Feb. 22, 1966 W. E. BRADLEY 3,236,240

IMPLANTABLE BLADDER STIMULATOR

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FIG. 1

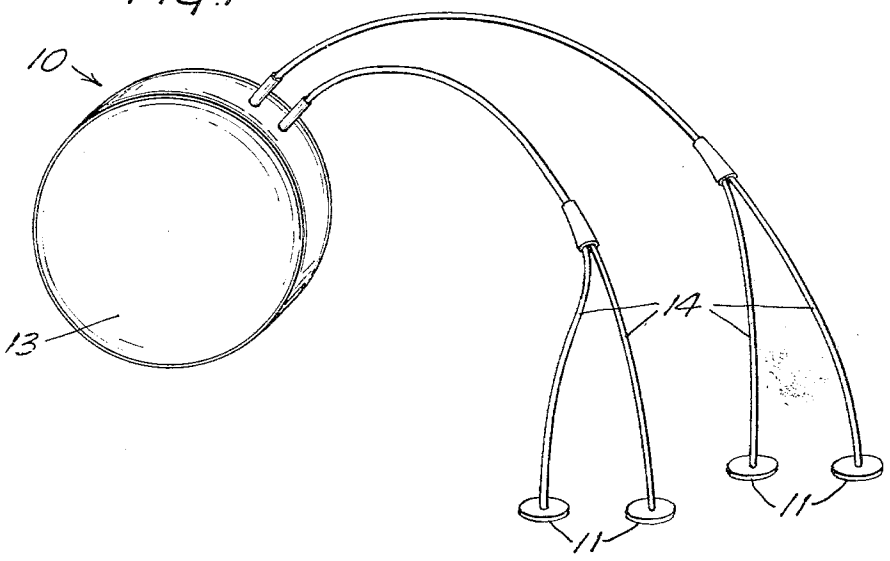

FIG. 2

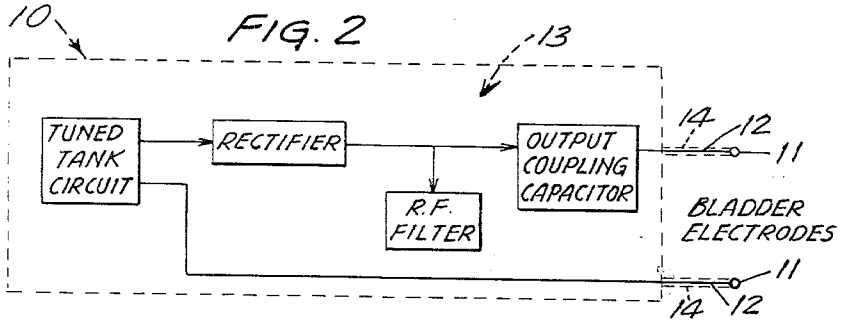

FIG. 3

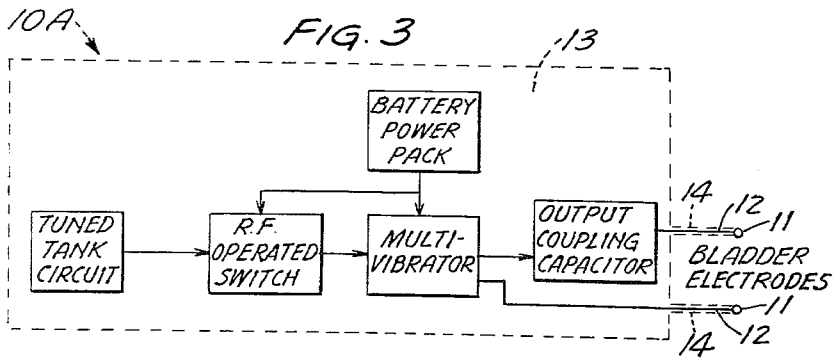

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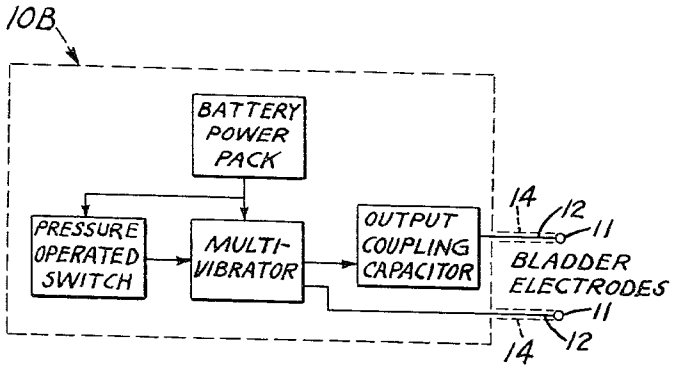
FIG. 4



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IMPLANTABLE BLADDER STIMULATOR

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9 Claims. (Cl. 128—421)

This invention relates to a method and means for artificially electrically stimulating the bladder of persons who have lost the ability to voluntarily empty the bladder because of spinal cord or other injury or disease. Prior to the present invention, the use of a catheter has been the only means of emptying the bladder of paraplegics and others similarly affected.

Urinary sepsis, secondary to neurogenic dysfunction associated with spinal cord trauma, is a well recognized clinical problem. Prolonged use of indwelling catheters in paraplegic patients produces significant bacteriuria, cystitis, vesical calculi, and pyelonephritis. It has been shown that use of an indwelling catheter for 24 hours results in bacteriuria in 50% of patients and in 98–100% of patients after four days.

With antibiotic therapy and closer attention to bladder rehabilitation during and after World War II, the mortality rate in paraplegics from urinary sepsis has declined. However, of approximately 746 veterans with spinal cord injury who died during the period of nine years following World War II, death was attributed to urinary tract infection in 64%. In another series of patients, urinary tract damage was found in 65% of those dying from other causes.

Bladder tonus, or the response of bladder smooth muscle to the stretch imposed by filling, has been described as an intrinsic property of smooth muscle and not reflex in nature. Changes in this response are shown to follow physical alteration in the bladder tissue. Regular, complete evacuation of the neurogenic bladder with avoidance of infection and damage, is therefore an aid in preserving normal tonus and facilitating rehabilitation of bladder function. Electrical excitability of the mammalian bladder has been demonstrated.

