

[54] **IMPLANTABLE ELECTRONIC STIMULATOR ELECTRODE AND METHOD**

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[51] Int. Cl. **A61n 1/36**

[58] Field of Search **128/404, 410, 411, 416, 418 P, 128/419 R, 421, 422**

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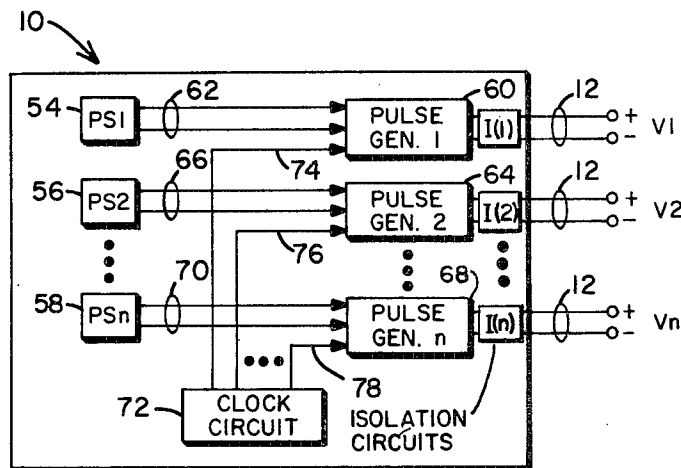
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[57] **ABSTRACT**

An apparatus for implantation in the body to locally stimulate a mass of electrically excitable tissue without stimulating nearby tissue structures, and the method of so stimulating the tissue is described. The apparatus includes a plurality of electrodes, each of the electrodes including a pair of conductors for carrying signals of positive and negative polarity, each of said conductors having a plurality of electrically conductive coupling points for coupling to the mass of tissue. Apparatus is also described for providing timed sequenced electrical impulses to the plurality of electrodes so that only one of the electrodes has a voltage applied between its input terminals at any given time. An insulating backing placed between the electrodes and tissue structures surrounding the implanted stimulator for eliminating undesirable secondary tissue stimulation is also described. The method of applying controlled time-spaced electrical impulses to a mass of electrically excitable tissue structure for causing stimulation of that tissue structure is also described.

