METHOD AND APPARATUS FOR CONTROLLING ANAL INCONTINENCE

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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. 3.

FREQUENCY RESPONSE TO 2 VOLT SQUARE-WAVE SIGNALS

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FIG. 3.
**Fig. 4.**

NORMAL RESPONSE

**Fig. 5.**

PARAPLEGIC RESPONSE

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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 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 15 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 anus. 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...
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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 con-

3,650,275 3 other relatively inert conductors may be used. Preferably, the leaves 20 and 22 are formed of a plurality of thin leaves of gold which are bent to match the cur-

ture 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 in-

sertion.

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 base 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 side-

wardly from the ends of the hole 24 to that a length of each lead protrudes from the reduced neck 14 to facilitate solder-

ing 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 dimen-

sion 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 1½ inches. The maximum diameter of the tip 12 was approximately 1 inch 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 max-

imum 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 illus-

trated in FIG. 3. There 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 ener-

gized from busses 38 and 48 serves to generate repetitive pul-

ses for timing the square wave output signal. The time base is an RC circuit comprising 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 82 and a resistor 68 in series with base 81.

The reset mechanism takes on 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 poten-
tial 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. With the discharging of 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 cir-

cuit comprises two NPN-transistors 74 and 76, and two NPN-

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 of transistors. Transistor 74 is the inverting transistor 80 is conducting. Its collector load current flows through a pair of resistors 82 and 84 which form a voltage di-

vider. 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 con-

ducting.

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 di-

vider 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 ap-

pearing 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. How-

ever 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, con-

tinuing until the next oscillator pulse occurs. The process need not be described in detail because it is precisely the comple-

ment of the switching operation described above.

Since the bistable circuit 72 stays in each of its two conduct-

ing 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 potentialmeter 104 and a 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 of 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.

<table>
<thead>
<tr>
<th>Circuit Element</th>
<th>Parameters or Designation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Battery</td>
<td>32 5.0 v.</td>
</tr>
<tr>
<td>Capacitor</td>
<td>58 47 Microfarad 35 v.</td>
</tr>
<tr>
<td>Resistor</td>
<td>60 68 Kohms 9/16</td>
</tr>
<tr>
<td>Unijunction</td>
<td></td>
</tr>
<tr>
<td>Transistor</td>
<td>64 2N 4455</td>
</tr>
<tr>
<td>Resistor</td>
<td>66 680 ohms 9/16</td>
</tr>
<tr>
<td>Resistor</td>
<td>68 82 ohms 9/16</td>
</tr>
<tr>
<td>Transistor</td>
<td>74 MF 6525</td>
</tr>
<tr>
<td>Transistor</td>
<td>76 MF 6525</td>
</tr>
<tr>
<td>Transistor</td>
<td>78 2N 5087</td>
</tr>
<tr>
<td>Transistor</td>
<td>80 2N 5087</td>
</tr>
</tbody>
</table>

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 xylcocaine, or transection 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 epithelium overlaying 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, the water pressure was 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 square 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 z'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 waveform 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.

* * * * *