

July 20, 1965

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3,195,540

POWER SUPPLY FOR BODY IMPLANTED INSTRUMENTS

Filed March 29, 1963

2 Sheets-Sheet 1

Fig. 1

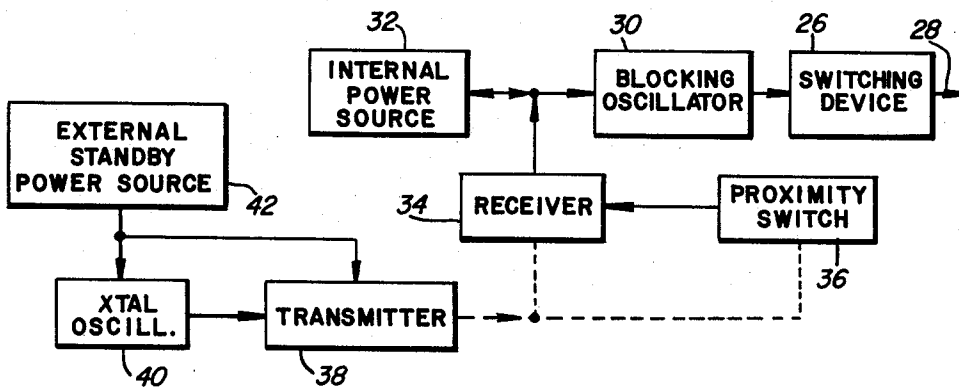


Fig. 2

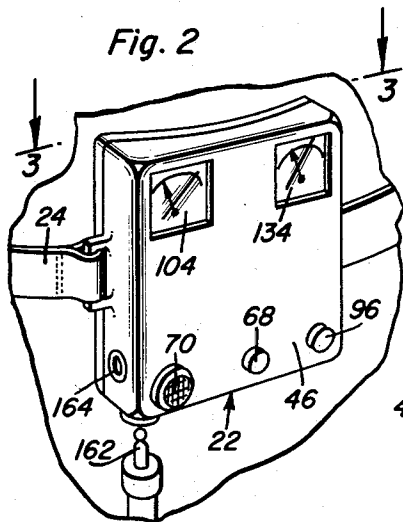


Fig. 3

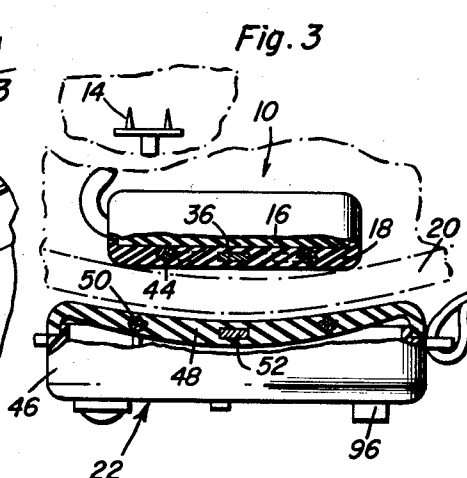
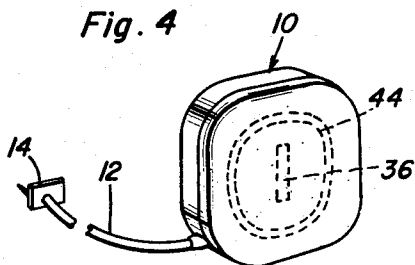


