United States Patent

Glover

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[54] **STIMULATOR APPARATUS FOR MUSCULAR ORGANS WITH EXTERNAL TRANSMITTER AND IMPLANTABLE RECEIVER**

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[51] **Int. Cl.** A61m 1/36

[58] **Field of Search** ....128/2.06 E, 2.06 R, 2.1 A, 128/2.1 B, 2.1 E, 2.1 P, 2.1 R, 419 P, 419 R, 421, 422, 423

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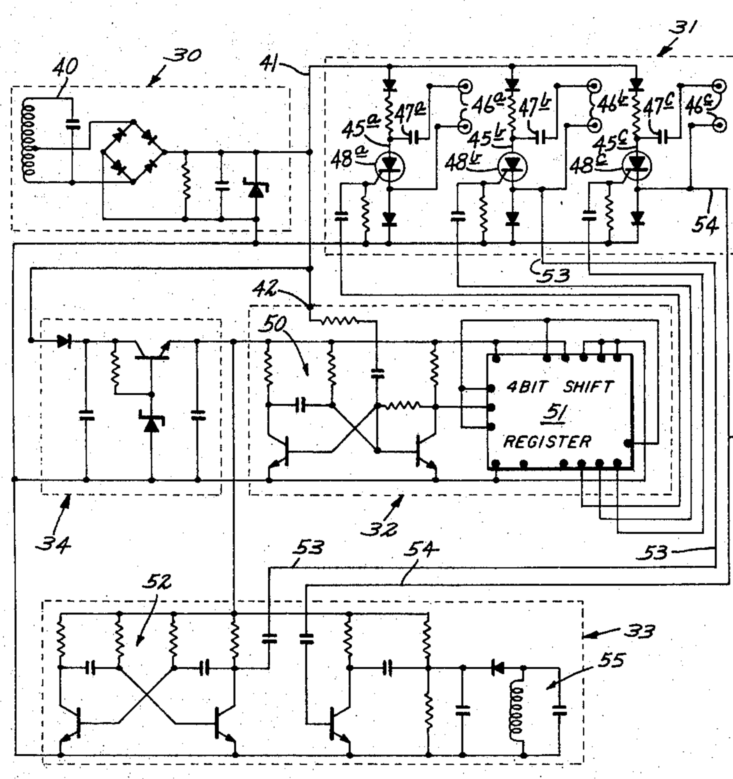
[57] **ABSTRACT**

A unit adapted to be implanted in a human body including a power supply for having power induced therein from a source external of the body, electrodes adapted to be attached to a muscular organ, such as a bladder or the like, capacitors and SCR's in circuit with said electrodes and said power supply for normally storing electrical energy and discharging said electrical energy through the electrodes upon conduction of the SCR's, triggering circuitry connected between the power supply and the SCR's for triggering the SCR's when the power induced in the power supply is temporarily interrupted and an FM transmitter connected to the power supply and between a pair of spaced apart electrodes so as to transmit a signal varying in frequency according to the resistance of the material between the electrodes; and an external control unit including means for inducing power into the internal power supply and controllable to periodically and temporarily remove power to control the energy supplied to the electrodes and an FM receiver with indicating means attached to provide an indication as to the operation of the muscular organ.

4 Claims, 2 Drawing Figures



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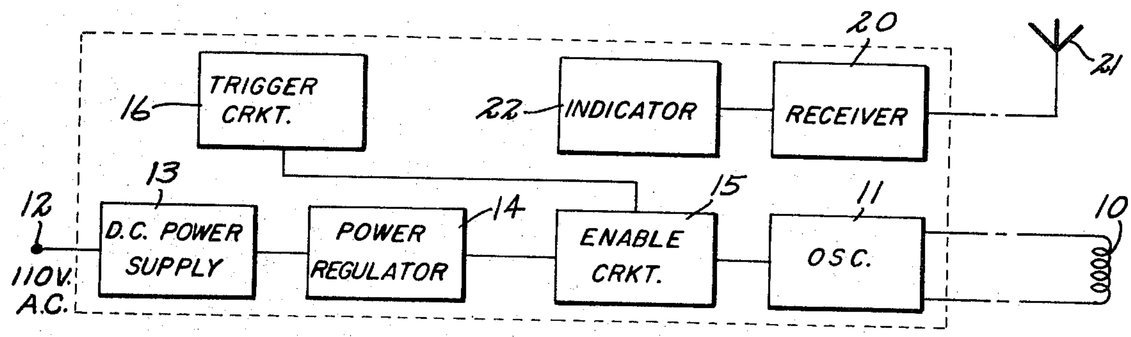

