

[54] **IMPLANTABLE VESICAL
STIMULATOR**[72] Inventors: **Jacques G. Susset**, Montreal, Quebec;
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Limited**, Ottawa, Ontario, Canada[22] Filed: **Nov. 17, 1967**[21] Appl. No.: **683,944**[30] **Foreign Application Priority Data**

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[58] Field of Search.....128/419-424

[56]

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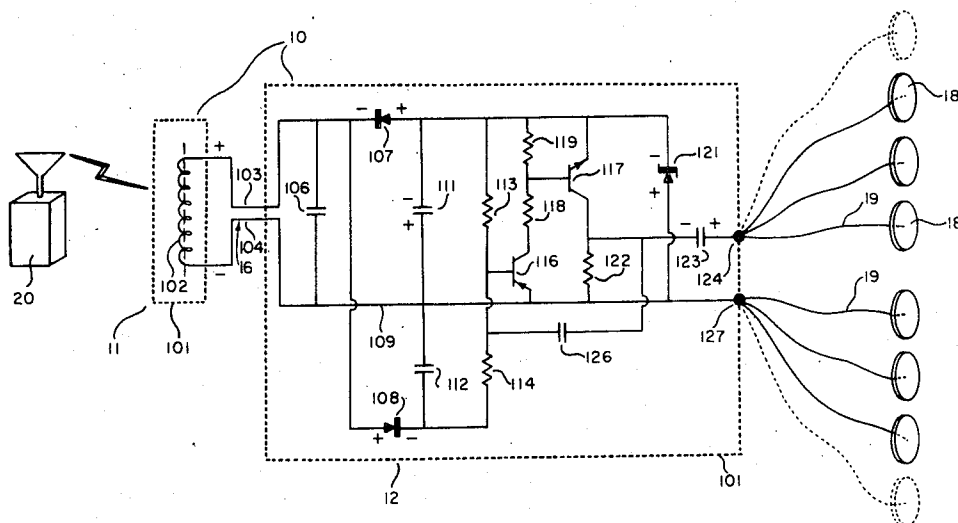
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[57]

ABSTRACT

A device and method for artificially electrically stimulating the body wall of a bladder by an electromagnetic wave which propagates through the bladder wall and is converted by a receiving mechanism into electrical stimulating pulses which are conducted to the bladder wall. But the receiving mechanism receives all its power from the outside source of electromagnetic energy and since it uses no internal power source for generating the electrical pulses to stimulate the bladder wall, a substantially permanent receiving mechanism is achieved which requires no free charging of an internal power supply.

