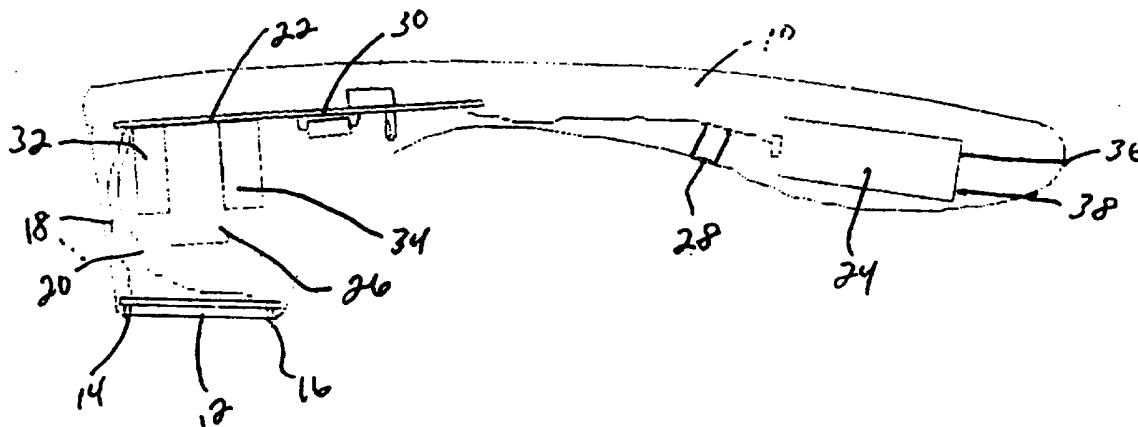




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(54) Title: ELECTROTHERAPY DEVICE



(57) Abstract

An apparatus for applying electrical current to biological tissue such as skin, bone or muscle. A portable housing (10) can be powered with a battery (24) or attached cord leading to an alternating current or direct current power supply. An amplifier (26) generates a high voltage direct current, and a controller (22) generates a high quality square waveform output. Such waveform comprises an output to an electrode assembly (12) in electrical contact with the biological tissue. The electrode assembly comprises at least one negative electrode (16) and at least one positive electrode (14) which generate an electric current through the biological tissue between the positive and negative electrodes. The electrode assembly is movable relative to the biological tissue so that the current path is continually changing. The electrode assembly can comprise a plurality of negative and positive electrodes to create multiple current paths through the biological tissue. The controller can selectively modify output signal functions such as the amplitude, pulse rate, pulse sweep, frequency, and frequency sweep rate to provide different electrical currents to the biological tissue. A display engaged with the controller indicates the output signal functions and provides controls for selectively modifying the output signal functions.

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ELECTROTHERAPY DEVICE

BACKGROUND OF THE INVENTION

The present invention relates to the field of therapeutic technology for healing biological tissue with electricity. More particularly, the present invention relates to an electrotherapy system for applying electrical microcurrents to biological tissue such as a person's body.

Electricity promotes healing of biological tissue damage and provides an anesthetic to pain. This result is believed to be related to the properties and characteristics of biological cells. Biological cells contain a bio-electrical potential across the stable cell membrane. The cells can be stimulated by a nerve signal or external stimulus which disrupts the ionic balance in the cell. Additionally, the polarity of a cell can be reversed in different states of rest or activity. One form of biological cell damage hinders the cell ability to return to an equilibrium condition. Electrical treatments are believed to stimulate biological cells to emulate or to regain normal cell function.

Electrical treatments have been attempted to treat arthritis, biological tissue damage, nerve damage, calcification and other ailments. Prior art devices have utilized different frequencies, pulse rates, amplitudes, and magnetic fields in the search for therapeutic and anesthetic treatments. Although alternating current electrical fields have been applied to

tissue, alternating currents can cause undesirable electrolysis at the contact point between an electrode and the tissue.

