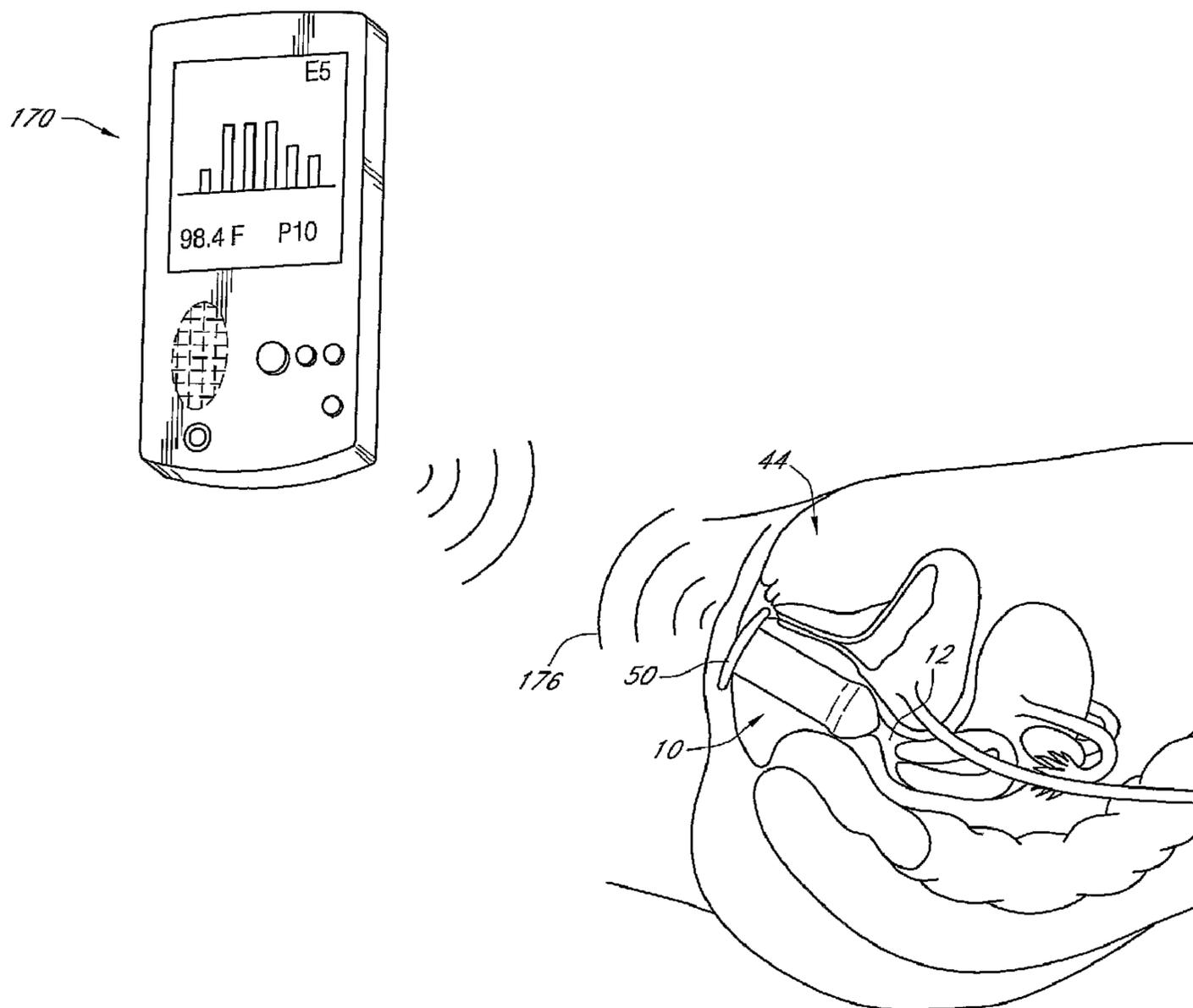




(86) Date de dépôt PCT/PCT Filing Date: 2006/11/08
 (87) Date publication PCT/PCT Publication Date: 2007/05/18
 (85) Entrée phase nationale/National Entry: 2008/05/06
 (86) N° demande PCT/PCT Application No.: US 2006/043751
 (87) N° publication PCT/PCT Publication No.: 2007/056559
 (30) Priorité/Priority: 2005/11/08 (US11/268,923)

(51) Cl.Int./Int.Cl. *A63B 21/00* (2006.01)
 (71) Demandeur/Applicant:
ANATOSOL, L.L.C., US
 (72) Inventeurs/Inventors:
HOFFMAN, CRAIG A., US;
HOFFMAN, GERRY M., US;
ENGLAND, MICHAEL JOHN, US
 (74) Agent: PARLEE MCLAWS LLP

(54) Titre : PERINEOMETRE AVEC BIORETROACTION SANS FIL
 (54) Title: PERINEOMETER WITH WIRELESS BIOFEEDBACK



(57) Abrégé/Abstract:

An exercising perineometer apparatus (10, 170) for home or clinical use assesses the strength of pelvic floor muscles (18, 20) and provides visual and audible biofeedback signals (186, 190) as training aids during pelvic muscle exercises. Impedance signals (Z)

(57) **Abrégé(suite)/Abstract(continued):**

proportional to pelvic muscle contraction forces are developed by a transducer sleeve (70) that is mounted on a shaft portion (46) of a pelvic probe assembly (10). A battery-powered RF transmitter module (164) contained within the probe assembly (10) transmits wireless feedback signals (176) to a hand-held monitor (170) that is equipped with an RF receiver (174), a visual display unit (186) and a piezoelectric speaker (190). The probe (10) reacts the pelvic contraction forces and thus provides a direct tactile feedback signal that is used in combination with the audible and visual feedback signals for improving the endurance and strength of pelvic muscles (18, 20).

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau(43) International Publication Date
18 May 2007 (18.05.2007)

PCT

(10) International Publication Number
WO 2007/056559 A1

(51) International Patent Classification:

A63B 21/00 (2006.01)

(21) International Application Number:

PCT/US2006/043751

(22) International Filing Date:

8 November 2006 (08.11.2006)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

11/268,923 8 November 2005 (08.11.2005) US

(71) Applicant (for all designated States except US):

ANATOSOL, L.L.C. [US/US]; 3716 Chimney Ridge Drive, Waco, TX 76708 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): HOFFMAN, Craig,

A. [US/US]; 3716 Chimney Ridge Drive, Waco, TX 76708 (US). HOFFMAN, Gerry, M. [US/US]; 3804 Lands End, Fort Worth, TX 76109 (US). ENGLAND, Michael, John [ZA/US]; 3824 Branch Road, Fort Worth, TX 76109 (US).

(74) Agents: GRIGGS, Dennis, T. et al.; 17950 Preston Road,

Suite 1000, Dallas, TX 75252 (US).

(81) Designated States (unless otherwise indicated, for every

kind of national protection available): AE, AG, AL, AM,

AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every

kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

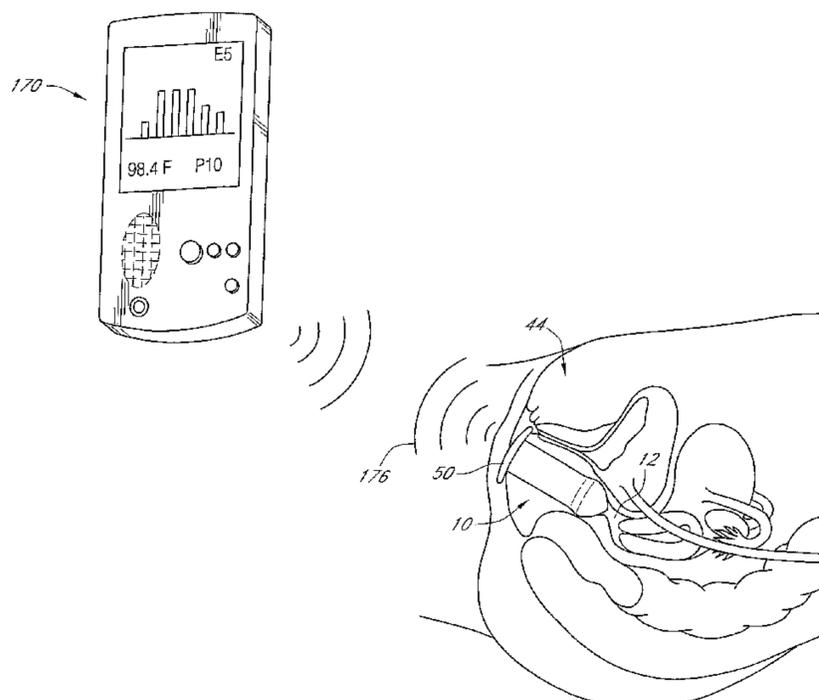
- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))
- as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))
- of inventorship (Rule 4.17(iv))

Published:

- with international search report

[Continued on next page]

(54) Title: PERINEOMETER WITH WIRELESS BIOFEEDBACK



(57) Abstract: An exercising perineometer apparatus (10, 170) for home or clinical use assesses the strength of pelvic floor muscles (18, 20) and provides visual and audible biofeedback signals (186, 190) as training aids during pelvic muscle exercises. Impedance signals (Z) proportional to pelvic muscle contraction forces are developed by a transducer sleeve (70) that is mounted on a shaft portion (46) of a pelvic probe assembly (10). A battery-powered RF transmitter module (164) contained within the probe assembly (10) transmits wireless feedback signals (176) to a hand-held monitor (170) that is equipped with an RF receiver (174), a visual display unit (186) and a piezoelectric speaker (190). The probe (10) reacts the pelvic contraction forces and thus provides a direct tactile feedback signal that is used in combination with the audible and visual feedback signals for improving the endurance and strength of pelvic muscles (18, 20).

WO 2007/056559 A1

WO 2007/056559 A1



— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

PERINEOMETER WITH WIRELESS BIOFEEDBACK

Technical Field

This invention is related to exercise devices for rehabilitating and strengthening the muscles of the pelvic floor, particularly the collective group of muscles referred to as the female pubococcygeal and related perineal musculature.

Background Art

Disorders that involve the pelvic area (bladder, pelvic floor muscle, rectum and uterus) are of great concern to women and health care providers as well. The lower pelvic muscles may become damaged or weakened through childbirth, lack of use, age, or as the result of surgical procedures. One of the symptoms related to a weakening of these muscles is urinary incontinence. Other pelvic disorders include chronic pelvic pain and vulvodynia (pelvic muscle dysfunction) that are sometimes experienced by young adult women. These disorders are caused by involuntary contractions (spasms) of the levator ani and perineal muscles. This condition is called vaginismus or pelvic floor tension myalgia and is accompanied by painful and difficult penetration of the vagina.

Various perineometer probe exercise devices have been developed in an attempt to restore the pelvic floor muscles, with the specific goal of strengthening the muscles that surround the urethra to overcome urinary incontinence in women. Of particular interest is the exercising device described in U.S. Patent 2,507,858 (Kegel). The Kegel exercising device includes a probe in the form of a pressurized sleeve that is inserted within the vagina to exercise the muscles

surrounding the vagina and to measure their strength. An external pressure gage is connected to the probe via a flexible air tube that extends externally of the vagina. The external gage provides a visual indication of muscle force applied during exercise.