3 Claims, 5 Drawing Figures

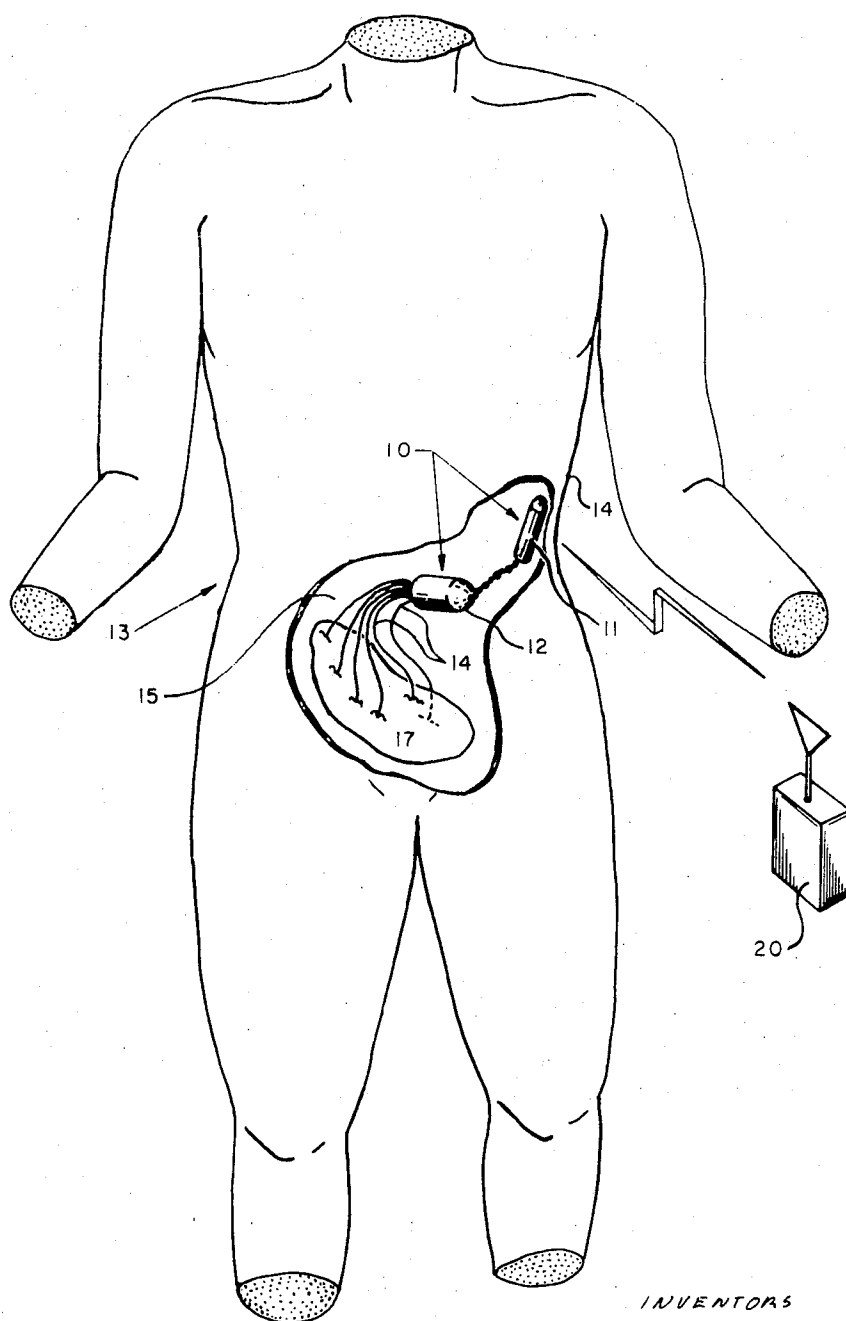


FIG. 1

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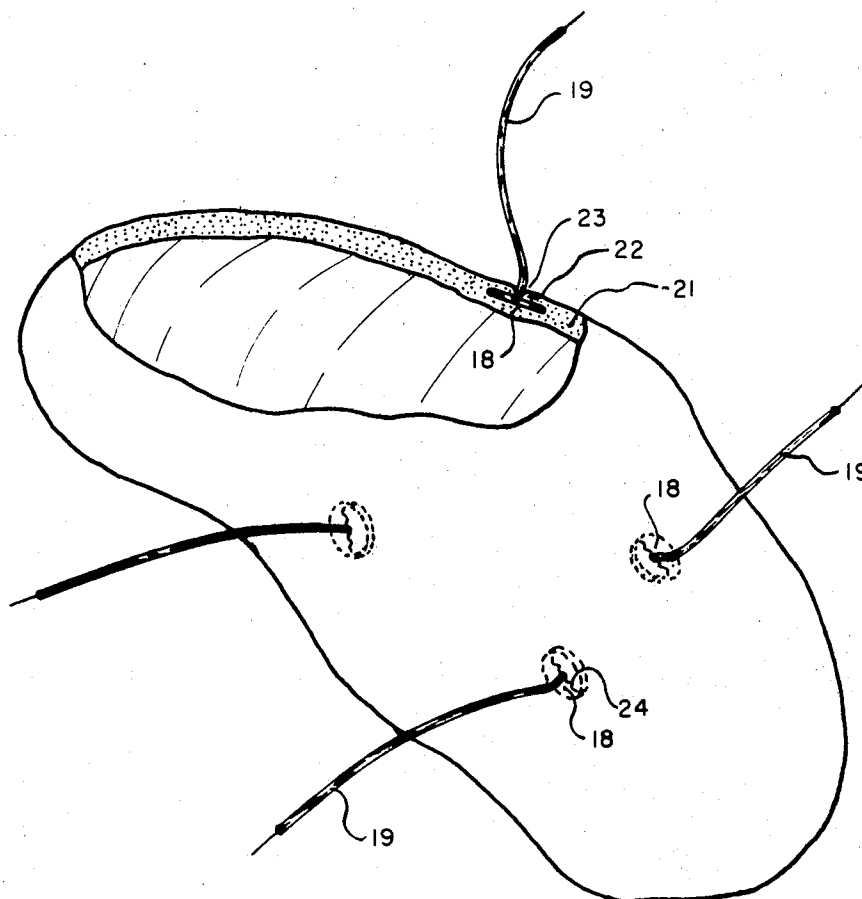


