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[54] METHOD AND APPARATUS FOR CONTROLLING ANAL INCONTINENCE

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[52] **U.S. Cl.** **128/407,** 128/422, 307/291, 328/39, 331/111

[51] **Int. Cl.** **A61n 1/34**

[58] **Field of Search** 128/404, 407, 408, 419, 421, 128/422; 331/51, 111, 113; 307/261, 291; 328/35, 39

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[57] **ABSTRACT**

An electrostimulation probe comprising a suppository body formed with a rounded bulbous head, a reduced neck, and a broadened hilt, is inserted into the anus of a patient suffering from incontinence. The rounded bulbous tip and reduced neck facilitate anal insertion and subsequent retention. The rounded neck is clasped by the *sphincter rectalis*, and is provided with a pair of spaced electrical contacts which rest against the sphincter. The broadened hilt limits insertion of the suppository body, and has a substantially flat base so as to permit the patient to sit or lie down comfortably with the device inserted. A pair of electrical leads are connected respectively to the contacts, which are energized by a square wave signal having an average value of zero volts, a peak potential between 1 and 2 volts, and in the frequency range from about 18 to Hertz. 20 hertz. Such electrostimulation causes tonic and physiological contraction of the sphincter muscle, with significant results in the control of incontinence.

6 Claims, 6 Drawing Figures

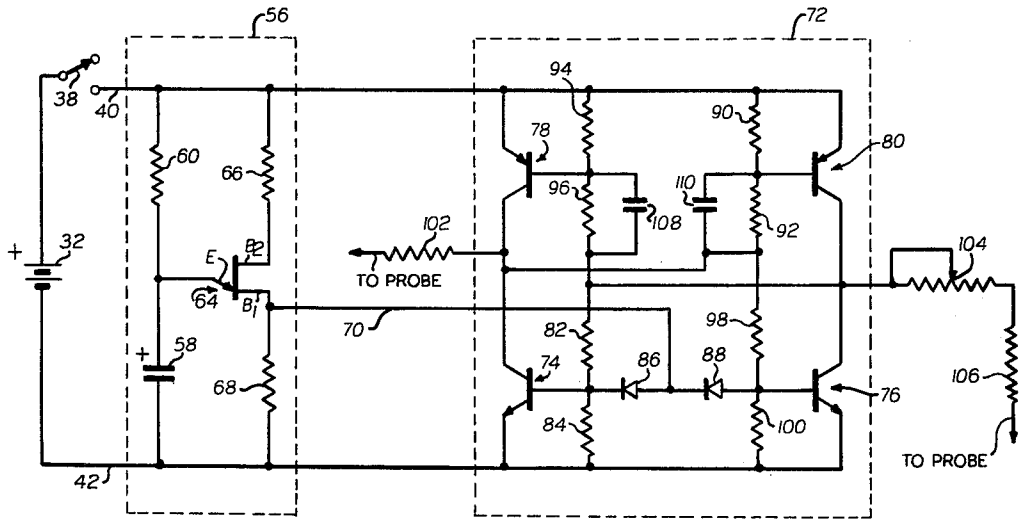


Fig. 1.

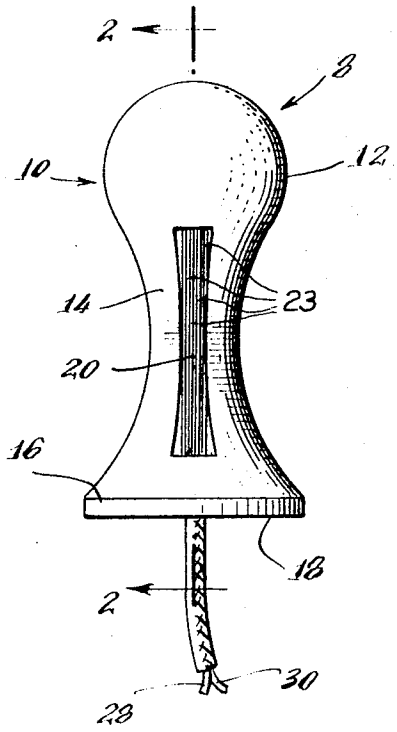


Fig. 2.