It is accordingly the principal object of this invention to provide a practical method and means for artificially electrically stimulating the bladder to permit regular, complete evacuation with the avoidance of infection and tissue damage.

It is a further object of this invention to provide an implantable internal bladder stimulator in the form of a radio frequency receiver with electrodes attached to the bladder, capable of providing the proper stimulation when used in conjunction with an external radio frequency transmitter.

It is another object of this invention to provide a passive internal bladder stimulator adapted to be implanted subcutaneously with electrodes attached to the bladder which derives its stimulation power from an external high power radio frequency transmitter.

It is another object of the present invention to provide a battery powered implantable bladder stimulator adapted to be triggered by a low power signal from an external pocket size radio frequency transmitter.

A still further object of this invention is to provide a battery powered implantable bladder stimulator adapted to be actuated through a pressure switch by external pressure applied to the skin over the switch.

Other and further objects of the invention are those inherent and apparent in the apparatus as described, pictured and claimed.

To the accomplishment of the foregoing and related ends, this invention then comprises the features hereinafter fully described and particularly pointed out in the claims, the following description setting forth in detail certain illustrative embodiments of the invention, these being indicative, however, of but a few of the various ways in which the principles of the invention may be employed.

The invention will be described with reference to the drawings in which corresponding numerals refer to the same parts and in which:

FIGURE 1 is a perspective view of an internal stimulator according to the present invention;

FIGURE 2 is a schematic block circuit diagram of an implantable bladder stimulator deriving its stimulation power from an external high power transmitter;

FIGURE 3 is a schematic block circuit diagram of an implantable bladder stimulator deriving its stimulation power from an internal battery power pack and adapted to be triggered from an external radio frequency transmitter; and

FIGURE 4 is a schematic black circuit diagram of an implantable bladder stimulator deriving its stimulation power from an internal power pack and adapted to be actuated by pressure.