FIG. 1

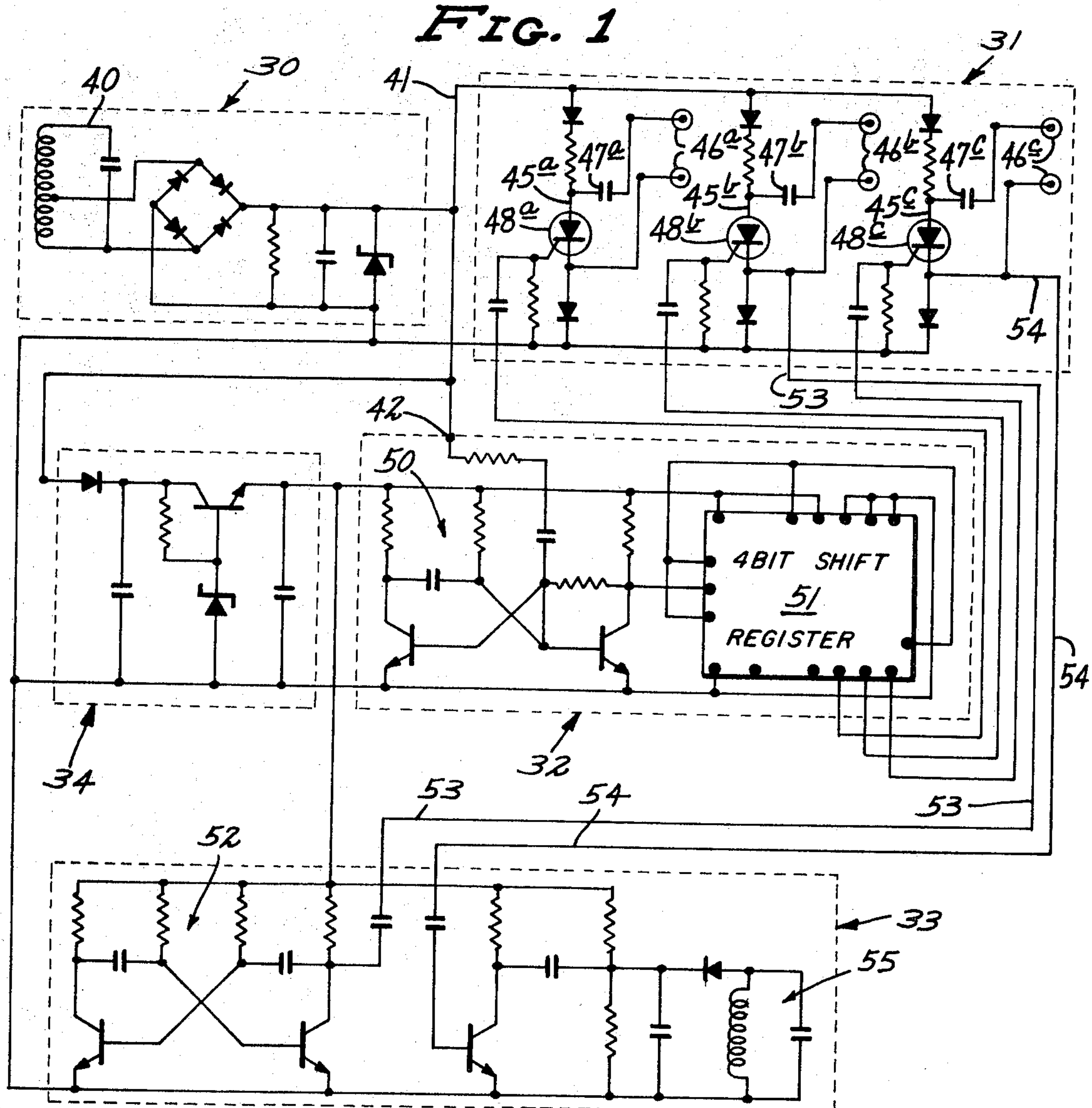

FIG. 2

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STIMULATOR APPARATUS FOR MUSCULAR ORGANS WITH EXTERNAL TRANSMITTER AND IMPLANTABLE RECEIVER