FIG. 2

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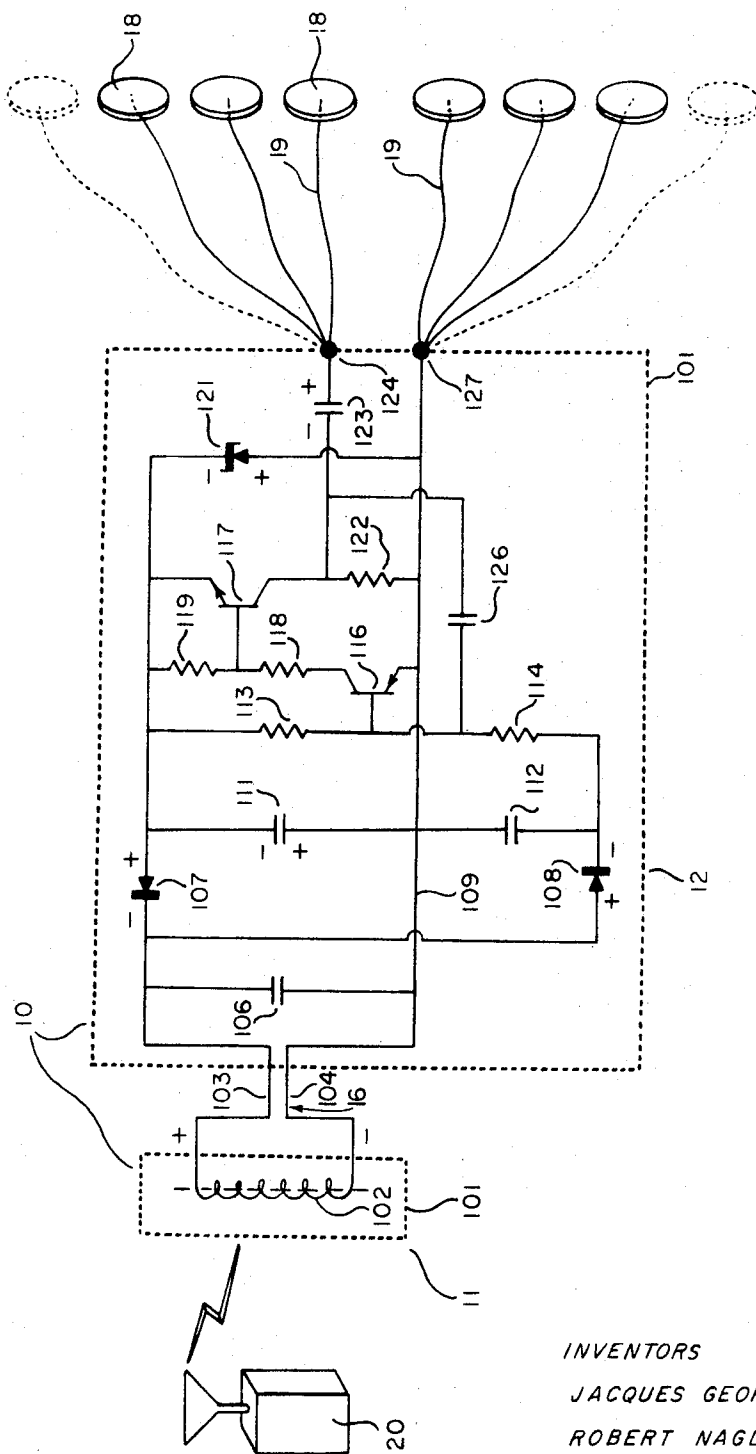


FIG. 3

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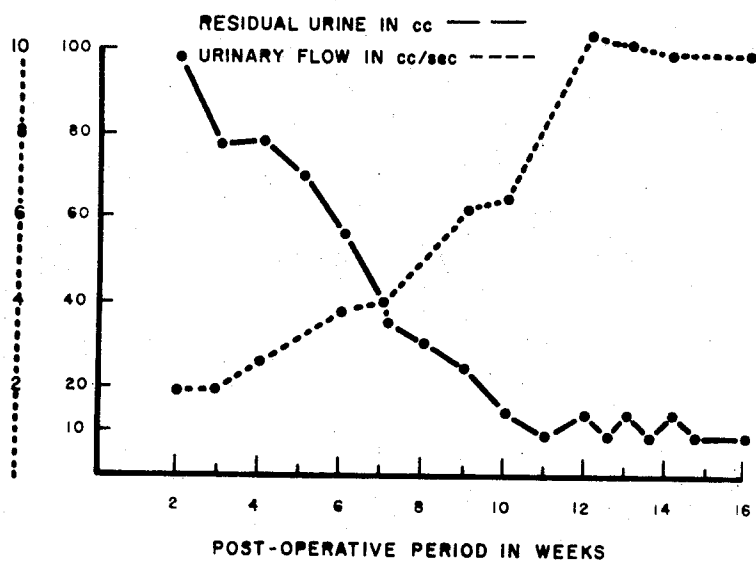


