

- [54] **EXTERNAL INDUCTIVE NEURAL STIMULATOR SYSTEM**
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- [51] Int. Cl. **A61n 1/42**
- [58] Field of Search **128/1-5, 2.1 R, 128/419 E, 419 R, 421, 423, 424, 404**
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ABSTRACT

A system for external stimulation of a nerve includes a coil of wire with a flux-concentrating core in the lumen of the coil. The core preferably has a T-shape, with the base of the T extending through the lumen of the coil providing the area of stimulation. The coil is pulsed by a discharging capacitor and circuitry is disclosed for charging the capacitor and generating discharge pulses of alternate polarity.

6 Claims, 6 Drawing Figures

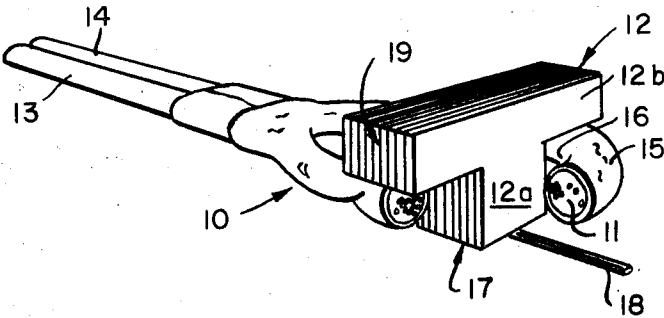


Fig. 1

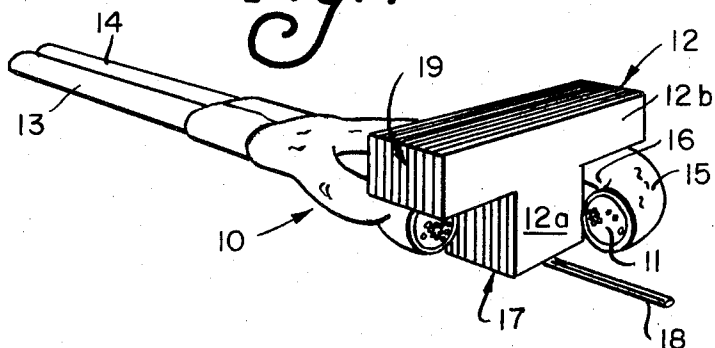
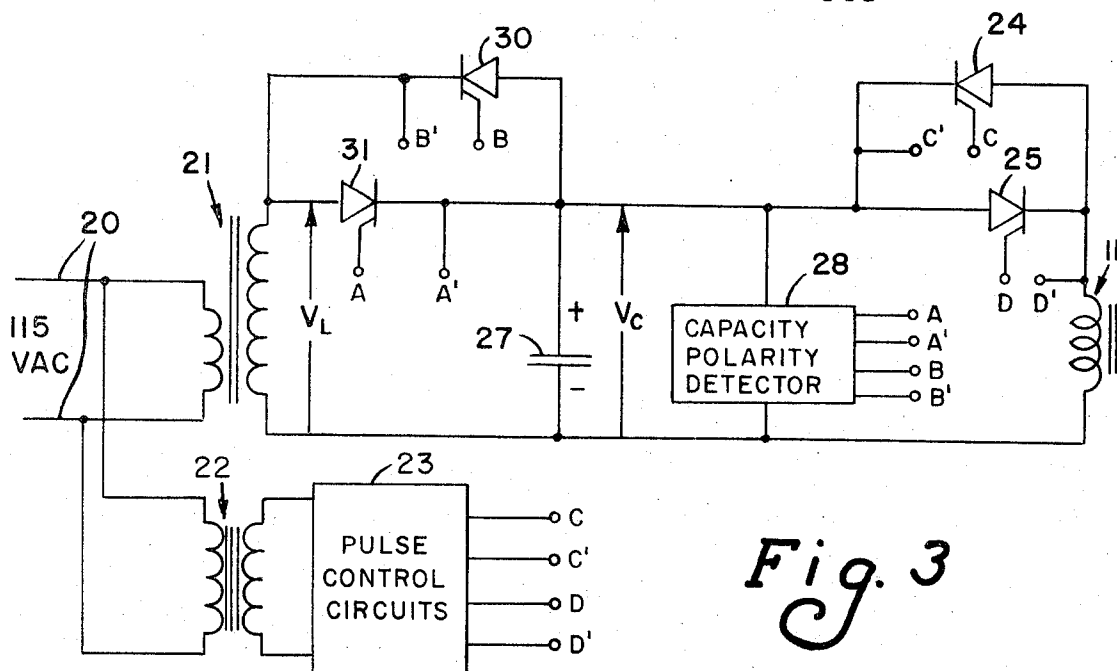
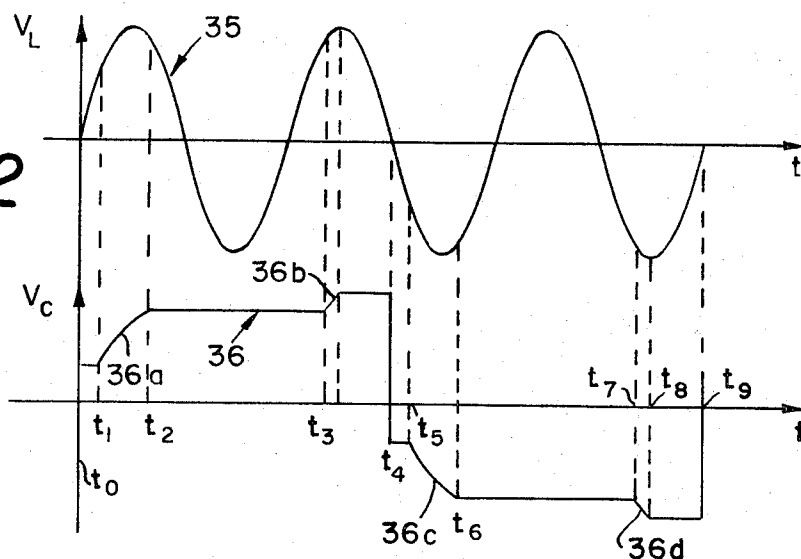
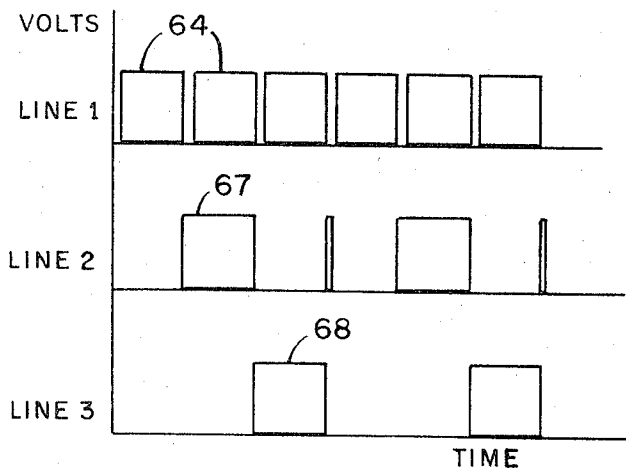
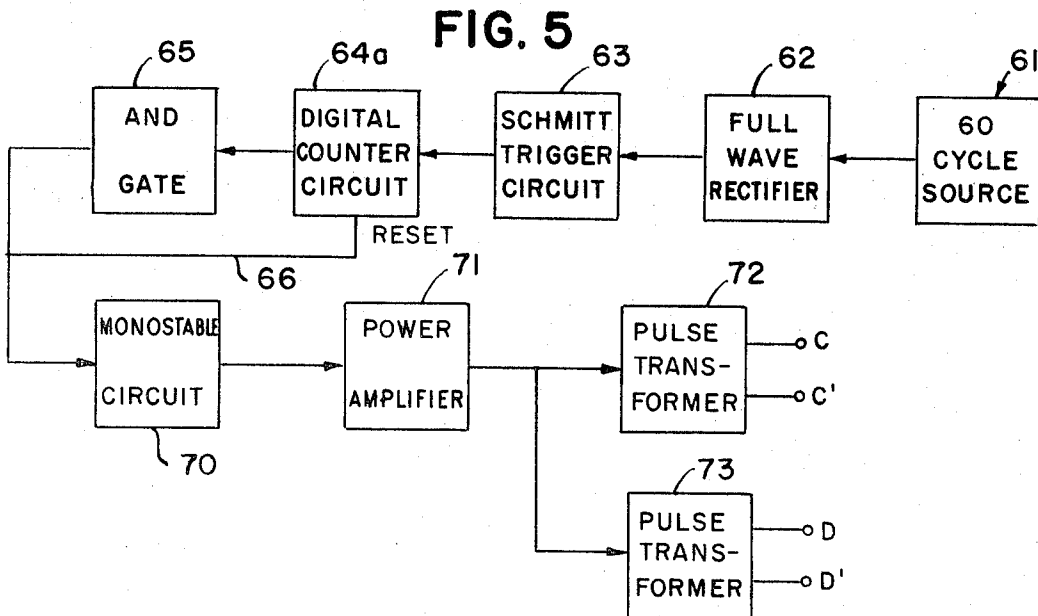
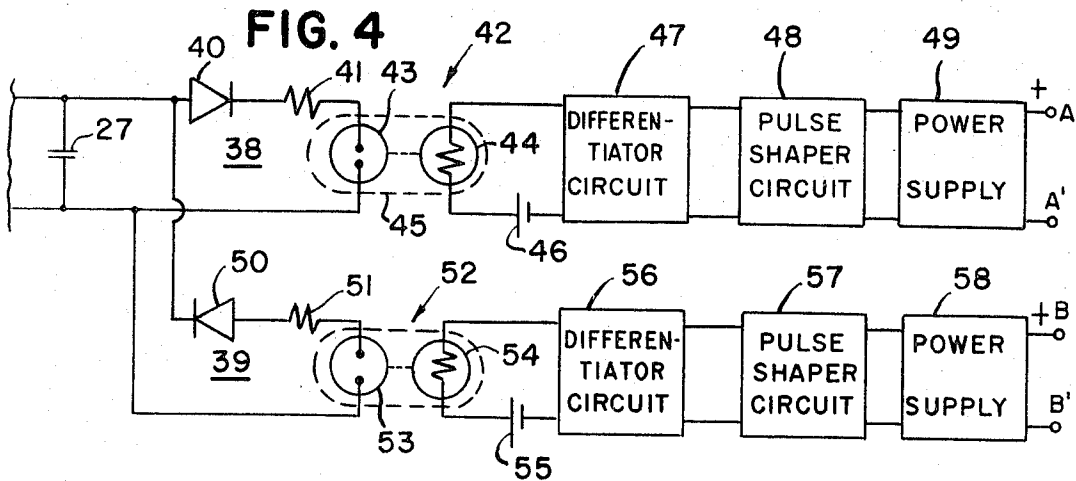