As shown in FIGURE 1, the stimulator comprises a receiver, indicated generally at **10**, and a plurality of electrodes **11** for attachment to the bladder. The electrodes **11** are connected to the receiver by electrical conductors **12**. The receiver is encased in a protective plastic mass **13** preferably composed of a synthetic resinous material. The conductors are similarly encased in a protective sheath **14**.

Referring to FIGURE 2 of the drawings, the bladder stimulator receiver unit includes a tuned tank circuit composed of an inductor and a capacitor in a parallel connected resonant circuit. Since such a circuit has the ability to store energy for a short period of time, its acts as a reservoir or tank. The inductor of the tank circuit acts as an antenna. Pulses of radio frequency energy from an external high power transmitter of conventional design are transmitted through a layer of body tissue to the receiver where they are rectified through a rectifier, into a unidirectional pulsating current. The radio frequency current is filtered out and the lower frequency pulse envelope signal is applied to the bladder through bladder electrodes **11** attached to the bladder wall, through an output coupling capacitor which blocks the direct current component of the signal. The bladder electrodes **11** are metallic terminals attached directly to the exterior wall of the bladder.

The receiver components are encased or embedded in a sterilizable, inert, non-irritating and non-toxic protective and insulating mass **12**, preferably of synthetic resinous material, with only the conductors **12** leading to the bladder electrodes **11** extending therefrom. These conductors are insulated by passing them through tubes **14**, preferably of similar synthetic resinous protective and insulating material, or coated with a similar substance. Substances such as silicone rubber, silastic resins, tetrafluoroethylene polymers, vinyl chloride and the like, are suitable materials for these purposes. Pure natural rubber may also be used.

The bladder electrodes may be formed from any inert non-toxic and non-irritating electrically conductive metal. Surgical grade stainless steel is a preferred material. However, other metals such as tantalum, gold, silver, platinum and alloys of these metals may also be used. According to one form the electrodes are circular discs of the order of about 0.5 to 1.5 centimeters in diameter and protected on one side with an insulating material. The electrodes may be solid or perforated or formed from metallic mesh. The electrodes are attached with silk

sutures or the like sewn through the outermost layer of the bladder wall with the exposed surface in direct contact with the wall. Two to four leads or more may be connected from the receiver to the bladder depending upon the size of the bladder.

The receiver-stimulator is implanted under the skin of the patient with the electrodes attached directly to the bladder wall. The transmitter which accompanies the receiver generates pulses of radio frequency energy of the same frequency of the tuned tank circuit modulated to the proper shape and pulse recurrence frequency to give the correct bladder stimulation. This is of the order of about one-half to two megacycles, and desirably about one megacycle. The transmitted radio frequency energy is applied to the patient by means of a small loop antenna at the end of a cable extending from the radio frequency generator. This loop is held next to the skin directly over the implanted receiver. The transmitted signal stimulates the bladder through the bladder electrodes and causes the bladder to empty.

Although the bladder has been found to be responsive to wide variations in applied signal the components of the stimulator are desirably selected to apply a biphasic signal of amplitude of aboue 1 to 50 volts depending upon the size of the electrodes, the voltage varying inversely with the contact area of the electrodes. The pulse recurrence frequency may be up to about 20 times the pulse duration and may be, for example, of the order of about 20 to 2000 cycles per second. In one typical instance 6 electrodes of 1 centimeter diameter were attached to a bladder and the applied signal was of the order of about 5 volt, 2 millisecond pulses at the rate of about 50 to 100 per second.

Referring to FIGURE 3 there is shown a self-powered receiver-stimulator, indicated generally at **10**A, which contains its own battery power supply. This receiver-stimulator includes a tuned tank circuit whose inductor similarly acts as an antenna. The pulses of radio frequency energy from a low power transmitter are transmitted to a radio frequency operated switch which controls the battery power pack to energize a multivibrator. The output of the multivibrator is applied to the bladder through an output coupling capacitor to block the flow of direct current while permitting pulsating current to pass. The stimulation is applied through the bladder electrodes **11** attached directly to the bladder wall.

