United States Patent

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[54] APPARATUS FOR ELECTROTHERAPY OF THE PUBOCOCCYGEUS

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[52] **U.S. Cl.** .....**128/422**, 128/2 S, 128/408

[51] **Int. Cl.** **A61n 01/06**

[58] **Field of Search**.....128/2, 24.1, 24.4, 407, 408, 128/422

[56] **References Cited**

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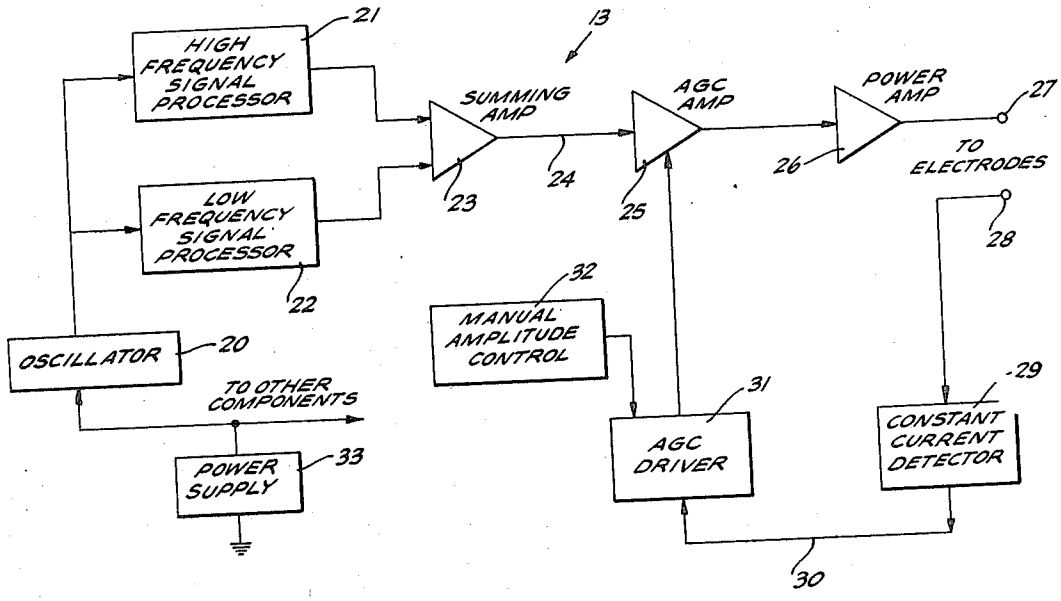
[57] **ABSTRACT**

Apparatus for electrotherapy of the pubococcygeus muscle group of a female. The apparatus includes an electrode member contoured for insertion into the vagina. Spaced electrodes on the member are supplied with a carrier signal comprising shaped, bipolar pulses in the frequency range of from 20 Hz. to 8 kHz., the signal being carrier modulated at a rate of between 0.2 Hz. and 10 Hz. The bipolar pulses exercise striated muscle, while the low-frequency modulation contracts smooth muscle and prevents continuous tetany. A condom-type vaginometer permits measurement of vaginal volume and of vaginal pressure resulting from contraction of pubococcygeus muscles.

4 Claims, 4 Drawing Figures



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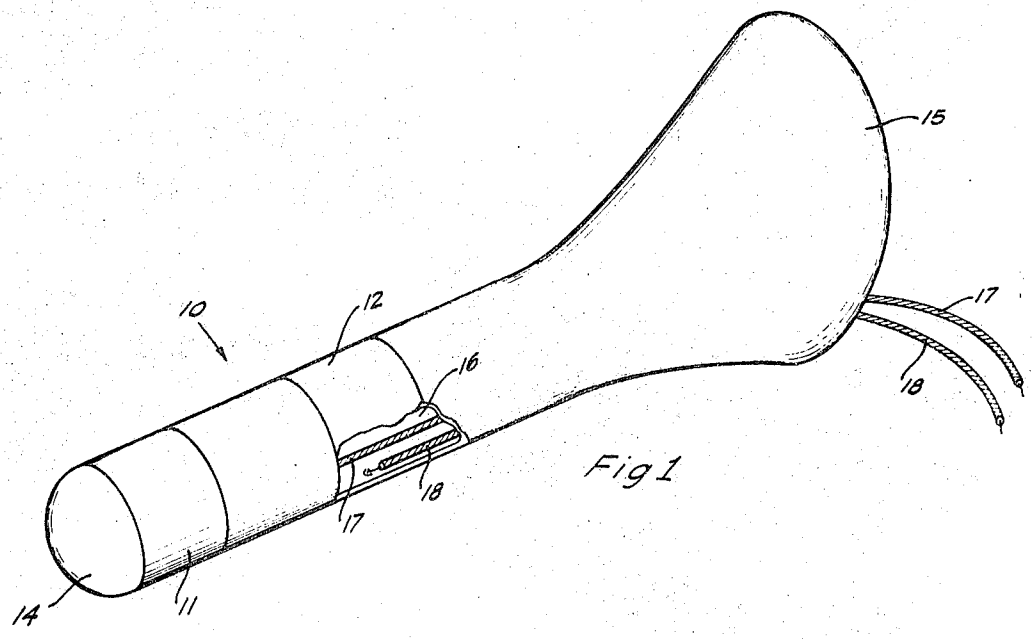