BACKGROUND OF THE INVENTION

1. Field of the Invention

In the body the operation of many muscular organs can become impaired, through injury to other portions of the body, without injury to the muscular organ itself. A typical example of this is the urinary bladder, in humans and other mammals, which is controlled by the brain through the spinal cord and a peripheral system of sympathetic and parasympathetic nerves and ganglia connected between the spinal cord and the bladder. A disturbance to any one of these nerve systems, the portions of the brain or spinal cord concerned with micturition or the peripheral system, will usually result in impairment of the micturition reflex, such that the patient is unable to empty his bladder properly, even though the muscle tissue of the bladder itself is healthy. This condition is referred to as the "neurogenic bladder," signifying that the bladder is incapacitated because of damage to the nervous system. When the operation of a muscular organ is impaired, through damage to other parts of the body, some other control for that organ must be incorporated into the system.

2. Description of the Prior Art

In the prior art many attempts have been made to solve this problem electronically. One such prior art device includes an implantable bladder stimulator with a battery power pack. Obviously this is undesirable since the patient would have to undergo surgery each time the batteries become low in electrical energy. In a similar prior art device a tuned tank circuit having a capacitor attached thereto with electrodes connected to the bladder so that the capacitor receives energy from the tank circuit to stimulate the electrodes, is implanted in the patient. This device is also undesirable since experience shows that three electrodes are necessary to produce adequate stimulation and emptying of the bladder. Each of these electrodes requires a pulse of 50 volts at 1 amp. for 1 millisecond. This represents a peak pulse power of 50 watts for each electrode, or a total of 150 watts peak power if all stimulus pulses are delivered simultaneously, as they must be in the case of the tank circuit and capacitor. In the prior invention no means of storing power is provided, so the power pulses delivered to the electrodes must be received at the tank circuit. The transmitter does not operate between stimulus pulses, but only at the time of the pulse for the duration of the pulse. Therefore the tank circuit receiver must receive 150 watts peak power. Since the coupling between the outside transmitter and the receiver located inside the body is very inefficient, the pulse power output of the transmitter must be in excess of 1 kilowatt.

SUMMARY OF THE INVENTION

The present invention pertains to stimulator apparatus for the external control of a muscular organ including an implantable unit having at least one electrode adapted to be affixed to the organ with controllable energizing means connected to the electrode for energization thereof and power means for receiving induced power and control signals from an external source connected to said energizing means for supplying electrical power thereto with control means connected to said power means for utilizing said control signals to control the energizing means; and an external unit having transmitting means for inducing power into the internal power means and modulating means connected to said transmitting means for supplying control signals thereto. Said external unit further including indicating means adapted to receive signals from said implantable unit for indicating the operation of the muscular organ.

It is an object of the present invention to provide new and improved stimulator apparatus for the external control of a muscular organ.

It is a further object of the present invention to provide stimulator apparatus including means for indicating the approximate operation of the muscular organ, such as the fullness of a bladder, etc.

These and other objects of this invention will become apparent to those skilled in the art upon consideration of the accompanying specification, claims and drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Referring to the drawings, wherein like characters indicate like parts throughout the figures:

FIG. 1 is a block diagram of the external unit; and

FIG. 2 is an electrical schematic diagram of the implantable unit.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to FIG. 1, an external or control unit is illustrated in block form. The control unit includes a remote transmitting or induction coil **10** adapted to be positioned adjacent to any desirable portion of a body, as will be described in detail presently. The remote transmitting coil **10** is connected to the output of a power oscillator circuit **11** by means of a cable having at least two conductors and a length sufficient to allow movement of the transmitting coil **10** to the desired area of a body. The power oscillator circuit **11** may be any desired oscillator capable of providing the required frequency and power output. In the present embodiment the output power of the power oscillator circuit **11** is variable over a range of 0 to approximately 50 watts at a frequency of approximately 350 kilocycles. It should be understood that any desired frequency and power output which will perform the desired functions can be utilized and the foregoing values are only for exemplary purposes. Further, the oscillator circuit **11** is not illustrated in schematic form since any oscillator circuit which can perform the desired functions may be utilized.