5 Improvements to perineometer exercise devices continue to be proposed, for example in U.S. Patent 6,063,045 (Wax) which describes a vaginal probe that includes an internal pressure sensor. The sensor is connected to an external display device via electrical conductors for monitoring the contraction of pelvic floor muscles. Biofeedback
10 patterns formed on the display device guide the patient through an exercise routine.

 Notwithstanding the existence of such conventional exercise devices, there is a continuing interest in an improved perineometer probe exerciser that allows the patient to exercise the vaginal muscle
15 groups in complete privacy at home or under clinical supervision, with dynamic real-time biofeedback, which is simple to use, has a low risk of injury and is easy to maintain. There is a further need for a biofeedback probe and monitor for use by women who are experiencing painful
20 pelvic spasms (pelvic floor tension myalgia), that provides visual as well tactile feedback signals as an aid for training pelvic muscle relaxation techniques.

Disclosure of the Invention

 The present invention provides a passive exercise device for the pelvic floor muscles, including the collective group of muscles
25 involved in sexual response. The invention features a self-contained perineometer probe for intravaginal use that communicates a wireless biofeedback signal to a small portable monitor. The monitor provides an audible signal output and a visual display that assist the patient to

monitor her efforts as self-directed or according to a prescribed training protocol as prompted by a pre-programmed routine contained in the display unit.

5 The invention in particular provides a perineometer for intravaginal use in connection with the development, training and rehabilitation of the female pubococcygeal and related perineal musculature. An impedance signal proportional to pressure forces applied during contraction of the pelvic floor muscles is developed by a pressure transducer mounted on an insertable vaginal probe. The
10 transducer impedance signal is converted to a digital data feedback signal by a miniature electronics module contained within the probe. The digital feedback signal is communicated to an external monitor via a high frequency wireless radio frequency transmitter contained in the electronics module.

15 The digital data impedance signal is received and converted to a visible display and/or an audible signal in real time by a hand-held monitor for biofeedback training purposes. The electronics module is completely self-contained with an internal wireless RF transmitter, antenna and battery. Since the probe is worn intravaginally with
20 minimal external reveal, it can be used in the home in complete privacy or under clinical supervision.

25 According to one aspect of the invention, the pressure transducer is in the form of a flexible sleeve that is wrapped or fitted around a probe shaft that forms a housing that contains the battery and electronic modules. For best results, the transducer sleeve is substantially coextensive in length with the female pubococcygeal and related perineal musculature that surrounds the vaginal cavity. The sensing body of the pressure transducer is a variable resistance element that exhibits a change in electrical impedance in response to a change in

the amplitude of a pressure force or mechanical stress applied to the transducer sleeve. According to another aspect of the invention, the variable resistance element of the pressure transducer is provided by a body of an insulating or weakly conductive polymer composition containing a dispersed matrix of particles of at least one strongly conductive material selected from the group consisting of metals, alloys and reduced metal oxides. A thin layer of the weakly conductive polymer composition is sandwiched between first and second conductive electrodes, and then arranged in the form of a sleeve.

According to another aspect of the invention, the transducer sensing body is provided by a textile fabric sleeve assembly composed of textile form electrodes, textile form variable resistance elements and textile form conductive members arranged in the form of a sleeve.

According to yet another aspect of the invention, the transducer sensing body is provided by a flexible, multi-layer laminate of an outer contact layer of a non-conductive dielectric material, a middle layer of a polymeric piezoelectric material having metallized coating layers on either side thereof, and a base layer of a non-conductive dielectric material, arranged in the form of a sleeve.

The transducer sleeve is fitted about the external surface of the probe shaft which serves as a reaction core member. The probe shaft supports the transducer sleeve and reacts compression loading applied by the pubococcygeal and related perineal musculature during pelvic contractions. The transducer sleeve is stressed in accordance with changes in applied loading and produces a dynamic impedance output signal that changes in proportion to the pelvic contraction pressure, while the reaction forces from the core member provide direct tactile sensory feedback.

Since the probe is retained during exercise and the reaction core member is substantially coextensive with the pelvic muscles, it can be sensed or felt when the muscles are contracted against it. The exercising device of the invention encourages pelvic muscle reeducation and strengthening by (1) giving direct tactile sensory feedback to the patient during exercise which allows the patient to identify the pelvic floor muscles and confirm that the probe is properly engaged; (2) developing muscle strength and endurance due to the work required of the muscles to contract against the reaction core member, thereby creating muscle memory; and (3) giving audible and/or visual sensory feedback that is directly related to performance during exercise, thus instilling patient confidence that the device is being used properly and that the exercises are having the desired training effect.

Brief Description of the Drawing Figures

Fig. 1 is a simplified sectional view of the pelvic region of the female anatomy, showing the perineometer probe of the present invention inserted within the intravaginal cavity in the operative sensing position;

Fig. 2 is a side elevational view, partly in section, of the perineometer probe of the present invention;

Fig. 2A is a front elevational view thereof;

Fig. 3 is a sectional view of the perineometer probe, taken along the line 3-3 of Fig. 2;

Fig. 4 is a perspective view of the perineometer probe of the present invention;

Fig. 5 is a perspective view of a transducer sleeve, shown removed from the perineometer probe;

Fig. 6 is a developed plan view of a polymeric composition form transducer sleeve, shown in its flat configuration prior to assembly onto the perineometer probe;

5 Fig. 7 is an enlarged sectional view of a portion of the polymeric composition transducer sleeve, taken along the line 7-7 of Fig. 6;

Fig. 8 is a developed plan view of a textile form fabric transducer sleeve, shown in its flat configuration prior to assembly onto the perineometer probe;

10 Fig. 9 is a peeled-away perspective view of the textile form fabric transducer sleeve of Fig. 8;

Fig. 10 is a developed plan view of a flexible polymeric piezoelectric form transducer sleeve, shown in its flat configuration prior to assembly onto the perineometer probe;

15 Fig. 11 is a sectional view of the flexible polymeric piezoelectric transducer sleeve, taken along the line 11-11 of Fig. 10;

Fig. 12 is simplified block diagram of an R.F. transmitter module that is contained within the shaft of the perineometer probe;

20 Fig. 13 is front elevation view of a hand-held monitor that receives RF wireless signals from the perineometer probe transmitter module and provides a visual display of the pressure waveform and audible feedback signals in response to pelvic contractions;

Fig. 14 is simplified circuit block diagram of the hand-held monitor of Fig. 13;

25 Fig. 15 is a diagram that illustrates use of the perineometer in combination with the hand-held monitor, by a patient in the preferred lithotomy position;

Fig. 16 is a developed plan view of a transducer sleeve with multiple strip form transducer elements, shown in its flat configuration

prior to assembly onto the perineometer probe;

Fig. 17 is a perspective view of the strip form transducer sleeve shown assembled on a probe;

5 Fig. 18 is a developed plan view of a transducer sleeve with multiple band form transducer elements, shown in its flat configuration prior to assembly onto the perineometer probe;

Fig. 19 is a perspective view of the multiple band form transducer sleeve shown assembled onto a probe;

10 Fig. 20 is a developed plan view of a transducer sleeve with a spiral wrap transducer element, shown in its flat configuration prior to assembly onto the perineometer probe;

Fig. 21 is a perspective view of the spiral wrap form transducer sleeve shown assembled onto a probe;

15 Fig. 22 is a developed plan view of a transducer sleeve with multiple transducer elements arranged in a grid pattern, shown in its flat configuration prior to assembly onto the perineometer probe;

Fig. 23 is a perspective view of the grid form transducer sleeve shown assembled onto a probe;

20 Fig. 24 is a side elevational view, partly in section, of a wireless perineometer probe having an inflatable transducer sleeve according to an alternative embodiment of the present invention;

Fig. 25 is a sectional view thereof, taken along the line 25-25 of Fig. 24;

25 Fig. 26 is a perspective view of the inflatable transducer sleeve shown in Fig. 24; and

Fig. 27 is a circuit diagram of a piezoelectric transducer contained in the transducer module of Fig. 24.

Best Mode for Carrying Out the Invention

The specification which follows describes the preferred embodiments with reference to portions of the female pelvic anatomy that are shown in Fig. 1, and with reference to the lithotomy position indicted in Fig. 15. The perineometer probe 10 of the present invention is inserted in the vaginal cavity 12 while the patient is reclining in the slightly elevated lithotomy position. In that position, the patient is lying on her back, knees raised, with her head slightly elevated relative to the pelvic region. Her torso is on an approximate 30 degree angle with respect to horizontal, which results in a half-sitting position, which is the preferred position for pelvic exercise training.

Referring now to Fig. 1 and Fig. 15, the perineometer probe 10 is positioned within the vaginal cavity 12 for reacting pressure forces applied by pelvic muscle contractions. The lower wall 14 and the upper wall 16 of the vagina are connected to muscles, tissues, and nerves, that are indicated generally at 18, 20, and collectively referred to herein as the pubococcygeal and related perineal musculature. Fig. 1 also shows the uterus 22, which has an internal void known as the uterine body cavity 24, the cervix 26, the external os 28, which is the external opening of the cervix facing the vaginal cavity 12.

Other portions of the female anatomy shown in Fig. 1 include the bladder 30, ureter 32, the urethra 34, the labium minus 36, the labium majus 38, which join together in the region adjacent the clitoris 40, near the vaginal introitus 42, all clustered about the region generally known as the perineum 44.

Referring now to Fig. 2 and Fig. 4, the perineometer probe 10 includes an elongated body portion or shaft 46 that is terminated on its distal end by a slightly enlarged and rounded head portion 48 and on its proximal end by a handle 50, which also functions as a closure cap. The

handle 50 is fitted with threads 52 engaging mating threads 54 that are formed on the proximal end of the probe body. The interface between the handle and the probe body is sealed by an O-ring seal 56.

5 As the patient is resting in the elevated lithotomy position shown in Fig. 11, the patient grasps the probe handle end 50 with her fingers. The patient then inserts the head portion 48 of the probe through the vaginal introitus 42 and into the vagina until the probe 10 is fully inserted, with the handle 50 engaging substantially flush against the labium minus 36. Upon full insertion, the probe head portion 48
10 extends into the vaginal cavity 12. The lower and upper vaginal walls 14, 16 close against the elongated body portion 46 to positively hold the probe 10 within the vaginal cavity.

The proximal end 58 of the elongated shaft portion 46 is adapted to seat at the introitus 42 of the vagina. The enlarged head
15 portion 48 of the probe body is adapted to seat within the pelvic cavity 12. As shown in Fig. 4, the enlarged head portion 48 is characterized by a sloping retainer surface 60 that transitions smoothly from the shaft portion 46 along an outwardly flared, conical profile until it reaches an annular rim portion 62 at the limit of the outwardly flared profile. The
20 enlarged head portion 48 then transitions smoothly from the annular rim portion 62 along a rounded portion 64 having an inwardly sloping surface 66 that forms a tapered profile. The tapered portion is terminated on the distal end by a rounded nose portion 68, which facilitates insertion.