Fig. 4



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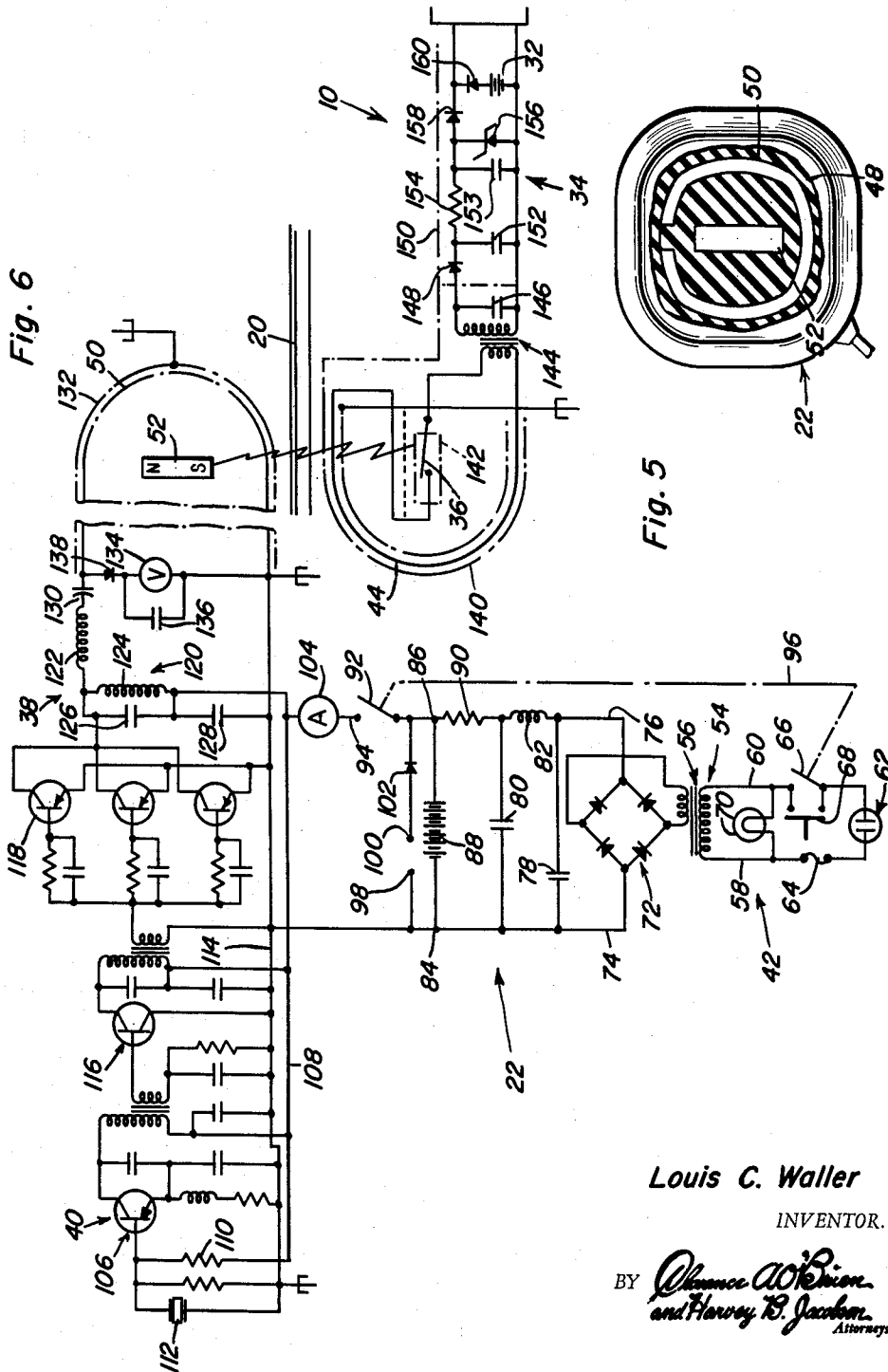
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2 Sheets-Sheet 2



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1

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POWER SUPPLY FOR BODY IMPLANTED INSTRUMENTS

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10 Claims. (Cl. 128-422)

This invention relates to the supply of power to an instrument or device implanted in a human body and more particularly to an emergency standby power supply for a body implanted device such as a cardiac pacemaker having its own internal power source through which continuous normal operation is maintained.