9 Claims, 9 Drawing Figures



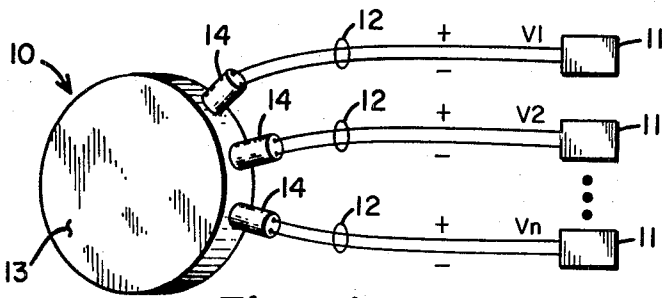


Fig. 1

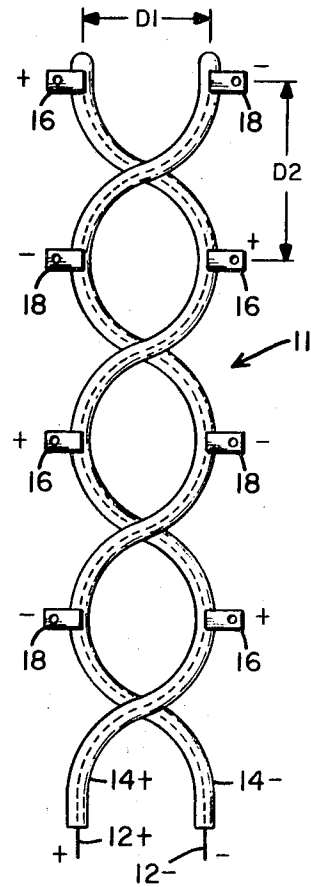


Fig. 3

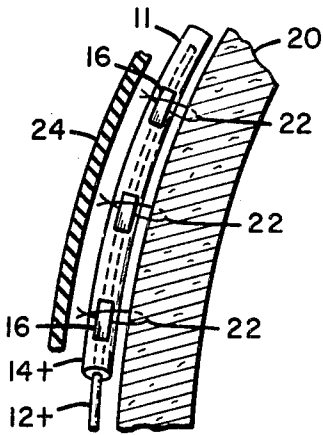


Fig. 5

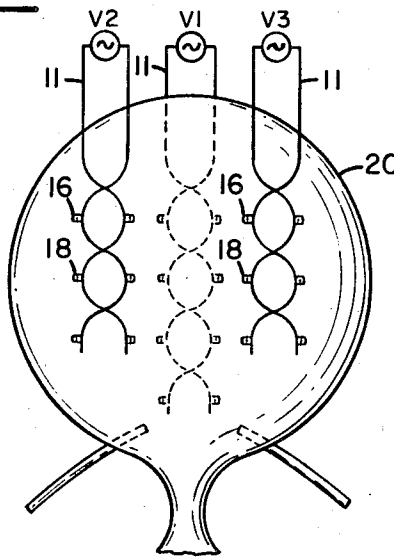


Fig. 4

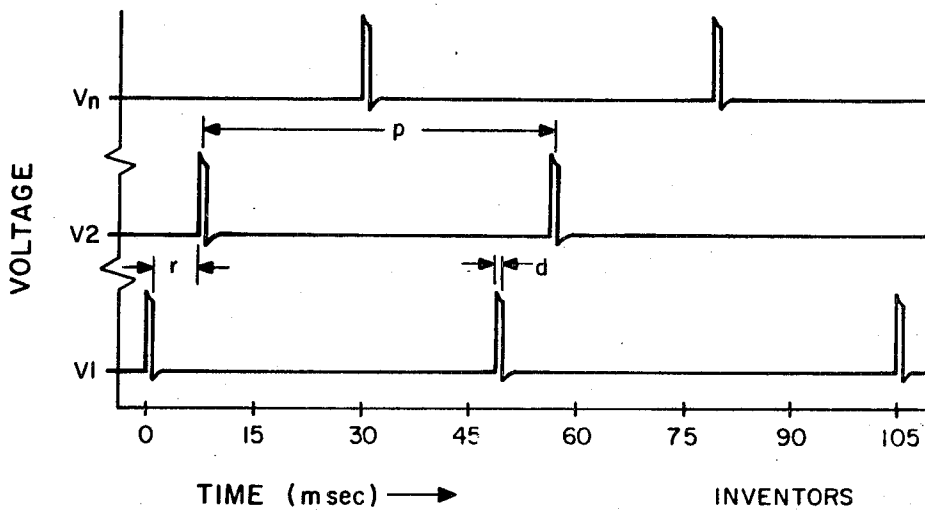


Fig. 2

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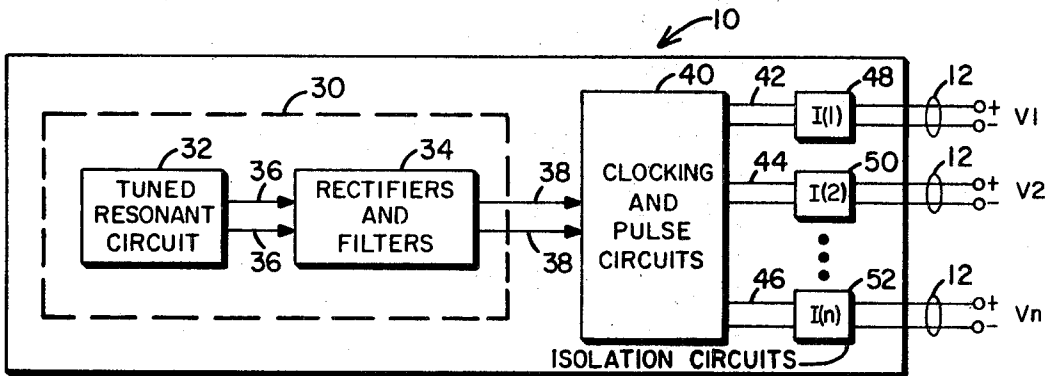