25 According to the preferred embodiment, a pressure transducer sleeve 70 is fitted around the shaft portion 46 for sensing and providing an indication of pelvic muscle contraction pressure. As shown in Fig. 3 and Fig. 5, the transducer sleeve 70 is a flexible member 72 in tubular form that contains a variable impedance element 71 capable of

exhibiting a change in electrical impedance in response to changes in the amplitude of pressure forces applied to the transducer sleeve.

Referring now to Fig. 3 and Fig. 5, the variable impedance element 71 is distributed around and generally uniformly throughout a substantial portion of the flexible member 72. The impedance element 5 71 is sandwiched between first and second conductive electrodes 73, 75 that are disposed in electrical contact with the variable impedance element. Preferably, the conductive electrodes are formed by depositing metallization layers of a conductive metal, for example silver, on 10 opposite side surfaces of the impedance element 71. A base layer 77 of a dielectric insulating material is applied to the external side surface of the first conductive electrode 73, and an outer layer 79 of a dielectric insulating material is applied to the external side surface of the second conductive electrode 75.

15 According to this probe configuration, when the pelvic floor muscles 18, 20 contract against the probe, the enlarged head portion 48 produces a differential contact zone of engagement in which the pressure forces of pelvic contraction are concentrated primarily along the externally facing contact surface 72 of the transducer sleeve 70. 20 This clamping action creates a tight banding of pelvic muscle tissue around the transducer sleeve 10. The compressed muscle tissues 18, 20 engage against the flared retainer surface 60 of the head portion, which opposes expulsion of the probe from the vagina while a contraction is underway.

25 The shaft portion 46 is preferably in the form of a tubular sidewall 74 that surrounds an internal pocket 76. The distal end of the pocket 76 is sealed by the head portion 48 which forms the distal boundary of the pocket. A battery module 78, providing a supply potential, for example, of 6 volts DC, and a signal processor circuit

module 80 are received in tandem alignment within the pocket 76.

A conductive DC supply input terminal 82 is mounted in the pocket between the probe head portion 48 for electrical contact engagement against the negative terminal (-) of the battery module. The distal end of the signal processor circuit module 80 is fitted with a conductive DC supply input terminal 84 for making electrical contact against the positive terminal (+) of the battery module 78. The distal end of the signal processor circuit module 80 is also fitted with a conductive DC supply input terminal 85 for connection to the negative supply input terminal 82. A conductive interconnect portion 86, connected to the negative supply input terminal 82, extends along the tubular sidewall 74 of the shaft 46 into electrical contact engagement against the negative supply input terminal 85 of the transmitter module 80.

The proximal end of the signal processor circuit module 80 is fitted with an RF output terminal 88 for making electrical contact against an antenna input terminal portion 90 of a dipole antenna 92 that is encapsulated within the handle 50. The RF output terminal 88 engages the antenna input terminal 90 and establishes firm electrical contact when the handle 50 is tightly sealed against the probe body 46. The electrical contact terminals are also brought into electrical contact engagement with the battery electrodes and complete a series electrical circuit when the handle 50 is tightly sealed against the probe body.

According to one aspect of the invention, ON/OFF control of the DC supply voltage is provided by bias spring 94 acting in cooperation with the handle 50. The spring 94, preferably a Bellville spring washer, is interposed between the DC battery module 78 and the signal processor circuit module 80 for urging the circuit module for movement away from electrical contact engagement with the positive terminal of the DC battery module. According with this arrangement,

the handle 50 is disposed in threaded engagement with the shaft portion and engages against the circuit module 80 for moving the module axially through the pocket 76 against the bias force of the spring 94.

5 This spring bias action allows the DC voltage input terminal 84 of the transmitter module to be moved into and out of electrical contact engagement with the positive output terminal of the battery in response to clockwise and counter-clockwise rotation of the handle 50 relative to the shaft 46, thus making contact with the battery module and completing the DC supply circuit when the probe is activated ON, and
10 breaking contact with the battery module and interrupting the DC supply circuit when the probe is turned OFF. The bias force of the spring 94 also maintains the RF signal output terminal 88 of the signal processor circuit module 80 in signal contact engagement with the RF signal input terminal 90 of the antenna 92 when the handle 50 is tightly sealed
15 against the probe body.

The probe body 46, head portion 48 and handle 50 are fabricated from an injection moldable polymer material, preferably medical grade polymer resin that is a dielectric or electrically non-conductive, for example acrylic resin. The internal conductor terminals
20 82, 84, 86 and 90 are made of a flexible carbon impregnated conductive polymer composition which may be, for example silicone polymer. The external contact surfaces of the probe 10, including the transducer sleeve 70, are covered by a biologically inert coating layer 96 of a seamless medical grade silicone elastomer, which is preferred because
25 of its high biocompatibility.

The silicone elastomer coating layer 96 transmits the pelvic pressure faithfully and its performance is temperature independent. Because the coating layer 96 is seamless and smooth, there are no joints or crevices to trap contaminants. Preferably, the coating layer 96 should

be in the range of about 1/8 inch - 3/16 inch (about 3 mm – 5 mm) of a compressible elastomer material, which will allow shortening of the muscle fibers to induce muscle cell hypertrophy (increased muscle mass).

5 Referring now to Fig. 6 and Fig. 7, a variable impedance signal Z is conducted on signal conductors 98, 99 that are attached to the signal output nodes of a transducer sleeve 100. The impedance signal Z is proportional to pressure forces applied during contraction of the pelvic floor muscles 20, 22. This feedback signal is developed by a sensing
10 body in which the variable impedance element is provided by commercially available transducer materials.

According to a first transducer embodiment, shown in Fig. 6 and Fig. 7, the sensing body of the transducer sleeve 100 is formed by a compressible body 102 of an insulating or weakly conductive polymer
15 composition containing a dispersed matrix of particles 104 of at least one strongly conductive material selected from the group consisting of metals, alloys and reduced metal oxides, and first and second conductive electrodes 106, 108 disposed in electrical contact with the polymer composition. The conductive electrodes are covered by coating layers
20 110, 112 respectively, of a dielectric insulating polymer composition, preferably medical grade polymer resin that is a dielectric or electrically non-conductive, for example acrylic resin.

According to another transducer embodiment, shown in Fig. 8 and Fig. 9, the sensing body of a transducer sleeve 120 is provided by a
25 textile form variable resistance element 122 interleaved with textile form conductive members 124, 126. The variable resistance element and conductive members are enclosed between textile form non-conductive base and covering layers 128, 130. The textile layers are formed of woven nylon or polyester yarns. The conductive members are

formed by printing the facing surfaces of the covering layers 128, 130 with deposits of conductive inks or polymer pastes containing metals, metal oxides or semi-conductive materials such as conductive polymers or carbon.

5 Preferably, the variable impedance element 122 exhibits quantum tunneling conductance when deformed. This is a well known property of polymer compositions in which a filler material selected from powder-form metals or alloys, electrically conductive oxides of
10 such elements and alloys, and admixtures thereof with a non-conductive elastomer. The filler material is dispersed within the elastomer and remains structurally intact. The voids present in the starting filler powder become infilled with elastomer and particles of filler become set in close proximity during curing of the elastomer.

According to yet another embodiment, shown in Fig. 10 and
15 Fig. 11, the sensing body of a pressure transducer 140 is a multi-layer flexible laminate comprising a base contact layer 142 of a flexible, non-conductive sheet material, for example, Mylar™ polyester film, a middle polymeric piezoelectric sheet 144 having moralized coating layers 146 and 148 on either side thereof, and an outer contact layer 150
20 of a flexible sheet material, for example, Mylar™ polyester film.

Preferably, the polymeric piezoelectric sheet 144 is a film of polyvinylidene fluoride (PVDF), a fluoroplastic resin that is commercially available as pellets for extrusion and molding. PVDF film is known to possess piezoelectric characteristics in its beta phase. Beta-
25 phase PVDF is produced from ultra pure film by stretching it during extrusion. Both surfaces of the film extrusion are then moralized, and the film is subjected to a high voltage to polarize its atomic structure. When compressed or stretched, the polarized PVDF film generates a voltage across the moralized surfaces, in proportion to the induced

strain.

The electrical equivalent or characteristic impedance Z of the piezoelectric film element 144 is a voltage source in series with a capacitance. The voltage source is the piezoelectric generator itself, and this source is directly proportional to the applied stimulus (pressure or strain). The transducer output voltage will absolutely follow the applied pressure, and the output voltage is then buffered, filtered and scaled in the signal processor module 80 before it is converted to a digital data feedback signal.

The polyester film layers 142 and 150 are adhesively attached to the metallized coating layers 146, 148 respectively. Additionally, the base layer 142 is adhesively bonded to the probe shaft 46. The piezoelectric material 144 is preferably a layer of polarized polyvinylidene fluoride (PVDF) film sandwiched between the metallized coating layers 146, 148 of electrically conductive metal. Preferably, the polymeric piezoelectric sheet 144 is approximately 28 microns in thickness, and the metallized coating layers 146, 148 are silver deposits of about 0.1 microns in thickness.

Referring again to Figs. 4 and 5, the pressure transducer sleeve is formed by rolling a rectangular swatch of flexible material according to one of the transducer embodiments 70, 100, 120 or 140 described above to produce a transducer sleeve having a tubular form. The transducer swatch is provided in a length dimension approximately equal to the load surface length L of the probe and a width W approximately equal to the O.D. circumference of the tubular shaft sidewall 74. The transducer swatch is then rolled and adhesively bonded onto the tubular housing 64. Alternatively, the transducer swatch is rolled into tubular sleeve form, forming a tubular body 72 as indicated in Fig. 5, and the proximal end of the probe is then inserted

into the sleeve and sealed. Optionally, the transducer sleeve 70 can be molded onto the tubular shaft sidewall 46 to accommodate a polymeric transducer material.

5 Preferably, the transducer sleeve 70 has an extended pressure-responsive area 72 that is substantially coextensive in length with the run of the pelvic floor muscles 18, 20. Consequently, when the probe 10 is fully inserted with the handle 50 engaging the labium majus 38, the pressure responsive area will span the pelvic floor muscles of most adult women.

10 Preferably, the transducer sleeve 70 is attached to the probe sidewall 46 by an adhesive deposit. Excellent coupling is obtained through adhesive attachment using pressure sensitive adhesive supplied by 3M Corporation, such as 3M Product No. Y-9485. The adhesively coupled transducer sleeve 70 provides high transducer sensitivity, low
15 mechanical and acoustic impedance to produce accurate transducer output signals throughout a broad range of loadings. The flexible transducer sleeve 70 provides a linear voltage output for a given force, enabling the sensing of movements as low as respiration and pulse. Moreover, because of the toughness and flexibility of the polymeric materials, the transducer
20 sleeve 70 is resistant to breakage caused by rough handling.