Fig 1

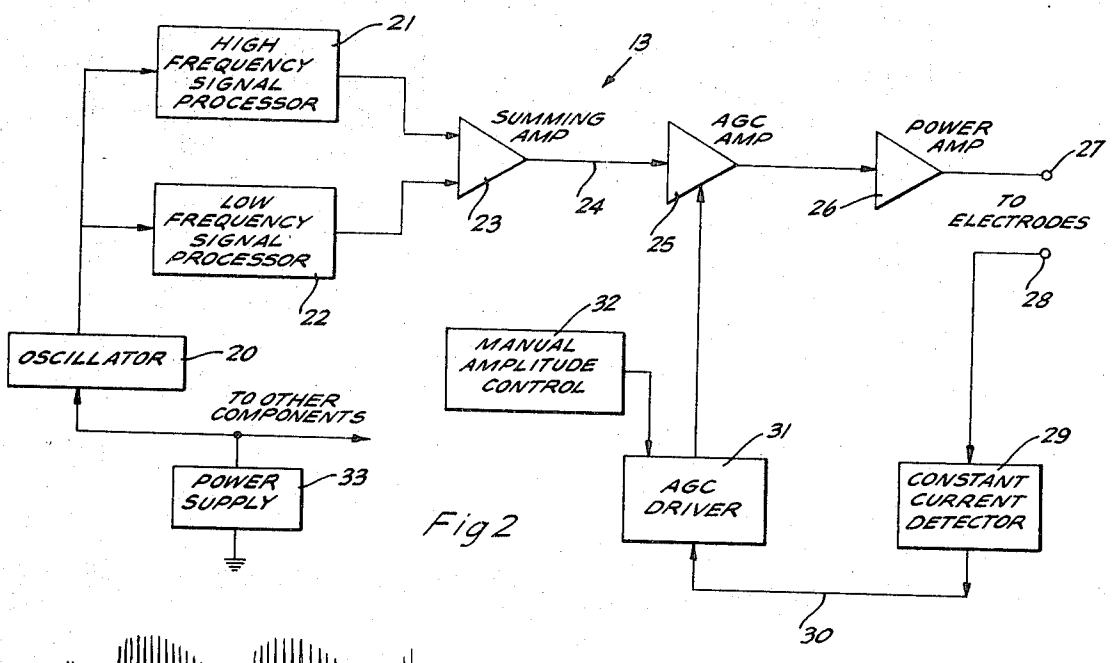

Fig 2

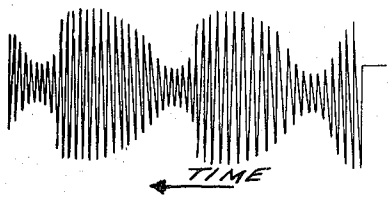

Fig 2a

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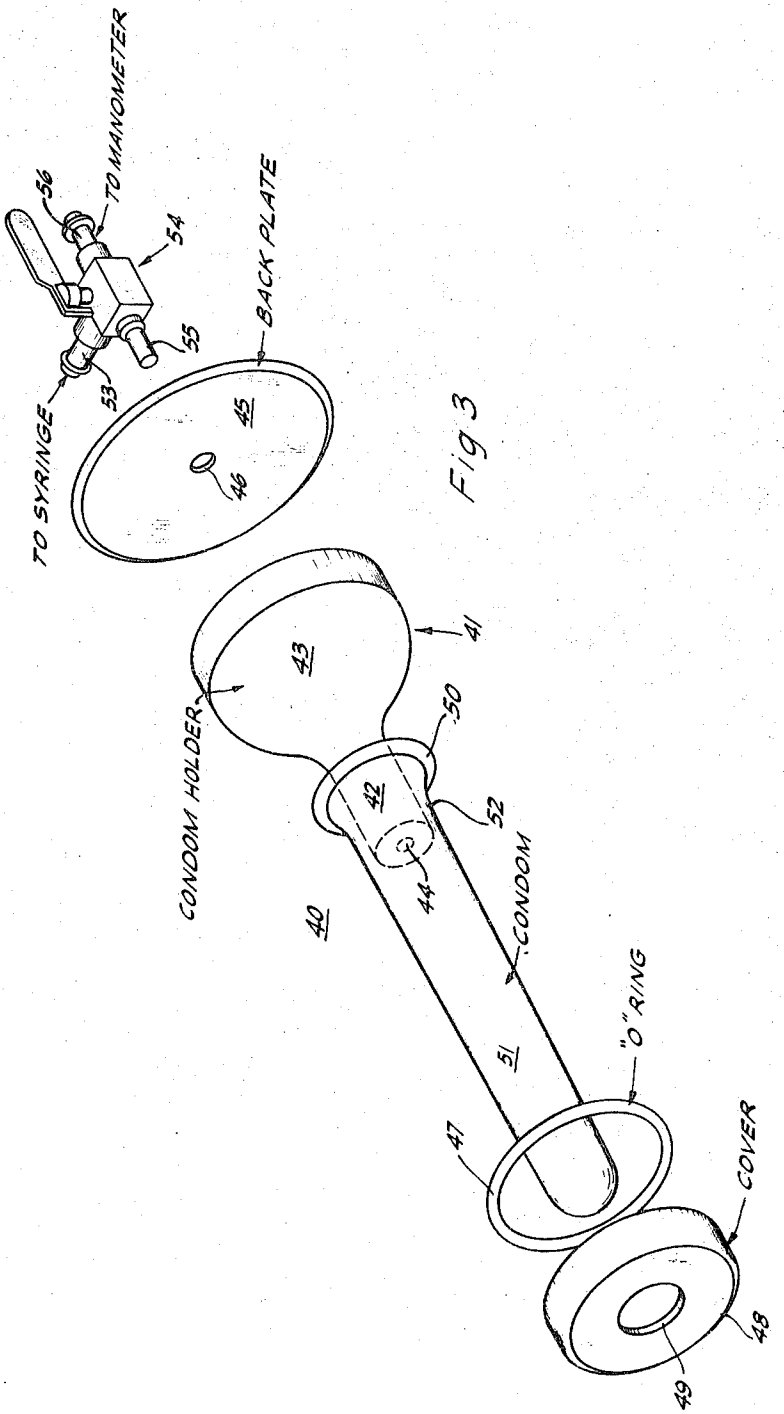

Fig 3

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APPARATUS FOR ELECTROTHERAPY OF THE PUBOCOCCYGEUS

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to an apparatus for electrotherapy of the pubococcygeus muscle group of a female, and to a vaginometer permitting measurement of vaginal volume and of vaginal pressure resulting from contraction of pelvic muscles.

2. Description of the Prior Art

Primary muscular support for the female urogenital area is provided by two muscle groups, the iliococcygeus and the pubococcygeus. If the pubococcygeus muscles are atonic or functioning inadequately, a number of urogenital anomalies such as urinary stress incontinence and uterine prolapse may result. Moreover, poor functioning of the pubococcygeus muscles is a significant cause of female frigidity or sexual inadequacy.

Proper adjustment to sexual relations by married persons is a significant element of happiness in marriage. Unsatisfactory adjustment can, and frequently does lead to unhappiness, to adverse affects on personality, and in many cases, to divorce. Therefore, it is important that married persons learn to perform their respective sexual roles as well as possible, and that physicians have the means available to assist them in doing so. To this end, awareness of the role played by the pubococcygeus muscles in female frigidity is of considerable importance.

In typical cases of apparent female frigidity, the strength of the pubococcygeus has been tested and the muscles found to be functioning at less than about 10 percent of their optimum. In the past, gynecologists have treated this problem by perscribing a series of exercises to be performed by the female to tone up the pubococcygeus muscles. These exercises included voluntary contraction of the muscles in the midpelvic area, and particularly of the muscles surrounding the middle one-third of the vagina. The result of such exercise was a very marked improvement in sexual appreciation and response of the female. Often patients reported that they were feeling more sexually, and many indicated that they were experiencing vaginal orgasms for the first time in their lives.