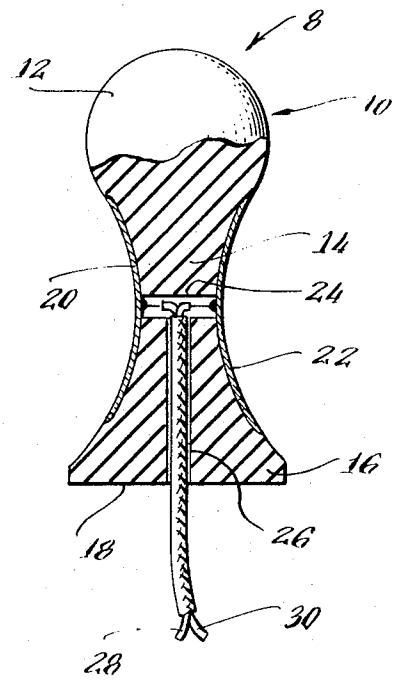
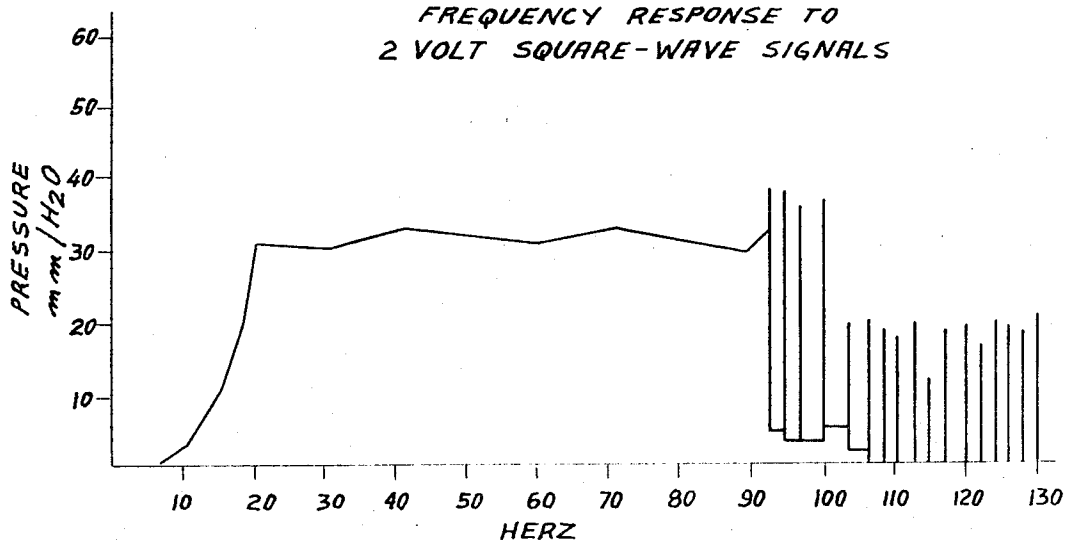
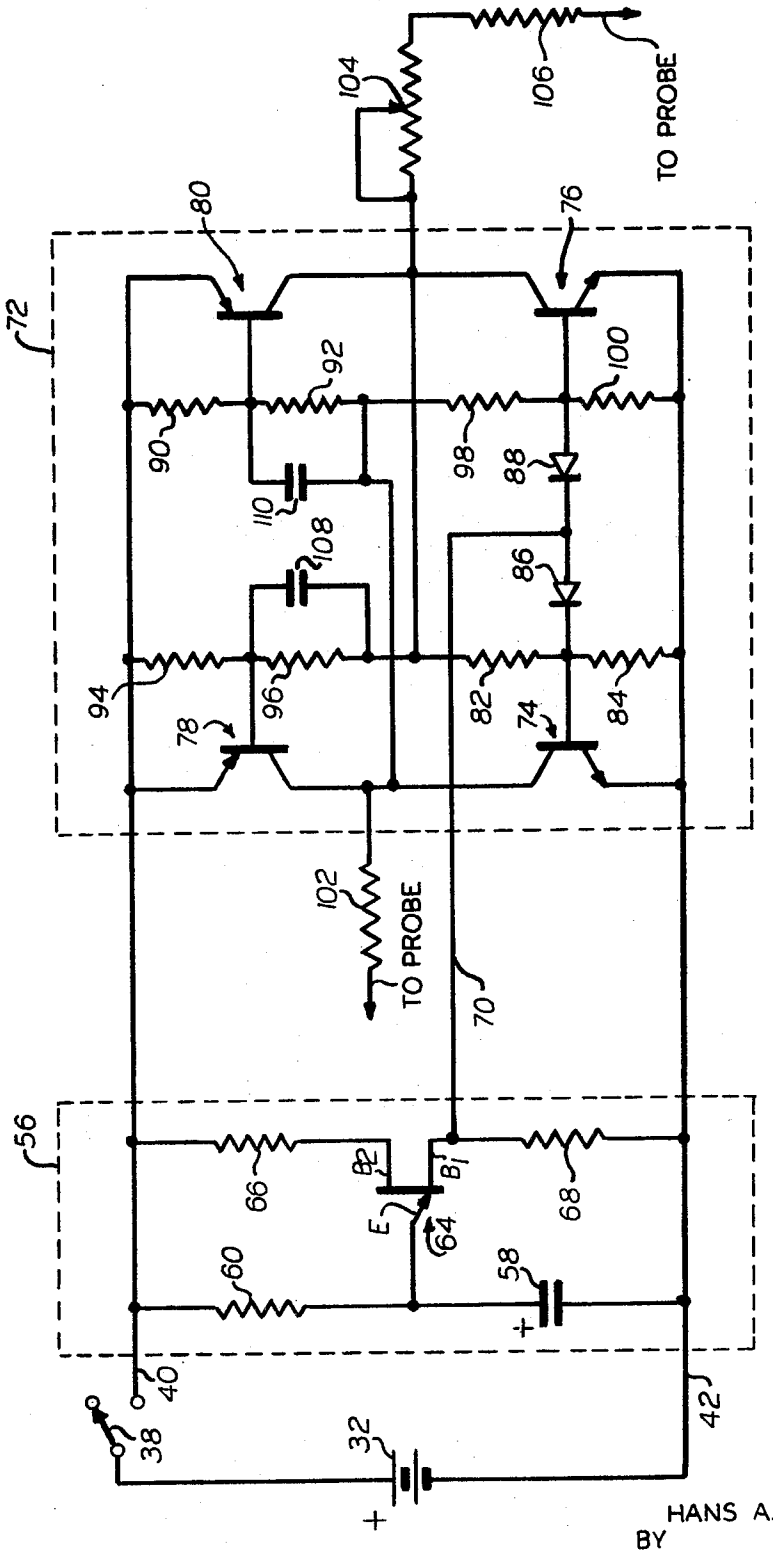


Fig. 6.