Recent developments in medical science have seen the introduction of electronic devices into the human body by surgery for the purpose of performing or assisting in the performance of physiological functions previously performed by human organs. Devices of this type have become more prevalent for the purpose of controlling the pulse rate or beat rhythm associated with the normal and proper functioning of the human heart where the nervous system which otherwise controls the pulse rate has become defective to this extent. Artificial electronic pacemakers have accordingly been implanted in the human body just below the skin tissue usually employing a one transistor blocking oscillator and switching transistor powered by a long life mercury cell battery in order to produce guided energy in the form of electrical pulse signals and electrically conducted to the pulse controlled muscles of the heart by electrodes to restore satisfactory heart rhythm.

Body implanted devices of the aforementioned type are usually implanted just underneath the skin in the left abdominal wall between one-half to one inch in depth so as to facilitate its removal and exchange in the event of battery failure or other malfunctioning. The estimated life of the battery cells utilized is about five years so that when the battery cells fail, the patient's heartbeat reverts to the condition before implantation of the pacemaker device. Under these circumstances, a minor medical emergency is created and requires the services of thoracic and cardio-vascular surgeons usually available at the larger metropolitan centers for the purpose of removal and replacement of the electronic cardiac pacemaker device. It will therefore be appreciated, that since battery failure cannot be accurately predicted, a person having a body implanted device may be at an inaccessible location when the aforementioned emergency arises. Any regular attending physician that may be available, would have very little knowledge of electronics and would properly hesitate to do anything with regard to changing of the body implanted device. The patient may therefore be subjected to a great amount of discomfort and danger before transportation is available to a medical center having the facilities for removal and replacement of the body implanted device. Externally powered cardiac pacemakers have also been proposed for short term use and have proved to be both unreliable and dangerous because of undercoupling or overcoupling unavoidably occurring because of variations in the inductive coupling relationship through the dielectric barrier of body tissue between the external unit and the implanted receiver.

It is therefore a primary object of the present invention to provide means for immediately alleviating discomfort caused by battery failure or other unexpected malfunctioning of a continuously operative body implanted device such as a cardiac pacemaker of the internally powered type by providing an external standby source of power through which the body implanted device may be restored to proper and continuous operation through radiated energy transfer through a layer of body tissue. As a re-

2

sult thereof, the danger to the patient may be eliminated and the responsibility of an attending physician lessened.

As a further object of the present invention in accordance with the foregoing object, the present invention provides a method of supplying power to an implanted pacemaker or other power requiring instrument implanted in a human body in a safe and reliable manner with a minimum amount of hazard both to the patient and the operator.

In accordance with the foregoing objects, the present invention may be applicable to presently available cardiac pacemakers having internal power sources such as mercury cells, the pacemaker device being modified in accordance with the principles of the present invention for cooperation with an externally applied standby power supply device through which operation of the internal body implanted pacemaker device may be monitored and externally powered for a prolonged period of time until the defect is permanently corrected or for conserving power of the internal source.

An additional object in accordance with the foregoing object, is to provide an emergency standby power supply capable of replacing the internal power source associated with a body implanted device of the cardiac pacemaker type appropriately modified for such purpose without any danger that normal operation of the body implanted device may be adversely affected because of extraneous energy fields. Accordingly, an important feature of the present invention is the provision of a proximity switch arrangement operative to provide a command signal whereby transfer of energy to the implanted device will be restricted to the energy radiated from a properly applied and readily available emergency standby power supply mounted externally on the patient.

These together with other objects and advantages which will become subsequently apparent reside in the details of construction and operation as more fully hereinafter described and claimed, reference being had to the accompanying drawings forming a part hereof, wherein like numerals refer to like parts throughout, and in which:

FIGURE 1 is a flow diagram illustrating the system involved in the present invention.

FIGURE 2 is a perspective view of the standby power supply device forming an important part of the present invention.

FIGURE 3 is a partial sectional view with parts broken away and shown in section taken substantially through a plane indicated by section line 3-3 of FIGURE 2 showing the components of the present invention operatively positioned relative to each other.

FIGURE 4 is a perspective view of the body implanted component of the invention consisting of the cardiac pacemaker instrument modified in accordance with the present invention.

FIGURE 5 is a bottom plan view of the standby power supply component shown in FIGURE 2 with parts broken away and shown in section.