As indicated in Fig. 12, the tubular shaft 46 serves as a reaction core member that supports the transducer sleeve 70 and reacts compression loading applied during contractions of the pelvic floor muscles 18, 20. As the pelvic floor muscles contract, the transducer
25 sleeve 70 is stressed in accordance with changes in applied loading and yields a variable impedance output signal Z in accordance with the changes, while the support shaft 46 reacts the compression forces and provides tactile sensory feedback directly to the patient.

Referring now to Fig. 12, the variable impedance signal Z is input to the signal processor circuit module 80 via conductors 98, 99 that are electrically connected to the metallization deposit layers of the transducer. The signal processor circuit module 80 includes a low noise amplifier 160, an analog-to-digital converter (ADC) 162, and an RF transmitter 164. The analog impedance signal Z from the transducer sleeve 70 is first buffered, filtered and amplified by the low noise amplifier 160, and then converted to a digital data signal by the analog-to-digital converter (ADC) 162. Preferably, the components of the signal processor circuit module 80 are implemented by conventional RF integrated circuit (RFIC) technology.

The digitized feedback signal is input to the RF transmitter 164 which is operable in the 433 MHz band which is dedicated for scientific and medical purposes, at 25 milliwatts (0.025 joule/sec) nominal power output. Under this arrangement, the transmitted signal has an effective range of about 2 meters, which provides sufficient signal strength for reliable reception by a hand-held monitor.

Referring now to Fig. 13 and Fig. 14, a hand-held monitor 170 includes an RF receiver 174 that receives a wireless feedback signal 176 via an internal antenna 178. The wireless feedback signals are fed into a display driver 180 that provides feedback data signals 182 to an audio and visual indicator 184. The indicator provides a visual graphic presentation of a pelvic contraction, for example, the waveform 186, and audio output signals in response to pelvic contractions.

The monitor 170 may also be configured to display other data, such as intravaginal temperature, for example, 98.4° F (36.9° C); the elapsed time of pelvic contraction, for example E 5 (5 seconds); and the numerical pressure tension value of the contraction strength in cm water, for example P10 (10 cm water). Negative values of pelvic tension

pressure (relative to the nominal “at rest” pelvic tension level) can also be displayed when the probe is used to monitor relaxation training exercises for treatment of pelvic muscle spasm disorders. Preferably, the displayed pressure tension value and the waveform are updated ten
5 times per second or more during contractions.

The visual display presentation is implemented by a conventional liquid crystal display screen 188, preferably with backlighting. A piezoelectric speaker 190 and a headphone jack 192 provide audio output. Controls are provided for power on-off function
10 (switch 194), display reset (switch 196), volume control function (dial 198) and pressure calibration (normalize pressure display to read zero for “at rest” pelvic pressure level - switch 200).

In the above described embodiments, ultra-low power radio frequency (RF) transmission is preferred for wireless high speed data
15 transmission to the receiver 174. One-way or two-way wireless data communication links may be implemented. Any short range, wireless RF data communication protocol, for example Bluetooth, Wi-Fi or Zigbee, may be used for this purpose.

Optionally, the probe 10 can be fitted with a thermal
20 transducer for sensing and providing an indication of pelvic temperature, for example for monitoring the onset of ovulation. Although the probe is sealed by a removable handle in the exemplary embodiments, the probe and handle can be hermetically sealed if desired.

25 Alternative embodiments of the transducer sleeve are shown in Figs. 16-23. These transducer sleeves each include one or more discrete transducer elements that are interconnected and embedded or enclosed in an annular sleeve body. In each sleeve embodiment, the impedance element of the transducer strips is constructed with a selected one of the

conventional transducer materials described above.

Referring to Fig. 16 and Fig. 17, a transducer sleeve 210 includes multiple discrete transducer strips 212, 214, 216 and 218 embedded or enclosed within a flexible body 220 of a compressible polymer composition, for example a closed cell polymer foam resin. The transducer strips extend along the length of the probe shaft, and are evenly spaced around the circumference of the shaft. The impedance elements are interconnected in parallel circuit relation, collectively providing a common impedance output signal Z.

Referring to Fig. 18 and Fig. 19, a transducer sleeve 230 includes multiple discrete transducer bands 232, 234, 236, 238 and 240 embedded or enclosed within a flexible body 242 of a compressible polymer composition, for example a closed cell polymer foam resin. The transducer bands encircle the probe shaft, and are evenly spaced along the length of the shaft. The impedance elements are interconnected in parallel circuit relation, providing a common impedance output signal Z.

Referring to Fig. 20 and Fig. 21, a transducer sleeve 250 includes a single elongated transducer strip 252 embedded or enclosed within a flexible body 254 of a compressible polymer composition, for example closed cell polymer foam resin. The transducer strip is wrapped around the probe shaft in a spiral pattern, and is secured thereto by an adhesive deposit. The impedance element is a continuous strip or body of a selected one of the conventional transducer materials described above.

Referring to Fig. 22 and Fig. 23, a transducer sleeve 260 includes multiple discrete transducer patches 262, 264, 266, 268 and 270 arranged in a checker board pattern and embedded or enclosed within a flexible body 272 of a compressible polymer composition, for example

closed cell polymer foam resin. The transducer patches are evenly spaced apart in a rectangular grid array throughout the sleeve body. The impedance elements of the patches are interconnected in parallel circuit relation, providing a common impedance output signal Z.

5 An alternative wireless perineometer probe 300 is shown in Figs. 24-27. In this embodiment, an air bladder 302 senses pelvic contraction pressure. The air bladder 302 is in the form of an elongated, annular sleeve having an outer sidewall 302A and an inner sidewall 302B separated by an annular air pressure chamber 304. The air bladder
10 302 is fitted around and attached to the shaft 46, preferably by an adhesive deposit, and is coupled in fluid communication with a pressure transducer module 306 via an inlet port 308 that intersects the shaft sidewall 46. Although a double-walled bladder is illustrated, a single-wall bladder, hermetically sealed around the shaft 46 on its proximal
15 and distal ends, can be substituted. Various medical grade rubber materials can be used to fabricate the bladder. Preferably, the bladder is fabricated of a seamless, medical grade, low-modulus, non-latex, soft nitrile composition, having a sidewall thickness in the range of 4 mils - 6 mils.

20 The air bladder 302 is inflated by admission of pressurized air through a check valve 310 and a fill tube 312. The check valve and fill tube are coupled in fluid communication with the annular bladder chamber 304 via an inlet port 316 that is formed through the shaft sidewall 46. Access to the check valve 310 is provided by removing the
25 handle 50, and the bladder chamber is pressurized manually by a small hand pump. The internal bladder pressure is communicated to the transducer module 306 via a flow passage 318 that is connected in fluid communication with an internal bellows chamber 320 disposed within the transducer module 306, as shown in Fig. 27.

A resilient membrane 322, attached across the bellows chamber, is mechanically coupled to a piezoelectric crystal transducer 324. As the membrane 322 deflects and extends, it applies mechanical stress across the crystal in proportion to the magnitude of the air pressure in the bellows chamber. The electrical impedance Z of the piezoelectric crystal transducer changes in proportion to the applied pressure, and this impedance signal is input to the transmitter module 80 via the signal conductors 98, 99. The piezoelectric crystal transducer 324 is preferably comprises natural, reprocessed crystalline quartz with a long discharge time constant operable in the charge mode as a dynamic pressure sensor.

The electrical equivalent or characteristic impedance Z of the piezoelectric crystal 324 is a voltage source in series with a capacitance. The voltage source is the piezoelectric generator itself, and this source is directly proportional to the applied stimulus (pressure or strain). The transducer output voltage will follow the applied pressure, and the output voltage is then buffered, filtered and scaled in the signal processor module 80 before it is converted to a digital data feedback signal. After being scaled and digitized, the pelvic contraction pressure signals are transmitted as wireless RF signals to the hand-held monitor 170, as indicated in Fig. 15.

Industrial Applicability

The perineometer probe and monitor assembly of the present invention allows a patient to exercise the vaginal muscle groups in complete privacy at home or under clinical supervision. The exerciser probe provides dynamic real-time biofeedback with visual as well tactile feedback signals as an aid for training pelvic muscle relaxation techniques. The biofeedback probe and monitor assembly of the present

invention is also intended for use by women who are experiencing painful pelvic spasms (pelvic floor tension myalgia).

CLAIMS

1. Perineometer probe apparatus (10) receivable within a pelvic cavity (12) for sensing contraction pressure applied by pelvic floor muscles (18, 20) and transmitting wireless signals proportional to pelvic muscle contraction forces to a portable monitor (170), said probe apparatus (10) comprising:
- 5
- a shaft (46) having a sidewall (74);
 - a transducer (70) circumscribing and extending along at least a portion of the shaft sidewall (74), the transducer (70) including a
 - 10 variable impedance element (71) capable of exhibiting a change in electrical impedance in response to pelvic muscle contractions against the transducer sleeve (70); and
 - a signal processor circuit (80) at least partially enclosed by the shaft sidewall (74) and electrically coupled to the variable impedance
 - 15 element (71) for producing a wireless feedback signal (176) containing information related to the pelvic muscle contractions.
2. Perineometer probe apparatus (10) according to claim 1, wherein the transducer (70) comprises a swatch of flexible material (72) rolled in tubular form, and the variable impedance element (71) is
- 20 distributed substantially uniformly throughout a region of the flexible material (72).
3. Perineometer probe apparatus (10) according to claim 1, wherein the transducer (70) comprises a swatch of flexible material (210) rolled in tubular form, and the variable impedance element (71)
- 25 comprises multiple transducer strips (212, 214, 216, 218) extending through the swatch along the length of the shaft (46) and circumferentially spaced apart from each other around the shaft (46).

4. Perineometer probe apparatus (10) according to claim 1, wherein the transducer (70) comprises a swatch of flexible material (230) rolled in tubular form, and the variable impedance element (71) comprises multiple transducer bands (232, 234, 236, 238) extending
5 through the swatch around the shaft sidewall (74) and axially spaced from each other along the length of the shaft (46).

5. Perineometer probe apparatus (10) according to claim 1, wherein the transducer (70) comprises a swatch (250) of flexible material extending in a spiral wrap pattern around the shaft sidewall
10 (76).

6. Perineometer probe apparatus (10) according to claim 1, wherein the transducer (70) comprises a swatch of flexible material (260) rolled in tubular form, and the variable impedance element (71) comprises multiple transducer patches (262, 264, 268, 270) disposed in
15 the swatch and arranged in a grid array pattern.

7. Perineometer probe apparatus (10) according to claim 1, wherein the transducer (70) comprises a compressible body (102) of dielectric, insulating or weakly conductive polymer composition containing a dispersed matrix of particles (104) of at least one strongly
20 conductive material selected from the group consisting of metals, alloys and reduced metal oxides, and first and second conductive electrodes (106, 108) disposed in electrical contact with the compressible body (102) of polymer composition.

8. Perineometer probe apparatus (10) according to claim 1,
25 wherein the sensing body (70) comprises first and second textile form

conductive electrodes (124, 126) and a textile form variable resistance element (122) disposed in electrical contact with the textile form conductive electrodes (124, 126).