FIG. 5

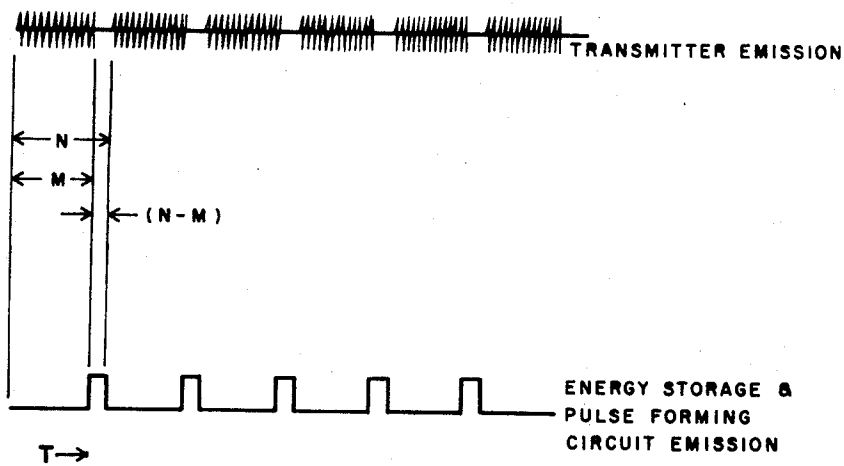


FIG. 4

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IMPLANTABLE VESICAL STIMULATOR

This invention relates to a method and apparatus for electrically stimulating organs of the body.

Stimulation of the bladder by artificial means may become necessary where a patient, particularly a paraplegic, is unable to properly urinate. It is estimated that more than 50 percent of all deaths of paraplegic patients result from urinary complications, due mainly to the persistence of large amounts of residual urine in the bladder. The evacuation of this residual urine is normally impossible because of degenerated motor systems of the bladder.

Traditionally a catheter has been used to rid the bladder of residual urine; however, recently much effort has been directed to artificially stimulating, as by electrical impulses, the urinary bladder to contract causing residual urine to void. Such artificial stimulus has been accomplished by implanting a pair of electrodes in the bladder wall and running the wires out of the body wall to an electrical device which emits an electrical pulse. This pulse induces contraction of the bladder. Bradley in U.S. Pat. No. 3,236,240 issued 22 Feb. 1966 discloses the use of an implantable bladder stimulator in which an encapsulated radio receiving device is implanted in the body of a mammal such that an R.F. signal from an external transmitter is used to initiate a pulsed current through electrical wires embedded in the bladder wall so as to induce contraction thereof.

Such stimulators suffer from several disadvantages; they are bulky; there is a danger of premature discharge from the battery in the receiver, if receiver is so equipped, due to infiltration of body fluid into the encapsulated battery disposed within the body; repeated surgery is necessary to replace the battery. Moreover, these devices do not induce sufficient contraction of the bladder in humans to cause complete evacuation of the residual urine.

The present invention overcomes the above disadvantages by stimulating the bladder within the body cavity with a series of electrical impulses of predetermined duration and frequency until voiding ensues. These electrical impulses are generated within the body cavity from energy and a control signal supplied from outside the body.

The invention contemplates a system for stimulating a bladder of a mammal with energy supplied from a source exterior to said mammal including:

1. means exterior to said mammal for providing radio frequency energy of a predetermined time width and having a predetermined pulse repetition period larger than said time width;

2. means for receiving and storing said energy during said time width to provide a source of energy supply, said means encapsulated in a biologically inert substance for placing within the body;

3. means for generating a stimulating pulse from the source of energy supply during the interval that means (1) does not emit radio frequency energy, said means encapsulated in a biologically inert substance for placing within the body; and

4. means for conveying said stimulating pulse to said bladder wall including a plurality of electrodes for embedding in the walls of the bladder so that contraction of the bladder and voiding of the urine occur during the generation of said stimulating pulse.