Square waveform electrical currents are known to be effective for promoting healing and curative effects. Consequently, efforts have been made to create square waveforms for application to biological tissue. However, such efforts have not produced a satisfactory device for generating pure waveforms at high voltage. Representative examples of prior art devices, including devices having positive and negative electrodes attached to a person's body, are described in the following references.

In United States Patent No. 4,554,923 to Batters ,(1985), an electrically conductive glove was placed on a person's hand. Electric current was passed through the glove and hand to reduce pain and edema in the person's joints. The glove permitted an electrode to be stationary relative to the hand and facilitated electrical contact between the glove and hand without an external conductive medium.

In United States Patent No. 4,509,521 to Barry (1985), headache pain was treated by applying an electrode to a person's neck or head, and by attaching a single ground electrode to a distal portion of the person's body. Electrical pulses from the electrode were applied between 60 and 150 volts and with a pulse width between 35 and 45 microseconds. The patent opined that each pulse should have the characteristics of a square waveform, and that other waveform shapes were not successful in providing

relief. However, the disclosed device utilized a 20 turn primary and a 200 turn secondary transformer for altering the input to output voltage after the waveform was created. This device has inherent limitations because internal resistances in the transformer break down the waveform quality and prevent the formation of a square waveform.

United States Patent No. 4,233,965 to Fairbanks (1980) described a device having two electrodes and a magnet for transmitting electricity through a person's body. One of the electrodes cooperated with a concentric electromagnet to produce a magnetic field for driving current into the tissue and toward a second electrode near the person's head. Rectangular or square wave positive polarity pulses were applied through a first electrode, and electrolysis at the tissue-electrode interface was minimized by the spreading effects of the magnetic field. Low voltage treatments between 20 and 27 volts DC at up to 400 microamps were applied continuously for up to eight hours.

United States Patent No. 3,946,745 to Hsiang-Lai et al. (1976) described a device for generating an electrical signal comprising successive pulse pairs of opposite polarity, referred to as biopulses. Each biopulse included a fore-pulse and an aft-pulse having a reverse polarity. An electrode was attached to the tissue, and a signal pulse generator included a transformer for increasing the biopulse voltage. The output transformer generated an irregular waveform transmitted directly to the electrode load. To reduce the distortion of the output, a pair

of resistors connected in parallel were substituted for the transformer so that open circuiting of a resistor would flow current through the other resistor. However, the patent disclosure anticipated that open circuiting of both resistors was possible, and that a potentially dangerous hazard might exist.

These electrical devices demonstrate the difficulty of generating a high voltage square waveform for application to biological tissue. Although transformers have been positioned between low voltage circuits and electrodes to step up the voltage after the waveform is generated, the waveform is significantly distorted. High quality transformers reduce the amount of waveform distortion but are expensive and do not efficiently produce the desired microcurrent treatment. A need, therefore, exists for an improved system for providing electrical stimulation to a person's body.

SUMMARY OF THE INVENTION

The present invention provides an apparatus for applying electrical current to biological tissue. The invention comprises a housing for movement proximate to the biological tissue, a power supply, an amplifier engaged with the power supply for generating a high voltage, a controller engaged with the amplifier for generating a square waveform output, and an electrode assembly having negative and positive electrodes for movement relative to, for electrical contact with, and for transmitting electrical current through the biological tissue.

In alternative embodiments of the invention, the electrode assembly can comprise a plurality of negative and positive electrodes. The negative electrodes can be oriented in a circular array, and the positive electrodes can be oriented in a circular array concentric with and having a larger radius than the circular array for the negative electrodes. The controller can selectively modify the amplitude, pulse rate, frequency, and sweeping functions of the output signal, and such functions can be indicated with a display. The display and controls permit the adjustment of such functions, and can be monitored or adjusted with a microprocessor. A single negative electrode can be paired with a single positive electrode, or two positive electrodes can be paired with a single negative electrode to create multiple current paths through the biological tissue.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 illustrates a schematic view of a housing and enclosed components.