In the present embodiment the control unit is adapted to receive power from a 110-volt AC source, represented by terminal **12**. The 110 volts AC are supplied to an isolation transformer and rectifier **13**, which supplies the required quantity of DC power to the remainder of the circuitry. A power output regulator **14** is connected to the isolation transformer and rectifier **13** and regulates the amount of power supplied to the oscillator circuit **11** and, thus, the amount of output power from the oscillator circuit **11**. An oscillator enable circuit **15** is illustrated between the power output regulator **14** and the oscillator circuit **11**. The enable circuit **15** includes a monostable multivibrator or the like the operation of which is controlled by a trigger circuit **16**, which includes a free-running multivibrator or the like. The trigger circuit **16** provides periodic and/or sequential signals to the enable circuit **15**, which signals cause the enable circuit **15** to periodically and/or sequentially change states. When the enable circuit **15** is in the normal state the power oscillator circuit **11** is supplying power to the remote transmitting coil **10**. When the enable circuit **15** switches states, the power oscillator circuit **11** is turned off until the enable circuit **15** returns to its original state. No specific circuitry is illustrated for the enable circuit **15** and trigger circuit **16** since the exemplary circuits described are well known to those skilled in the art and any circuit which will perform the desired functions may be utilized.

In the present embodiment, the free-running multivibrator of the trigger circuit **16** is constructed so that it is unsymmetrical and one side remains conducting for 5 milliseconds while the other side is adjustable to provide a variable output repetition rate in the range of approximately 0 to 50 completed cycles per second. The monostable multivibrator of the enable circuit **15** receives signals or pulses from each side of the free-running multivibrator in the trigger circuit **16** and provides an output pulse approximately one-tenth to two-tenths milliseconds in duration each time a signal or pulse is applied thereto from the trigger circuit **16**. Thus, the enable circuit **15** supplies a first pulse to the power oscillator circuit **11** when the trigger circuit **16** switches and 5 milliseconds later, when the trigger circuit **16** switches states, the enable circuit **15** supplies a second pulse to the power oscillator circuit **11**. The trigger circuit **16** remains in the second state for the period of time to which it is adjusted and the enable circuit **15** remains in its normal state. After the predetermined period of time has passed the trigger circuit **16** again switches states for 5 milliseconds and the enable circuit provides two output pulses approximately 5 milliseconds apart. The power oscillator circuit **11** is deenergized or shut off for the duration of the output pulses from the enable circuit **15**. Thus, the enable circuit **15** and trigger circuit **16** in essence modulate the output of the power oscillator circuit **11** or superimpose control signals on the output thereof.

Also included in the control unit is an FM (frequency modulated) receiver **20**, including detector and demodulator, having an input affixed to a receiving antenna **21**, which antenna **21** may be remotely positionable so that it can be placed adjacent various portions of a body. An indicator or calibrated meter readout **22** is attached to the output of the FM receiver **20** so as to provide an indication of changes in frequency of the output. The indicator **22**, for example, may be calibrated in terms of material contained in a bladder ranging from empty to full. Various other types of receivers and indicators might be utilized wherein a variable characteristic other than frequency is utilized to provide an indicator of the operation of the muscular organ being controlled, but the present system is utilized because it is believed to be the most accurate under various changing conditions, such as variation in electrical power, variations in muscular material being operated upon, variations in distances between transmitters and receivers, etc.

FIG. 2 illustrates an implantable unit which cooperates with the control unit of FIG. 1 to provide complete stimulator apparatus. The implantable unit includes power means generally designated **30**, controllable energizing means generally designated **31**, control means generally designated **32**, transmitting means generally designated **33** and a regulated power supply for the control means **32** and transmitting means **33**, generally designated **34**. The power means **30** includes a tank circuit **40** tuned to the frequency of the power oscillator circuit **11** in the control unit. Since the entire circuitry illustrated in FIG. 2 is implantable, generally within the body of a human or other animal, it is inaccessible from the exterior and power is induced into the tank circuit **40** by the transmitting coil **10**. The electrical power from the tank circuit **40** is rectified, filtered and at least partially regulated to provide DC power at the line **41**.