Fig. 2





EXTERNAL INDUCTIVE NEURAL STIMULATOR SYSTEM

BACKGROUND AND SUMMARY

The present invention relates to a system for stimulating nerves. In the eighteenth century, Galvani demonstrated that he could make a frog's leg twitch by exposing the nerve and contacting it with two electrodes charged at different potentials, thereby causing a current to flow in the nerve. Since that time, the stimulation of nerves electrically has become a useful therapeutic and diagnostic tool in medicine. However, most of the stimulation has been effected by the technique first demonstrated by Galvani — using metal electrodes to physically contact the nerve, either by exposing the nerve or piercing the skin with needle electrodes.

The presence of a metallic electrode presents a number of serious problems to a living system. Over a period of time, the electrode deteriorates, and the resulting metallic salt may poison the system. Trauma is caused both by the surgical procedure required to expose the site of stimulation and the introduction of the stimulating electrodes. Improper attachment of electrodes can cause constriction and atrophy of a neural trunk.

Further, if the nerve is to be exposed, there is need for a surgeon to expose the nerve. Even if needle electrodes are inserted, so as to avoid the danger of infection, chemical action occurs at the interface between the body fluids and the exposed metallic surface of the electrodes. Other undesirable effects produced by the use of metallic electrodes contacting the nerves or other body tissue include an uncomfortable sensation of electric shock and pain during application. Plate electrodes must be properly attached to the tissue in order to provide good electrical continuity if areas of high current density and resulting skin burns are to be avoided.

Work has also been conducted on an inductive transducer for stimulating nerves, as reported by Maass and Asa in a paper entitled "Contactless Nerve Stimulation and Signal Detection by Inductive Transducer," *IEEE Transactions on Magnetics*, Vol. Mag-6, No. 2, June, 1970, p. 322.