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FIG. 3.



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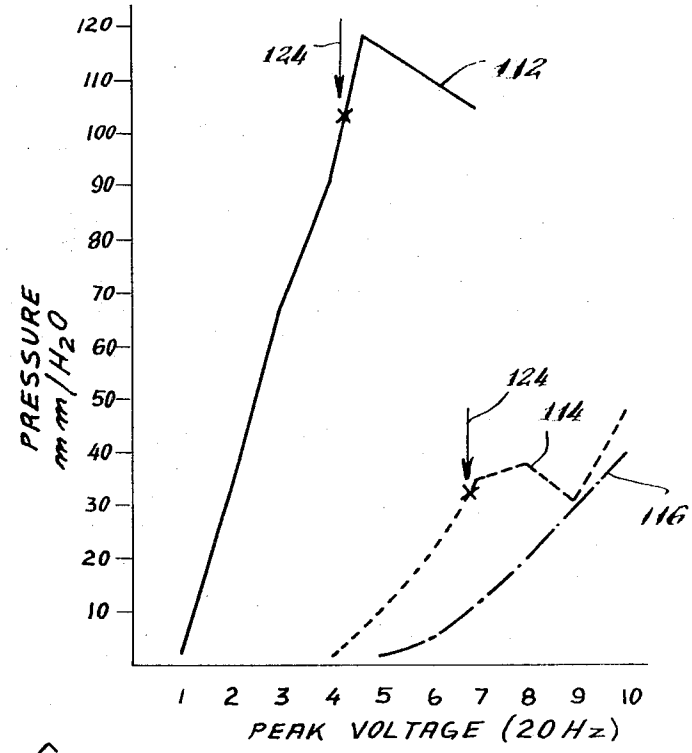


Fig. 4.
NORMAL RESPONSE

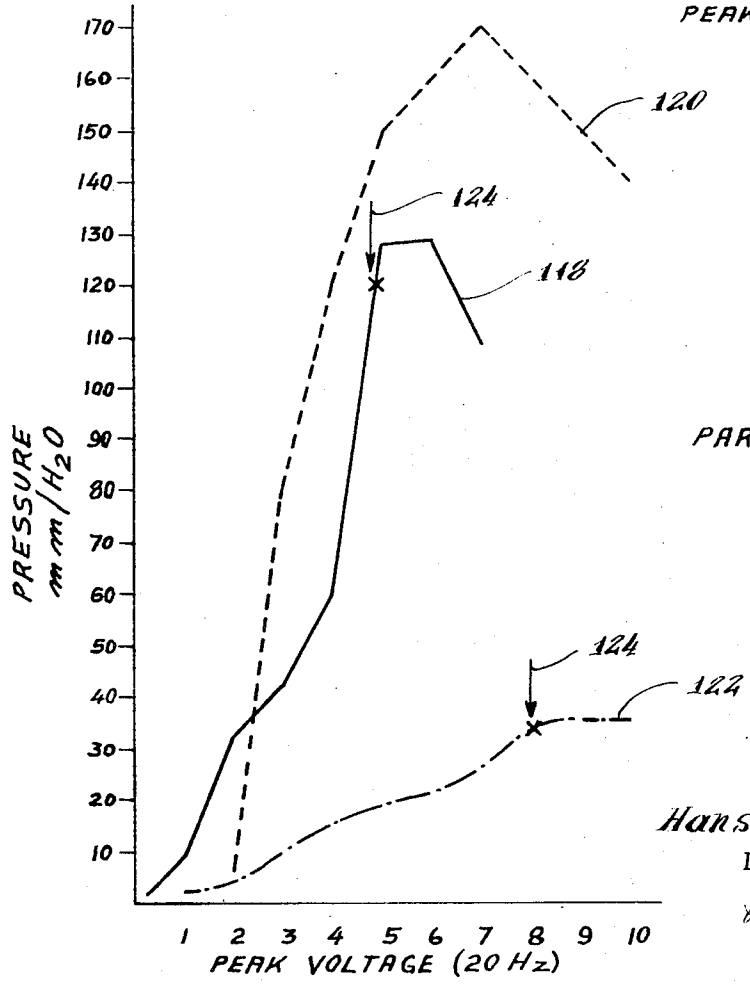


Fig. 5.
PARAPLEGIC RESPONSE

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METHOD AND APPARATUS FOR CONTROLLING ANAL INCONTINENCE

FIELD OF THE INVENTION

This invention relates generally to the area of prosthetic assistance, and particularly concerns the control of anal incontinence by electrical stimulation of the *sphincter rectalis*.

