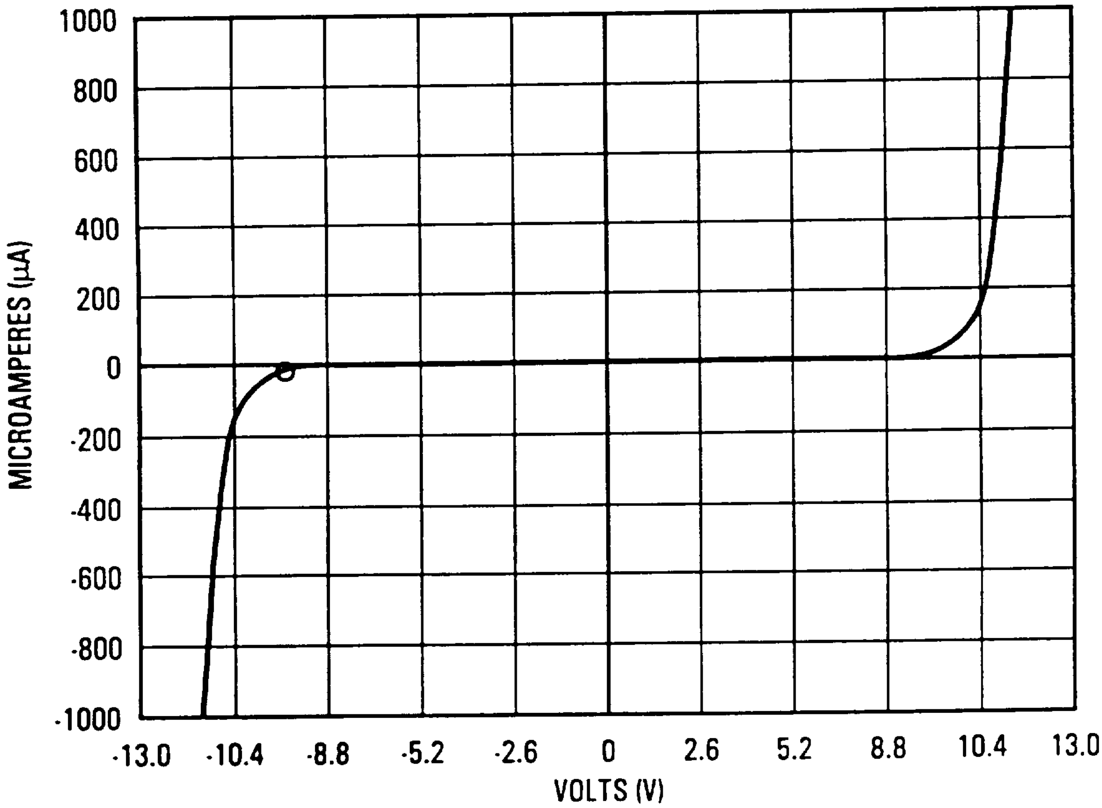
1000
800
600
400
200
0
-200
-400
-600
-800
-1000
MICROAMPERES (μA)
-13.0
-10.4
-8.8
-5.2
-2.6
0
2.6
5.2
8.8
10.4
13.0
VOLTS (V)

FIG. 27

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 96/15848

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61N1/375

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 A61N

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.
A	US,A,5 333 095 (STEVENSON) 26 July 1994 cited in the application see abstract see column 5, line 43 - column 6, line 8 see column 6, line 51 - line 64 see column 9, line 10 - line 29 see column 10, line 13 - line 18 see column 1 - column 2 ---	1,2,4,7, 15-19, 24,25
A	WO,A,95 16493 (INTERMEDICS) 22 June 1995 cited in the application see abstract ---	1,15
P,A	EP,A,0 705 621 (MEDTRONIC) 10 April 1996 see abstract --- -/--	1,15

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

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

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"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

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

1

Date of the actual completion of the international search	Date of mailing of the international search report
24 January 1997	-7. 02. 97

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	Taccoen, J-F

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 96/15848

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP,A,0 331 959 (SIEMENS ELEMA AB) 13 September 1989 see abstract -----	1,15

1

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 96/15848

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US-A-5333095	26-07-94	EP-A-	0623363	09-11-94
WO-A-9516493	22-06-95	US-A-	5486202	23-01-96
		CA-A-	2178472	22-06-95
		EP-A-	0734275	02-10-96
EP-A-0705621	10-04-96	AU-A-	3299995	18-04-96
		CA-A-	2159701	05-04-96
		JP-A-	8112361	07-05-96
EP-A-0331959	13-09-89	AU-A-	3076789	31-08-89
		DE-D-	68920171	09-02-95
		JP-A-	1262874	19-10-89