The present invention provides a coil of wire which is excited by a discharging capacitor. In the lumen of the coil there is a laminated core, preferably formed from plates having a T-shape. The base of the T is placed through the center of the coil, and the bottom of the base of the T is placed in proximity to the nerve desired to be stimulated.

The present invention uses inductive stimulation of a nerve wherein the stimulating voltage is applied to the nervous structure by means of an induced electric field. This completely eliminates any metallic contact between the nervous structure and the stimulating device and it is, therefore, advantageous in use as compared with a metallic electrode system. The induced electric field may be generated by discharging a capacitor through the coil that surrounds the base of the T-plate laminated core.

I have developed a circuit which discharges a capacitor through the stimulation coil. This circuit has been found to operate well to discharge capacitors of relatively high value and it is thus highly advantageous in the practice of the invention.

Other features and advantages of the present invention will be apparent to persons skilled in the art from the following detailed description of a preferred embodiment accompanied by the attached drawing.

THE DRAWING

FIG. 1 is a perspective view of a neural stimulating device constructed according to the present invention with a portion of the wire coil cut away;

FIG. 2 is an idealized graph illustrating the voltage waveform of the 60 cycle sinusoidal input voltage and the voltage across the discharge capacitor;

FIG. 3 is a circuit schematic diagram, partly in functional block form, of a preferred system for energizing the stimulator of FIG. 1;

FIG. 4 is a circuit schematic diagram partly in functional block form, of the capacity polarity detector of FIG. 3;

FIG. 5 is a circuit schematic diagram, partly in functional block form, of the pulse control circuit of FIG. 3; and

FIG. 6 is a timing diagram for explaining the operation of the circuitry of FIG. 5.

DETAILED DESCRIPTION

By way of general description, the neural stimulator of the present invention applies a stimulating current to a nerve structure by means of an induced electric field produced by a time-varying magnetic field. The device is external to the body, and need be placed only in proximity to the nerve that is to be stimulated. To obtain the magnetic field, a capacitor is discharged through a coil which is provided with a laminated core having a branch which extends through the lumen in the coil.

Neither exposure of the nerve to be stimulated nor contact between the stimulator and the nerve is required for proper operation.

The unit has been in operation and has provided consistent stimulation of neural pathways in both humans and dogs, with no apparent ill effects. Stimulation of a human test subject has resulted in excitation of phrenic, ulnar and femoral nerve trunks and numerous nerves in face, neck shoulders, arms and hands. Use of the instant device has resulted in no sensation of pain or electric shock to the subject even though no anesthesia is applied.

Referring now to FIG. 1, a neural stimulating device or stimulator is generally designated by reference numeral 10, and it includes a coil 11 (one quarter of which is broken away for clarity) and a laminated magnetic core 12.

The coil 11 is formed into a generally toroidal shape from a continuous piece of wire. In one embodiment, the coil 11 included twenty turns of No. 16 enameled copper wire, and it had a self-inductance of 16.4 microhenrys. The coil had an internal diameter of 2.00 cm. and an outside diameter of 4.00 cm. The ends of the coil 11 are connected to first and second insulated lead wires 13 and 14 which conduct the stimulating current pulse to the coil 11; and the coil may be coated with an epoxy coating 15 for insulation purposes.

The magnetic core 12 preferably takes the form of a plurality of T-shaped plates, each plate including a base 12a, and an upper cross bar 12b. The width of the base 12a may be approximately twice the width of the cross bar 12b because magnetic flux paths are generated

from both lateral ends of the cross bar 12b, and the flux returns through the base 12a. With the addition of the magnetic core 12, wherein each plate was similarly dimensioned to have an overall length of the cross bar of approximately 2 inches and a height of approximately 1 inch, the self-inductance of the stimulator coil increased to 24.5 microhenrys. It will be observed that the bases 12a of each of the lamination plates, when they are stacked, is placed into the lumen 16 of the coil 11. The function of the metallic core 12 is to concentrate the magnetic flux. For stimulation the coil and the laminated core are placed such that the nerve 18 is located in a plane perpendicular to the axis of the base 12a of the core, such as is diagrammatically illustrated by the nerve.