Figure 2 illustrates one embodiment of a circuit utilizing the invention.

Figure 3 illustrates one embodiment of an electrode pattern.

Figure 4 illustrates an alternative embodiment of an electrode pattern.

Figure 5 illustrates another embodiment of an electrode pattern.

Figure 6 illustrates an alternative embodiment of a circuit incorporating the present invention.

Figure 7 illustrates a display for indicating the operation of the system and further illustrates switches for controlling modifications to operating functions.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention provides a unique apparatus for supplying microcurrent stimulation to biological tissue. As used herein, the term "biological tissue" includes skin, muscle, bone, nerves, tendons, and other parts of a biological organism such as a person or domestic animal. Although the invention is principally described herein for use with human patients or subjects, the invention is equally beneficial to livestock and other domestic animals.

Referring to Figure 1, a schematic diagram of the apparatus is illustrated. Housing 10 is constructed from an inorganic or organic material which can be formed in the desired shape. Housing 10 is preferably formed with a plastic, injected resin or other material that resists electrical conductivity. Electrode assembly 12 is formed with positive charge electrode 14 and negative charged electrode 16. Electrode assembly 12 is connected with electrically conductive wires 18 and 20 to controller 22, which in turn is engaged with battery 24. Amplifier 26 can boost the nine volt direct current ("VDC") of battery 24 to a high voltage between 50-500VDC.

Controller 22 includes manually operated switch 28 for selectively providing power from battery 24 to amplifier 26. Controller 22 also includes printed circuit board ("PCB") 30 to provide a direct current square waveform output for transmission to electrode assembly 12. Manual switch 28 can selectively permit or cease the transmission of the output to electrode assembly 12. PCB 30 can support components such as switching regulator 32. A sensor such as motion switch 34 can switch off battery 24 if electrode assembly 12 is not moved relative to the biological tissue within a selected period of time.

Power supply or battery 24 provides power to controller 22 and electrode assembly 12. In one embodiment of the invention, battery 24 can comprise a nine volt battery contained within housing 10. In a preferred embodiment of the invention, battery ²⁴~~22~~ comprises a rechargeable battery that can be recharged by attaching ^{negative terminal}~~contacts~~ 36 and ^{positive terminal}~~38~~ to a converter (not shown) communicating with an alternating power source. In another embodiment of the invention, battery 24 can be replaced with another form of power supply such as a wire (not shown) attached to housing 10 for communicating direct current to controller ²²~~20~~. In another embodiment of the invention, the power supply can comprise a rectifier or electrical circuit for converting the alternating current to direct current.

In operation, housing 10 is manipulated so that electrode assembly 12 is continually moved over the biological tissue such as the subject's skin. Continual movement of electrode assembly

12 restricts electric current "channeling" through low resistance paths in the subject by continually changing the location of positive charge electrodes 14 and negative charge electrodes 16. Distribution of electric microcurrents is spread to maximize the benefits of the system, and overexposure to low resistance paths within the subject is restricted.

By regulating continual movement of electrode assembly 12, the system significantly enhances the healing and curative effectiveness of the apparatus. Prior art techniques having fixed electrodes transmit electric current through the paths of least resistance, potentially missing certain areas of desired treatment. Conversely, the present invention provides a sweeping movement which continually changes the relative position of positive charge electrodes 14 relative to negative charge electrodes 16, thereby changing the current paths through the subject. This movement transmits electric current through the subject in a substantially uniform, flux-like manner.

Figure 2 illustrates a representative circuit for one embodiment of the invention. Battery 24 has negative terminal 36 engaged with lead wire 40 and has positive terminal 38 connected to common lead identified as "C". Manual switch 28 selectively opens or closes the conductivity path leading to negative terminal 36 to provide direct current power supply to the system. Amplifier 26 cooperates within the circuit and with microchip 42 and transistor 44 to step-up the nine volt battery potential to a high voltage in the preferred range between 50 and 500 volts.