Fig. 6

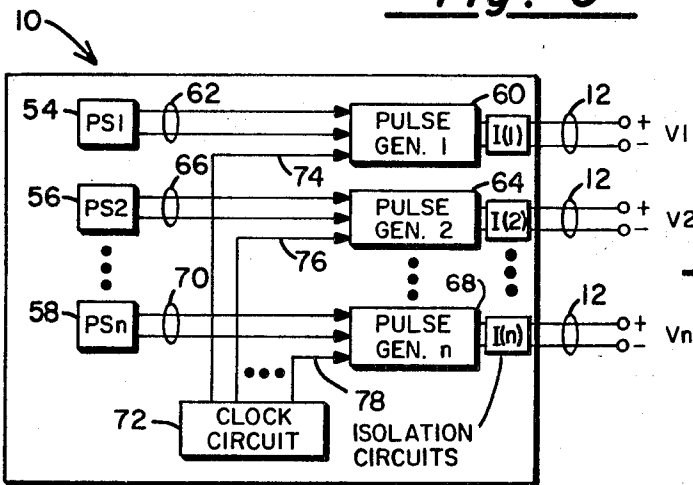


Fig. 7

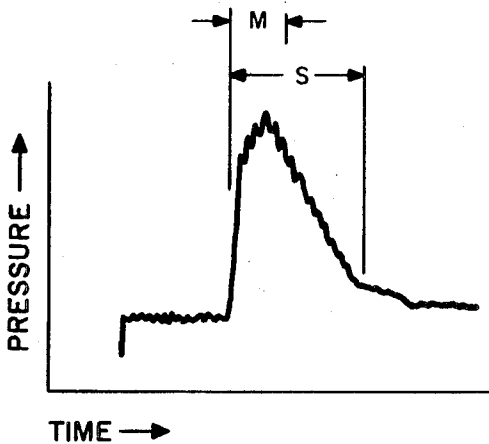


Fig. 8

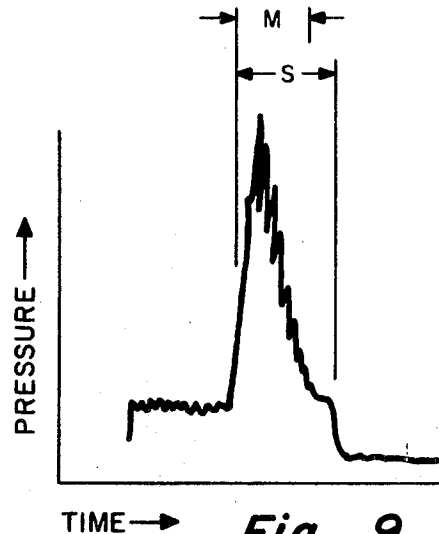


Fig. 9

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**IMPLANTABLE ELECTRONIC STIMULATOR
ELECTRODE AND METHOD**

The invention described herein was made in the course of work under a grant or award from the Department of Health, Education and Welfare.

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to apparatus and method for artificially and electrically stimulating masses of electrically excitable tissue. More specifically, this invention relates to an apparatus and method for electrically stimulating tissue in those persons who have lost the voluntary neural control of this excitable mass because of injury or disease, such as for example, loss of bladder function due to spinal cord injury.

2. Description of the Prior Art

Certain systems for artificially stimulating muscle activity are known to the prior art. One of the systems developed in the prior art is described in U.S. Pat. No. 3,236,240. The apparatus therein disclosed utilized spaced-apart electrodes to stimulate large areas of the bladder smooth muscle with volitionally generated electrical signals. It has been found that stimulation of such large areas usually results in stray electrical signals causing stimulation of nearby muscles and excitable tissue, an undesired secondary effect. In some instances, it has been determined that the stimulating signals cause a dual effect, the bladder muscle attempts to contract, as desired for evacuation thereof, but also the contraction of the external urethral sphincter takes place thereby inhibiting the evacuation of fluid from the bladder. Previous methods and apparatus of stimulating large tissue masses exhibit a disadvantage in that additive fields in the vicinity of the stimulated muscle can still occur owing to the parallel connection of multiple electrodes. That is, by the simultaneous application of a plurality of electrical fields resulting from the application of equal voltages to each of the electrodes, there will be generated at various points in the stimulated muscle, electrical fields that are greater than the individual fields resulting from each of the electrodes. Since the surrounding muscle tissue of concern often contains rapidly accommodating nerve fibers with low stimulus thresholds, these increases in field strength can be sufficient to cause undesired muscle fiber stimulation.

SUMMARY

In summary, then, this invention comprises a method and apparatus for locally stimulating masses of electrically excitable tissue in the presence of other excitable physiologic structures. Unless specific limitation is set forth, "muscle" will often be used generically to cover all masses of electrically excitable tissue structures. The apparatus developed includes circuitry for providing nonsimultaneous or sequentially timed electrical impulses to various portions of the excitable mass. A plurality of electrodes are electrically coupled to the mass, for instance the detrusor muscle of a urinary bladder, for providing electrical stimulation to the neural conducting system innervating the muscle in response to the application of electrical energy to individual ones of the electrodes. Clocking and gating circuits are used for controlling the time and sequence of application of electrical impulses to the electrodes in a manner such that only one electrode is energized at any given time. In order to maximize the effectiveness of the nonsimultaneous or sequentially timed electrical impulses, specially formed electrodes are utilized. These electrodes are bipolar in construction and are arranged to have a plurality of electrically conductive connection points for coupling to the muscle at a plurality of positions. Insulation is provided for electrically isolating the electrodes from contiguous muscle structures that might receive undesired stimulations.

Urinary sepsis secondary to neurogenic dysfunction associated with spinal cord trauma, has been recognized as a clinical problem. Further, it has been recognized that prolonged use of indwelling catheters in paraplegic patients produces significant bacteriuria, cystitis, vesical calculi, and

pyelonephritis. Bladder tonus, or the response of the 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 inflection 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. Further, various forms of implantable muscle or bladder stimulators have been described, as indicated by U.S. Pat. No. 3,236,240.