THE PRIOR ART

The general idea of electrical stimulation of muscle tissue has a long history, and recently has culminated in the impressive successes now achieved in the area of cardiac pacemaking. In other respects, however, electrical muscle stimulation is still largely experimental, and has not become an established therapeutic procedure.

Anal incontinence is a condition of considerable physical inconvenience and psychological embarrassment which afflicts some patients, generally as a result of neurogenic failure, or in some cases senile atrophy of the sphincter muscle. It is highly desirable that some way be found for controlling this condition.

In experiments with electrical stimulation of the *sphincter rectalis* to control this condition, it was discovered that the techniques employed in the area of cardiac pacemaking and other electrical muscle stimulation procedures are not applicable. Anal incontinence presents a distinct problem calling for a different kind of electrical muscle stimulation, if anal incontinence is to be controlled effectively by this means.

In cardiac pacemaking, repeated short contractions of the heart muscle are desired, followed by relatively long intervals of relaxation between contractions. In contrast, if *sphincter rectalis* stimulation is to control anal incontinence effectively, continuous contraction over a long period of time must be achieved. Obviously, even a single brief relaxation of the sphincter over a period of many hours could result in incontinence when the patient relies entirely upon the electrical stimulation.

SUMMARY AND OBJECTS OF THE INVENTION

Accordingly, the present invention is directed to controlling anal incontinence and eliminating its physical inconvenience and psychological embarrassment. The aim is to accomplish this by means of electrical stimulation of the *sphincter rectalis*, resulting in continuous tonic and physiological contraction of the sphincter muscle without lapses over long periods of time so as to achieve total continence.

At the same time, however, it is an object of the invention to accomplish these results with minimal amounts of electrical power, both for medical reasons and reasons of product design. The medical reasons involve the avoidance of injury to the adjacent tissue through electrical burns, as well as avoiding over-stimulation of the tissue with consequent loss of muscle contraction response.

So far as product design is concerned, it would be quite desirable to provide electrical stimulation apparatus for the control of anal incontinence which will operate for long periods of time on the energy available from a small battery power supply. This would make the apparatus completely portable, allowing the patient to live as normal a life as possible. This is another consideration which dictates a design aiming at minimal power consumption.

The present method for the control of anal incontinence comprises the steps of putting a pair of spaced electrodes against the *sphincter rectalis* and applying a signal across these electrodes which is effective to maintain the sphincter in a continuously contracted condition for the duration of the signal. In more specific terms, the signal is a voltage varying at a rate in the range from about 18 to about 90 Hertz, having an average potential of zero so as to avoid tissue polarization, and a substantially square waveform with a peak potential of not more than about 2 volts.

The apparatus for practicing this invention comprises a probe including a suppository body formed of a physiologically inert insulating material, and including a rounded bulbous tip adapted for insertion into and subsequent retention within the anus of the patient. A reduced neck is joined at one end to the bulbous tip, and a broadened hilt at the other end of the neck serves to limit anal insertion of the device. The reduced neck rests against the *sphincter rectalis* when the device is inserted, and has spaced-apart electrical contacts mounted thereon. These contacts are formed of a physiologically inert conductive material, and they serve to stimulate the sphincter electrically during use of the device. A pair of electrical leads is provided for the respective contacts, the leads coming out of the probe and being connected to the type of electrical drive described in the previous paragraph. Additionally, the broadened hilt of the suppository body has a substantially flat base to permit the patient to sit or lie down comfortably when the device is inserted.

BRIEF DESCRIPTION OF THE DRAWING

FIG. 1 is a side elevational view of a rectal probe according to the present invention.

FIG. 2 is a front view partly in section and partly in elevation of the same probe.

FIG. 3 is a schematic circuit diagram of the presently preferred electrical generator for energizing the electrodes of the probe.

FIG. 4 is a diagram showing the response of normal dogs to three different types of electrical stimulation of the *sphincter rectalis*.

FIG. 5 is a graph showing corresponding data in relation to dogs suffering from experimentally induced loss of *sphincter rectalis* function.

And FIG. 6 is a graph of *sphincter rectalis* response as a function of the electrical stimulation frequency.

The same reference characters refer to the same elements throughout the several views of the drawing.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The *sphincter rectalis* stimulation apparatus of this invention includes a rectal probe **8** of the type illustrated in FIGS. **1** and **2**. This probe comprises a suppository body **10** integrally molded of a physiologically inert material such as silicone rubber, medical grade, to avoid tissue necrosis. This material is available from the Dow Chemical Company under the trademark Elastomer. The suppository body **10**, which is inserted into the anus of the patient, is formed with a rounded bulbous tip **12** adapted for smooth insertion with a minimum of discomfort to the patient. The bulbous tip **12** tapers to a reduced neck **14**, which then widens out again to a broadened hilt **16**, terminating in a substantially flat base **18**. After anal insertion has been accomplished, the fact that the bulbous tip **12** has a larger diameter than the reduced neck **14** facilitates retention of the suppository body **10** by causing the body **10** to be cammed inwardly instead of being expelled in response to sphincter contraction. The broadened hilt **16**, which is also wider than the reduced neck **14**, serves to limit insertion of the suppository body **10** so that it is not intruded too far into the anal opening.