The magnetic flux generated by current flowing in the coil 11 emanates from the bottom 17 of the base 12a of the T-plate laminations, and it spreads out in planes which extend radially of the axis of coil 11. The flux then re-enters the core at the outer ends of the cross bar 12, which ends are collectively designated by reference numeral 19. The excitation current, as will be discussed in greater detail presently, generates pulses which alternately change polarity; and these pulses occur in a periodic manner. Hence, the resulting magnetic flux changes in direction periodically.

Turning now to FIG. 3, reference numeral 20 denotes two inputs to which a conventional 60-cycle 110 volt alternating current source is connected. The input terminals 20 are connected to the primary winding of a transformer 21 and to the primary winding of a step-down transformer 22. The secondary winding of the transformer 22 is connected to the input of a pulse control circuit 23 which is responsive to the timing of the alternating input voltage to generate trigger pulses, as discussed in more detail in connection with FIGS. 5 and 6. One such pulse is transmitted to the terminals C, C' and the other is transmitted to the terminals D, D'.

The trigger pulses of the pulse control circuit 23 control the firing of two silicon control rectifiers (SCR) designated respectively by reference numerals 24 and 25 in the upper right-hand corner of FIG. 3. The anode of the SCR 24 and the cathode of SCR 25 are connected together and to one terminal of the coil 11. The cathode of SCR 24 is connected to the anode of SCR 25 and directly to one terminal of a storage capacitor 27. The other terminal of capacitor 27 is connected in common to the other terminal of the coil 11 and to one terminal of the secondary winding of transformer 21.

Connected across the capacitor 27 is a capacitor polarity detector functionally shown in the block designated 28 (and seen in more detail in FIG. 4) which senses the polarity of the charge stored on the capacitor 27, and depending upon the sensed polarity, generates an output signal on either the output lines A, A' (if the polarity is positive according to the convention marked) or on the lines B, B' if the polarity on the capacitor 27 is negative relative to the convention indicated.

The other terminal of the secondary winding of transformer 21 is connected directly to the cathode of a third silicon control rectifier 30 and to the anode of a fourth silicon control rectifier 31. The SCR 30 is triggered by a positive signal on the lines B, B' from the capacity polarity detector 28; and the SCR 31 is triggered by a positive signal generated on the lines A, A' of the polarity detector 28.

Turning now to FIG. 4, there is seen in more detail the circuitry of the capacity polarity detector 28. In this drawing, the discharge capacitor is again shown at 27. The capacity polarity detector is divided into two channels—one being generally designated by reference numeral 38, and the other being generally designated by reference numeral 39. These channels are similar, and their function is to generate output signals which are the logical inverses of each other.

The channel 38 includes a diode 40 having its anode connected to one terminal of discharge capacitor 27, a resistor 41 in series with the diode 40, and an optical isolator generally designated 42. The optical isolator 42 comprises a neon light 43 and a light-sensitive resistor 44 packaged together, as illustrated by the dashed line 45.

The resistor 44 decreases in value in accordance with an increase in the intensity of the light of the source 43 to provide very high electrical isolation. Other optical isolators such as a solid state device including a light-emitting diode and light-sensitive solid state detector may be used with like results. The resistor 44 is connected in series with a source of D.C. voltage 46, and the resulting signal is fed to a differentiator circuit 47, the output of which is fed to a pulse shaper circuit 48, which is a high gain conventional limiting amplifier. The output of the pulse shaper circuit 48 controls a power supply 49, the output terminals of which are designated A, A' which are the same as the correspondingly designated output lines and control lines in FIG. 3.

Similarly, the channel 39 includes an input diode 50 having its cathode connected to the anode of the diode 40, and in series with a resistor 51 and a second isolating optical element generally designated 52. The resistor 51 is in series with a neon light source 53 of the device 52; and the photo-sensitive resistance 54 is connected in series with a battery 55, the circuit feeding a differentiator circuit 56. The output of the differentiator circuit 56 feeds a pulse shaper circuit 57 which, in turn, controls a power supply circuit 58, the output of which supplies power to the lines B, B'.

Turning now to FIG. 5, there is shown a functional block diagram for the pulse control circuit 23. It includes a 60 Hz source generally designated by reference numeral 61 from which it derives both power and timing. The source 61 may include the previously described transformer 22. The 60 Hz source feeds a full wave rectifier circuit 62 which in turn feeds a Schmitt trigger circuit 63. The Schmitt trigger circuit 63 is of conventional design, and it is a low-threshold circuit for forming square wave pulses from the half sine wave output signals of the full wave rectifier 62, such as are seen on line 1 of FIG. 6 and designated 64. The pulses 64, however, are illustrated with somewhat exaggerated separation for clarity of illustration.