It is a primary object of this invention to provide a method and apparatus for providing electrode means, delivering electrical impulses to the electrode means extending over an adequate mass and at a sufficient depth in the mass of excitable tissue to activate the neural conduction system innervating the mass. Yet another object of this invention is to provide apparatus including electrode means, circuitry for providing nonsimultaneous electrical impulses to the electrode means electrically coupled to various portions of an excitable tissue structure. Still another object of this invention is to provide an implantable stimulator that utilizes a plurality of electrodes with the electrode being electrically coupled to the excitable tissue structure, for instance the detrusor muscle of the urinary bladder, for providing electrical stimulation to the neural conducting system innervating the structure, in response to the application of timed electrical energy impulses. Still another object of this invention, is to provide an implantable muscle stimulator apparatus having electrode means with circuitry including clocking and gating circuits being utilized for controlling the time and sequence of application of electrical impulses to a plurality of such electrodes in a manner such that only one electrode is energized at any given time. Still another object of this invention is to provide a practical method and means for artificially and electrically stimulating the bladder muscle 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 electrodes coupled to a radio frequency receiver with the electrodes attached at a plurality of points to the bladder muscle, capable of providing properly timed stimuli of the bladder muscle when used in conjunction with an external radiofrequency transmitter. Still another object of this invention is to provide a passive internal bladder muscle stimulator adapted to be implanted subcutaneously and being provided with electrodes which are electrically attached to the bladder muscle, wherein the stimulator derives its properly timed stimulation power for each of the electrodes from an external high-power radiofrequency transmitter. Yet a further object of this invention is to provide an implantable muscle stimulator that is so operated in a nonsimultaneous manner of activation of a plurality of electrodes, and is so insulated, that contiguous tissue structures to which the electrodes are coupled are not stimulated. Also, the stimulator provides nonsimultaneous impulses to a plurality of electrodes by way of output circuits electrically isolated and arranged so that current flow between the output circuits is prevented thereby preventing the generation of massive current fields between the electrodes. The foregoing and other more detailed and specific objectives will become apparent from the following detailed description of the invention 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 principle of the invention may be employed.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be described with reference to the drawings in which:

FIG. 1 is a perspective view of an internal implantable stimulator according to the present invention;

FIG. 2 illustrates the timed sequential application of electrical pulses to individual stimulator electrodes when, for example, $n=3$, or three output circuits are utilized;

FIG. 3 illustrates a type of bipolar electrode design utilizing two coils of conductor and having a plurality of electrical interconnection points;

FIG. 4 illustrates a characteristic placement of electrodes on a urinary bladder, with two electrodes near the lateral ligaments on the ventral surface and one electrode on the caudal-rostral midline of the dorsal surface;

FIG. 5 illustrates a method of electrically connecting an electrode into the depth of a muscle structure, and illustrates the insulating backing for providing electrical isolation of stimuli from contiguous excitable structures surrounding a muscle;

FIG. 6 is a schematic block circuit diagram of an implantable muscle stimulator deriving its stimulation power from an external power transmitter, and having clocking and pulse circuits for applying electrical impulses to only one electrode at a time;

FIG. 7 is an alternative embodiment of the invention, and is a schematic block circuit diagram of an implantable muscle stimulator utilizing a separate power source and pulse circuit for each bipolar electrode with isolating clock circuitry for determining the pulse application sequence so that only one electrode is energized at any instant of time;

FIG. 8 is a plot of a characteristic muscle pressure response derived from the simultaneous application of a plurality of electrical impulses; and

FIG. 9 is a characteristic plot of pressure response obtained from a muscle having a plurality of electrical impulses sequentially applied.

DESCRIPTION OF THE PREFERRED EMBODIMENT

As shown in FIG. 1, the implantable stimulator comprises a receiver, indicated generally at 10, and a plurality of bipolar electrodes 11 for attachment to the muscle. The electrodes 11 are connected to the receiver 10 by electrical conductors 12. The receiver 10 is encased in a protective mass 13, preferably sterilizable, inert, nonirritating and nontoxic protective material, for example composed of a synthetic resinous material. The conductors 12 are similarly encased in protective sheets 14, shown foreshortened to expose the conductive wires 12. The electrodes 11 are bipolar and receive voltage signals V_1 through V_n respectively. Each of the electrodes 11 is adapted for coupling to a pair of lines 12, with one of the lines 12 being designated + and others of the line 12 being designated -.

As summarized above, the invention embodies a method and apparatus for applying electrical stimuli to large masses of excitable muscle tissue without current spread to excitable tissue contiguous to the muscle to be stimulated. The stimuli are applied through the multiple bipolar electrodes 11 with the two poles of each electrode being electrically isolated from any of the poles of the other electrodes. In addition, the stimuli are developed in a manner whereby only one electrode has a voltage applied between its poles at any given time. In this regard, attention is directed to FIG. 2. There it can be seen that voltage pulses are applied to the bipolar electrodes in a non-simultaneous or ordered manner so that additive stimulus fields are prevented. In FIG. 2, voltage along the vertical axis is plotted versus time along the horizontal axis, with the time being expressed in groupings of milliseconds.