As a result, the body **10** comes to rest with the reduced neck **14** clasped by the *sphincter rectalis*, the bulbous tip **12** protruding into the rectum, and the broadened hilt **16** remaining outside the ans. When it is necessary to remove the probe **8**, the external portion **16** is thus readily accessible to facilitate withdrawal. As an additional feature of the suppository body **10**, the flat base **18** thereof permits the patient to sit or to lie down upon his back in relative comfort when the device is in use.

The probe **8** also includes a pair of electrodes **20** and **22** mounted on opposite sides of the reduced neck **14** for electrical stimulation of the *sphincter rectalis*. Each of these electrodes is a thin leaf of physiologically inert but electrically conductive material, such as gold, although stainless steel and

other relatively inert conductors may be used. Preferably, the leaves **20** and **22** are formed of a plurality of side-by-side wires **23** although satisfactory results can be obtained with thin continuous leaf material. The choice of silicone rubber as the material for the suppository body **10** is of course entirely compatible with the use of stainless steel for the contacts **20** and **22**, and in addition provides electrical insulation between the contacts. While there are a number of possible methods for securing the contacts **20** and **22** in place upon the suppository body **10** the presently preferred method is to form the contacts of thin leaves of gold which are bent to match the curvature of the reduced neck **14** and are then simply glued in place. Any method will do, however, if it results in contacts **20** and **22** which lie relatively flat against the surface of the reduced neck **14** so as to avoid injury to the patient upon insertion.

In order to provide individual electrical connections to the contacts **20** and **22**, the suppository body **10** may be provided with a hole **24** drilled transversely through the reduced neck **14**, and another hole **26** drilled longitudinally upward from the base **18** and intersecting the transverse hole **24**. A pair of leads **28** and **30** enter the longitudinal hole **26** from outside the base **18**, and extend upwardly through the length of the longitudinal hole to the transverse hole **24**. Then the leads **28** and **30** extend in opposite directions through the transverse hole **24** to reach their respective electrical contacts **20** and **22**, to which they are soldered. When mounting the electrical contacts **20** and **22** upon the suppository body **10**, the leads **28** and **30** can first be inserted into the holes **26** and **24**, and pulled sidewardly from the ends of the hole **24** so that a length of each lead protrudes from the reduced neck **14** to facilitate soldering to the associated contact. Afterwards, the leads **28** and **30** can be pulled back down through the longitudinal hole **26** while the contacts **20** and **22** are placed adjacent the reduced neck **14** and glued in place.

In order to enable workers in the field to practice this invention readily, it will be helpful to have some idea of the dimension of the rectal probe **8** which enable it to fit comfortably and functionally within the rectal opening of a patient. In a particular preferred embodiment, the overall length of the suppository body **10** from the base **18** to the tip of the rounded bulbous tip **12**, was about 3 inches. The measurement from the extremity of the rounded bulbous tip **12** to the thinnest portion of the reduced neck **14** was approximately 1⅞ inches. The maximum diameter of the tip **12** was approximately 1¼ inches, and the minimum diameter of the reduced neck **14** was approximately one-half inch. The maximum diameter of the broadened hilt **16** should be somewhat in excess of the maximum diameter of the rounded bulbous tip **12**. The contacts **20** and **22** were approximately one-quarter inch wide and 1½ inches long. They were so placed upon the reduced neck **14** that they extended to within about half an inch of the base **18**.

Best experimental results were achieved with an electrical signal of square wave shape applied across the contacts **20** and **22** by means of the leads **28** and **30**. One illustrative circuit which has been found to accomplish this successfully is illustrated in FIG. **3**. There it is seen that a battery **32** energizes a positive bus **40** and a negative bus **42** through an on-off switch **38**.

A conventional unijunction relaxation oscillator **56** energized from busses **38** and **42** serves to generate repetitive pulses for timing the square wave output signal. The time base is an RC circuit comprising a capacitor **58** charging through a series resistance **60**. The switching function for the relaxation oscillator is accomplished by a unijunction transistor **64**, the emitter E (switching electrode) of which is connected to the positive side of the timing capacitor **58**. Load current for the unijunction is drawn through a resistor **66** in series with base **B2** and a resistor **68** in series with base **B1**.

The relaxation oscillator operates in the following well known manner. Initially, the unijunction **64** is cut off, and the timing capacitor **58** charges through the resistance **60**. When the capacitor voltage reaches the threshold switching potential of the unijunction **64**, the unijunction turns on, and timing capacitor **58** then discharges through the emitter and base **1** of the unijunction and the resistor **68**. When the discharging process drops the unijunction emitter voltage below the cutoff level, the unijunction **64** ceases conducting and the charging cycle starts again. Since the value of the resistor **60** determines the RC timing constant, it determines the capacitor charging time, which in turn determines the pulse repetition rate.