FIGURE 6 is an electrical circuit diagram associated with the system and apparatus of the present invention.

Referring now to the drawings in detail, it will be observed from FIGURES 2, 3, 4 and 5, that the apparatus of the present invention involves the body implanted device generally referred to by reference numeral 10 which in the illustrated example, is a cardiac pacemaker having its own internal power source through which electrical signals may be dispatched through the electrical conductor 12 to a pair of electrodes 14 attached to the appropriate muscles through which the heartbeat rhythm is regulated or paced. The body of the device 10 is therefore embedded in an epoxy resin 16 having an outer coating of silicon rubber 13 so as to render it compatible

with the environment of the human body within which it is implanted. Accordingly, the body of the device 10 is implanted just below the skin tissue 20 constituting the dielectric barrier through which energy is radiated as more clearly seen in FIGURE 3. When the internal power source associated with the device 10 fails, power may be transferred to the device for restoring operation thereof by means of the external, standby power supply component generally referred to by reference numeral 22. Accordingly, the component 22 may be positioned substantially in contact with the skin of the patient and held in such position in any suitable manner as for example by means of the belt 24 attached thereto and suitably encircling the patient's body.

Referring now to FIGURE 1, it will be observed that the operational system to which the present invention relates, includes a switching device 26 from which an electrical output 28 is derived at the pulse rate designed to pace proper operation of the heart muscles as aforementioned. The switching device is operated by means of a blocking oscillator component 30 and power for operation thereof is furnished by an internal power source 32 usually consisting of mercury cells as aforementioned. The components 26, 30 and 32 form part of the usual pacemaker device. However, when the internal power source 32 fails, power for continued operation of the body implanted device may be obtained through the receiver component associated with the body implanted device and generally referred to by reference numeral 34. Also operatively associated with the receiver component 34, is a receiver disabling proximity switch 36 whereby the receiver component is rendered operative to receive the energy transferred thereto only from a predetermined location external to the body. Thus, the system of the present invention also includes a transmitter component 38 by means of which energy is transferred to the receiver component when operatively positioned relative thereto, this operative positioning being sensed by the proximity switch 36. Also operatively associated with the transmitter component 38, is a crystal oscillator component 40 by means of which energy at the proper frequency may be controllably radiated by the transmitter component. Power for operation of the oscillator and transmitter components is furnished by an external standby power source 42 which is both portable and rechargeable as well as connectible to alternative power sources that may be available.

The receiver and proximity switch components associated with the body implanted device are embedded within the epoxy resin 16 in a properly shielded condition as hereafter explained. The receiver component will therefore be provided with an antenna or receptor loop 44 that is partially shielded but exposed so as to receive energy radiated thereto by means of the external standby power supply component 22. Also mounted within the receptor loop formation 44, is the proximity switch component 36 which consists of a magnetically actuated switch device embedded within a non-ferrous shield. The power supply component 22 also involves an outer casing made of shielding material 46 while a skin-contacting face thereof is made of a flexible plastic 48 within which a coupling antenna loop 50 is embedded. The coupling loop 50 is also partially shielded and exposed for the purpose of radiating energy to the receptor loop 44 when the component 22 is properly positioned relative thereto as illustrated in FIGURE 3. Also embedded within the plastic face 48, is a permanent magnet 52 arranged to create a magnetic field to which the proximity switch 36 responds when the component 22 is properly positioned relative to the implanted device 10. Accordingly, when the component 22 is rendered operative to radiate energy, only upon proper positioning thereof a command signal will be dispatched to the proximity switch so as to render the receiver component 34 operative to transfer energy to the operating components of the pacemaker device under optimum energy coupling conditions.