Similar marked improvement in other urogenital anomalies have been reported as a result of exercise of the pubococcygeus muscle. For example, women who experience urinary incontinence found that after a program of exercise of the pubococcygeus muscle they were able to control bladder release to a degree not previously possible.

Electrotherapy has been used extensively in the past to exercise muscles of various parts of the body in cases where natural muscle function has been lost or diminished. In such cases, the production of painless, graduated muscular exercise by electric stimulation reproduces the physical and chemical phenomenon connected with normal muscular work. But despite the widespread use of electrotherapy for other parts of the body, there have been virtually no reports of the application of such therapy to the female urogenital area.

SUMMARY OF THE INVENTION

In accordance with the present invention, there is provided an apparatus for electrotherapy of the female pubococcygeus muscle group. The apparatus includes an electrode member which is contoured for insertion into the vagina and by means of which a programmed electrical signal may be applied to cause exercise of both striated and smooth pubococcygeus muscles. Use of the inventive apparatus results in significant improvement in the tone, strength and functioning of the pubococcygeus muscles. Benefits of such use including significant reduction in female frigidity, relief from urinary incontinence difficulties and improvement of other urogenital anomalies.

The present electrotherapy apparatus includes electrical circuitry which provides a carrier signal comprising shaped bipolar pulses and having a carrier frequency in the range of from 20 Hz. to 8 kHz., the signal being carrier modulated at a rate of between 0.2 Hz. and 10 Hz. The bipolar pulses exercise striated muscles, and are shaped so that a relatively low-current initially is applied to the muscle, with a higher current being applied once the muscle has contracted. The low-frequency pulse modulation exercises smooth muscle and prevents continuous tetany.

To measure the condition and performance of the pubococcygeus muscle, there is also disclosed a novel condom-type vaginometer which permits measurement of the vaginal volume and of the pressure resulting from contraction of pubococcygeus muscles. The vaginometer comprises a generally cylindrical condom holder having a shank region over which the open end of a condom is stretched. An O-ring and an annular cover maintain the condom on the holder.

In use, the condom portion of the vaginometer is inserted in the vagina and filled with water via an axial opening through the condom holder. The vaginal volume may be measured by determining the amount of water required to fill the condom. By connecting a manometer to the vaginometer, the pressure resulting from contraction of pubococcygeus muscles may be measured directly.

Thus, it is an object of the present invention to provide apparatus for electrotherapy of the female pubococcygeus muscles.

Another object of the present invention is to provide an electrotherapy apparatus including an electrode member contoured for insertion into the vagina, and means for supplying a programmed electrical signal to the electrode member for exercise of muscles in the pelvic region.

It is another object of the present invention to provide an electrotherapy apparatus including circuitry to supply a carrier signal comprising shaped bipolar pulses of a relatively high frequency, the carrier signal being modulated at a relatively low frequency.

Yet another object of the present invention is to provide an apparatus for electrotherapy of the pubococcygeus muscle group and including means for exercising both striated and smooth muscle and for preventing continuous tetany.

Still another object of the present invention is to provide an apparatus for the electrotherapy of pubococcygeus muscles including means for applying a relatively low current to the muscles before they have contracted and a relatively larger current thereafter.

A further object of the present invention is to provide a novel vaginometer.

It is a further object of the present invention to provide a vaginometer of the condom-type, useful for measuring vaginal volume and vaginal pressure resulting from contraction of pubococcygeus muscles.

BRIEF DESCRIPTION OF THE DRAWINGS

Still other objects, features and attendant advantages of the present invention will become apparent to those skilled in the art from a description of the preferred embodiments constructed in accordance herewith, taken in conjunction with the accompanying drawings, wherein like numerals designate like parts in the several figures, and wherein:

FIG. 1 is a perspective view of an electrode member contoured for insertion into the vagina, and useful as part of the inventive apparatus for electrotherapy of the pubococcygeus muscle group;

FIG. 2 is an electrical block diagram showing typical circuitry useful for providing a programmed electrical signal to the electrode member of FIG. 1;

FIG. 2*a* graphically illustrates a typical waveform produced by the circuitry of FIG. 2; and

FIG. 3 is a perspective view of a novel condom-type vaginometer useful for measuring vaginal volume and vaginal pressure resulting from contraction of pubococcygeus muscles.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to the drawings, and particularly to FIGS. 1 and 2 thereof, there is shown a preferred embodiment of the inventive apparatus for electrotherapy of the pubococcygeus muscle group. In general, the apparatus comprises a generally tubular electrode member **10** (FIG. 1) which is contoured for insertion into the vagina. Member **10** includes a pair of longitudinally spaced, circumferential electrodes **11** and **12** to which is supplied a programmed electrical signal from the circuitry **13** of FIG. 2.