Microchip 42 is engaged with common "C" and drives transistor 44 to pull large currents through amplifier 26. Transistor 44 can comprise a cascading transistor such as a Darlington Power Transistor which uses one internal transistor to boost the current for another internal transistor.

In the circuit illustrated in Figure 2, the output voltage from amplifier 26 is shown at 400 volts direct current ("VDC"). Diode 46 rectifies and smooths the current from the high voltage side of amplifier 26. Capacitor 48 is charged at a voltage of 400VDC, and current is selectively transmitted as output signal to negative charge electrode 16 with Field Effect Transistor ("FET") 50. The switching of FET 50 is controlled with microchip 52, which provides a timer function to FET 50 through transistor 54. Microchip 52 controls the pulses of the output signal. In one embodiment of the invention, microchip 52 can drive FET 50 at 400 VDC, between 5-100 microseconds, ten times per second. Microchip 52 can provide a potentiometer function wherein the width and rate of such functions is modified.

FET 50 is engaged with electrode assembly 12, and specifically with negative charge electrode or electrodes 16. The output signal delivered by FET 50 to negative charge electrodes 16 comprises an extremely high quality square waveform at 400 VDC. This result is significantly more effective than prior art techniques which created a waveform at low voltage, and then stepped-up the voltage with a transformer. This enhancement occurs because the quality of transformers significantly

increases the cost, and because transformers have internal resistances which degrade the purity of the resulting waveform. By creating a square waveform shape at the final voltage of 400VDC, a pure waveform output is delivered from FET 50 to electrode assembly 12.

The circuit illustrated in Figure 2 shows only one possible construction of the invention, wherein a high voltage signal is cleanly switched to generate a pure square waveform from the output signal to electrode assembly 12. It will be appreciated that other circuits and devices performing the equivalent function are contemplated within the scope of the invention. Representative examples of such circuits and devices include switching power regulators, or might include voltage multiplier circuits comprised of diodes and capacitors which convert an alternating current signal to a high voltage direct current output.

Microchip 56 can comprise a power saving device which selectively opens the circuit to battery 24 when capacitor 48 is fully charged, thereby avoiding power losses from battery 22 during the time after capacitor 48 is fully charged and before capacitor 48 is discharged.

Microprocessor 60 can be engaged with the circuit shown in Figure 2 to control numerous functions related to the output signal amplitude, pulse rate, and pulse magnitude. For example, microprocessor 60 can "sweep" the pulse rate or frequency across selected ranges. Microprocessor 60 can control the pulse width,

the width sweep period, the width sweep depth, the frequency, the frequency sweep depth, and the frequency sweep period.

Additionally, microprocessor 60 can control other functions such as switches, sound effects and sensation feedback sensors or monitors. All of these functions can be indicated on display 62 engaged with microprocessor 60. Although microprocessor 60 simplifies the operation of these various functions, it will be appreciated that other circuits and devices can perform the same functions within the scope of the invention.

Referring to Figure 3, one embodiment of electrode assembly is illustrated wherein a plurality of negative charge electrodes 16 are positioned within an interior array 64, and a plurality of positive charge electrodes 14 are positioned within an exterior array 66. As shown in Figure 3, the interior and exterior arrays 64 and 66 substantially form concentric circles wherein each negative charge electrode 16 is equidistant from two positive charge electrodes 14. This configuration creates two microcurrent paths at different vector angles for each negative charge electrode 16, thereby increasing the microcurrent path coverage for each negative charge electrode 16.

Regardless of which direction electrode assembly 12 is moved relative to the biological tissue or a subject, the microcurrent between a negative charge electrode 16 and one positive charge electrode 14 will sweep across the biological tissue in a path which complements the path covered by the microcurrent with the other paired positive charge electrode 14, thereby enhancing the

surface coverage of the microcurrents. While the sweeping effect of one positive charge electrode 14 and one negative charge electrode 16 can accomplish surface coverage, such coverage is more complete and provides greater redundancy if a plurality of electrodes are incorporated within electrode assembly 12.