Referring now to FIGURE 6, it will be observed that the external standby power source component 42 includes an electrical converter section 54 having a voltage step-down transformer 56, the primary winding of which may be electrically connected by the powerlines 58 and 60 to the usually available source of 110 volts A.C. current 62. Connected in the powerline 58 is a safety fuse element 64 while the powerline 60 may be interrupted by either an "on-off" switch element 66 or a by-pass charging switch 68 connected in parallel with the switch element 66. Also connected across the powerlines, is an indicator lamp 70 whereby the availability of voltage from the 110 volt A.C. source will be indicated. The secondary winding of the transformer 56 is connected across the input terminals of a full wave bridge rectifier 72 so that a pulsating D.C. voltage will appear across the lines 74 and 76 connected to the output terminals of the rectifier when the A.C. source 62 is available. Also associated with the converter section 54, is a filter network including the capacitors 78 and 80 connected across the lines 74 and 76 with the inductor 82 connected in the line 76 whereby the pulsating D.C. output of the rectifier is smoothed out providing a 12 volt D.C. output at the terminals 84 and 86 of a nickel-cadmium type of rechargeable battery 88. A current limiting resistor 90 is also provided in the line 76 so as to regulate charging of the battery 88 by the converter section 54 when the A.C. source 62 is available. It will therefore be apparent, that when the switch element 92 is closed, a D.C. output voltage of proper value will be established across the lines 94 and 74 for supply to the oscillator and transmitter components 38 and 40. The D.C. voltage will be derived from the converter section 54 when the A.C. source 62 is available which will at the same time charge the battery 88 so as to maintain a full charge thereon. Accordingly, the switch elements 66 and 92 are ganged by a manually operated switch actuator 96 in order to simultaneously render the converter section 54 operative and close the power circuit to the oscillator and transmitter components so that power may either be derived from the A.C. source 62 if available or alternatively from the rechargeable battery source 88, when the A.C. source 62 is not available. If it is desired to recharge the rechargeable battery 88 after prolonged use without any A.C. source available, the switch 68 may be closed rather than the gang switch elements 66 and 92 so that the converter section 54 may be rendered operative without closing the power circuit in order to only recharge the battery 88. Under emergency situations, an auxiliary battery source may be connected into the power source component 42. Accordingly, negative and positive terminals 98 and 100 are respectively connected to the powerlines 74 and 76 with a polarity protecting diode 102 in series therewith. Any battery source such as dry cells may therefore be connected to the terminals 98 and 100 as a replacement for the rechargeable battery 88. It will also be observed, that a milliammeter 104 is connected in the output powerline 94 so that the current being drawn by the oscillator and transmitter components may be monitored.

The oscillator component 40 is a two-stage, crystal controlled type of device, in which the first stage includes the transistor 106, the base of which is biased by the positive voltage line 108 connected to the output line 94 of the power circuit through the bias resistor 110. The base is also connected to the crystal element 112 to which the negative grounded line 114 is connected. Also connected to the line 114 through an R-L-C network is the emitter of the transistor 106 arranged thereby to produce oscillations in the output collector circuit connected across the lines 108 and 114. The output collector circuit is inductively coupled to the base of the second stage transistor 116 with the output from the collector thereof being inductively coupled to a three-stage transistorized transmitter component 38.

The transmitter component 38 includes three transistor stages each of which has a transistor 118, the base of

5

which is coupled to the output of the oscillator component through a parallel R-C network. Each of the emitters of the transistors 118 is connected to the common ground line 114 while the collectors thereof are connected to an output control network 120 including the inductors 122 and 124 with the inductor 124 being connected in parallel with the capacitor 126. Connected across the power-line 108 and the ground line 114 is a capacitor 128 in the output network 120 whereby the impedance of the transistor collectors may be matched with the coupling loop 50 having a low impedance and capacitively coupled to the output network 120 by means of the loading capacitor 130. The coupling loop from which energy is radiated at the proper frequency for transfer to the body implanted device 10, will be shielded by the shield 132. Also connected across the coupling loop 50, is an RF monitoring voltmeter 134 across which the capacitor 136 is connected and with which a meter diode 138 is connected in series. It will therefore be apparent, that the voltmeter 134 will not only reflect voltage oscillations when the coupling loop is radiating the energy supplied thereto, but will also measure varying impedance loading of the coupling loop 50 as produced by operation of the implanted device 10 only when a coupling loop 50 is operatively positioned with respect to the implanted device for transfer of energy. Accordingly, the voltmeter 134 will provide means for monitoring operation of the implanted device inasmuch as impedance loading variations thereof will be in accordance with the output pulse rate of the internal unit as will become apparent hereafter from the circuit arrangement of the receiver. It will also be observed, that the permanent magnet 52 is positioned within the loop 50 so that its proper position relative to the device 10 may be sensed by the proximity switch 36 associated therewith. The transmitter may be operated at a frequency of 27 megacycles with an output of 1 to 2½ watts in order to deliver power to the embedded device, the output being necessarily limited so as to meet all radiation requirements of the Federal Communications Commission.