Referring in greater detail to FIG. 1, electrode member **10** includes a closed end **14** of generally hemispherical shape, and an open end **15** which is outwardly flared. Member **10** preferably is constructed of plastic or other smooth, electrically nonconductive material. Electrodes **11** and **12** are flush with the exterior surface of member **10**, and are positioned with electrode **11** adjacent end **14** and electrode **12** spaced approximately one-third of the way back toward end **15**. The interior **16** of tubular member **10** houses a pair of electrode wires **17** and **18** which are respectively connected to electrodes **11** and **12** interiorly thereof. Electrode wires **17** and **18** extend out through flared end **16**, and are connected to the electrical circuitry of FIG. 2, as described below.

For effective electrotherapy of the pubococcygeus muscle group, it is desirable to supply to electrodes **11** and **12** a signal having both high-frequency and low-frequency components. Illustrative circuitry for providing such a signal is shown in FIG. 2. Referring thereto, circuitry **13** includes an oscillator **20** having a frequency in the range of from 20 Hz. to 8 kHz., and preferably in the range of from 150 Hz. to 1 kHz. Bipolar output pulses from oscillator **20** are shaped by a high-frequency signal processor **21**, typically a passive filter network, which provides a gradual rise time to each pulse. As will be described below, this shaping is desirable to provide initially low current to the striated muscles of the pubococcygeus, followed by a relatively higher current once these muscles have contracted. The output of oscillator **20** also is shaped by a low-frequency signal processor **22** which in effect introduces a low-frequency carrier modulation in the frequency range of from 0.2 to 10 Hz., and preferably in the range of from 0.5 to 1 Hz.

The shaped and modulated signals from processors **21** and **22** are combined in a conventional summing amplifier **23** to provide on a line **24** a carrier signal comprising shaped bipolar pulses and having a frequency in the range of from 20 Hz. to 8 kHz., the carrier signal being modulated at a low frequency in the range of from 0.2 to 10 Hz. This signal on line **24** is amplified by an automatic gain control (AGC) amplifier **25** and by a power amplifier **26**, and the amplified signal provided via a terminal **27** to one of electrodes **11** and **12** of member **10**. The other of electrodes **11** and **12** is connected to a terminal **28** associated with a constant current detector **29**.

The average current flowing between electrodes **11** and **12** is sensed by constant current detector **29** which provides along a line **30** a signal indicative of the sensed current level. The signal on line **30** is supplied to an automatic gain control (AGC) driver **31** which in turn controls the gain of AGC amplifier **25** in a manner so as to maintain the average current between electrodes **11** and **12** at a generally constant level. A manual amplitude control **32** associated with AGC driver **31** permits operator selection of the average current level provided to electrode member **10**. Preferably, average current levels below about **250** milliamperes may be employed. A power supply **33** provides DC power to operate oscillator **20** and the other components of circuitry **13**.

The circuitry of FIG. 2 is illustrative only, and other electronics may be used to produce the programmed electrical signal to electrode member **10**. However, the excitation signal provided to electrodes **11** and **12** should include both high-frequency and low-frequency components. The reason for this is that the pelvic area muscle group includes both striated and smooth muscle, both of which must be considered in any process of pelvic rehabilitation. Experiments have proved that effective, painless vaginal muscle stimulation requires bipolar pulses of relatively high frequency (20 Hz. to 8 kHz.) to contract striated muscle and relatively low frequency (0.2 to 10 Hz.) bipolar pulses to contract the smooth muscle. The optimum frequencies for these bipolar pulses vary somewhat from patient to patient, but generally are in the range of from 150 Hz. to 1 kHz. for the high-frequency component and from 0.5 to 1 Hz. for the low-frequency component. As mentioned hereinabove, the low-frequency component may be introduced by carrier modulating a high-frequency signal comprising bipolar pulses.