While it is intended that the implantable stimulator 10 will be utilized with various kinds of muscles, specific examples of pulsing rates have been developed for the detrusor muscle of a urinary bladder. In this regard, experiments show effective stimulus application rates for bladder muscles is between approximately 10 and 40 pulses per second with pulse durations between 0.5 and 5 milliseconds at each bipolar electrode 11, with voltage amplitude of up to about 50 volts. Stimulus rates up to 120 pulses per second with durations as short as 0.1 mil-

liseconds are found to be effective for intestine and other muscle stimulation. Of course it is readily apparent that different times and rates of pulse occurrence and sequencing for the turning on and off of pulses to the electrodes 11 are contemplated by this invention, when certain contractile sequences of acceptable tissue are desired. It should further be understood that the manner of coupling the electrodes 11 to the muscle structure is important, and that other durations d and different pulse spacings p will be required to achieve the desired contractile operation.

To facilitate the proper electrical coupling to the muscle, the electrode shown in FIG. 3 was developed. The bipolar electrode is referred to generally as 11, with the leads being designated 12+ and 12-. It has been determined electrode 11 of this design is especially efficient for providing a stimulus current over an adequate mass and at a sufficient depth in the detrusor muscle to activate the neural conduction system innervating it. The conductors 12+ and 12- are fashioned from flexible coils or wires of Platinum-Iridium (Pt-Ir) wire or other suitable implantable conductor such as carbon-impregnated cloth, etc. The conductors 12+ and 12- may be constructed from other metals such as tantalum, gold, silver, and alloys of these metals with other metals. As stated above, the receiver 10 components are encased or embedded in a sterilizable, inert, nonirritating and nontoxic protective insulating mass 13, preferably of a synthetic resinous material, with only the conductors 12 leading to the muscle stimulating electrodes 11 extending therefrom. These conductors 12 are insulated by encasing them in a similar synthetic resinous protective and insulating material, or by coating them with a similar substance. Substances which operate both for the stimulator 10 and the wires 12, with the desired insulating characteristics, are silicone rubber, silastic resins, tetrafluoroethylene polymers, vinyl chloride and the like, and are suitable materials for these purposes. Pure natural rubber may also be used. A first plurality of conductive tabs 16 may be electrically connected to the wire 12+, and a second plurality of tabs 18 may be electrically coupled to wire 12- for ease of connection. Each of the tabs contains an aperture for use in fastening the electrode 11 to the muscle. This will be described in more detail below. These tabs 16 and 18 are constructed of the same material as the conductors 12+ and 12-. The distances D_1 and D_2 can be varied and adjusted to accommodate different muscle sizes. It should be noted also that greater or fewer numbers of tabs 16 and 18 can be utilized both in parallel or in series with the conductors 12+ and 12-. Further, for any particular muscle stimulation, the number of tabs and electrical interconnections may vary among the various electrodes 11. It will be appreciated, of course, that a variety of electrode configurations may be successfully employed in connection with the present invention. For example, in lieu of the conductive tabs referred to hereinabove, various areas of electrical insulation may be bared from the conductor surface, and the electrodes effectively coupled to the tissue in this fashion. Also, in FIG. 3 of the drawings, a single electrode is illustrated, and it will be appreciated that two, three, or more electrodes may be utilized, and may be energized in sequential order, or may be energized as multiple pairs. In some instances, it may be desirable to utilize relatively large grid patterns which include a substantial number of individual electrode elements.

A characteristic placement when three electrodes 11 are used is illustrated in FIG. 4 on a bladder 20. In this arrangement, the electrode 11 supplied with energy source V_1 is applied at the caudal-rostral midline of the dorsal surface, shown in dashed line, and the two electrodes 11 energized by sources V_2 and V_3 , are placed near the lateral ligaments on the ventral surface. In this arrangement, it is noted that the number of attachment points can be varied to accommodate different sized bladders 20. In the configuration shown, the ventral electrodes each utilize six tabs, whereas the single dorsal electrode utilizes eight tabs. For this arrangement, bladders of approximately 150 to 300 cc. capacities can be accommodated. Additional electrodes 11 may also be added to stimulate larger bladders.

In FIG. 5 there is shown a sectional view of a portion of the bladder muscle 20, together with a portion of an electrode 11. Only the 12+ wire together with the 14+ insulation is shown. In this arrangement, there are three tabs 16, each having wires or thread 22 sewn through the apertures therein and for a predetermined depth into the muscle. In this arrangement, the wires 22 are metal sutures, and are inserted approximately 2 to 3 millimeters into the bladder wall and tied to the holes in tabs 16. This arrangement provides for electrical contact from the conductor 12+ into the detrusor muscle. The electrodes 11 so designed and attached were made of a flexible design to follow the contour of the bladder during micturition. The wires 22 can be of the same material as the electrode wires 12+ and 12-, or other suitable electrically conductive materials. Once the electrodes are sutured to the muscle, a thin sheet of insulating material, for instance, silastic, is placed over the electrodes to prevent stimulation of contiguous excitable structures. In FIG. 5, this insulation is represented in cross section as element 24, and characteristically, can be in the order of 0.005 inch in thickness.