5 9. Perineometer probe apparatus (10) according to claim 8, wherein the variable impedance element (122) comprises a polymer composition that exhibits quantum tunneling conductance in response to mechanical deformation.

10 10. Perineometer probe apparatus (10) according to claim 1, wherein the transducer (70) comprises a multi-layer, flexible laminate of a first layer (142) of a dielectric or non-conductive sheet material, a second layer (150) of dielectric or non-conductive sheet material, and intermediate layer (144) of a polymeric piezoelectric material having metallized conductive coating layers (146, 148) on either side thereof disposed between the first non-conductive layer (142) and the second
15 non-conductive layer (150).

11. Perineometer probe apparatus (10) according to claim 1, wherein:

the transducer (70) comprises an air bladder (302) disposed around the shaft (46); and

20 the variable impedance element (71) comprises an air pressure transducer assembly (306) having a pneumatic input (318) coupled in fluid communication with the air bladder (302), the air pressure transducer assembly (306) exhibiting a change in electrical impedance in response to compression forces applied to the air bladder (302), for
25 conducting electrical impedance signals (Z) proportional to air pressure in the air bladder (302) to the electronic circuit module (80).

12. Perineometer probe apparatus (10) according to claim 1, comprising in combination:

5 a monitor (170) including a radio frequency receiver (174) for receiving a wireless signal (176) produced by the signal processor circuit (80) and a display device (184) coupled to the receiver for displaying a visual representation (186) of feedback information contained in the wireless signal (176).

13. A method of exercising and training pelvic muscles (18, 20) surrounding a pelvic cavity (12) of a patient, comprising the steps:

10 providing a perineometer probe (10) having a pressure sensitive transducer (70) capable of exhibiting a change in electrical impedance in response to pelvic contractions applied to the transducer (70);

15 inserting the probe (10) into a pelvic cavity (12) of a patient; contracting the patient's pelvic muscles (18, 20) against the transducer (70);

producing a wireless radio frequency signal (176) containing feedback information related to the pelvic contractions;

20 communicating the wireless radio frequency signal (176) to a portable monitor (170);

displaying a visual representation (186) of feedback information contained in the wireless signal (176) on the portable monitor (170) so that the feedback information can be observed by the patient during a training exercise; and

25 communicating a tactile feedback signal directly to the patient via transmission of reaction forces through pelvic muscles (18, 20) engaged about the probe (10) while the patient is observing a visual waveform display (186) on the portable monitor (170).