The invention will now be described by way of example reference being had to the accompanying drawings in which:

FIG. 1 is a representation of the stimulator in a body of a mammal such as a human;

FIG. 2 is a representation of the electrodes embedded in the bladder wall;

FIG. 3 is a schematic diagram of the receiver;

FIG. 4 is a graph indicating the timing relation between the signal output of the transmitter and that of the stimulator; and

FIG. 5 is a graph indicating the efficiency of voiding a human bladder using the embodiments of the invention.

Referring to FIG. 1, a stimulator 10 including an antenna element 11 and an energy storing and pulse forming circuit 12

is disposed in a body 13 by surgery. The antenna element 11 is embedded near the body wall 14 and the energy storing and pulse forming circuit 12 in the body cavity 15. An interconnecting cable 16, later to be described, is disposed between elements 11 and circuit 12. Embedded in the walls of a bladder 17 are platinum disc electrodes 18 electrically connected to the circuit 12 by insulated wires 19. An exterior transmitter 20 excites the stimulator 10 in a manner later to be described.

Referring to FIG. 2, six disc electrodes 18 of platinum (although any biologically inert and non-oxidizing material may be used such as tantalum, vanadium, stainless steel or graphite) having a diameter of 7 mm are embedded into the bladder wall 21 by making a small tunnel 22 with a fine mosquito forceps. A disc electrode 18 is inserted into the tunnel 22 and the entrance 23 thereof is closed with a fine silk suture 24 in order to maintain the electrode 18 in position. The six electrodes 18 are disposed at regular intervals along two concentric circles of 3 electrodes each; one circle, corresponding to the mid portion of the bladder, the other circle, midway between the tip of the bladder and the lower circle.

In order to ensure a fast spreading of current the polarity of the electrodes are alternated and placed in the following order: in the lower circle a negative electrode in the anterior wall 26, a positive electrode in the right and left lateral wall 27, 28; in the upper circle, a positive electrode in the posterior wall 29 and two negative electrodes on the anterior wall 31. All the electrodes in both circles are equally spaced from all the other electrodes.

Referring to FIG. 3, the stimulator 10 comprises two elements, the receiving element 11 and the energy storing and pulse forming circuit 12, interconnected by the cable 16. The element 11 and circuit 12 are encapsulated within a biologically inert substance 101 such as silicone rubber or as sold under the trade mark "Silastix." Within the element 11 an antenna comprising a coil 102 wound on a ferrite rod the ends of which are respectively connected to the inner conductors 103, 104 of the cable 16. The conductors 103 and 104 terminate across a capacitor 106 which has one terminal connected to the cathode of a diode 107 and the anode of a diode 108. The other terminal of the capacitor 106 is secured to a common electrical reference conductor 109. Two capacitors 111 and 112 are interconnected between the anode of diode 107, the cathode of diode 108, and the conductor 109. Two resistors 113, 114 connect the base of a transistor (first translating device) 116 to the anode and cathode of the diodes 107 and 108. The emitter of the transistor 116 is connected to the conductor 109 while the collector thereof is connected to the base of a transistor 117 through a resistor 118 such that the two transistors 116 and 117 are in cascade. The anode of the diode 107 is directly connected to the emitter of the transistor 117, and coupled to the base of the transistor 117 through a resistor 119. The cathode of a 20-volt zener diode 121 is also connected to the anode of diode 107, while the anode of the zener diode 121 connects to the conductor 109. This zener diode 121 limits the amount of charge in the storage capacitor 111 to no more than 20 volts as will become apparent. The collector of the transistor 117 is connected through a resistor 122 to the conductor 109 while a capacitor 123 connects this collector to a positive electrode terminal 124. Any signal at the collector of the transistor 117 is fed back through a capacitor 126 to the base of the transistor 116. The conductor 109 terminates at a negative electrode terminal 127. To each of the electrode terminals 124 and 127 respectively the electrodes 18 are connected by conducting wires 19 such that an equal number of electrodes 18 are connected to each terminal. The electrodes 18 connected to terminal 124 are disposed in the bladder wall 21, one in the lower circle on the anterior wall, the other two in the upper circle on the anterior wall. Those electrodes 18 connected to the positive terminal 127 are disposed in the bladder wall 21, one each in the right and left lateral wall in the lower circle, and the third in the posterior wall of the upper circle.

The stimulator 10 is encapsulated in a biologically inert substance, for example, silicone rubber, and by surgery the receiving element 11 is embedded in the body wall near the surface thereof while the larger energy storing and pulse forming circuit 12 is embedded in the body cavity under the recti muscles. The electrodes 18 are embedded in the walls 21 of the bladder 17 as previously described.