Returning to FIG. 5, the output of the Schmitt trigger 63 feeds a digital counter circuit 64 which may be conventional flip-flop circuits arranged to serially count the input pulses. In the present case, the digital counter circuit contains two flip-flops and is capable of counting up to four input pulses. The "1" outputs of the two flip-flop circuits in the digital counter circuit 64a are fed to the inputs of an AND gate 65, the output of which is fed back along a line 66 to reset the digital counter circuit. Hence, the combination of the digital counter circuit 64a, AND gate 65 and reset line 66 is

to provide a "count three" circuit since after the outputs of each of the flip-flops have gone to a "1," the digital counter circuit is reset. This is illustrated in lines 2 and 3 of FIG. 6 which are the outputs respectively of the two flip-flop circuits in the digital counter 64a, line 2 illustrating the output of the lowest order flip-flop and line 3 indicating the line of the higher order flip-flop. The flip-flops trigger on a negative-going pulse. Hence, the first flip-flop is set by the trailing edge of the first of the pulses 64, and the output of this first flip-flop is illustrated by the pulse 67. The first flip-flop is reset at the end of the second occurring pulse 64, and as the first flip-flop resets, the second flip-flop sets so as to produce pulse 68. At the end of the third pulse 64, the first flip-flop again sets, but the combination of a set output at both of the flip-flops causes the AND gate 65 to reset the counter 64a. The cycle is illustrated a second time for this same operation.

The output of the AND gate 65 also feeds a monostable circuit 70 having an output pulse lasting for a predetermined time interval. This output pulse energizes a power amplifier 71 which, in turn, energizes first and second pulse transformers 72 and 73. The outputs of the pulse transformers 72, 73 may be amplified, if desired. The resulting signals energize respectively the line pairs C, C' and D, D', as illustrated, which are connected, as seen in FIG. 3, to trigger the SCRs 24, 25. The SCRs 24, 25 are connected in opposing polarity between the capacitor 27 and coil 11 so that the charge on the capacitor will flow through the coil irrespective of its polarity.

OPERATION

Before describing the overall system operation, the operation of the capacity polarity detector 28 as seen in FIG. 4 will be described first. When the voltage on the discharge capacitor 27 goes positive, the diode 40 is forward biased. When the voltage across neon lamp 43 reaches a sufficient value, the lamp will conduct and emit light, thereby reducing the resistance of the photosensitive resistor 44. Current will then flow to the input of the differentiator circuit 47 from the battery 46. The differentiator circuit 47 causes the resulting signal to have a sharper rise time, and the pulse shaper circuit 48, causes the resulting signal to have faster rise and fall times to trigger the power supply 49. The lamp 43 does not conduct until the voltage across it reaches 70-80 volts; hence this threshold provides a delay between the time the input waveform crosses zero volts and the time that the capacitor 27 is charged. It is during this delay that the capacitor 27 is discharged. Similarly, the channel 39 produces power at the terminals B, B' when the voltage on the discharge capacitor reverses polarity.

Turning now to the pulse control circuit 23, as seen in FIG. 5, the full wave rectifier circuit 62 produces a half sine wave for each half cycle of the periodic input source 61. The Schmitt trigger circuit 63 forms these half sine waves, which are positive, into square waves such as those seen on line 1 of FIG. 6; and these are fed to the digital counter circuit 64a. This circuit, as already mentioned, in combination with the AND gate 65 results in a "count three" circuit which energizes the monostable circuit at the termination of every third pulse. It will be appreciated that the input sine wave from the 60 cycle source crosses zero at a time in between adjacent ones of the pulses 64. Hence, the result-

ing signal from the monostable circuit 70 occurs at the end of every third half cycle of the input periodic waveform and at a time when it is crossing zero voltage, or shortly thereafter. This has the effect of isolating the charging of the capacitor 27 from the discharging thereof into the stimulating coil 11 on a time basis, as explained above. The power amplifier 71 amplifies the output signal of the monostable circuit 70 to energize the pulse transformers 72, 73 for the short duration during which the monostable circuit 70 generates a pulse. The width of this pulse is narrow, as explained more fully below, so that the capacitor 27 is not discharged at the same time that it is being charged to avoid shorting of the charging source.