As previously described in conjunction with FIG. 1, the amplitude of the DC power on the line **41** is externally variable through the output regulator **14**. The DC power on the line **41** is connected to the controllable energizing means **31** and to the regulated power supply **34**. It should be noted that the filtering in the power means **30** is such that control signals superimposed on the energy induced into the tank circuit **40** appear at the line **41**. Further, the regulated power supply **34** has sufficient regulation so that control signals superimposed on the DC power at the line **41** have substantially no effect on the output thereof. Thus, with regard to effect on the remainder of the circuitry, control signals and DC voltage are available on line **41** while only a regulated DC voltage is applied to the control means **32** and transmitting means **33** from the regulated power supply **34**. The line **41** having control signals thereon is also connected to an input **42** of the control means **32**.

The controllable energizing means **31** includes a plurality of stimulator circuits **45*a***, **45*b***, **45*c***, etc., each of which includes a pair of electrodes **46*a***, **46*b***, **46*c***, a storage capacitor **47*a***, **47*b***, **47*c***, and an SCR (silicon controlled rectifier) **48*a***, **48*b***, **48*c***, respectively. The pair of electrodes **46*a*** and the storage capacitor **47*a*** are connected to the line **41** across the output of the power means **30** so that the storage capacitor **47*a*** is normally charged to the output voltage thereof. The SCR **48*a*** is connected in circuit with the pair of electrodes **46*a*** and storage capacitor **47*a*** so that conduction of the SCR **48*a*** provides a discharge path for the storage capacitor **47*a*** through the pair of electrodes **46*a***. A plurality of stimulator circuits **45*a*–45** are utilized to increase the chances that at least one of the stimulator circuits **45*a*–45*c*** will remain operable in the event of component failures, etc. The electrodes **46*a*** are adapted to be affixed to the muscular organ it is desired to control, such as a bladder or the like, and discharge of the storage capacitor **47** through the electrodes **46** stimulates the muscular tissue causing operation or contraction thereof. In general the amplitude of the power output from the power means **30** is adjusted, through the output regulator **14**, so that the voltage supplied to the electrodes **46*a***, **46*b***, **46*c***, etc., is sufficient to provide the desired results without causing adverse effects.

The control means **32** includes a monostable multivibrator **50** and a 4-bit shift register **51**. While many or all of the circuits in the implantable unit may be provided in integrated form, the 4-bit shift register **51** is the only one so illustrated, since this is the most common form for commercially purchased shift registers at the present time and since illustrating all of the circuitry contained therein would lend nothing to this explanation. The 4-bit shift register is connected so that pulses from the monostable multivibrator **50** are received therein to provide serial readout or commutated signals, at the four outputs thereof, with the first three outputs being utilized to trigger the SCR's **48*a***, **48*b*** and **48*c***, and the fourth output being applied to reset the shift register **51** and prepare it for the next series of input pulses. It should be understood that many circuits might be utilized to sequentially apply triggering signals to the various stimulator circuits **45*a***, **45*b*** and **45*c***, and the 4-bit shift register **51** is utilized because of its simplicity, size and relatively small expense.

The monostable multivibrator **50** is constructed so that it provides an output pulse having a duration of approximately 7 milliseconds upon actuation thereof. As previously described, the line **41** has a DC voltage prevalent thereon with control signals, consisting of negative-going pulses or periods during which there is an absence of DC voltage, of a duration between one-tenth and two-tenths of a millisecond. These control signals appear in pairs approximately 5 milliseconds apart, with each pair being separated by some predetermined or adjustable time. Since the control signals are only 5 milliseconds apart and the first control signal changes the state of the monostable multivibrator **50**, for a duration of 7 milliseconds, the second control signal on the line **41** has no effect on the monostable multivibrator **50**. Thus, the first control signal in a pair of control signals appearing on the line **41** causes the monostable multivibrator **50** to produce a pulse which, through the shift register **51**, triggers one of the SCR's **48*a***, **48*b*** or **48*c***. Once the SCR **48*a***, **48*b*** or **48*c*** is triggered it continues to conduct even after the triggering pulse is removed therefrom. Five milliseconds after the first control signal appears on the line **41**, causing one of the SCR's **48*a***, **48*b*** or **48*c***, to be triggered, a second control signal appears on the line **41** and temporarily removes the DC voltage from across the conducting SCR **48*a***, **48*b*** or **48*c***, thereby, terminating the conduction. At some predetermined time later a second pair of control signals appear on the line **41** and the next SCR **48*a***, **48*b*** or **48*c*** is triggered into temporary operation. Thus, as long as the trigger circuit **16** is energized to provide control signals in the implantable unit, the controllable energizing means **31** is energized to stimulate the muscular organ to which the electrodes **46*a***, **46*b*** and **46*c*** are attached.