The transmitter 20, which may be of standard design is excited to provide a continuous electromagnetic wave having a specific time width and pulse repetition frequency which induces voiding of the bladder in a manner which will become apparent. During transmitter excitation energy is received by element 11 and stored in circuit 12. During that period of time when the transmitter is automatically turned off the stored energy in circuit 12 is discharged and the pulse is conveyed to the electrodes 18 in a manner now to be explained.

During excitation of the transmitter 20, the element 11 detects the radiation because the coil 102 and capacitor 106 make the element 11 a tuned circuit for the frequency of operation of the transmitter 20, for example, 100 kilohertz. The storage capacitor 111 is charged negatively during that part of the cycle that conductor 103 is negative with respect to conductor 104; during the other half cycle, the diode 107 prevents current from flowing to charge capacitor 111. During this half cycle, when conductor 103 is positive with respect to conductor 104, the capacitor 112 is charged positive. This places the junction of the resistors 113 and 114, the base of the transistor 116, positive with respect to the conductor 109 biasing transistors 116 and 117 to cut off. This makes the base of transistor 117 more negative than its emitter and causes conduction thereof. By virtue of this conduction, a trigger signal appears at the base of transistor 117 causing it to conduct through the resistance 122 discharging storage capacitor 111. The voltage appearing across the resistor 122 appears across the terminals 127 and 124 and is conveyed to the electrodes 18. The capacitor 123 provides isolation and coupling. When the transmitter 20 is re-excited transistors 116 and 117 are biased to cut off by the rapid charging of capacitor 112. Charging of the storage capacitor 111 is also re-instituted. This method is then repeated 10 - 20 times per second in a manner as will now be described.

Referring to FIG. 4 the transmitter 20 emits a continuous wave signal having a time width of M milliseconds and a pulse repetition period of N milliseconds, it being provided the N is a number greater than M.

The stimulator 10 produces, as is now apparent, a stimulating pulse when the transmitter is not emitting a signal. As a result, the stimulator 10 provides a pulse having a time width of (N-M) milliseconds and a pulse repetition period of N milliseconds. Now if N is selected to be 100 and M, 99, the stimulator will provide a stimulating pulse of 1 millisecond duration and cycle at a frequency of 10 cycles per second because the transmitter 20 has a pulse repetition period of 100 milliseconds and a time width of 99 milliseconds. If the pulse repetition period, M, of the transmitter 20 is 49 milliseconds, a cycling of 20 c.p.s. is obtained. When the transmitter 20 is placed next to the body wall and turned on the stimulator 10 pulses and urine flows.

Since the storage capacitor 111 is only minutely discharged during any period (N-M), it is preferable during the operation of the stimulator 10, that as complete voiding of the bladder is accomplished, that the transmitter be slowly moved away from the body wall prior to the turning off of the transmitter permanently. In this manner, the storage capacitor 111 is charged to a lesser degree during the time width M of the transmitter. This reduction in the storing of energy prevents a final large discharge of capacitor 111 through transistor 117 and a resulting large stimulating pulses which may be detrimental to the user when the transmitter is turned off. The maximum amplitude of the stimulating pulse is controlled by the zener diode 121, which limits the storage potential across the storage capacitor 111. This is preferably set at 20 volts.

The following parts list gives suitable values of the components of the stimulator 10 when the transmitter frequency of 100 kilohertz with a time width of 99 milliseconds and a pulse repetition period of 1/10 second is used.

resistors	113	33K ohms
	114	18K ohms
	118	500 ohms
	119	5K ohms
	122	500 ohms
capacitors	106	.01 ufd
	111	47 ufs (tantalum)
	112	.002 ufd
	123	180 ufd
	126	100 pf
diodes	107	silicone
	108	silicone
	121	zener 20V
transistors	116	silicone
	117	silicone

EXAMPLE 1

(The Use of the Receiver for Bladder Stimulation in Dogs)

Receivers which were designed to provide a bipolar square wave pulse of 10 cycles per second for a duration of 1 millisecond and had an amplitude of 10 volts and having electrical circuit substantially as shown in FIG. 3 were implanted in four dogs — two males and two females averaging 35 pounds in weight.

Prior to the implantation, a bilateral sacral neurotomy was performed following the usual technique in the same operating stage. An abdominal incision was made. Nervi erigentes and hypo-gastric nerves were first severed to leave no doubt about the completeness of vesical denervation.