Having considered the general operational system, and the application of electrodes to the muscles, attention will next be directed to FIG. 6 wherein there is shown a schematic block circuit diagram of an implantable muscle stimulator deriving its stimulation power from an external transmitter. The portion of the stimulator 10 shown enclosed within dashed block 30 includes a tuned resonant circuit 32, which characteristically can be comprised of an inductor and a capacitor in a parallel-connected resonant circuit. Such a circuit has the ability to store energy for short periods of time and tends to act as an energy reservoir. Further, the inductor of the tuned circuit 32 acts as an antenna, for picking up pulses of radiofrequency energy from an external high-power transmitter of conventional design (not shown), where such energy is transmitted through layers of body tissue to the tuned circuit 32. The tuned circuit 32 is coupled to a circuit identified as rectifiers and filters 34 as indicated by arrow 36. The signals provided by the tuned resonant circuit 32 are rectified into DC signals by filtering out the radiofrequency and the DC voltage so developed is applied at the output of the rectifiers and filters 34. In this invention, the signals are directed on lines 38 to clocking and pulse circuits 40 wherein the signals applied from lines 38 are converted to pulses and are alternatively applied to lines 42, 44, and 46 in substantially nonsimultaneous order. The signals provided on lines 38 are converted to pulses by means of pulse generators, or multivibrators, of types available commercially, and these pulses are applied to the bipolar electrodes 42, 44, and 46 for durations determined by the clocking circuitry. The clocking circuitry can be selected from various types of circuit components and arrangements well known in the prior art. Isolation elements I1, labeled 48; I2 labeled 50; and In labeled 52, are provided for isolating the electrodes electrically. Such isolation between electrodes can be provided for example by isolation transformers, or by simple diode arrangements for performing isolation as is well known. The signals from the isolation elements are taken directly to the electrodes with the wires being indicated by reference numeral 12, as previously used. It can be seen that the function of the clocking and pulse circuits 40 is to provide a planned application of signals to the isolation elements 48, 50, and 52 in a manner similar to that illustrated in FIG. 2. Only one of the bipolar lines 12 will carry signals at any given time.

An alternative embodiment is illustrated in FIG 7, wherein there is shown in schematic block diagram form an alternative implantable muscle stimulator 10. In this arrangement, a plurality of power sources indicated as PS1 labeled 54; PS2 labeled 56; and PSn labeled 58, is utilized, with a separate one of the power sources used for each of the bipolar electrodes 11. In this arrangement, there is utilized a plurality of pulse generators, with pulse generator 1, labeled 60, being coupled by line 62 to power source PS1. In a similar manner, pulse generator 2, labeled 64, is coupled by lines 66 to power source PS2. Finally, pulse generator n, labeled 68, is coupled by lines

70 to PSn. The output signals from the pulse generators 60, 64 and 68 are controlled by the clock circuit 72 respectively. A clock circuit 72 can be any well-known isolating clock circuitry, such as ring counters, or the like, used to determine the pulse enabling sequence to each of the electrodes. In this manner, the output line 74 from clock circuit 72 controls pulse generator 1, a signal on line 76 controls pulse generator 2, 7 and the signal on line 78 controls pulse generator n. The output signals from the pulse generators 60, 64 and 68 are applied on lines 12 in a nonsimultaneous arrangement as described above. It is readily apparent that the duration of the pulses occurring on lines 74, 76 and 78 determine the duration *d* of the power pulses in conjunction of the availability of energy signals on lines 62, 66 and 70, respectively. It is further apparent, that the time duration between occurrences of signals on lines 74, 76 and 78 will determine the elapsed time between the activating pulses available on lines 12. Further, the duration of the count in clock circuit 72 until it completes the cycle will determine the duration *d* between consecutive signals on any given line V1, V2, and Vn.

In FIG. 8 there is illustrated on characteristic pressure response curve for the situation wherein a muscle is stimulated by the simultaneous occurrence of three electrical signals. Application thereby indicating that only partial voiding of the bladder has occurred. In this figure, M denotes micturition.

FIG. 9 illustrates a characteristic pressure response obtained in a bladder wherein pulses were applied nonsimultaneously through three electrodes as described above. In this operation, it can be seen that the intravesical pressure rise upon stimulus S application led to a more complete bladder evacuation as indicated by a drop in residual pressure following the termination of the application of the stimulus S. Again, M denotes micturition.

Experimentation with the evacuation of the urinary bladder leads to the conclusion that it is necessary to select the appropriate application of electrical stimuli to effect a detrusor contraction leading to sequential opening of the sphincters. Pressure increases leading to sphincter opening are achieved in an optimum fashion when the stimuli are nonsimultaneously applied via electrically isolated bipolar electrodes to the detrusor muscle, while limiting the current spread to surrounding excitable structures below their stimulus threshold. In a specific example of the simultaneous stimulation of three electrodes, as illustrated characteristically in FIG. 8, experimental results yielded an intravesical pressure rise to approximately 33 centimeters of water, but with only 20 cc. of a 200 cc. bladder being voided. In the experimental operation, there was no visible sign of current field spread observed, but due to the poor voiding response, it is believed that there was current spread to the pudendal nerve, thereby forcing the external sphincter to contract. Further experimentation with the application of sequential stimulating pulses, with a characteristic response curve shown in FIG. 9, demonstrated that there was a sharp intravesical pressure increase followed by rapid evacuation of the entire capacity of the 200 cc. bladder with no sign of stimulus spread. In FIG. 9, the sharp peaks in the pressure response curve correspond to the pulsatile contractions of the bladder and forceful streams from the urethra.