Turning now to FIG. 2, the continuous 60-cycle sinusoidal input voltage is designated by reference numeral 35; and it is shown on the same time scale as the voltage, V_c which is the voltage across the discharge capacitor 27. The capacitor 27 is a non-polarized capacitor, and the inductance 11 is a schematic showing of the inductance of the stimulating transducer 10. The function of the pulse control circuit 23 is to trigger the SCRs 24, 25 to thereby discharge the capacitor 27 at every third zero crossover of the periodic input voltage 35. Because this occurs at odd half cycles, the subsequent polarities for charging the capacitor 27 will alternate.

The SCRs 30, 31 are connected in circuit with the input transformer 21 in opposing polarity; and the function of these two switches is to selectively charge the capacitor 27 in response to the output signals of the polarity detector 28.

The following description of the operation of the circuit of FIG. 3 will assume a pulse rate of 45 pulses per second — that is, one pulse for every third half cycle of the sinusoidal waveform 35. Assuming that at time $t = t_0$, the polarity of the voltage on capacitor 27 is positive, the polarity detector 28 generates a voltage at the terminals A, A', as already discussed, to cause SCR 31 to conduct and thereby charge the capacitor 27 positively along the portion 36a of the capacitor voltage curve 36, as seen in FIG. 2. These voltage waveforms are idealized, as has already been mentioned. The conduction of the charging SCRs 30, 31 occurs at a time after the discharging SCRs 24, 25 have ceased conducting.

During the next positive half cycle of the voltage V_L , namely at the time t_3 of FIG. 2, the polarity detector 28 again causes the SCR 31 to conduct to charge the capacitor 27 along the portion 36b of the curve 36 to a higher positive potential. It will be observed that this occurs prior to the time of the termination of the third count of the "count three" circuitry in the pulse control circuit 23. Hence, at the next zero crossover of the 60-cycle voltage V_L , namely at time t_4 in FIG. 2, the pulse control circuit 23 generates an output pulse at the terminals C, C' and D, D' thereby causing SCR 25 to conduct and discharging capacitor 27 through the stimulator coil 11. During this conduction time, the input or charging SCRs 30, 31 are non-conducting; and the capacitor 27 is thereby isolated from the input voltage.

It will be observed that during discharge, the capacitor 27 forms a series RLC circuit including the inductance of coil 11. Hence, as seen in FIG. 2, the voltage across the discharge capacitor will actually go negative due to the energy stored in the inductance as the capac-

itor discharges. The time duration of the pulse which causes SCRs 24, 25 to conduct is shorter than the time required for the voltage on the discharge capacitor to reach the maximum value at the reverse polarity. Discharge of capacitor 27 ceases when SCR 25 becomes reverse-biased due to the inductor-capacitor elements in the circuit which cause a ringing effect in the current. This results in leaving a charge on the capacitor of a polarity inverse to that which it carried prior to discharge; and this residual charge then is sensed by the capacitor polarity detector and enhanced. That is, during the next negative half cycle of the input line voltage, the capacitor 27 is charged still further negatively according to the portion 36c of the curve 36 of FIG. 2. This, of course, is caused by the circuitry in channel 39 of the capacity polarity detector 28, as seen in FIG. 4, and the resulting output voltage at the terminals B, B' which causes the switch 30 (FIG. 3) to conduct, thereby connecting the capacitor 27 in series with the secondary of the input transformer 21.

During the next negative half cycle of the line voltage, the capacitor 27 is charged still further negatively according to the portion 36d of the waveform 36; and at a subsequent zero crossover (namely, time t_9), the pulse control circuit 23 generates a pulse along the output lines C, C' and D, D' to discharge the negatively-charged capacitor 27 through SCR 24 and the stimulator coil 11.

The sequence of operation continues in the manner described, wherein the capacitor 27 is charged and discharged at mutually exclusive times and in alternate polarity at the rate of 45 cycles per second. This design overcomes a principal problem in charging and discharging a large capacitor (the capacitor 27 may be of the order of 500 microfarads) and charged to 150 volts at rates as high as 45 times per second. The present invention has been able to charge and discharge a capacitor to values as high as 300 volts, and with straightforward changes in the count logic, it will be appreciated that the repetition rate for pulsing the stimulation coil 11 may be changed without changing the frequency of the primary 60-cycle source. Alternatively, although the system may become somewhat more complicated, a variable frequency input source could be used in place of the 60-cycle source as disclosed.