The output of the unijunction relaxation oscillator **56** is a train of positive pulses developed across the load resistor **68** by the successive discharges of the timing capacitor **58** through the emitter-base **1** circuit of the unijunction **64**. This pulse train has good frequency stability, which is one of the characteristic advantages of unijunction time base circuits.

The unijunction output pulse train is applied over a lead **70** to a bistable circuit or flip-flop **72**. Each successive output pulse from the relaxation oscillator **56** reverses the state of the bistable circuit **72** in the following manner. The bistable circuit comprises two NPN-transistors **74** and **76**, and two PNP-transistors **78** and **80**. These are grouped into two diagonal pairs **74, 80** and **76, 78**, with each diagonal pair of transistors conducting simultaneously, and alternating conduction with the other diagonal pair. Assume that at a given moment transistor **80** is conducting. Its collector load current flows through a pair of resistors **82** and **84** which form a voltage divider. The potential at the center point of the voltage divider **82, 84** drives the base of transistor **74** high to make the latter transistor conduct at the same time that transistor **80** is conducting.

When the next output pulse from relaxation oscillator **56** appears on the lead **70**, it is applied through an isolating diode **86** to the base of transistor **74**, but has no effect on that transistor because it is already conducting. The same output pulse however is also applied through another isolating diode **88** to the base of transistor **76**, turning that transistor on. When this happens, the collector potential of transistor **80** drops due to the low impedance path presented by the now conducting transistor **76**, and as a result the positive base drive formerly transmitted to transistor **74** through resistor **82**, is now terminated, and as a result transistor **74** turns off. When transistor **74** turns off, it ceases to draw collector current through the voltage divider formed by resistors **90** and **92**. This removes the negative base drive from transistor **80**, which consequently also shuts off. At the same time, the collector current now drawn by transistor **76** traverses the voltage divider formed by the resistors **94** and **96**. The resulting negative base drive to the transistor **78** turns that transistor on. It will therefore be appreciated that the effect of the oscillator output pulse appearing on lead **70** and coming through the diode **88**, is to turn transistors **76** and **78** on, while cutting transistors **74** and **80** off. In effect, the flip-flop **72** is switched.

Thereafter, the flip-flop remains in the state to which it has been switched, because the collector current of transistor **78** flows through the voltage divider comprising resistors **98** and **100**, and the resulting voltage developed across resistor **100** provides the necessary positive base drive to transistor **76** to keep the latter in conduction. At the same time, the collector current of transistor **76** flows through the voltage divider comprising resistors **94** and **96**, so that the voltage developed across resistor **94** provides the necessary negative base drive to keep transistor **78** in conduction.

The next positive output pulse from the oscillator **56** appearing on lead **70** will switch the flip-flop **72** back again. This pulse passes through the diode **88** but has no effect on transistor **76** because the latter is already conducting. However the pulse, in passing through diode **86** as well, turns on transistor **74**. This in turn causes transistor **80** to turn on and transistors **76** and **78** to turn off. This state also is stable, continuing until the next oscillator pulse occurs. The process need not be described in detail because it is precisely the complement of the switching operation described above.

Since the bistable circuit **72** stays in each of its two conducting states until the occurrence of the next output pulse from

the relaxation oscillator **56**, the circuit **72** will spend equal time (on the average) in each of its two stable states, provided the consecutive output pulses from the oscillator **56** are evenly spaced (on the average). Since unijunction relaxation oscillators are noted for their frequency stability, this condition is met. As a result, over any substantial number of full cycles of operation, each state of the bistable circuit **72** will average out to substantially a 50 percent duty cycle. This is important, because it permits the average potential of the electrical stimulation applied to the *sphincter rectalis* to be zero. This avoids electrical polarization of the biological tissue, which would have quite undesirable effects as described subsequently. It should also be noted that the value of the resistor **60** determines the pulse repetition rate of the relaxation oscillator **56** so as to select the desired operating frequency, but does not affect the 50 percent duty cycle. The output pulses from the relaxation oscillator **56** can be closer together or further apart in time as determined by the value of the resistor **60**, but as long as they occur at a steady rate for any given resistance value, the interval between successive reversals of the bistable circuit **72** will be equal.

When the transistors **78** and **76** are conducting, output lead **30** is connected through a resistor **102** to the high collector potential of transistor **78**, while output lead **28** is connected through a potentiometer **104** and resistor **106** to the substantially lower potential developed across resistors **94** and **96** by the collector current of transistor **76**. Accordingly, in this state of the bistable circuit **72**, the output lead **30** is driven high and the output lead **28** is driven low. After the bistable circuit **72** is switched to its opposite state, transistors **74** and **80** are conducting and transistors **76** and **78** are cut off. At that time the polarities of the output leads **28** and **30** are reversed because lead **28** assumes the high collector potential of transistor **80**, while output lead **30** assumes the low potential developed across resistors **90** and **92** as a result of the collector current of transistor **74**. It will therefore be understood that the output on the leads **28** and **30** is a square wave synchronous with the switching frequency of the bistable circuit **72**. The output leads **28** and **30** of FIG. **3** are the same as the input leads **28** and **30** to the contacts **20** and **22** of FIGS. **1** and **2**. Accordingly, the square wave output of the circuit of FIG. **3** is the electrical drive used for stimulating the *sphincter rectalis* of the patient.