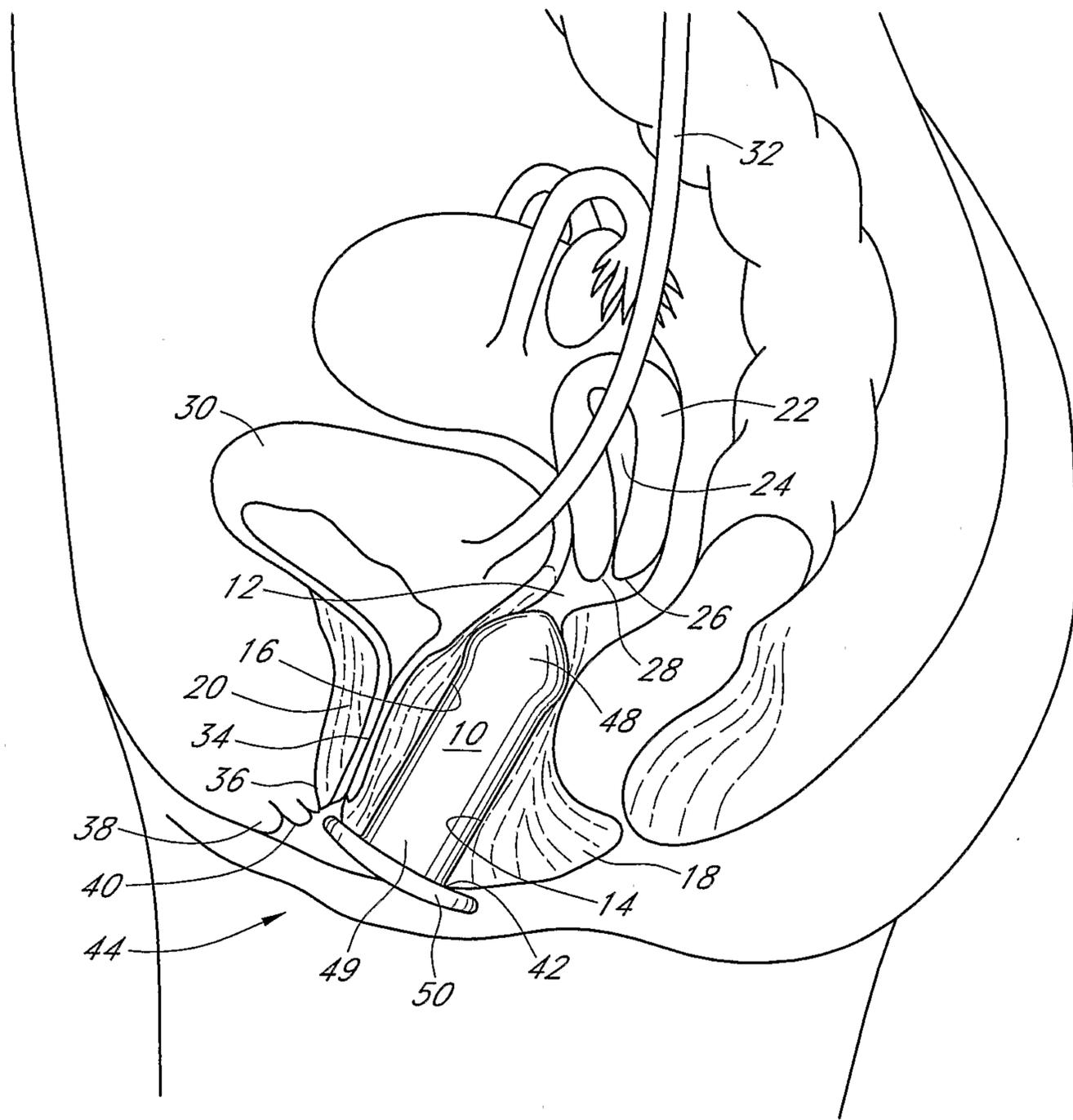


FIG. 1

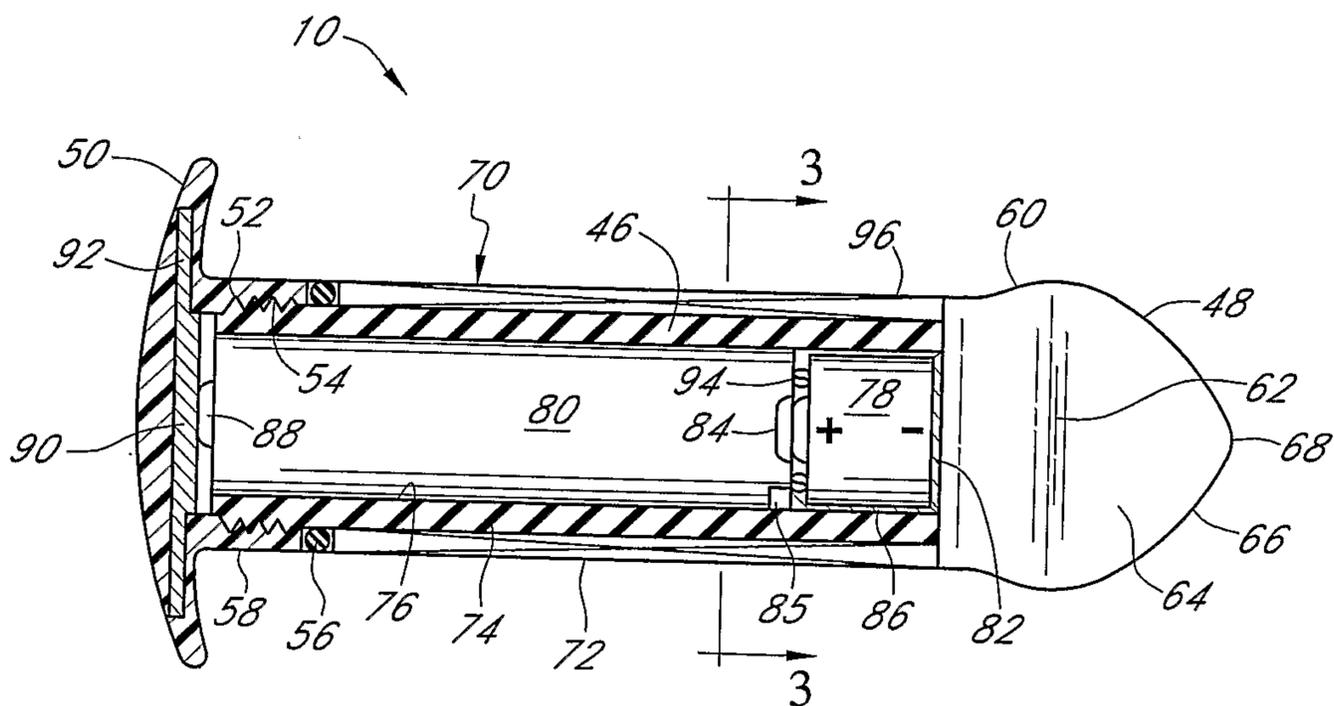


FIG. 2

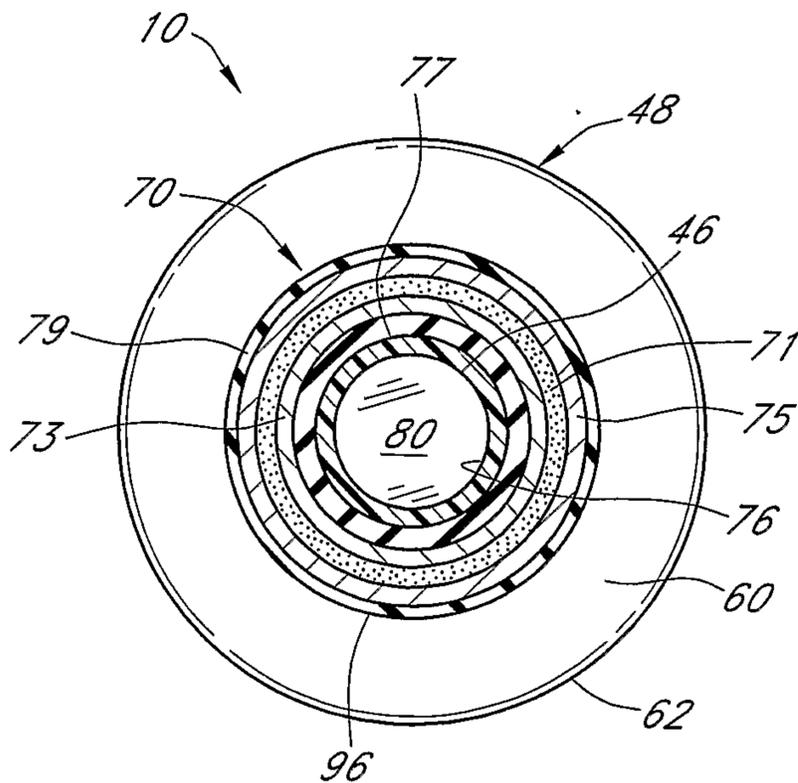


FIG. 3

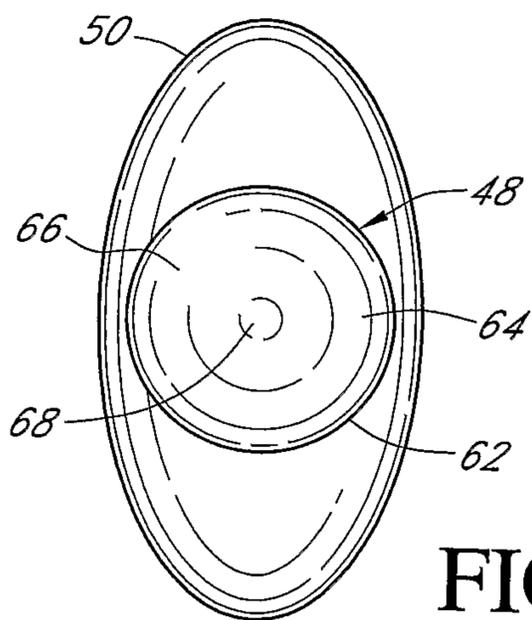


FIG. 2A

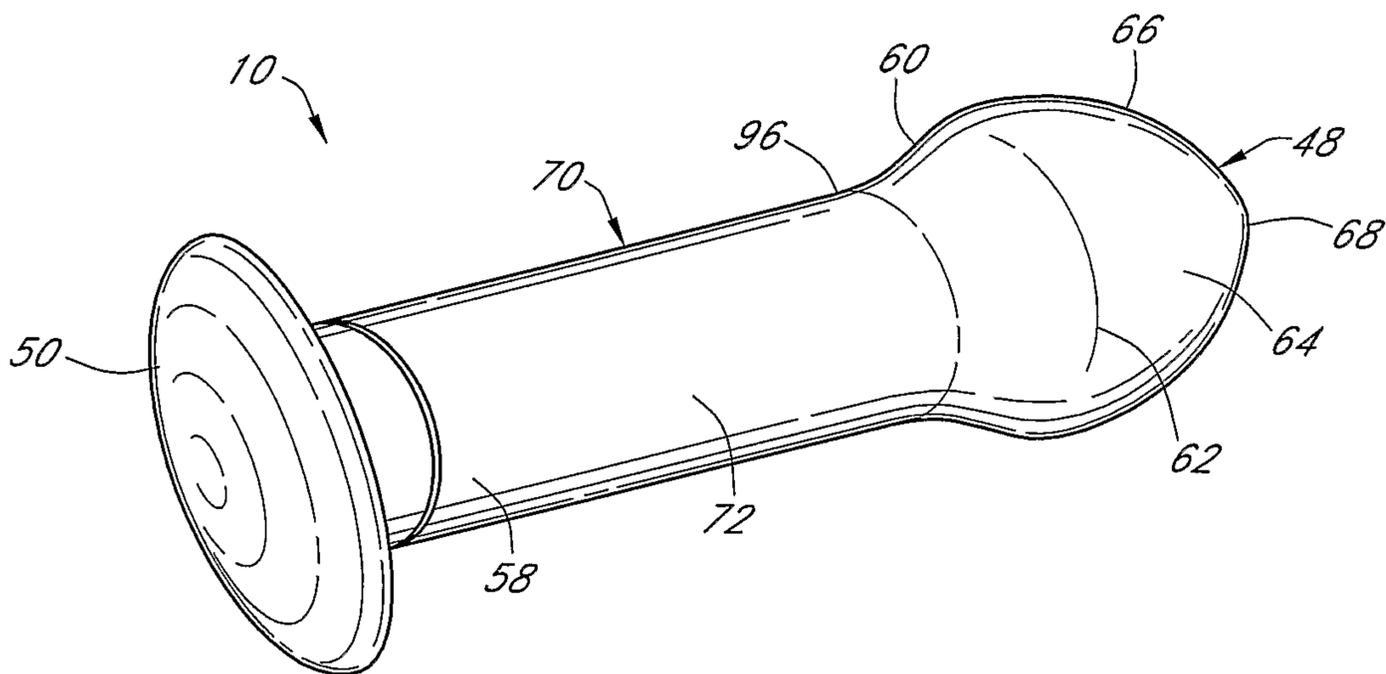


FIG. 4

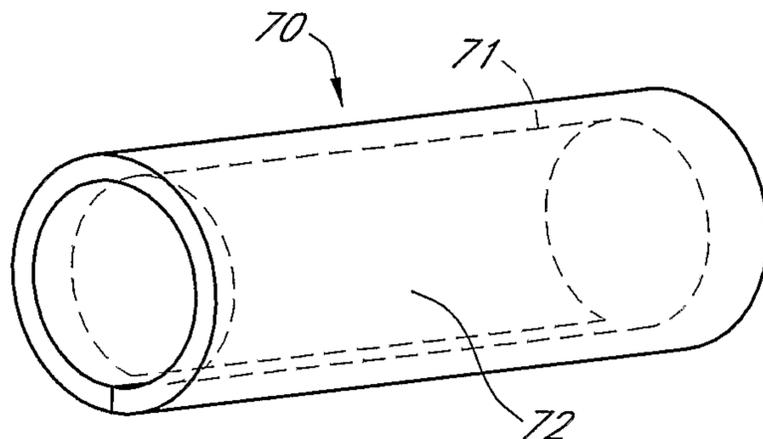


FIG. 5

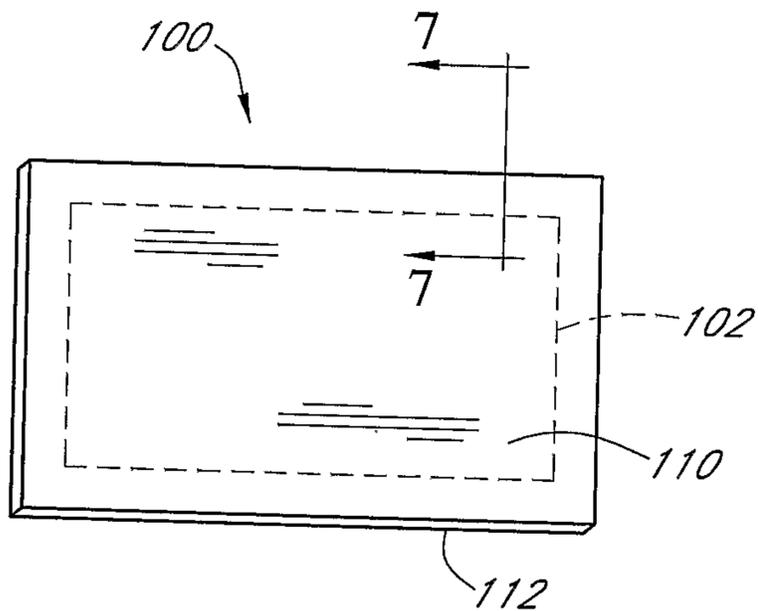


FIG. 6