With the described system, successful tetanic stimulation of the ulnar, femoral and phrenic nerve trunks and numerous small fibers and trunks in the face, neck, hands, shoulders, etc., has been accomplished on humans without any accompanying sensation of pain or shock and with no apparent harmful physical effects.

Having thus described in detail a preferred embodiment of the present invention, persons skilled in the art will be able to modify certain of the structure which has been described and to substitute equivalent elements for those disclosed while continuing to practice the principle of the invention; and it is, therefore, intended that all such modifications and substitutions be covered as they are embraced within the spirit and scope of the appended claims.

I claim:

1. A system for external tetanic stimulation of nerves comprising: a coil of conductive wire wound into a generally flat, circular shape providing a central lumen; magnetic core means extending through said lumen for concentrating the flux lines in the core extending through the lumen and providing an application surface

for contacting an external body surface to apply electromagnetic energy, said application surface extending transverse of said core means to transversely cut the flux lines concentrated therein; and circuit means including a source of electrical energy, a discharge capacitor, first control switch means for selectively coupling said capacitor to said coil, timing circuit means for periodically triggering said first switch means to discharge said capacitor means through said coil, and detector means responsive to the charge on said capacitor and including second control switch means for charging said capacitor at a time when said first switch means is not discharging the same and for electrically isolating said capacitor from said source means when said first switch means is discharging said capacitor.

2. The system of claim 1 wherein said core means comprises a plurality of T-shaped laminations stacked together and providing a base and a cross bar, the bases of said T-plates extending through the lumen of said coil, the collective bottoms of said legs of said T-plates providing said application surface extending perpendicular to the axis of the base of said T-plates.

3. In a system for the electromagnetic stimulation of nerves, the combination comprising a conductive coil of wire providing a central lumen; core means extending through said lumen for concentrating the magnetic flux generated by said coil; a discharge capacitor; first switch means for selectively connecting said capacitor to said coil; a source of periodically alternating voltage; second switch means for selectively connecting said source to charge said capacitor; polarity detector circuit means responsive to the polarity of voltage on said capacitor for selectively energizing said second switch means to charge said capacitor to a peak voltage having the same polarity as the existing voltage on said capacitor; and pulse control circuit means for selectively energizing said first switch means to discharge said capacitor through said coil to generate a stimulating pulse in mutually exclusive time relation with said polarity detector means, whereby said capacitor is isolated from said source when said capacitor is discharged.

4. The system of claim 3 wherein said first switch means includes first and second control switch means connected between said capacitor and said coil for coupling respectively current of forward and reverse polarity to said coil; and wherein said pulse control circuit means includes logic counter circuit means responsive to said source voltage for generating a control signal every predetermined number of half cycles thereof; monostable circuit means responsive to said control signal for generating an output pulse when said capacitor is isolated from its associated charging voltage; and means for coupling said output pulse of said monostable circuit to said first and second control switch means to cause the same to conduct, said control signal of said logic circuit means occurring approximately at a time when said alternating voltage is experiencing a zero crossover and the discharge current through said coil ringing only in one polarity, thereby leaving a residual voltage on said capacitor of polarity opposite to the original voltage for sensing by said polarity detector circuit means.

5. The system of claim 3 wherein said second switch means includes third and fourth control switches; and wherein said polarity detector circuit means comprises first and second channel circuit means for generating a charge control signal respectively during alternate

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half cycles of said source voltage; and means for coupling the output signals of each of said channel circuit means respectively to said third and fourth control switch means, said third and fourth control switch means being connected in circuit between said source and said capacitor for coupling respectively current of forward and reverse polarity to said capacitor.

6. The system of claim 5 wherein each of said channels of said polarity detector circuit means includes means for generating a unipolar signal, optical isolation

means responsive to said unipolar signal for generating a second electrical signal proportional thereto; and circuit means including threshold circuit means coupled to said capacitor for generating an output signal as long as the voltage on said capacitor is above a predetermined value, said output signal occurring exclusive of times immediately adjacent zero crossover voltages thereof.

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