Figure 4 illustrates another embodiment wherein electrode assembly is formed with electrodes 16 in elliptical exterior array 68 and electrodes 14 within interior array 70. Figure 5 illustrates an alternative embodiment of the invention wherein a single negative charge electrode 72 is positioned in an interior configuration relative to and equidistant to a single positive charge electrode 74. As shown in Figures 3-5, different electrode configurations can accomplish a functional equivalent result without departing from the scope of the invention.

Figure 6 illustrates an alternative embodiment of a circuit representative of the present invention. As shown, battery 24 is connected to low voltage bus 76 to power microprocessor 78, power transistor 80 and amplifier or transformer 82. The nine volt battery potential is stepped-up to 400VDC and is smoothed with rectifier 84 (which includes an output capacitor). Any fluctuations in such high output voltage are detected with voltage sensor 86 for transmission to microprocessor 78. If the high voltage drops below a selected threshold level, microprocessor 78 runs transistor 80, switching at 30kHz and injecting energy into transformer 82, thereby causing rectifier

84 to charge up the internal capacitor described above to the selected voltage.

Microprocessor 78 selectively controls FET 88 for generating a high quality square waveform output transmitted to electrode assembly 12 as the square waveform output signal. Current sensor 89 is positioned between FET 88 and electrode assembly 12 to monitor current pulses transmitted to electrode assembly 12 and to transmit a signal to microprocessor 78 indicating such current pulses. Signals indicating such data can be transmitted to display 90 on the low voltage side of microprocessor 78, and can permit microprocessor 78 to monitor and control current pulses emitted by electrode assembly 12.

Motion sensor 92 can be engaged between low voltage bus 76 and microprocessor 78 to monitor movement of electrode assembly 12 attached to housing 10. Motion sensor 92 generates a signal to microprocessor 78 if electrode assembly 12 is not moved for a selected interval of time, and microprocessor 78 can be programmed to cease all electric power transmitted to FET 88 and to electrode assembly 12. This power disconnect creates a power switch which prevents electrode assembly 12 from continuously providing electrode current to the same segment of biological tissue, and provides a power conservation feature for preventing power drains from battery 24 when electrode assembly 12 is not in use. As shown in Figure 7, display 90 can indicate numerous functions performed by microprocessor 78 and other components of the system.

Although the invention has been described in terms of certain preferred embodiments, it will be apparent to those of ordinary skill in the art that modifications and improvements can be made to the inventive concepts herein without departing from the scope of the invention. The embodiments shown herein are merely illustrative of the inventive concepts and should not be interpreted as limiting the scope of the invention.

WHAT IS CLAIMED IS:

1. An apparatus for applying electrical current to biological tissue, comprising:
 - a housing for movement proximate to the biological tissue;
 - a power supply;
 - an amplifier engaged with said power supply for generating a high voltage direct current;
 - a controller engaged with said amplifier for generating a square waveform output; and
 - an electrode assembly engaged with said controller for electrical contact with the biological tissue and for transmitting said output to the biological tissue when said electrode assembly is moved relative to the biological tissue, wherein said electrode assembly comprises at least one negative electrode and at least one positive electrode proximate to said negative electrode for transmitting electric current from said output through the biological tissue between said positive and negative electrodes.
2. An apparatus as recited in Claim 1, wherein said electrode assembly comprises a plurality of negative electrodes and a plurality of positive electrodes.

3. An apparatus as recited in Claim 2, wherein said negative electrodes are arranged in an interior array, and wherein said positive electrodes are arranged in an array exterior to said negative electrodes.

4. An apparatus as recited in Claim 2, wherein said negative electrodes are arranged in a first circular array, and wherein said positive electrodes are arranged in a second circular array having a radius greater than said first circular array, and wherein said first and second circular arrays are concentric.