The receptor loop 44 of the receiver component 34 will be shielded by a Faraday shield 140 while the proximity switch 36 is provided with a non-ferrous shield 142 as hereinbefore indicated. The receptor loop is rendered impervious to extraneous energy fields while the proximity switch 36 will respond to the presence of the permanent magnet of Alnico material when proper coupling exists. Accordingly, upon closing of the proximity switch 36 the receptor loop circuit is completed so that radiant energy emitted from the coupling loop 50 will be effective to produce a current flow at the proper frequency through the primary of the coupling transformer 144. Connected across the secondary of the transformer 144 is the capacitor 146 arranged to form therewith a resonant circuit for the energy transferred thereto rendering the receiver frequency selective. Thus, an A.C. carrier signal at the required frequency will be rectified by the diode 148 in a regulating circuit section also having a shield 150 thereabout so as to render it impervious to extraneous energy fields. Also connected across the output lines from the resonant circuit is an RF by-pass capacitor 152 arranged to remove radio frequency components in the signal rectified by diode 148 in order to pass the D.C. pulse components only. A current limiting resistor 154 is also connected in the output line while a safety capacitor 153 and voltage regulating Zener diode 156 are provided for the purpose of removing low frequency A.C. ripple currents and by automatically clamping the voltage at a predetermined level, avoid the development of too high a voltage which may adversely affect operation of the pacemaker device and create a hazard for the patient. It will therefore be apparent, that the regulating circuit through which power is transferred to the operating component of the pacemaker device will be both selective as to carrier frequency and limit the amplitude of the pulses sup-

6

plied to the load. Also, the receiver is connected by the power isolating diode 158 to the device 30 to unidirectionally load the receiver at the output pulse rate of the external power source. In this manner, externally generated energy will be prevented by diode 160 from charging the internal battery supply 32 while the unidirectional loading of diode 158 will prevent discharge of the internal cells forming the internal source 32 or loading thereof by the external power supply. Further, the varying load so imposed on the receiver will be reflected in the loading of the coupling loop 50 whereby it may be monitored by the voltmeter 134.