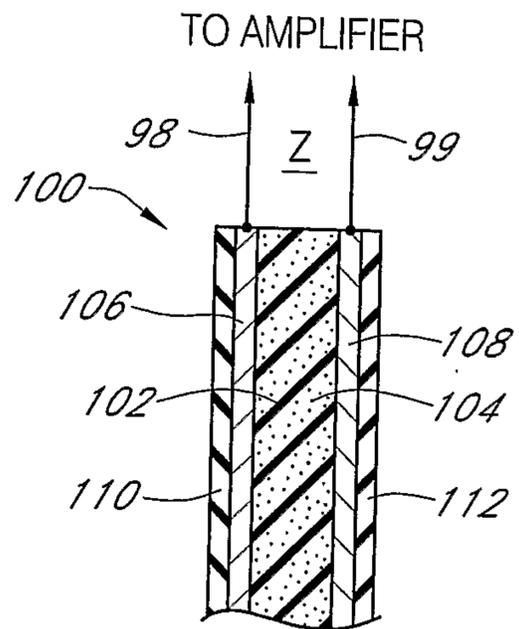


FIG. 7

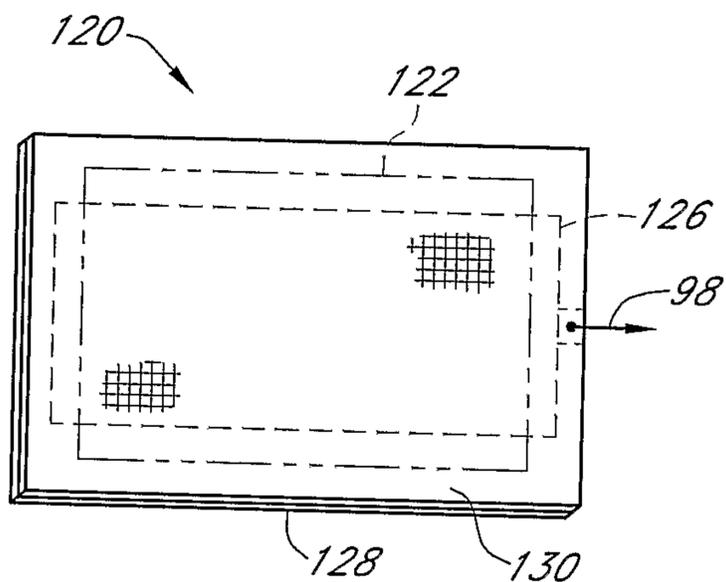


FIG. 8

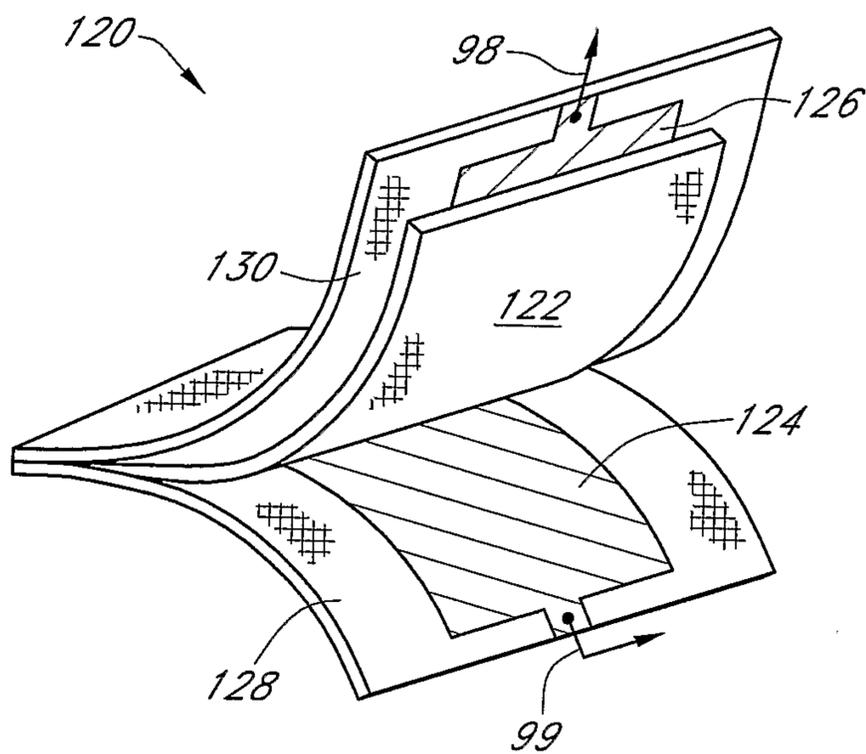


FIG. 9

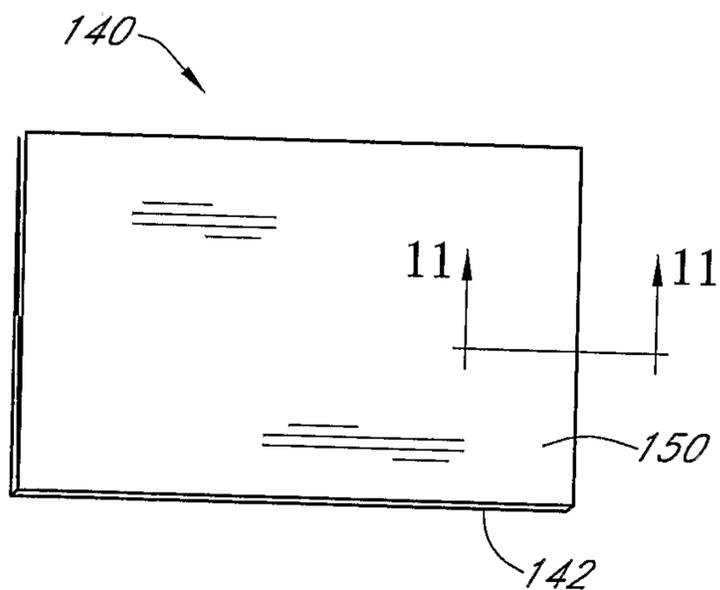


FIG. 10

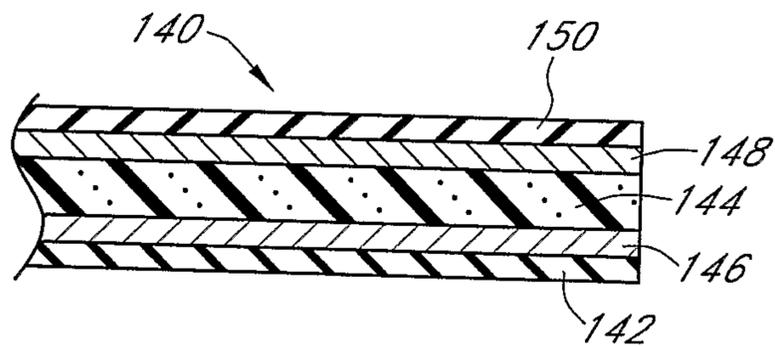


FIG. 11

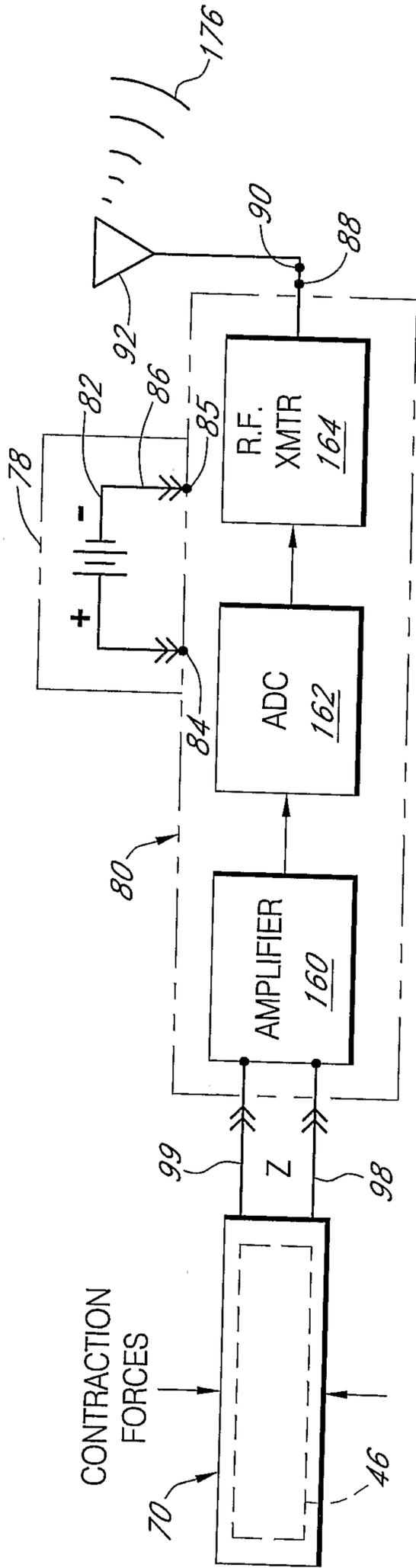


FIG. 12

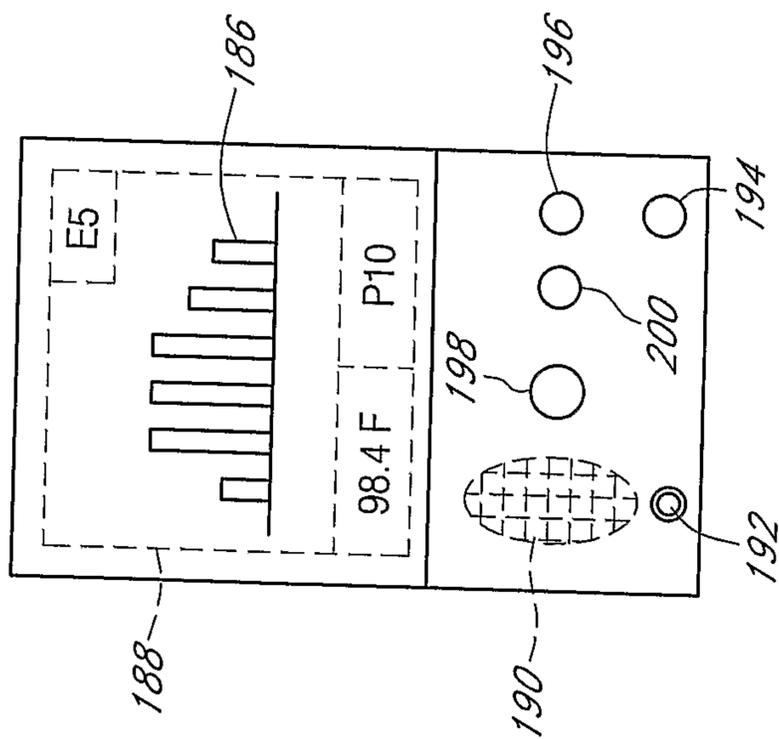


FIG. 13

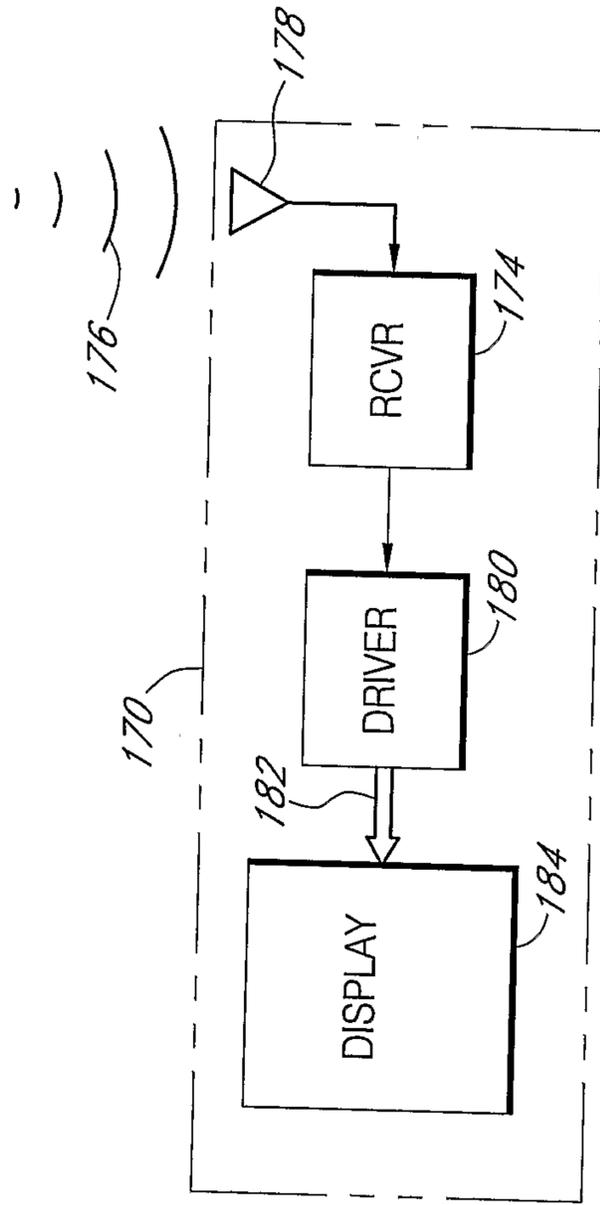