This type of receiver-stimulator is likewise encased in a resinous protective and insulating material **13** and implanted directly in the body of the patient under the skin. It has the advantage of permitting the use of a smaller more portable transmitter of pulses of radio frequency energy. Along with this is the disadvantage of a limited life, dependent upon the life of the battery power pack. However, the greater mobility of the patient permitted by the self-powered unit will in most cases outweigh this disadvantage.

It has been found that effective and complete emptying of the bladder with no residual urine may be accomplished through use of the receiver-stimulator according to the present invention. Emptying is time-cycled and the bladder is emptied at regular intervals. For example, a timer may be used to trigger the transmitter every four hours for a period of three minutes. It will be understood, of course, that the length and frequency of stimulation may vary widely dependent upon the fluid intake, the condition of the patient, and other variables.

The implanted stimulator may be used over an extended period of time with minimal tissue reaction in the region of the electrodes and only slight thickening of the subcutaneous tissues around the site of implantation of the receiver. Meanwhile, infection and subsequent bladder tissue changes resulting from the use of urethral catheters is avoided and bladder tonus is maintained, preserving an intact organ and sphincters. Instead of utilizing radio frequency signals as described, ultrasonic vibrations may be used in a similar manner.

In FIGURE 4 there is shown a modified form of stimulator, indicated generally at **10**B, which also contains its own battery power supply. The circuit of this stimulator includes a pressure operated switch which may be actuated by finger pressure exerted on the overlying skin. The pressure switch controls the battery power pack to energize a multivibrator. The output of the multivibrator is applied to the bladder through an output coupling capacitor and the stimulation is applied to the bladder as previously described. By means of this form of stimulator the patient has greater freedom and direct control over evacuation of his bladder. This unit is insulated and embedded in protective material in the same manner as the other forms of stimulator and is implanted so that the pressure switch may be easily actuated by finger pressure on the skin overlying the unit.

It is apparent that many modifications and variations of this invention as hereinbefore set forth may be made without departing from the spirit and scope thereof. The specific embodiments described are given by way of example only and the invention is limited only by the terms of the appended claims.

I claim:

1. A volitional stimulator for the stimulation of a distended bladder to cause the emptying thereof intermittently at widely spaced time intervals dictated by liquid intake into the bladder, said stimulator including

(A) means for producing controllable intermittent electrical stimuli having an amplitude of about 1 to 50 volts and a pulse recurrence frequency of the order of about 20 to 2000 cycles per second, said frequency being up to about 20 times the pulse duration,

(B) at least two separate electrode means for direct attachment to the bladder wall at variable relatively widely spaced distances,

(C) flexible electrical conductor means connecting said electrode means to said means for producing electrical stimuli,

(D) means for actuating said means for producing electrical stimuli to turn said means "on" to apply a pulsing electrical stimulus to the bladder wall through said electrode means,

(E) means for manually controlling said actuating means for applying said stimulus for a short time interval sufficient to substantially empty said bladder intermittently at said widely spaced time intervals dictated by liquid intake into the bladder,

(F) said means for producing electrical stimuli and said conductor means being encased in an inert non-toxic and non-irritant protective material in a relatively flat wafer-like envelope and elongated flexible sheaths, respectively, for implantation within the body.

2. A stimulator according to claim **1** further characterized in that said means for producing electrical stimuli is a radio frequency receiver.

3. A volitional receiver-stimulator for the stimulation of a distended bladder to cause emptying thereof intermittently at widely spaced time intervals dictated by liquid intake into the bladder, said stimulator including

(A) a radio frequency receiver,

(B) at least two separate electrode means for direct attachment to the bladder wall at variable relatively widely spaced distances,

(C) flexible electrical conductor means connecting said receiver and electrode means,

(D) means within the receiver for applying a pulsing electrical stimulus to the bladder through said electrode means,

(E) means for actuating said stimulus applying means to turn said means "on" for short time intervals sufficient to substantially empty said bladder at said in-

termittent widely spaced time intervals dictated by liquid intake into said bladder,

(F) said receiver and conductor means being encased in an inert non-toxic and non-irritant protective material in a relatively flat wafer-like envelope and elongated sheaths, respectively, for implantation within the body.