Standby power transferring operation will therefore be apparent from the foregoing description. The described components will therefore be effective to power a two-transistor type of pacemaker so as to produce an output similar to that produced by its own internal battery source 32. In practice, 10 volts D.C. at 5 to 7 milliamperes of pulse power output was produced by the pacemaker device with the actual power utilized at the external coupling loop 50 of slightly less than one watt. The entire external component 22 may therefore be miniaturized as illustrated and worn by a belt about the patient's body in proximity to the implanted pacemaker device without any danger of excess power injuring the patient because of movement thereof during operation as in the case of prior externally powered cardiac pacemakers. The internal receptor loop and receiver component may also be miniaturized and incorporated within the pacemaker envelope. The power supplied by the power input component 42 derived either through the converter section 54 or the rechargeable battery source 88 will therefore supply power to the oscillator component 40 in order to regulate the output of the transmitter component 38 causing radiation of energy from the coupling loop 50 at a fixed radio frequency carrier signal at the required frequency for operating the pacemaker device. The energy so radiated to the receptor loop 44 is inductively coupled through the transformer 144 to the resonant tank circuit 146 tuned to the carrier frequency so that the output thereof will be rectified by the diode 148 and filtered for passage of the D.C. pulses only with the radio frequency components removed by the by-pass capacitor 152. Inadvertent low frequency A.C. ripple currents will also be removed by the safety capacitor 153 to avoid detrimental operation of the pacemaker device while other A.C. fluctuations will be filtered out by the Zener diode 156 which is also operative to regulate the D.C. output voltage operating the components of the pacemaker device in by-passing relation to the internal source 32 in a reliable and safe manner when the internal source 32 is depleted or malfunctions. It will also be apparent, that the foregoing operation can only occur when the external component 22 is properly positioned relative to the receiver component of the pacemaker device, this operative positioning being sensed by the closure of the proximity switch 36 so as to render the receptor loop operative. Operation of the pacemaker device may then be monitored through the voltmeter 134 exposed on the face of the component casing 46 as shown in FIGURE 2 since the loading of device 30 will be imposed on the receiver when coupled to loop 50. Malfunctioning of the pacemaker device may thereby be detected after the gang switch operator 96 is actuated, this switch actuator also being exposed on the casing of the component 22 in order to simultaneously close the power circuit and render the converter section 54 operative as hereinbefore described. Connection may then be made through a jack connection 162 to an available A.C. power source. When so operative, the indicator lamp 70 also exposed on the casing 46 will be illuminated. Proper operation of the power components may then be monitored by the milliammeter 104 also exposed on the casing of the component 22. In the absence of the A.C. source as for example when the patient is being transported, the device

may continue to operate from the power supplied by the component 22 in view of the rechargeable battery 33 also associated therewith. Should any emergency arise where an additional battery supply is required, connection may be made to the terminals 98 and 100 through another jack connection 164. The rechargeable battery 33 may then be recharged for subsequent use from the usual A.C. source in which case the by-pass charging switch 63 will be depressed. The apparatus of the present invention will therefore represent the solution to an existing problem which now exists with implantable types of battery powered biomedical instruments by providing a standby source of energy for operation thereof. Also, the apparatus will respond to a command for transferring power only when two conditions are met consisting of a closure of the proximity switch when the coupling loops are in proper relative positions. Also, in view of the proximity switch and the aforementioned shieldings, extraneous energy fields will be prevented from causing any adverse operational effects.

Although the diode 160 is provided as shown in FIGURE 6, to prevent charging of the internal battery source 32, when mercury type of cells are utilized, it is contemplated as part of the present invention to replace this type internal battery source by a rechargeable type in which case the diode 160 is to be omitted. The external standby power supply may then be used to recharge the internal battery source in addition to effecting emergency operation of the body implanted instrument.

The foregoing is considered as illustrative only of the principles of the invention. Further, since numerous modifications and changes will readily occur to those skilled in the art, it is not desired to limit the invention to the exact construction and operation shown and described, and accordingly all suitable modifications and equivalents may be resorted to, falling within the scope of the invention as claimed.

What is claimed as new is as follows:

1. In combination with a continuously operative device adapted to be implanted within a human body constituting a dielectric barrier and having an internal power source for normal operation thereof, power receiving means operatively connected to said implanted device for supplying power thereto bypassing the internal power source when depleted or malfunctioning, external standby power supply means adapted to be mounted externally of the human body in spaced relation to the implanted device and the power receiving means for radiating energy to the power receiving means through said dielectric barrier to resume said continuous operation of the implanted device and the power receiving means after said normal operation of the internal power source thereof begins to falter, means operatively connected to the external power supply means for indicating variations in the loading thereof to monitor operation of the implanted device, proximity control means operatively mounted by said power receiving means for preventing any transfer of energy thereto except by the standby power supply means, and means mounted on the standby power supply means for operating the proximity control means when the standby power supply means is properly positioned relative to the power receiving means, said power receiving means comprising, receptor loop means adapted to be implanted within the human body adjacent to and below the outer tissue thereof for exposure to energy radiated by the standby power supply means, resonant circuit means, transformer means inductively coupling said resonant circuit means to said receptor loop means, and regulating circuit means operatively coupling said resonant circuit means to the implanted device in parallel relation to the internal source without loading or charging thereof.

