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Garbe et al.

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[54] **APPARATUS AND METHOD FOR INCONTINENCE CONTROL**

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Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 859,136, Sept. 18, 1969, abandoned.

[30] **Foreign Application Priority Data**

Sept. 20, 1968 Great Britain 50930/68

[52] **U.S. Cl.** **128/408,** 128/421, 128/423

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

[58] **Field of Search** ..... 128/38 R, 404, 407, 405, 128/408, 421, 422, 423

[56] **References Cited**

UNITED STATES PATENTS

3,411,507	11/1968	Vingrove	128/422
539,501	5/1895	Boyd	128/407
3,650,275	3/1972	Von der Nozel	128/407
1,149,971	8/1915	Wagoner	128/407
870,927	11/1907	Boyd	128/407
3,025,858	3/1962	Browner	128/422

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[57] **ABSTRACT**

The apparatus is operable to control female urinary incontinence and includes an elongated, generally finger shaped insert which is made from an electrical insulating material, which is substantially rigid, which is sized to fit completely within a vagina and which is adapted to be worn completely within a vagina for an extended period of time. A pair of electrodes are spaced apart along the length of the insert and connections are provided for connecting the electrodes to a source of electric potential located within or without the insert. Each one of the electrodes is located on the periphery of the insert so as to be in position to contact internal surface areas of the vagina when the insert is placed therein for the purpose of applying an electric signal to surface areas for tetanizing relevant muscle tissue located within the body proximate vaginal surface areas located between the surface areas contacted by the electrodes.

The method includes the steps of inserting the insert completely within the vagina of an incontinent female and retaining the insert in the vagina for an extended period of time while simultaneously applying to the electrodes on the insert a signal which is defined by a plurality of pulses each having a peak voltage of up to 20 volts and a duration of from 10 to 300 microseconds. Preferably the pulses are generated at a frequency of from 25 to 200 pulses per second.

26 Claims, 3 Drawing Figures

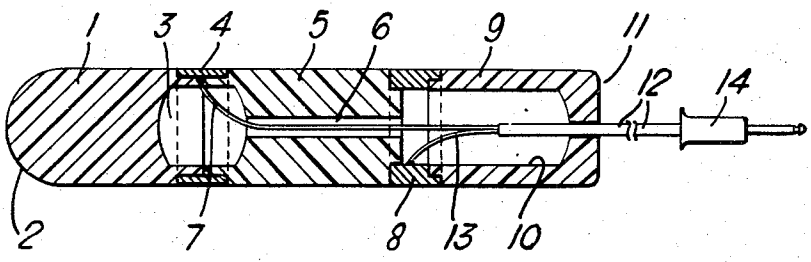

Fig. 1.