The potentiometer **104**, which is wired as a rheostat, serves to adjust the load current drawn by the body tissues of the patient. The circuit is designed to have an output impedance such that even under short circuit conditions, the load current is of the order of a couple of milliamperes; therefore it is obvious that the current actually drawn through the impedance represented by the body tissues of the patient will be substantially less, and therefore at a safe level. The resistors **106** and **102** are in series with the output, and contribute to the limiting of the output current. The capacitors **108** and **110** are included in the circuit to bypass base transients of the transistors **78** and **80** respectively.

While the circuits for the electrical generator of FIG. **3** are a matter of design choice, and the choice of parameters for and types of circuit elements in the illustrated electrical generator of FIG. **3** are within the ability of the skilled art worker, a highly desirable electrical generator in accordance with FIG. **3** has been employed in working the present invention using the following circuit parameters and element designations.

Circuit Element		Parameters or Designation
Battery	32	5.6 v.
Capacitor	58	47 Microfarad 35 v.
Resistor	60	68 Kohms ½ w.
Unijunction Transistor	64	2N4853
Resistor	66	680 ohms ½ w.
Resistor	68	82 ohms ½ w.
Transistor	74	MPF 6552
Transistor	76	MPF 6552
Transistor	78	2N 5087
Transistor	80	2N 5087
Resistor	82	47 Kohms ½ w.
Resistor	84	47 Kohms ½ w.
Diode	86	IN 914
Diode	88	IN 914
Resistor	90	47 Kohms ½ w.
Resistor	92	47 Kohms ½ w.
Resistor	94	47 kohms
Resistor	96	47 Kohms ½ w.
Resistor	98	47 Kohms ½ w.
Resistor	100	47 Kohms ½ w.
Resistor	102	270 ohms ½ w.
Potentiometer	104	Max R=5 Kohms
Resistor	106	270 ohms ½ w.
Capacitor	108	.02 microfarad 50 v.
Capacitor	110	.02 microfarad 50 v.

It will be understood that the above defined circuit elements are incorporated herein by way of illustration and not by way of limitation.

The therapeutic effect of the apparatus of FIGS. **1** through **3** is best described in terms of the experimental results actually obtained. Comparative studies have been performed on normal and paraplegic dogs, the normal group serving as a scientific control while the paraplegic dogs gave an indication of the ability of this invention to restore lost function of the *sphincter rectalis*. In the test group, paraplegia of the sphincter was experimentally induced by either of two methods, spinal anesthesia with xylocaine, or transsection of the spinal cord in the lumbar area. In both cases, fecal incontinence appeared quite promptly as a result, and this was thought to be analogous to naturally occurring neurogenic *sphincter rectalis* dysfunction.

An electrical stimulation device similar to that of FIGS. **1** aNd **2**, but proportioned to the experimental animals, was inserted into the rectal opening so that the *sphincter rectalis* clasped the reduced neck **14** thereof, thereby coming in contact with the spaced electrodes **20** and **22**. In other cases, the output electrodes used for the purpose of electrical stimulation were in the form of needles inserted directly into the sphincter muscle on opposite sides of the anus of the experimental animal. In the terminology used for the purposes of this patent application and the appended claims, any reference to an electrode placed "against" the *sphincter rectalis*, or similar terminology, should be understood to apply generically to both types of electrode placement, i.e., placement of the electrode in contact with the epidermis overlying the *sphincter rectalis*, as well as insertion of the electrodes through the epidermis and directly into the sphincter muscle itself.

Pressure changes within the anal canal of the experimental animals, just inside the *sphincter rectalis*, were monitored by insertion of a small rubber balloon filled with water and connected to a water manometer. In the first series of tests, the stimulation frequency was 20 Hertz throughout, and water pressure changes were plotted as a function of peak voltage for three different types of wave forms: low duty cycle pulses, sine wave, and square wave. FIG. **4** graphically illustrates the results obtained with normal dogs. Trace **112** shows that, for square wave energization, the water pressure obtained increased from a low value at an energization level of 1 volt peak, to over 115 millimeters of water at an energization potential of somewhat more than 5 volts peak. Trace **114** shows the corresponding results for sine wave stimulation as the peak voltage was varied. Trace **116** is the corresponding curve for a low duty cycle pulse wave form. The conclusion drawn from the graph of FIG. **4** is that with normal dogs, the square wave (trace **112**) gives maximum results with minimum power consumption and lowest peak voltage levels.

The results were somewhat different for the paraplegic dogs, as shown in the graph of FIG. **5**. The onset of reaction to stimulation with all three kinds of signals, the square wave signal represented by trace **118**, the sine wave signal represented by trace **120**, and the low duty cycle pulse wave form represented by trace **122**, occurred at a lower voltage level, and hence a lower power level. In addition, above 2 volts the trace **120** corresponding to the sine wave rises steeply and after a certain point exceeds the response represented by the

square wave trace **118**. This however does not necessarily lead to the conclusion that sine wave stimulation is superior.