Six electrodes were implanted in the bladder wall according to the above-described technique. These electrodes had been connected to the energy storing and pulse forming circuit 12 in two bundles of three, making easy the identification of positive and negative poles. The encapsulated circuit 12 and receiving element 12 were thread lateral to the left rectus muscle and placed in the subcutaneous tissue in the flank midway between abdominal and sacral incisions.

In the four animals, the initial stimulation during the operation was entirely successful and caused complete vesical evacuation.

The stimulation was carried out four times a day at 9 A.M., 1 P.M., 5 P.M. and 9 P.M. The dog was kept on normal fluid intake. The average flow obtained by stimulation corresponded to figures found during acute experiments with the corresponding current. That is to say, about 3 to 4 cc/sec. No major post-operative complication occurred during the first weeks in any of the dogs. The dogs looked healthy; none was paralyzed due to the lower level of the nerve section and urinary incontinence was not noted.

In one dog, the stimulation became suddenly inefficient. The dog was sacrificed and two electrodes were found to be disconnected due to breaking of the conductive wires.

In the second dog, the effect of the stimulation became gradually less efficient over the 9th and 10th day when two electrodes lost their contact with the vesical wall.

In the third dog, the stimulation remained efficient for 2 weeks. At that time, the skin ulcerated in the vicinity of the receiver element 12. The skin finally ruptured and the receiver element 12 and encapsulated circuit 12 were rejected. This compelled us to sacrifice the dog.

The fourth dog did extremely well. For 3 months stimulation caused complete vesical emptying. A cinecystogram was done which showed complete vesical evacuation. Unfortunately, this dog died of pulmonary infection. The post-mortem examination failed to demonstrate any burn at the point of implantation of electrodes. The bladder capacity was still in the initial range of 250 cc and the vesical wall appeared healthy.

EXAMPLE 2

(Electromagnetic Converter for Bladder Stimulation in Humans)

A stimulator 10 of electrical circuit and electrical parameters as previously described was used as a human stimulator. Eight platinum disc electrodes were implanted in the bladder according to the above described technique in 2 circles of 4 electrodes equally spaced from each other in order to provide sufficient stimulation to the larger size human bladder. As before, the electrodes 18 were connected to the circuit 12 in two bundles of four making easy identification of the positive and negative poles respectively connected to terminals 123 and 124. The stimulator 10 was thread lateral to the left rectus muscle and placed in a subcutaneous tissue in a flank midway between the abdominal and sacral incisions. As before the stimulator 10 was insulated with apoxy and silicone rubber as were the interconnecting wires 19 between the platinum disc electrodes 18 and the stimulator 10 prior to insertion within the body.

A stimulator 10 was implanted in a 30 year old male who sustained a spinal cord injury at the level of T4 some 3 years previously. Subarachnoidal alcoholization carried out some 2 years subsequent to the spinal cord injury left him with complete flaccidity of the lower limbs and pelvic floor, and complete absence of sensation below T4. The anal sphincter was atonic and the bulbo-cavernosus reflex absent.

The upper urinary tract was normal on Intravenous Pyelogram and there was no vesico-ureteral reflux present on the cystogram. The urine was markedly purulent and contained various bacteria on repeated bacteriological studies. A cystometrogram revealed flaccidity of the bladder. On cystoscopy, the bladder mucosa was markedly inflamed with moderate trabeculation and cellule formation. The bladder neck was widely open and there was no evidence of urethral obstruction.

Numerous unsuccessful attempts were made to remove the indwelling catheter utilizing large doses of urecholine. He was unable to void and 600 cc of residual urine were regularly present in the bladder. He spiked a high fever not infrequently and on three occasions litholapaxy for bladder calculi was carried out.

During the surgery necessary for the implanting stimulator no response was noticed. The bladder was continuously drained by an indwelling Foley catheter for 1 week following surgery during which time no stimulation was attempted. From the second postoperative week, the patient stimulated his bladder every 3 to 4 hours according to fluid intake. The stimulation can be carried out across his clothes either in bed or in a wheel chair. He places the external transmitter 20 close to, but not touching the skin, over the internal receiving element 12 and commences stimulation by exciting the transmitter. The urinary flow appears almost immediately. The voltage reaching the electrodes is inversely proportional to the distance between the external transmitter 20 and internal receiving element 12 allowing for current adjustment after implantation.