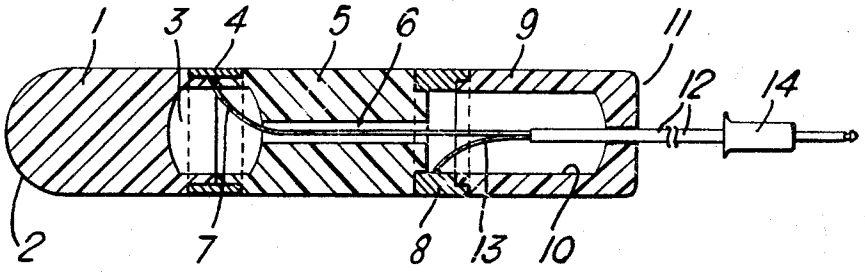

Fig. 2

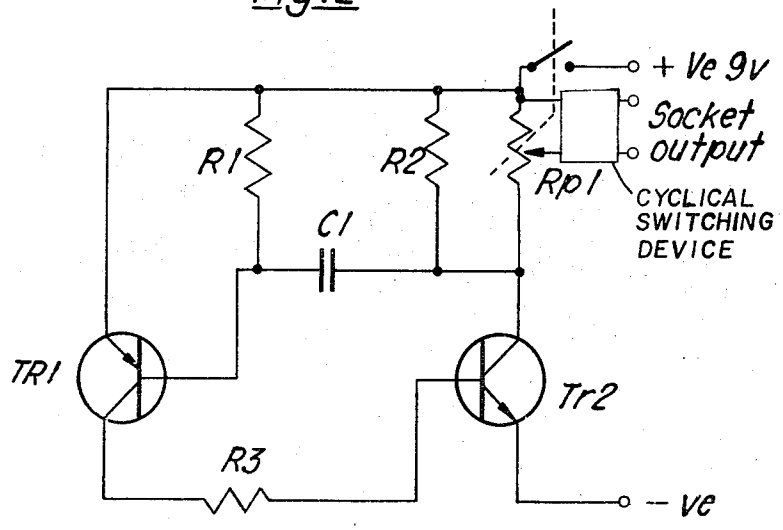

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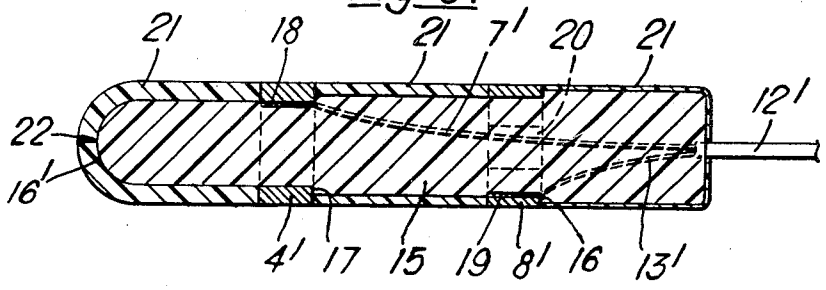
Fig. 3.



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APPARATUS AND METHOD FOR INCONTINENCE CONTROL

RELATED PATENT APPLICATION

This application is a continuation-in-part of our copending U.S. Pat. application Ser. No. 859,136 filed on Sept. 18, 1969 and now abandoned which claims priority from an application filed in Great Britain on Sept. 20, 1968.

BACKGROUND OF THE INVENTION

The present invention relates to an apparatus for controlling female urinary incontinence. The invention also relates to a method for controlling female urinary incontinence thereby to protect a bed, furniture or clothing against soilage by a female who is normally incontinent.

Heretofore it has been proposed to use a ring pessary or surgically implanted electrodes for applying an electric signal to vaginal surface areas for tetanizing relavant muscle tissue for controlling female urinary incontinence. The ring pessary, of course, could also serve as a support for the uterus. The apparatus of the present invention differs from a ring pessary in that it includes an elongated, generally finger shaped insert which is of simple design, which is easy to construct and which is easy to insert within a vagina. In this respect the insert of the present invention can be inserted by a patient whereas it is virtually impossible for most patients to employ a ring pessary without professional assistance.

Devices for tetanizing muscle tissue for controlling female urinary incontinence have been looked upon with suspicion since many of the prior devices were not adequately tested to make certain that they were truly efficacious in controlling female urinary incontinence. Moreover, electrical devices applied to the body are prone to cause injury in the longterm. From numerous tests and case histories it has been found that the insert of the present invention and a signal applied thereto having the parameter ranges to be described hereinafter are indeed efficacious in controlling female urinary incontinence.

Long ago, around the turn of the century (1900 A.D.) various devices for applying electric current to mucous cavities of the body were proposed. At the time these devices were proposed the effect of electricity upon the body was not fully understood. In this respect the devices proposed at that time were claimed to have a beneficial or vitalizing effect upon the "parts" presumably, the tissues through which the electrical current was passed. These antiquated devices included electrodes and circuitry for applying a direct current and in some cases an alternating current to the electrodes. However, these devices were not concerned with the control of female urinary incontinence. Moreover, medical practitioners today have serious doubts whether these antiquated devices had any beneficial effect at all. In this respect human experience, and suffering, has shown that the hypothesis underlying the presumed effect of many of these antiquated devices was based upon pure conjecture and on the hope that the mysterious force called electricity would have a beneficial effect on the mucous cavities (anal and vaginal cavities) of the body and the organs located therein.

Examples of electric devices of this type developed at the turn of the century are disclosed in the following U.S. Patents: No. 494,520 issued to B.Y. Boyd on Mar. 28, 1893; No. 527,788 issued to C.E. Hebard on Oct. 23, 1894; No. 563,387 issued to M.E. Keller on July 7, 1896; and No. 870,927 issued to B.Y. Boyd on Nov. 12, 1907.

In contrast to these previously proposed devices which were claimed to have some nebulous beneficial effect upon the anal or vaginal cavities of the body, the apparatus of the present invention is specifically adapted for controlling female urinary incontinence. Moreover according to the teachings of the present invention an elongated, generally finger shaped insert and an electrical signal having parameters falling within specific ranges to be described hereinafter are beneficially utilized in controlling female urinary incontinence. With respect to the latter, literature describing the previously proposed devices have not specified or defined the parameters of the electrical signals which were applied by these old devices to the mucous cavities of the body.