In the treatment of fecal incontinence by means of electrostimulation of the *sphincter rectalis* muscle, the goal is to restore normal muscular contraction in order to close the anal opening in a physiological manner. In the course of the experiments performed on dogs, it was observed that the difference in anal canal pressure before and after the experimental induction of paraplegia, was only between 12 and 15 millimeters of water. (This value might be slightly greater in cases of chronic paraplegia, as a result of progressive atrophy of the sphincter muscle.) Since this is not a very great pressure difference, it is not necessary to produce a muscular contraction which would increase the anal pressure to the extreme values achieved by the sine wave trace **120** when the peak potential rises much above 2 volts. Moreover, such pressures would be unphysiological. For effective anal pressures not exceeding 35 millimeters of water, square wave stimulation (represented by trace **118**) allows for the lowest electrical power and voltage levels for a given pressure response. Since it is desirable to keep the electrical energy level as low as possible in order to avoid tissue damage or overstimulation and consequent fatigue of the muscle, it follows that a square wave output is the method of choice.

In fact the application of excessive electrical voltage and power levels resulted in clonic contractions, not only of the *sphincter rectalis* muscle, but over the entire perineal area, and extending into the extremities. The onset of such spasms is marked with *x's* and indicated by arrows **124** on the graph traces **112**, **114**, **118** and **122** (FIGS. **4** and **5**). Such contractions are of course undesirable in themselves, and in addition the graphs of FIGS. **4** and **5** show that after the onset of clonic contractions the degree of response to the applied stimulus had a tendency to fall off.

FIG. **6** demonstrates the variation of pressure response as a function of changes in frequency. As the graph of FIG. **6** shows, the response fell off rapidly below 18 Hertz, while at frequencies above 90 Hertz the response was short muscular twitches followed by intervals of relaxation, rather than the desired tonic contraction. At frequencies between 18 and 90 Hertz, the response was substantially uniform, and the results not greatly affected by the specific choice of frequency within that range.

Accordingly, it appears that the method of choice for the present purpose is electrical stimulation of the *sphincter rectalis* by means of a square wave having a peak potential not greater than about 10 volts and preferably between about 1 and 2 volts, and a frequency in the range from 18 to 90 Hertz.

It is important to note that one of the advantages of square wave stimulation is the fact that such a wave form has an average potential of zero. This avoids polarization of the muscle tissue to which the electrical stimulation is applied. If a direct current is conducted through muscle tissue and continued for upwards of about 4 minutes, the muscle becomes polarized and relaxes. Then a new contraction cannot be produced by the same method for an interval of about 10 minutes. The control of incontinence, however, requires constant muscular contraction over long periods of time. A gap of 10 minutes in the protection afforded by electrical stimulation can easily result in fecal incontinence, thereby defeating the purpose.

Moreover, it has been noted that a device constructed and used in the manner described controls urinary incontinence as well as anal incontinence. Thus with paraplegic patients who generally exhibit both anal and urinary incontinence, the use of the one device will control both conditions. Accordingly, when a patient using the device deenergizes it for the purposes of eliminating feces, he can expect simultaneous urination.

It will now be realized that the method and apparatus of the present invention provide significant advantages in the control of rectal incontinence and the obvious physical inconvenience and psychological embarrassment which such a condition entails.

Since the foregoing description and drawings are merely illustrative, the scope of protection of the invention has been more broadly stated in the following claims, and these should be liberally interpreted so as to obtain the benefit of all equivalents to which the invention is fairly entitled.

The invention claimed is:

1. The method of controlling anal incontinence due to failure of the *sphincter rectalis* function, comprising the steps of:

putting a pair of spaced electrodes against the *sphincter rectalis;*

applying an alternating signal having an average value of about zero across said spaced electrodes to contract said *sphincter rectalis*, and

maintaining said sphincter in a steady contracted condition by continuing to apply said signal to said electrodes.

2. The method of claim **1** wherein said signal is a voltage having a frequency rate in the range from about 18 to about 90 Hertz.

3. The method of claim **2** wherein said signal is substantially a square wave.

4. The method of claim **3** wherein the peak potential of said signal is not greater than about 10 volts.

5. The method of claim **3** wherein the peak potential of said signal is between about 1 and 2 volts.

6. In apparatus for use in controlling incontinence, a rectal probe including:

a suppository body formed of an insulating material and including a rounded bulbous tip adapted for insertion into and subsequent retention within the anus of a patient, a reduced neck joined at one end to said bulbous tip, and a broadened hilt joined to said reduced neck at the other end thereof to limit anal insertion of said suppository device so that said reduced neck rests against the *sphincter rectalis;*

and a pair of spaced-apart electrical contacts energizable by an external voltage source and secured to the external surface of said reduced neck whereby to rest against said *sphincter rectalis* during insertion;

a pair of electrical leads for connection to said external voltage source and connected to said contacts respectively for energization thereof; and

an electrical generator connected to said leads for energizing said contacts, said generator comprising:

a time base oscillator for producing a series of timing pulses;

and a bistable circuit arranged to switch between alternate states in response to successive ones of said timing pulses, and to apply a substantially square wave output to said leads as a result of said switching.

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