As indicated above, evacuation of the urinary bladder requires appropriate application of the electrical stimuli to effect a detrusor contraction, leading to sequential opening of the sphincters. It has been determined that these contractile responses are obtained when pulses are applied at a rate of approximately 10-40 per second with durations of approximately 0.5 to 5 milliseconds and amplitudes up to about 50 volts. The foregoing mentioned experiments were conducted by applying bipolar pulses of 1-millisecond duration at a rate of 20 per second with an approximate amplitude of 30 volts.

Since relatively large current fields are generated when stimulating the detrusor muscle, a combination of insulating the electrodes from the contiguous muscle structures, together with the nonsimultaneous application of energizing signals to the electrodes from electrically isolated outputs has

been employed to restrict the spread of current fields to excitable structures surrounding the bladder. The nonsimultaneous application of pulses to the electrodes attached to the muscle causes less spread than simultaneous application of pulses thereto. This can clearly be understood by considering that the stimuli applied to each electrode are electrically independent and electrically isolated from one another. If a point in the muscle equidistant from the three electrodes is considered, the field generated at this point by each electrode is identical if the electrodes are the same and equal voltages are applied to them. Consequently, the application of pulses to the electrodes simultaneously results in a field at this point of approximately triple intensity, where three electrodes are used, while nonsimultaneous application gives a single field intensity occurring three times as often. Since the surrounding tissue of concern contains rapidly accommodating nerve fibers with low stimulus thresholds, the increase in frequency of stimulus application to these fibers does not greatly affect their function, but the lower current at this point helps the field of strength to remain below stimulus thresholds of the nerve fibers. If a point nonequidistant from the electrodes is considered, the contribution of each electrode to the current field will be different and the total field somewhat less than that described above. Sequencing results in decreases in the field at the point, with this decrease being realized when changing from simultaneous to nonsimultaneous stimulus application. A further decrease in the contribution of each electrode to a distant current field is realized by electrically insulating the electrodes from any contiguous tissue other than the muscle to be stimulated, with this insulation being accomplished by the placing of an insulating material between the attached electrodes and the contiguous structures. Further current field localization can be realized by electrically isolating the electrode poles so that no current can flow between them.

From the foregoing, it is clear that the various stated objectives and purposes of the invention have been achieved by the apparatus and method described. It is recognized that various alternations in dimensions, circuit component selections, tolerances, and timing, and the like, will become apparent to those skilled in the art without departing from the spirit and scope of the invention. Accordingly, what is intended to be protected by Letters Patent is set forth in the appended claims.

We claim:

1. Apparatus for stimulating a mass of electrically excitable tissue comprising:

- a. a plurality of electrically conductive electrode means for electrically coupling to a mass of electrically excitable tissue, said electrode means including a pair of electrically conductive wires, a first plurality of electrical interconnection elements electrically coupled to one of said pair of conductive wires, and a second plurality of electrical interconnection elements electrically coupled to the other of said pair of conductive wires, electrically conductive connection means for electrically interconnecting each of said interconnection elements with predetermined portions of the tissue to be stimulated, insulation means for insulating said pair of electrically conductive wires while leaving said first and second pluralities of interconnection elements exposed, and isolation means coupled to said plurality of conductors for electrically isolating each of said electrode means from the others of said electrode means;
- b. pulse-generating means for providing predetermined timed sequences of electrical pulses, said pulse-generating means including tuned circuit means for responding to radiofrequency signals for providing power signals; rectifier and filter means coupled to said tuned circuit means for providing direct current signals in response to said power signals; and
- c. control means coupled intermediate said plurality of electrodes and said pulse-generating means for controlling the time and sequence of application of said electrical

pulses to individual ones of said electrode means, said control means including clocking means for controlling said time and sequence of application of said electrical pulses to only one of said electrode means at any given time, and including pulse circuit means coupled to said rectifier and filter means for generating pulses in response to said direct current signals, a plurality of insulated electrical conductors electrically coupled intermediate said pulse circuit means and said plurality of electrically conductive electrode means for transmitting said pulses to said electrode means; said clocking means coupled to said pulse circuit means for controlling the sequence of said transmitting of said pulses to individual ones of said plurality of electrically conductive electrode means in a predetermined order.

2. Apparatus as in claim 1 and further including further insulation means for electrically insulating said plurality of electrode means from contiguous stimulatable tissue structures for inhibiting undesired stimulation thereof.