Referring to FIG. 5 it will be noted that in the postoperative period, the urinary flow was poor with a high residual urine volume. Over the subsequent 10 weeks, the urine flow rate increased and the residual urine volume decreased and then stabilized to an average flow of about 10 cc/sec with a maximum of 15 cc/sec. Residual urine varies between 0 - 20 cc with voiding of about 200 - 600 cc. When flow stops the patient discontinues stimulation. The patient has not complained of pain during stimulation. 2 weeks following surgery, his urine was clear and showed only occasional white blood cells and minimal bacteriuria. However, proteus mirabilis had been repeatedly grown in the urine during periods when repeated catheterizations for residual urine were undertaken throughout the postoperative period, determination or chronic pyelonephritis may explain the persisting urinary infection. A cinecystogram done 10 weeks postoperatively showed a homogenous contraction of the bladder comparable to a normal vesical contraction. The patient had not developed vesico-ureteral reflux. The Intravenous Pyelogram was unchanged and a cystoscopy done 3 months following the procedure failed to demonstrate any trace of local changes in

bladder mucosa at the sites of electrode implantation. Between stimulations, there is no urinary incontinence as long as the patient does not strain. Increase in the intra-abdominal pressure results in leakage of urine per urethra because of the incompetence of both internal and external sphincters.

What is claimed is:

1. A system for stimulating the bladder of a mammal with energy supplied from a source exterior to said mammal including:

- a. means exterior to said mammal for providing radio frequency energy of a predetermined time width and having a predetermined pulse repetition period larger than said time width;
- b. means including an antenna tuned to the radio frequency of means (a) and a storage capacitor for storing said energy during said time width, wherein said means (b) is encapsulated in a biologically inert substance for placing within a mammal;
- c. means for generating a stimulating pulse from the source of energy supply during the interval that means (a) does not emit radio frequency energy, said means includes a load and a second capacitor connected to said antenna and a first translating device in cascade with a second translating device, said second capacitor adapted to charge, during the time width of said means (a) to thereby bias said first translating device to cut off during said time width, and to discharge between the time widths to thereby allow said first translating device to conduct triggering said second translating device to conduct discharging said storage capacitor through said load across which a stimulating pulse is generated, said means being connected to said antenna and said storage capacitor and encapsulated in a biologically inert substance for placing within the mammal; and,
- d. means for conveying said stimulating pulse to said bladder wall including a plurality of electrodes for embedding in the walls of the bladder so that contraction of the bladder and voiding of urine from the same occur during the generation of said stimulating pulse.

2. A system for stimulating the bladder of a mammal with energy supplied from a source exterior to said mammal including:

- a. means exterior to said mammal for providing radio frequency energy of a predetermined time width and having a predetermined pulse repetition period larger than said time width;
- b. means including an antenna tuned to the radio frequency of means (a) and a storage capacitor for storing said energy during said time width, wherein said means (b) is encapsulated in a biologically inert substance for placing within a mammal;
- c. means for generating a stimulating pulse from the source of energy supply during the interval that means (a) does not emit radio frequency energy, said means includes a load and a second capacitor connected to said antenna and a first translating device in cascade with a second translating device, said second capacitor adapted to charge, during the time width of said means (a) to thereby bias said first translating device to cut off during said time width, and to discharge between the time widths to thereby allow said first translating device to conduct triggering said second translating device to conduct discharging said storage capacitor through said load across which a stimulating pulse is generated, said means being connected to said antenna and said storage capacitor and encapsulated in a biologically inert substance for placing within the mammal wherein the electrodes are adapted for embedding in the walls of the bladder in two circles, each electrode equally spaced from the other in its circle, the circles corresponding to the mid portion of the bladder and between the tip of the bladder and the lower circle.

3. In a system for stimulating the bladder of a mammal with energy supplied from a transmitter exterior to said mammal, said transmitter generating radio frequency energy of a predetermined time width and pulse repetition period, a stimulator for contracting the bladder, said stimulator including, an antenna tuned to the radio frequency of the transmitter, a storage capacitor for storing said energy during said time width, a load resistor connected to said storage capacitor, a second capacitor connected to said antenna and a first translating device which is in cascade with a second translating device, said second translating device connected in series with said load resistor and said storage capacitor, said second capacitor, adapted to charge during the time width of said

transmitter to bias said first translating device to cut off during said time width, and to discharge between time widths to thereby allow said first translating device to conduct, and trigger said second translating device to conduct discharging said storage capacitor through said load resistor across which a stimulating pulse is formed, and conductors connected across said load resistor including electrodes adapted to be embedded in the bladder wall, for conveying said stimulating pulse to the walls of the bladder so that contraction of the bladder and voiding of urine from the same occur during said stimulating pulses.

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