In addition to controlling female urinary incontinence the insert of the present invention also functions as a support for the vagina of the patient.

SUMMARY OF THE INVENTION

According to the invention there is provided an apparatus for controlling female urinary incontinence, the apparatus including an elongated, generally finger shaped insert which is made from an electrical insulating material, which is substantially rigid, which is sized to fit completely within a vagina and which is adapted to be worn completely within a vagina for an extended period of time. A pair of electrodes are spaced apart along the length of the insert and connections are provided for connecting the electrodes to a source of electrical potential. Each of the electrodes is located on the periphery of the insert so as to be in position in contact internal surface areas of the vagina when the insert is placed therein for the purpose of applying an electrical signal to the surface areas for tetanizing relevant muscle tissue located within the body proximate vaginal surface areas located between the surface areas contacted by the electrodes. Preferably the apparatus also includes a device for generating a signal which is applied to the electrodes and which is defined by a plurality of pulses each having a peak voltage of up to 20 volts and a duration of from 10 to 300 microseconds. Moreover the pulses are preferably generated at a frequency of from 25 to 200 pulses per second.

Also according to the invention there is provided a method for controlling female urinary incontinence including the steps of: inserting completely within the vagina of an incontinent female, an elongated finger shaped device having a pair of electrodes spaced apart along its length; retaining the device in the vagina for an extended period of time; and, simultaneously, applying to the electrodes a signal which is defined by a plurality of pulses each having a peak voltage of up to 20 volts and a duration of from 10 to 300 microseconds. Preferably, the pulses are generated at a frequency of from 25 to 200 pulses per second.

The peak voltage of the pulses is preferably varied to suit the requirement of the patient. For most patients a peak voltage of up to 9 volts is suitable. A generator giving a maximum of up to 10 volts is therefore employ-

able in the majority of cases and is preferred for standard equipment. Non-standard generators giving a higher peak voltage can be provided for special cases.

Preferably, the rise time of the pulses should be as short as conveniently possible in order to obtain the maximum effect for a given peak voltage, or in order that the peak voltage requirement of the patient is kept small.

Pulse frequencies in the upper part of the 25 to 200 per second range are especially advantageous in that they tend to suit a large proportion of patients. The pulse duration of the waveform is advantageously above 100 microseconds. The parameters of the waveform may all be made independently variable, but it is preferred in practice to have the recurrence frequency and pulse duration fixed at values chosen for the most clinically beneficial results, providing only for variation, preferably continuous variation, of the peak voltage.

Pulses which are of alternating polarity yield the best results, but for most patients it is satisfactory to provide pulses which are all of the same polarity as they are sufficiently effective and are obtainable by relatively simple circuitry. Discontinuous trains of pulses, e.g., for 20 seconds in every minute, are normally adequate and are attractive on grounds of power economy, especially where batteries are employed.

The insert which, preferably, is formed wholly of insulating material, conveniently a synthetic resinous material for example polymethylmethacrylate, polystyrene polyvinyl chloride or nylon, is preferably rigid but if desired may be made flexible or even inflatable. For hygienic reasons it may be provided in a disposable form and to achieve the requisite cheapness it may be formed of film or mesh. It may have any cross-section consistent with proper anatomical positioning of the electrodes, a circular cross-section being the most convenient. For ease of insertion and comfort in use, the insert is preferably provided with a rounded end.

The cross-sectional dimension of the insert preferably is at least 10 mm, a convenient dimension for general use being about 1.65 cm. For children, a dimension as low as 5 mm may be employed and for abnormal adults a dimension up to 30 or 40 mm may be appropriate.

The insert preferably is dimensioned to support the vagina against deformation by the pressure of adjacent organs, the aforesaid dimension of about 1.65 cm serving the purpose well in most women, and made sufficiently rigid for the purpose, e.g., by the use of a rigid insulating material or providing the insulating material with a rigid internal support.