The wave shape of the bipolar pulses comprising the relatively high-frequency component of the excitation signal to electrode member **10** is not critical. In fact, both sine wave and square wave signals have been found to work effectively. However, for optimum exercise of striated muscle, it is desirable that the pulses be shaped to provide an initially low current, followed by a considerably higher current as the muscle starts to contract. Similarly, the shape of the low-frequency carrier modulation is not critical. However, a relatively slow rise time again is desirable to provide an initially low current to the smooth muscles, followed by a higher current when these muscles begin to contract. FIG. 2*a* shows a typical signal produces by the circuit of FIG. 2; the shape of the low-frequency modulation is clearly evident. However, signals having waveshapes other than that illustrated in FIG. 2*a* may be used effectively with the inventive apparatus.

The low-frequency component of the excitation signal, in addition to causing contraction of smooth muscle, also functions to avoid continuous tetany of the striated muscles. This is desirable, since if the striated muscle were continuously contracted by the high-frequency component, the muscle would tend to accommodate or relax, and little or no effective exercise of the striated muscle would result despite continued application of the bipolar pulses. By interrupting or modulating the high frequency carrier at a low-frequency rate, such continuous tetany is avoided, and the striated muscle has no chance to accommodate or relax.

The shaping of the high- and low-frequency signal components also serves the function of eliminating very high-frequency components (in excess of several thousand Hz.) which develop heat within the tissue and/or stimulate the pain receptors. This insures that the electrotherapy will be painless to the patient. Moreover, the low-frequency component allows use of the present apparatus on both innervated and denervated muscles.

In operation, electrode member **10** is inserted into the vagina of the patient, possibly using a lubricant such as water. Electrode wires **17** and **18** are connected to terminals **27** and **28** of circuitry **13** (FIG. 2), and the manual amplitude control **32** is given to the patient. The patient increases the amplitude of the excitation signal from circuitry **13** to a point where pubococcygeus muscle contractions occur. Because of accommodation, the patient typically will increase the amplitude of the excitation signal from time to time during the treatment. Optimum muscle exercise was found to occur when electrodes **11** and **12** were positioned over the motor points of the pubococcygeus.

Significant improvement in the tone, strength and functioning of the pubococcygeus muscle group was found to result from regular use of the inventive electrotherapy apparatus. To facilitate actual quantitative measurement of this improvement, the vaginometer of FIG. 3 was developed. This device permits measurement of the vaginal volume and also of the vaginal pressure resulting when the pubococcygeus muscles are contracted.

Referring to FIG. 3, vaginomenter **40** comprises a generally cylindrical condom holder **41** having a vaginal shank region **42** of relatively small diameter and a flared body region **43** of relatively larger diameter. An axial opening **44** extends through condom holder **41**. Attached rearwardly of condom holder **41** is a disc-shaped back plater **45** having a central opening **46**. Vaginometer **40** also includes an O-ring **47** and an

annular cover 48 of plastic, hard rubber or the like. The diameter of central opening 49 in cover 48 is slightly larger than the outer diameter of shank region 42 of condom holder 41.

As illustrated in FIG. 3, the band 50 of a condom 51 is stretched over shank region 42 of holder 41, and the condom threaded through O-ring 47 and annular cover 48. The O-ring 47 and cover 48 then are positioned about shank region 42 to secure the condom open end 52 to holder 41. Cover 48 prevents condom 51 from forming an aneurism outside the vagina which would give erroneous pressure and volume readings. Further, the vaginal orifice shank 42 is provided to assist in holding the vaginometer in the vagina, and to eliminate false pressure readings which might otherwise result should the patient contract the vaginal orifice.

When vaginometer 40 is assembled as described, condom 51 may be filled with water or other fluid supplied underpressure from a syringe (not shown) via an inlet tube 530 (FIG. 3), a valve 54 and a tube 55 which communicate with the interior of condom 51 via axial openings 44 and 46. For pressure measurement, a manometer (not shown) is connected for fluid communication with the interior of condom 51 via a line 56, valve 54 and tube 55. Valve 54 permits selection of whether vaginometer 40 is connected to inlet tube 53, so as to permit filling of condom 51, or to line 56, so as to facilitate manometer measurement of vaginal pressure.