3. Apparatus for stimulating a mass of electrically excitable tissue comprising:

- a. a plurality of electrically conductive electrode means for electrically coupling to a mass of electrically excitable tissue;
- b. pulse-generating means for providing predetermined timed sequences of electrical pulses, said pulse generating means including a like plurality of power source means for generating sequences of signals, and a like plurality of pulse-generating means, each of said pulse-generating means electrically coupled to a respectively associated one of said plurality of power source means for providing said pulses to an associated one of said plurality of electrodes; and
- c. control means coupled intermediate said plurality of electrodes and said pulse-generating means for controlling the time and sequence of application of said electrical pulses to individual ones of said electrode means, said control means including clock circuit means coupled to said plurality of pulse-generating means for controlling said time and sequence of application of said pulses to only one of said electrode means at any given time, said clock circuit means including means for isolating each of said electrode means from the others of said electrode means.

4. Apparatus as in claim 3 wherein each of said electrode means includes a pair of electrically conductive wires, a first plurality of electrical interconnection elements electrically coupled to one of said pair of conductive wires, and a second plurality of electrical interconnection elements electrically coupled to the other of said pair of conductive wires, and insulation means for insulating said pair of electrically conductive wires while leaving said first and second pluralities of interconnection elements exposed.

5. Apparatus as in claim 4 and further including electrically conductive connection means for electrically interconnecting each of said interconnection elements with predetermined portions of the tissue to be stimulated.

6. Apparatus for stimulating a mass of electrically excitable tissue comprising:

- a. a plurality of electrically conductive electrode means for electrically coupling to a mass of electrically excitable tissue, said electrode means including a pair of electrically conductive wires, a first plurality of electrical interconnection elements electrically coupled to one of said pair of conductive wires, and a second plurality of electrical interconnection elements electrically coupled to the other of said pair of conductive wires, electrically conductive connection means for electrically interconnecting each of said interconnection elements with predetermined portions of the tissue to be stimulated, insulation means for insulating said pair of electrically conductive wires while leaving said first and second pluralities of interconnection elements exposed, and isolation means

coupled to said plurality of conductors for electrically isolating each of said electrode means from the others of said electrode means;

- b. pulse-generating means for providing predetermined timed sequences of electrical pulses, said pulse-generating means including tuned circuit means for responding to high-frequency signals for providing power signals; rectifier and filter means coupled to said tuned circuit means for providing direct current signals in response to said power signals; and
- c. control means coupled intermediate said plurality of electrodes and said pulse-generating means for controlling the time and sequence of application of said electrical pulses to individual ones of said electrode means, said control means including clocking means for controlling said time and sequence of application of said electrical pulses to only one of said electrode means at any given time, and including pulse circuit means coupled to said rectifier and filter means for generating pulses in response to said direct current signals, a plurality of insulated electrical conductors electrically coupled intermediate said pulse circuit means and said plurality of electrically conductive electrode means for transmitting said pulses to said electrode means; said clocking means coupled to said pulse circuit means for controlling the sequence of said transmitting of said pulses to individual ones of said plurality of electrically conductive electrode means.

7. The method of stimulating a mass of electrically excitable tissue while preventing undesired stimulation of contiguous tissue structures comprising the steps of:

- a. electrically affixing a set of spaced-apart electrodes to the mass of tissue to be stimulated, said step of affixing including the steps of:
 1. providing a plurality of electrical interconnection points on each of the electrodes;
 2. selecting predetermined points of contact; and

3. suturing with electrically conductive wire each of the electrical interconnection points to predetermined depths in the tissue to be stimulated for electrically coupling to the neural system innervating the tissue to be stimulated; and

b. generating pulses with a pulse source and applying the generated pulses to one electrode at a time in a predetermined sequence.

8. The method of claim 7 and further including the steps of:
a. implanting a controlled pulse source in the body; and

b. placing an insulating cover over the implanted pulse source and those portions of the electrodes other than said predetermined points of contact for further minimizing undesired stimulation of contiguous tissue structures.

9. A bipolar electrode for use with an implantable stimulator for stimulating electrically excitable tissue comprising:

a. a pair of electrically conductive wires for receiving bipolar pulses, one of said pair of electrically conductive wires being arranged in a predetermined serpentine pattern, and the other of said pair of electrically conductive wires being arranged in substantially a mirror image of said predetermined serpentine pattern and overlaps said one wire at a plurality of points;

b. a first plurality of spaced-apart electrical interconnection elements electrically coupled to one of said pair of conductive wires; a second plurality of spaced-apart electrical interconnection elements electrically coupled to the other of said pair of conductive wires; with individual ones of said first and second pluralities of interconnection elements paired and positioned at approximately the mid-points between associated ones of said plurality of overlap points; and

c. insulation means for insulating said pair of electrically conductive wires while leaving said first and second pluralities of interconnection elements exposed.

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