2. The combination of claim 1, wherein said standby power supply means comprises, pulse transmitting means having a low impedance coupling loop adapted to be op-

eratively positioned in spaced adjacency to said receptor loop means of said power receiving means for radiating pulse energy thereto, converter means operatively connected to said transmitting means for producing a rectified D.C. source of potential from an externally available source of A.C. potential, rechargeable power supply means operatively connected to the converter means for charging when the A.C. source is available, and switch means operatively connected to the converter means for continuously supplying the D.C. potential to the transmitting means for operation thereof by energy derived either from the A.C. source when available or the rechargeable power supply means when the A.C. source is not available.

3. The combination of claim 2, wherein said transmitting means includes a crystal-controlled oscillator, a pulse amplifier, means inductively coupling the oscillator and said pulse amplifier, an impedance matching output network operatively connected to the amplifier and a loading capacitor coupling the output network to the coupling loop.

4. The combination of claim 3, wherein said monitoring means comprises, a voltmeter operatively connected across said low loading coupling loop to measure impedance variations produced by operation of the implanted device by the internal power source.

5. The combination of claim 4, wherein said means for operating the proximity control means includes a magnet carried by said coupling loop, said proximity control means including magnetically actuated switch means closed in response to positioning of a said magnet in close spaced adjacency thereto by the coupling loop of the standby power supply means, said magnetically actuated switch means being mounted within said receptor loop means to operatively align the receptor loop means with the coupling loop in order to transfer energy therebetween when the switch means is closed.

6. In combination with a body implanted device having an internal power source, a receiver adapted to pick up radiant energy generated from an external source comprising, a receptor loop adapted to be implanted within the body for exposure to said radiant energy, resonant circuit means for restricting passage of energy received to a predetermined carrier frequency having D.C. pulse components, means inductively coupling said receptor loop to the resonant circuit means, and regulating circuit means operatively coupling the resonant circuit means to the implanted device for limiting the amplitude of said D.C. pulse components supplied to the implanted device in parallel relation to the internal power source.

7. The combination of claim 6 including receiver disabling means operatively mounted by the receptor loop and adapted to detect operational positioning of said external source of radiant energy relative to the receptor loop, said receiver disabling means including a proximity switch connecting the receptor loop to the inductive coupling means.

8. The combination of claim 7 wherein said regulating circuit means includes, filter means connected to said resonant circuit means for passing only said D.C. pulse components, amplitude limiting means connected to the filter means in parallel with the internal power source for dissipating excess energy supplied to the body implanted device by the D.C. pulse components, and unidirectional loading means connecting the filter means to the body implanted device in series between the amplitude limiting means and the internal source, and means for measuring the loading of the external source to monitor the internal power source.

9. In a system for artificially pacing the rhythm of a living organ by supply of electrical pulses thereto at a regulated pulse rate from an internally powered device, the combination of a receiver, a transmitter, a dielectric barrier spacing said receiver and transmitter, proximity sensing means operatively mounted by said receiver on one

9

side of the dielectric barrier for preventing transfer of signal energy to the receiver through said dielectric barrier, means mounted by the transmitter for operating the proximity sensing means and the receiver when the transmitter occupies a predetermined location on the other side of the dielectric barrier relative to the receiver, said transmitter including means for generating signal energy at a fixed carrier frequency, power supply means connected to said transmitter for modulating the signal energy with a D.C. pulse voltage having a regulated pulse rate, said receiver including frequency selective means tuned to said fixed carrier frequency for detecting signal energy radiated only from said transmitter, filter means connected to said frequency selective means for passing only said D.C. pulse voltage modulating the signal energy, unidirectional loading means coupling the filter means to an internally powered device, and amplitude limiting means connected to the filter means for limiting supply of said D.C. pulse voltage to the device to a voltage level below a predetermined value.

10. The combination of claim 9 including meter means connected to the transmitter for measuring variations in

10

loading imposed thereon by the internally powered device through said unidirectional loading means when signal energy is being transferred to the receiver, whereby operation of the device may be monitored from said other side of the dielectric barrier.

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