In operation, the condom portion 51 of vaginometer 40 is inserted into the vagina with shank portion 42 of condom holder 41 extending into the vaginal orifice. With valve 54 positioned to provide fluid communication between tubes 53 and 55, condom 51 may be filled with warm water from a syringe (not shown). Typically, the condom is unfused with water until a tare pressure of 30 millimeters of mercury (mm. Hg.) is observed. The patient then is asked to contract rapidly the vaginal and abdominal muscles. When this exercise is stopped, the condom water pressure again is checked. If the vaginometer pressure has changed, more water is infused and the exercise repeated until a constant pressure is obtained. This insures complete vaginal filling. The amount of water required to fill condom 51 then is indicative of the vaginal volume.

To determine vaginal pressure resulting from contraction of pubococcygeus muscles, vaginometer 40 is inserted in the vagina and filled with fluid as described above. The patient is asked to contract the vaginal muscles only, with the lungs empty. During the measurement, the abdomen may be palpated to ensure that the abdominal muscles are not contracting. To obtain the vaginal pressure reading, valve 54 is turned to provide fluid communication between the manometer line 56 and the interior of condom 51, via tube 55. Typically, the patient is asked to maintain this pubococcygeus contraction for about 10 seconds while a manometer pressure reading is taken.

The significant improvement is muscle tone, strength and functioning of the pubococcygeus resulting from treatment with the inventive electrotherapy apparatus is illustrated by the statistics in the following Table I, derived from actual patient case histories. In this table, the period of treatment in weeks is indicated for each patient, as well as the total number of treatments. Typically, individual treatments were of about one-half hour in duration. The vaginal volume and vaginal pressure resulting from contraction of pubococcygeus muscles prior to the treatment period is indicated, and the corresponding vaginal volume and pressure values measured at the end of the treatment period also are listed. Note that as a control, Table 1 includes data for two patients (Case Nos. 6 and 7) who received no treatment.

TABLE I

Patient case no.	Period of treatment, (weeks)	Number of treatments	Pre-treatment		Post-treatment	
			Volume, (ml.)	Vaginal pressure	Volume (ml.)	Vaginal pressure
1	16	22	130	5	125	118
2	12	35	150	0	140	110
3	9	25	150	*18	150	140
4	4	11	280	3	285	17
5	3.5	10	150	*3	150	*50
6	4	0	160	4	160	5
7	4	0	150	*5	155	*5

*Combined vaginal and abdominal pressure.

As is evident from Table I, in each case, a very significant increase in vaginal pressure resulted at the end of the treatment period. This increase in pressure is indicative of the improved pubococcygeus muscle tone, strength and functioning resulting from use of the inventive apparatus. Typically, patients noted a significant increase in sexual interest and activity after treatment with the inventive electrotherapy apparatus. Moreover, in cases of urinary incontinence and other female urogenital anomalies, definite improvements also resulted when the pubococcygeus muscles were exercised and toned up by use of the apparatus described herein.

Although reference is made herein for use of the apparatus in connection with the vagina of a female, it is to be understood that the apparatus may also be used for the male or female as a rectal probe or electrode.

While the invention has been described with respect to several physical embodiments constructed in accordance therewith, it will be apparent to those skilled in the art that various modifications and improvements may be made without departing from the scope and spirit of the invention.

I claim:

1. Apparatus for electrotherapy including, a pair of spaced electrodes; means developing a carrier wave which is substantially a sine wave having a frequency within the range of 150 Hz. to 1 kHz., means amplitude modulating said carrier wave with a modulating signal having a frequency substantially less than said carrier frequency and producing a series of recurrent bipolar pulses with each of said pulses having a duration established by said modulating signal and consisting of variations in its amplitude at said carrier wave frequency from a maximum positive value, to a zero value to a maximum negative value, to a zero value to a maximum positive value, and so forth; and means connected to said amplitude modulating means and continuously modifying said maximum positive values and said maximum minimum values such that they become progressively larger at a slower rate during initial development of each of said pulses than during subsequent development such that each of said bipolar pulses is defined by a slowly rising portion followed by a portion of substantially constant amplitude; and means applying said bipolar pulses to said electrodes.

2. Apparatus as set forth in claim 1 in which modulating frequency is in the range of 150 Hz. to 1 kHz.

3. Apparatus as set forth i claim 1 in which said modulating frequency is within the range of 0.5 Hz. to 1 kHz.

4. Apparatus as defined in claim 1 including means for limiting the current flow to said electrodes to a value which does not exceed 250 milliamperes.

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