The transmitting means **33** includes a free-running multivibrator **52** and an amplifier-transmitter **55**. The output of the free-running multivibrator **52** is connected directly to one of the pairs of electrodes **46*b*** by means of a lead **53** and the input of the amplifier-transmitter **55** is connected directly to one of the pairs of electrodes **46*c*** through a lead **54**. The signal from the free-running multivibrator **52** applied to the muscular organ between the electrodes **46*b*** and **46*c*** is a low-level signal (in this embodiment approximately 400 to 500 millivolts) so that it has no adverse effect on the organ. When the electrodes **46*b*** and **46*c*** are properly attached to a muscular organ, the output signal from the free-running multivibrator **52** is amplified and utilized to modulate the output of the transmitter in the amplifier-transmitter **55**. The impedance of the material between the electrodes **46*b*** and **46*c*** dictates the amount of the signal from the free-running multivibrator **52** which will reach the amplifier-transmitter **55**. Thus, the output frequency of the amplifier-transmitter **55** is representative of the impedance of the material between the electrodes **46*b*** and **46*c***. In a bladder for example, typically the impedance thereacross is approximately 400 ohms when the bladder is full, or the muscle is stretched, and approximately 100 ohms when the bladder is empty, or the muscle is relaxed. The variations in frequency of the amplifier-transmitter **55** output are, therefore, a direct indication as to the operation of a muscular organ, such as the content of a bladder. The meter readout or indicator **22** can thus be calibrated directly in the particular operation or indication it is desired to monitor, such as bladder content.

Thus, stimulator apparatus for the external control of a muscular organ is disclosed wherein an implantable unit, which can be produced in an extremely miniature size through integrated circuits and the like, is affixed to an internal muscular organ in the bodies of humans, mammals, other animals, etc., and all signals, including control signals and power, are induced therein from an external control unit. The stimulator apparatus provides means for the storage of power in the internal or implantable unit, enabling the external transmitter to operate a greater period of time, approximately 97 percent of the time as opposed to only 28 percent of the time in prior art devices. This enables the peak power of the transmitter to be reduced, generally by a factor of 50, and the power handling requirements of the internal receiver section may be reduced in like manner. The operation of the internal muscular organ is monitored by inducing power into the implantable unit and receiving signals from the internal transmitter. Further, control signals are superimposed upon the induced power signals to cause the implanted unit to stimulate the muscular organ and cause operation thereof. While specific times and frequencies have been set forth in the description of the preferred embodiment, it should be understood that these times and frequencies can be varied according to the needs of the particular function being performed or the particular patient being acted upon. Further, some specific circuits are disclosed to facilitate the explanation of the operation and, it should be understood, that these circuits are only exemplary and many other embodiments might be devised by those skilled in the art to perform the functions set forth.

What is claimed is:

1. Stimulator apparatus for the external control of a muscular organ comprising:

a. an external transmitter unit including

1. transmitting means for producing a substantially continuous wave power signal,
2. modulating means connected to said transmitting means for superimposing control signals on said power signal,

b. an implantable unit including

1. power means for inductively receiving said power signal from said external transmitter unit and operable to produce both supply potential and control signals therefrom,
2. at least one electrode adapted to be affixed to the organ desired to be externally controlled,
3. controllable energizing means connecting said power means to said electrode and operable to provide energization of said electrode to provide stimulation of said organ, and
4. control means connected to said power means and to said energizing means for controlling the operation of said energizing means in response to control signals from said power means.

2. The stimulator apparatus of claim **1** wherein said modulating means includes electrical means for sequentially interrupting the induction of power into said implantable unit by said transmitting means.

3. The stimulator apparatus of claim **1** wherein:

a, said implantable unit includes a plurality of said electrodes;

b. said controllable energizing means includes a plurality of parallel stimulator circuits each connected to a different pair of said electrodes; and

c. said control means is connected to each of said plurality of parallel stimulator circuits and includes means for selectively controlling the operation thereof.

4. The stimulator apparatus of claim **3** wherein each of said plurality of parallel stimulator circuits include an electrical energy storage device in circuit with a silicon controlled rectifier.

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