Especially when the insert has a circular cross-section, the electrodes preferably totally encircle the insert. This is especially convenient for the pelvic muscles in the region of the urethra are then tetanized irrespective of the orientation of the insert with the vagina; obviously the spacing of the electrodes should be suitable for the required tetanization. The minimum spacing desirable for general use is 1 cm. It may be substantially greater up to the maximum permitted by the length of the insert which may be as long as 12 cm or as small as 3 or 4 cm. A length of from 5.5 to 8.5 cm is normally preferred, about 7 cm being most convenient. A convenient spacing is about 2.5 cm or about 35 percent of the length, whichever is the smaller. Electrode widths, measured in the length direction of the insert, of from 2 to 8 mm are suitable.

In one convenient construction, the insert is constructed of sections held together by the electrodes which may be flush with the surface or stand proud of the surface, e.g., by about one-sixteenth inch, for improved electrical contact. In another convenient construction at least one of the electrodes is provided by metal plated on to the plug. The metal is preferably a non-corrosive one to ensure durability and the continued maintenance of good electrical contact; for this reason the plated metal is advantageously a precious metal.

In a method of manufacturing the apparatus which is preferred because of its convenience, the electrodes are fitted in the form of rings over a core of insulating material and further insulating material is moulded over the core to locate the electrodes and provide the apparatus with a smooth surface. This method is superior to methods involving positioning the rings as inserts in a mould as a first step; in practice such methods tend to require the rings to stand proud of the insulating material. Moreover a single entry moulding technique is possible if the core is shaped to provide passageways under the rings, for example being provided with flats.

The invention includes within its scope a method of protecting a bed, furniture, or clothing against soilage by a normally incontinent patient, in which method the patient is treated as aforesaid.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a longitudinal cross-section of an insert forming part of the apparatus of the present invention;

FIG. 2 is a schematic circuit diagram of an electrical circuit for generating a desired electrical signal which is applied to the insert shown in FIG. 1; and

FIG. 3 is a longitudinal cross-section of a modified insert.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

In the apparatus of FIG. 1, which is of circular cross-section, a piece 1 of rigid synthetic resinous insulating material, for example polystyrene, nylon or polyvinyl chloride turned from a rod thereof or produced by moulding is rounded at one end 2 to a semispherical shape. At its opposite end the piece 1 is formed with a shallow bore 3 and reduced in its outer diameter to fit firmly within a metallic ring 4 which serves as an electrode. At the mid point of the axial length of the ring 4, the piece 1 meets one end of another piece 5 of the same material, the said end being shaped similarly to the adjacent end of piece 1. The piece 5 is formed with an axial bore 6 which accommodates an electrical lead 7 connected with the ring 4. At its opposite end, the piece 5 is reduced in diameter to fit within a metallic ring 8 which constitutes the second electrode. The ring 8, which is thicker than the ring 4, has its internal diameter enlarged at the side remote from the piece 5.

A third piece 9 formed with a wide bore 10, and having an end 11 which is closed except at its centre where it is apertured to grip tightly the sheathing of a twin cable 12, is shaped at its open end to fit tightly within the side of the ring 8 axially remote from the piece 5.

The two cores of the cable provide the lead **7** and a lead **13** which is connected to the ring **8.**

The free end of the cable is provided with a jack plug **14,** complementary to a pulse output socket of the pulse circuit of FIG. **2.** This circuit which follows principles well understood in the art of electronic pulse generation, gives an output of positive-going pulses of fixed pulse duration and repetition frequency within the limits hereinbefore indicated and a peak voltage output which is variable continuously from 0 to 9 volts by potentiometer Rpl. In practice this potentiometer is advantageously combined with an on/off switch. The circuit is very simple and may be encased in a small container together with a battery. It is suitable for the range of resistive loads normally encountered in practice, i.e., from 600 ohms up to several kilohms. A patient can readily conceal the casing within the clothing so that control of incontinence may be achieved together with ambulation.

In a typical case the apparatus of FIG. **1** has a diameter of about 15 mm, electrodes of axial length about 5 mm, a centre to centre spacing of about 26 mm between the electrodes and a distance of about 20 mm between the first electrode and the cable-entry end.