4. A receiver-stimulator according to claim 3 further characterized in that said receiver includes a radio frequency tuned tank circuit, the inductor of said tank circuit being an antenna for an external radio frequency signal.

5. A receiver-stimulator according to claim 3 further characterized in that said receiver includes an output coupling capacitor to block the flow of direct current to said electrodes.

6. A receiver-stimulator according to claim 5 further characterized in that said receiver includes means for adapting said receiver to be powered by an external high power radio frequency generator and includes a rectifier for imparting unidirectional flow to the electrical stimulus to said electrodes and a filter to block the flow of radio frequency current.

7. A volitional receiver-stimulator for the stimulation of a distended bladder to cause emptying thereof intermittently at widely spaced time intervals dictated by liquid intake into said bladder, said stimulator including

(A) a radio frequency receiver,

(B) at least two separate electrode means for direct attachment to the bladder walls at variable relatively widely spaced distances,

(C) flexible electrical conductor means connecting said receiver and electrode means,

(D) means within said receiver for altering an externally transmitted radio frequency signal and applying a pulsing electrical stimulus to the bladder wall through said electrode means,

(E) means for applying said pulsing electrical stimulus for short time intervals sufficient to substantially empty said bladder at widely spaced time intervals dictated by liquid intake into said bladder,

(F) said receiver and conductor means being encased in an inert non-toxic and non-irritant protective material in a relatively flat wafer-like envelope and elongated flexible sheaths, respectively, for implanting within the body.

8. A volitional receiver-stimulator for the stimulation of a distended bladder to cause emptying thereof intermittently at widely spaced time intervals dictated by liquid intake into said bladder, said stimulator including

(A) a radio frequency receiver,

(B) at least two separate electrode means for direct attachment to the bladder walls at variable relatively widely spaced distances,

(C) flexible electrical conductor means connecting said receiver and electrode means,

(D) means within said receiver for altering an externally transmitted radio frequency signal and applying

a pulsing electrical stimulus to the bladder wall through said electrode means including:

(1) a tuned tank circuit, the inductor which serves as an antenna for an externally generated high power radio frequency signal,

(2) a rectifier for imparting unidirectional flow to the electrical stimulus to said electrode means,

(3) a filter to block the flow of radio frequency current, and

(4) an output coupling capacitor to block the flow of direct current to said electrode means,

(E) means for applying said pulsing electrical stimulus for short time intervals sufficient to substantially empty said bladder at widely spaced time intervals dictated by liquid intake to said bladder,

(F) said receiver and conductor means being encased in an inert non-toxic and non-irritant protective material in a relatively flat wafer-like envelope and elongated flexible sheaths, respectively, for implanting within the body.

9. A volitional method for artificially causing a distended bladder to be emptied intermittently at widely spaced time intervals dictated by liquid intake into said bladder, which method comprises the steps of

(A) implanting a means for producing electrical stimuli within the body,

(B) connecting said means directly to the bladder wall at at least two relatively widely spaced contact areas on opposite sides thereof,

(C) actuating said electrical stimulus producing means implanted within the body from externally of the body for short time intervals sufficient to substantially empty said bladder intermittently at relatively widely spaced time intervals dictated by liquid intake into said bladder,

(D) thereby applying pulsing electrical stimuli directly to the bladder wall for said short time intervals at said relatively widely spaced time intervals to contract the bladder wall and empty the contents thereof,

(E) said stimuli having an amplitude of about 1 to 50 volts and a pulse recurrence frequency of the order of about 20 to 2000 cycles per second, said frequency being up to about 20 times the pulse duration.

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