5. An apparatus as recited in Claim 1, wherein said amplifier generates a voltage equal to or greater than 300 volts.

6. An apparatus as recited in Claim 5, wherein said controller generates said output after said amplifier generates said high voltage.

7. An apparatus as recited in Claim 1, wherein said controller selectively modifies the frequency of said output.

8. An apparatus as recited in Claim 1, wherein said controller sweeps the frequency of said output through a selected frequency range.

9. An apparatus as recited in Claim 1, wherein said controller sweeps the pulse frequency of said output through a selected range.

10. An apparatus as recited in Claim 1, wherein said controller adjusts the duration of said output.

11. An apparatus as recited in Claim 1, wherein said power supply provides an alternating current, and further comprising a rectifier to convert the alternating current to direct current.

12. An apparatus as recited in Claim 1, further comprising a display engaged with said controller.

13. An apparatus as recited in Claim 11, wherein said display indicates the voltage of said output.

14. An apparatus as recited in Claim 11, further comprising a microprocessor engaged between said display and said controller for selectively modifying the pulse width, frequency, and voltage of said output.

15. An apparatus for applying electrical current to biological tissue, comprising:

- a housing for movement proximate to the biological tissue;
- a direct current power supply engaged with said housing;
- an amplifier engaged with said power supply for generating a high voltage direct current;

- a controller engaged with said amplifier for generating a square output;

- a plurality of negative electrodes engaged with said controller for transmitting said output to the biological tissue;

and

- a plurality of positive electrodes engaged with said power supply and in electrical contact with the biological tissue for permitting electrical currents to flow through the biological tissue between said positive electrodes and said negative electrodes.

16. An apparatus as recited in Claim 15, wherein each positive electrode is located proximate to a negative electrode to create an electrode pair, and wherein said output generates an electric current between each electrode pair in a path through the biological tissue.

17. An apparatus as recited in Claim 15, wherein two positive electrodes are located proximate to a negative electrode, and wherein said output generates two electric current paths through the biological tissue between each negative electrode and each proximate positive electrode.

18. An apparatus as recited in Claim 17, wherein said negative electrodes are oriented in a interior circular array, and wherein said positive electrodes are oriented in an exterior circular array concentric to said interior circular array.

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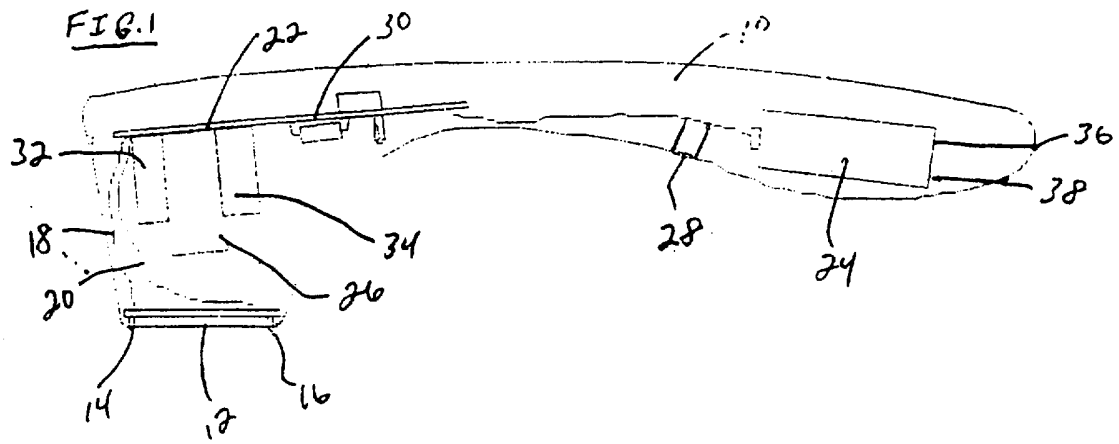