The modified apparatus shown in FIG. **3** is formed by fitting electrode rings of German silver **4'** and **8'** over a core **15** from hemispherically rounded end **16'**. The core, which is of circular cross-section throughout is stepped at **16** and **17** to give positive positioning of the rings. Both rings have the same external diameter but the internal diameter of the ring **8'** is greater than that of the ring **4'** so that the ring **8'** will pass over the step at **17.** Leads **7'** and **13'** from a cable **12'** are soft-soldered to the rings **4'** and **8'** respectively, before the rings are fitted over the core **15.** The core **15** is formed with flats at **18** and **19** at the positions where the leads join the electrode rings and a flat at **20** which enables the lead **7'** to pass under the electrode ring **8'**. The leads lie in contact with the core **15.**

Finally a coating **21** is applied over the core by injection moulding in a mould having an entry at the position of the arrow **22** to provide a final surface of cylindrical cross-section having a diameter equal to the external diameters of the rings **4'** and **8'** in which coating the leads **7'** and **13'** are embedded. During the moulding operation the moulding material flows under the rings at the position of the flats **18, 19** and **20** in a satisfactory manner. A multiple entry mould is unnecessary.

The coating and the core are preferably formed of the same thermoplastic material which is preferably chosen to mould to a smooth surface finish. An exceptionally smooth finish is obtainable using a high impact polystyrene containing an additive known in the trade as Butytine.

The overall length of the apparatus shown in FIG. **3** is 7.15 cm. The electrodes have an external diameter of 16.5 mm, an axial length of 4.8 mm and a spacing of 25 mm.

It is found that patients can show a very rapid response to treatment with apparatus as herein described. Successful results are obtained in a useful proportion of cases. It is found that a pulse circuit giving a peak voltage variable up to 5.5 volts, a pulse duration of 200 microseconds and a recurrence frequency of about 120 pulses per second is satisfactory for most patients. The voltage may be set by the patient to gain urinary control. If the voltage is too high the contraction of the perineal muscles can be painful.

Tests with over 1000 examples of the apparatus of the invention (pulse duration 200 microseconds, frequency 120 per second, and peak adjusted to up to 8.5 volts) have been carried out in the United Kingdom and several other countries, about 200 medical practitioners being involved. Included is controlled clinical work at 21 urological or gynaecological centres in England, Austria, Czechoslovakia, Germany, Netherlands, Jugoslavia and United States of America (three centres).

With any apparatus having electrodes for application to the human body, it is always necessary to consider the possibility of local tissue damage by electric currents. Electrolytic destruction of small areas of tissue is known to be possible even with a current as small as 300 microamperes DC applied continuously. Large areas of skin destruction have been reported with enuresis alarms which apply a 6 volt DC potential continuously. Accordingly, the practitioners concerned have been asked to search for any signs of damage by the apparatus and their reports have been negative, i.e., the apparatus is capable of producing the required muscular tetanization electrically without using hazardous electrical conditions. It appears that the brief duration of the applied pulses, the small mark to space ratios involved, and the natural fluid movements within the muscular and other tissues subjected to electrical currents by the particular electrode arrangement operate to allow migrating ions to recombine so that no unacceptably high concentration of any one ion can be built up.

Favorable reports have been obtained on the efficacy of the apparatus in the control of incontinence. In a typical series of 28 cases, the patients were instructed how to insert the plug and adjust the pulse generator to achieve urinary control. Continuous use was recommended, though it has been found that use whilst asleep at night is adequate, and more acceptable to some patients.

Of the 28 cases, 21 of which had varying degrees of cysotocele, rectocele and uterine prolapse, 23 were considered to be controlled or cured when reviewed after 2 or 3 months. One other improved for 6 weeks but then had a recurrence of her symptons and was treated surgically. In the remaining four cases there was no appreciable improvement.

Briefly, control was achieved in about 75 percent of the cases (23 in 28) by the simple use of the apparatus by the patient herself, i.e., without special nursing attendance or recourse to surgery.

The foregoing description of particular embodiments of the invention is given merely by way of illustration and various modifications which will occur to those skilled in the art may be adopted without departure from the ambit of the invention. This is especially true of the electrical circuit whose action can be obtained in a large variety of different ways.

We claim:

1. Apparatus for the control of female urinary incontinence, said apparatus comprising: an elongate, generally finger-shaped insert which is made from an electrical insulating material, which is substantially rigid, which is generally cylindrical and has a diameter ranging from 5 millimetres to 40 millimetres and a length ranging from 3 centimetres to 12 centimetres so as to

fit completely within a vagina and so as to support most vaginas against deformation by the pressure of adjacent organs, which is adapted to be worn completely within a vagina for an extended period of time and which has a pair of electrodes spaced apart along the length of said insert, means connected to said electrodes for generating a signal which is applied to said electrodes and which is defined by a plurality of pulses generated at a frequency of from 25 to 200 pulses per second, each pulse having a peak voltage of up to 20 volts and a duration of from 10 to 300 microseconds, and means for connecting said signal-generating means to a voltage source, each one of said electrodes being located on the periphery of said insert so as to be in position to contact internal surface areas of the vagina when the insert is placed therein for the purpose of applying said electric signal to said surface areas for tetanizing relevant muscle tissue located within the body proximate vaginal surface areas located between the surface areas contacted by said electrodes.