FIG. 3

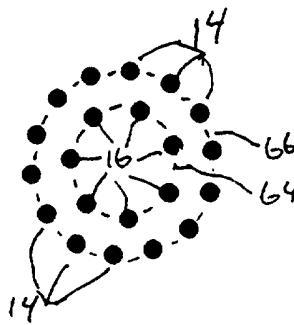


FIG. 4



FIG. 5

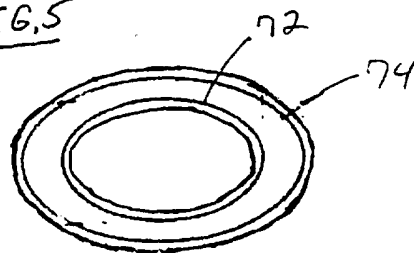
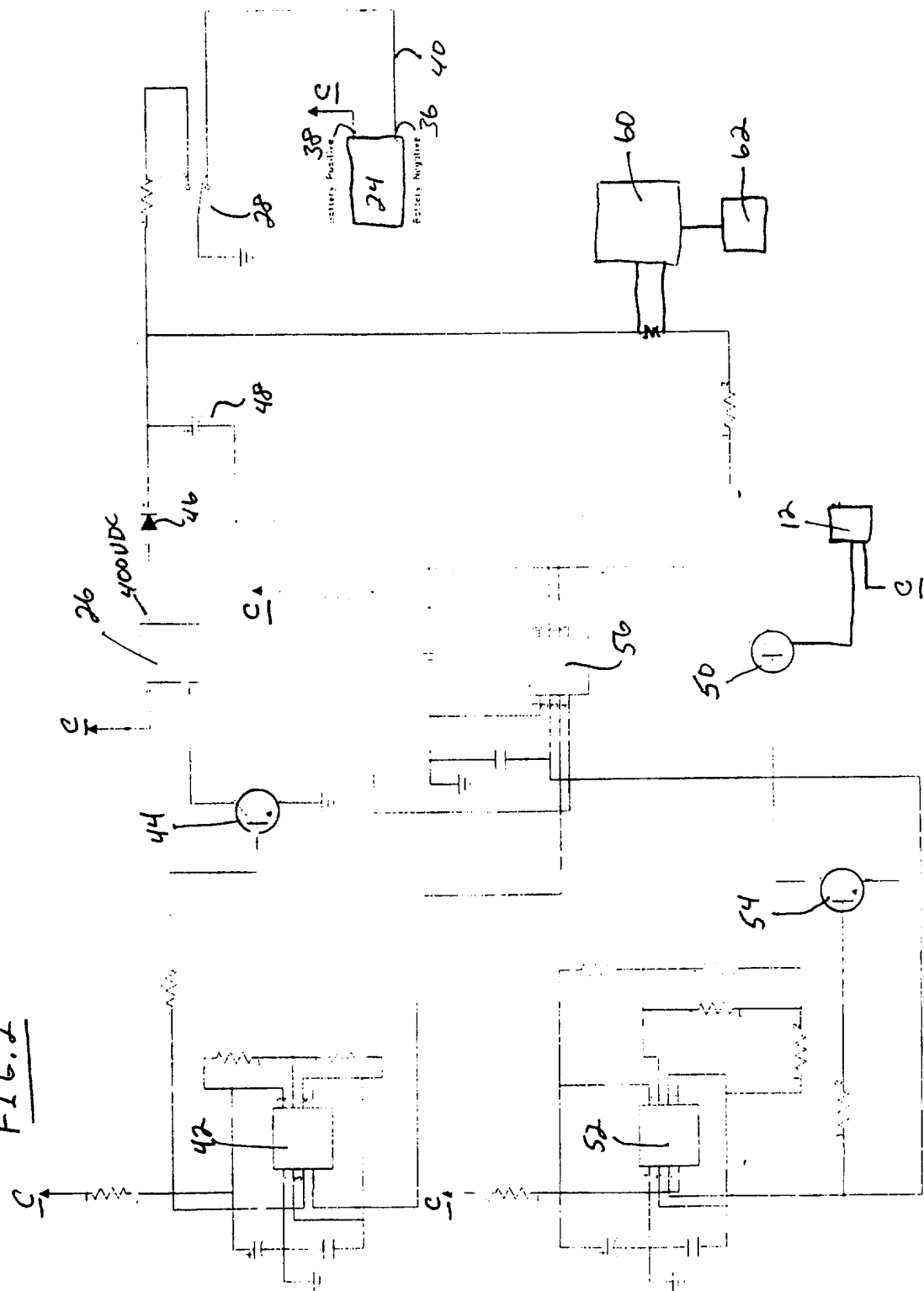
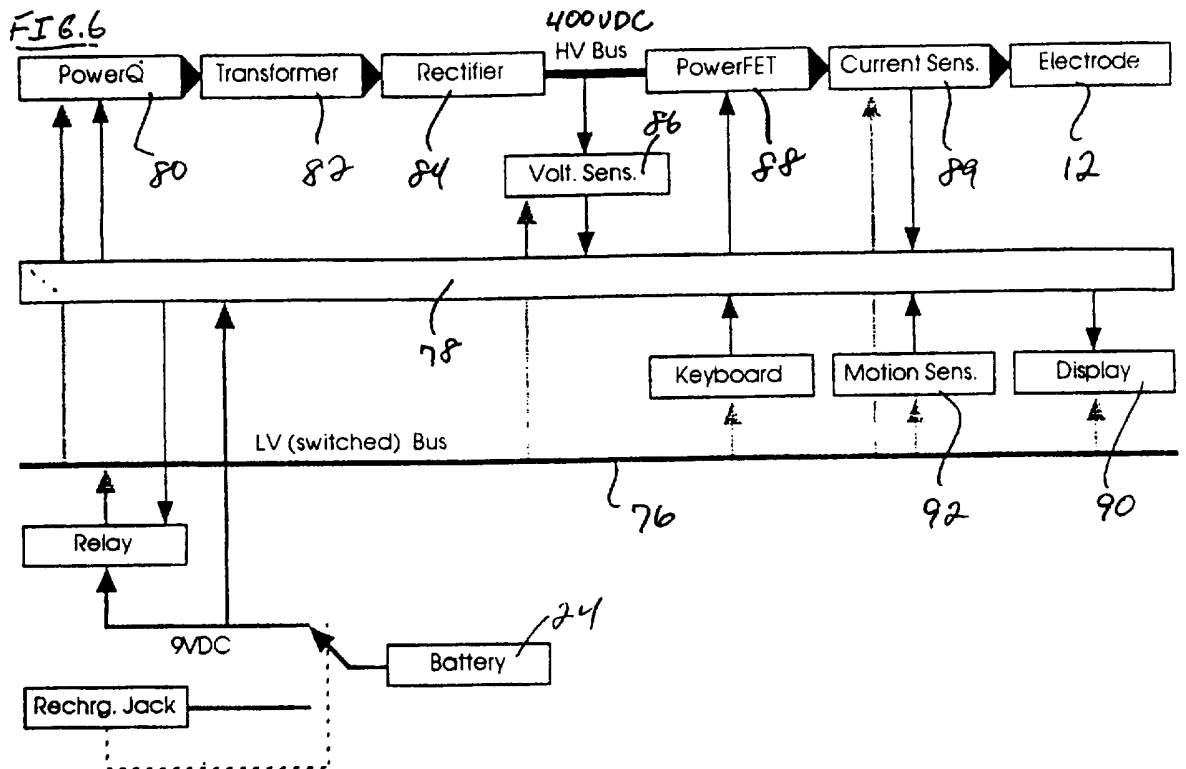


FIG. 2



**FIG. 7**