2. The apparatus as claimed in claim **1** wherein said electrodes are flush with the periphery of said insert.

3. The apparatus as claimed in claim **1** wherein said insert is generally cylindrical with a diameter of approximately 16.5 millimetres.

4. The apparatus as claimed in claim **1** wherein said length of said insert is between 5.5 centimetres and 8.5 centimetres.

5. The apparatus as claimed in claim **1** wherein said length of said insert is approximately 7 centimetres.

6. The apparatus as claimed in claim **1** wherein the spacing between said electrodes is equal to approximately 35 percent of the length of said insert.

7. The apparatus as claimed in claim **1** wherein the spacing between said electrodes is approximately 2.5 centimetres.

8. The apparatus as claimed in claim **1** wherein each one of said electrodes is generally ring-shaped and has a width between 2 millimetres and 8 millimetres.

9. The apparatus as claimed in claim **1** wherein said electrodes totally encircle said insert and said insert includes at least two sections held together by at least one of said electrodes.

10. The apparatus as claimed in claim **1** wherein said insert is rounded at one end to facilitate insertion thereof into and within a vagina.

11. The apparatus as claimed in claim **1** wherein said signal generating means generates positive pulses.

12. The apparatus as claimed in claim **1** wherein said signal generating means generates pulses with a peak voltage between 0 and 10 volts.

13. The apparatus as claimed in claim **1** wherein said signal generating means generates pulses with a peak voltage of approximately 5.5 volts positive.

14. The apparatus as claimed in claim **1** wherein said signal generating means generates pulses with a pulse duration between 100 and 300 microseconds.

15. The apparatus as claimed in claim **1** wherein said signal generating means generates pulses having a pulse duration of approximately 200 microseconds.

16. The apparatus as claimed in claim **1** wherein said signal generating means generates said pulses for a portion of a cycle of operation of said apparatus.

17. A method for controlling female urinary incontinence including the steps of: inserting completely within the vagina of an incontinent female, an elongate finger-shaped device having a pair of electrodes spaced apart along its length; retaining said device in said vagina for an extended period of time; and, simultaneously, applying to said electrodes a signal which is defined by a plurality of pulses generated at a frequency of from 25 to 200 pulses per second, each pulse having a peak voltage of up to 20 volts and a duration of from 10 to 300 microseconds.

18. The method as claimed in claim **17** wherein said pulses are positive pulses.

19. The method as claimed in claim **17** wherein said peak voltage is between 0 and 10 volts.

20. The method as claimed in claim **17** wherein said peak voltage is approximately 5.5 volts positive.

21. The method as claimed in claim **22** wherein said pulse duration is approximately 200 microseconds.

22. In an apparatus which is utilized for controlling female urinary incontinence and which includes means for generating a signal which is defined by a plurality of pulses generated at a frequency of from 25 to 200 pulses per second, each pulse having a peak voltage of up to 20 volts and a duration of from 10 to 300 microseconds, the improvement comprising, an elongate, generally finger-shaped insert which is substantially rigid which is generally cylindrical having a diameter ranging from 5 millimetres to 40 millimetres and a length ranging from 3 centimetres to 12 centimetres such that said insert is sized to fit completely within a vagina and sized to support most vaginas against deformation by the pressure of adjacent organs, which is adapted to be worn completely within a vagina for an extended period of time, which has a pair of electrodes spaced apart along the length of said insert, each one of said electrodes being located on the periphery of said insert so as to be in position to contact internal surface areas of the vagina when said insert is placed therein, and which has means for connecting said electrodes to said signal generating means.

23. The insert as claimed in claim **22** wherein the spacing between said electrodes is equal to approximately **35** percent of the length of said insert.

24. The insert as claimed in claim **22** wherein the spacing between said electrodes is approximately 2.5 centimetres.

25. The insert as claimed in claim **22** wherein said electrodes totally encircle said insert and said insert includes at least two sections held together by at least one of said electrodes.

26. The insert as claimed in claim **22** wherein said insert is rounded at one end to facilitate insertion thereof into and within a vagina.

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