FIG. 14

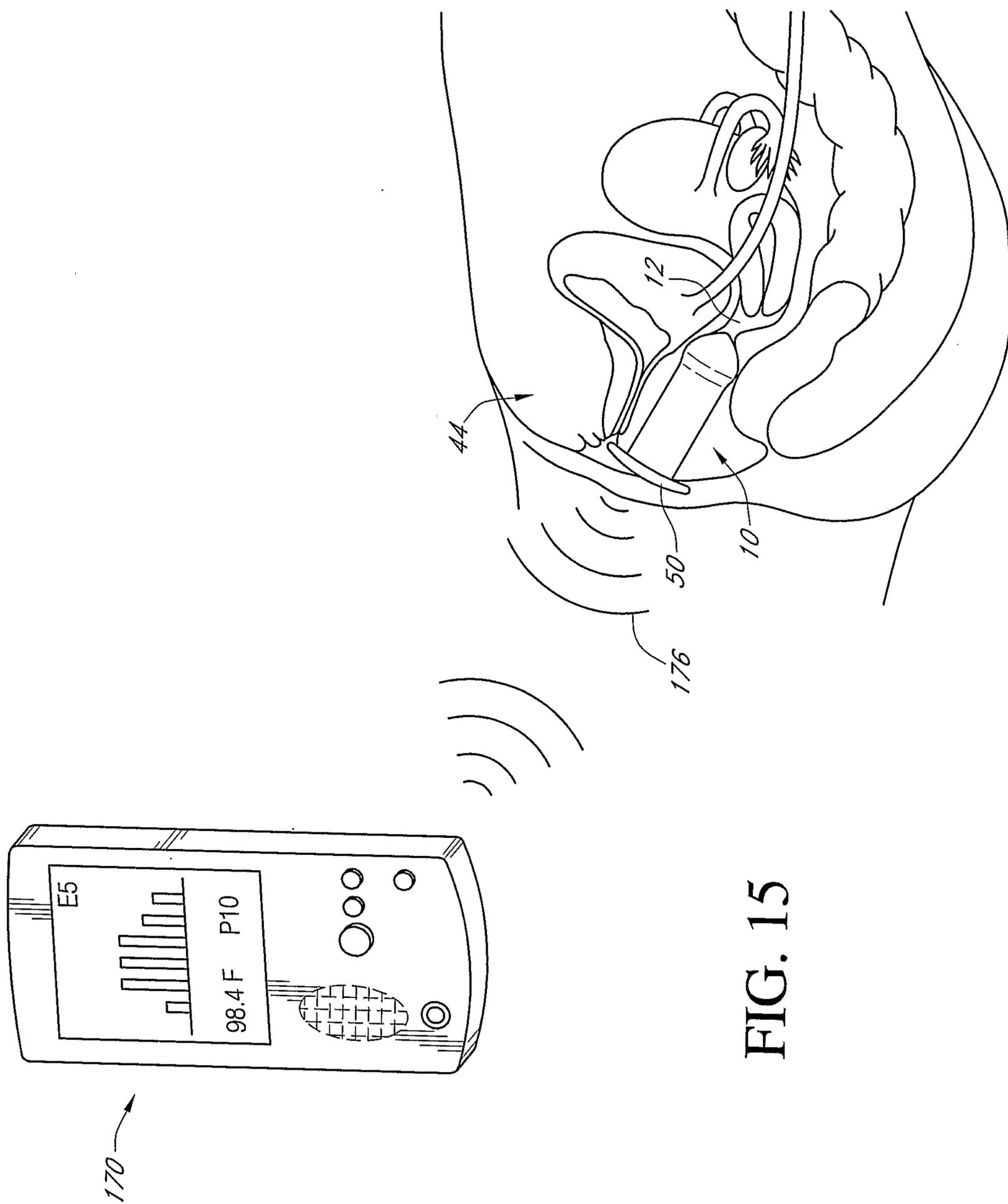


FIG. 15

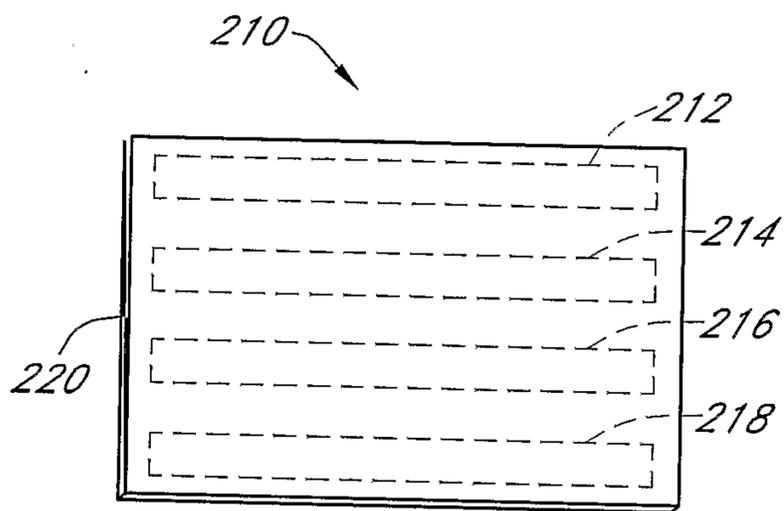


FIG. 16

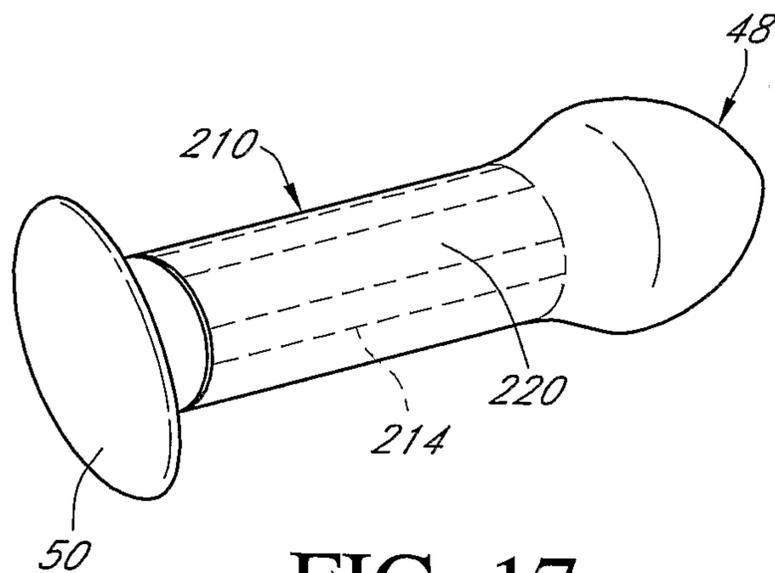


FIG. 17

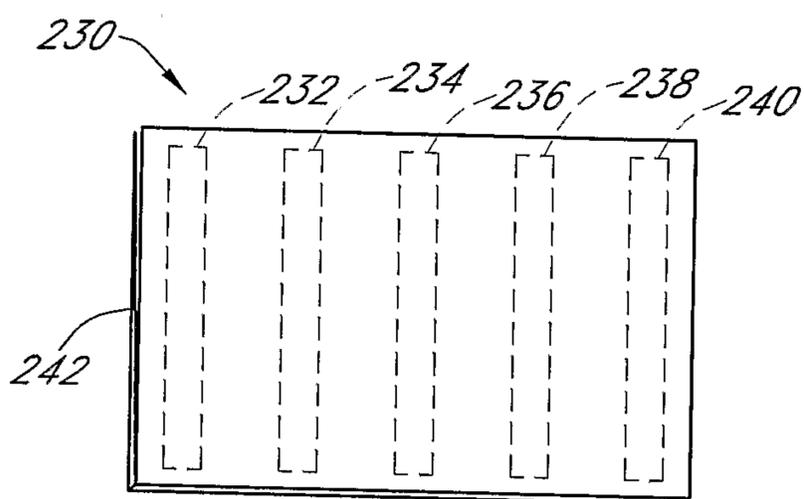


FIG. 18

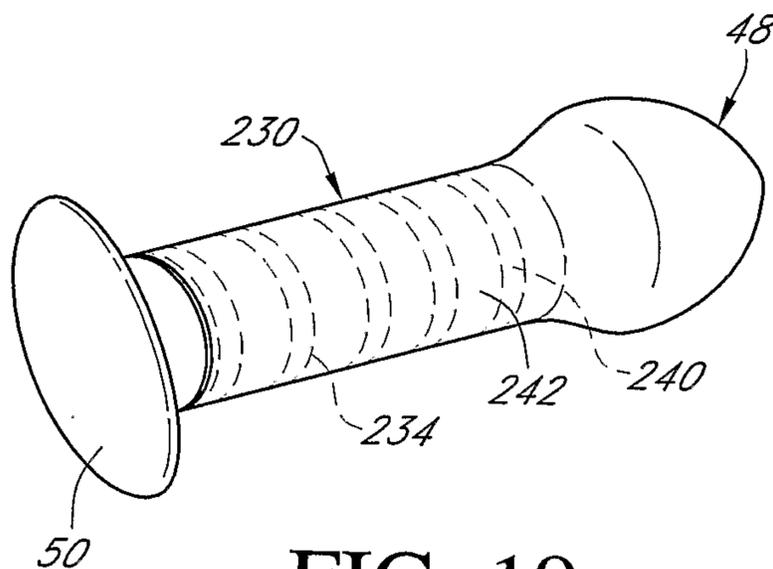


FIG. 19

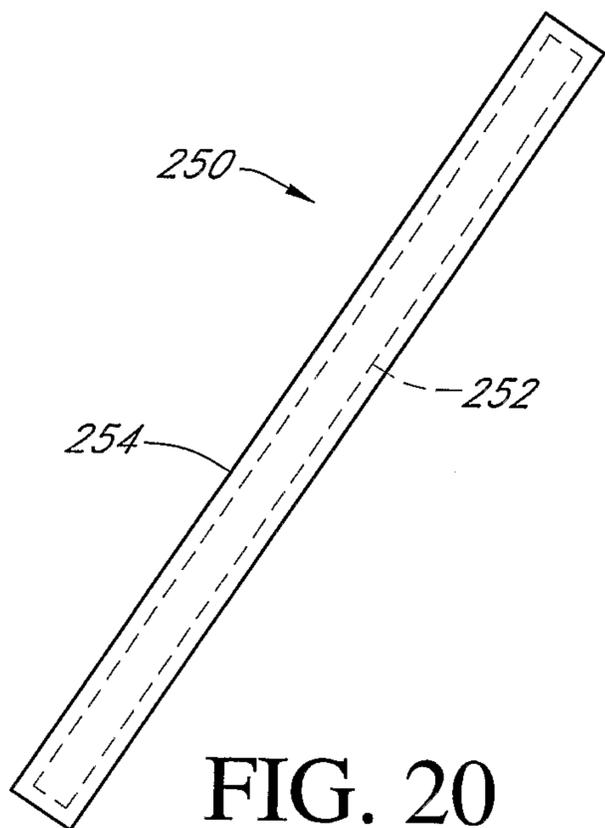


FIG. 20

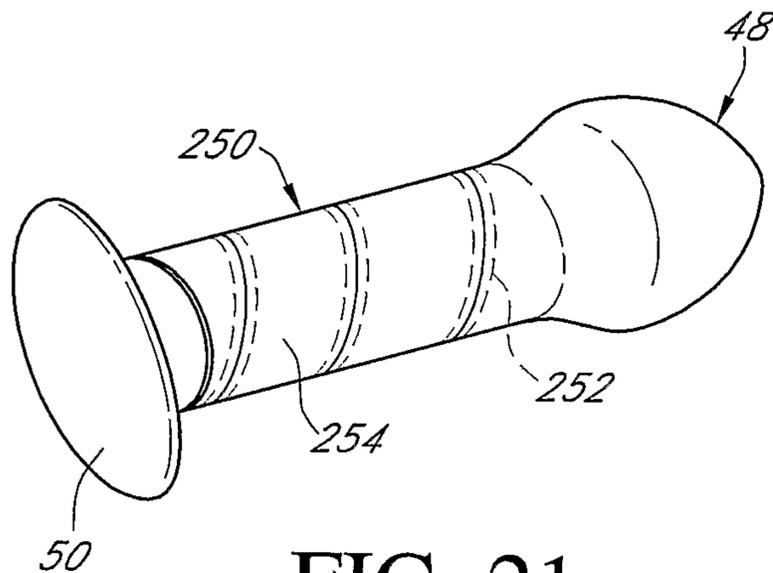


FIG. 21

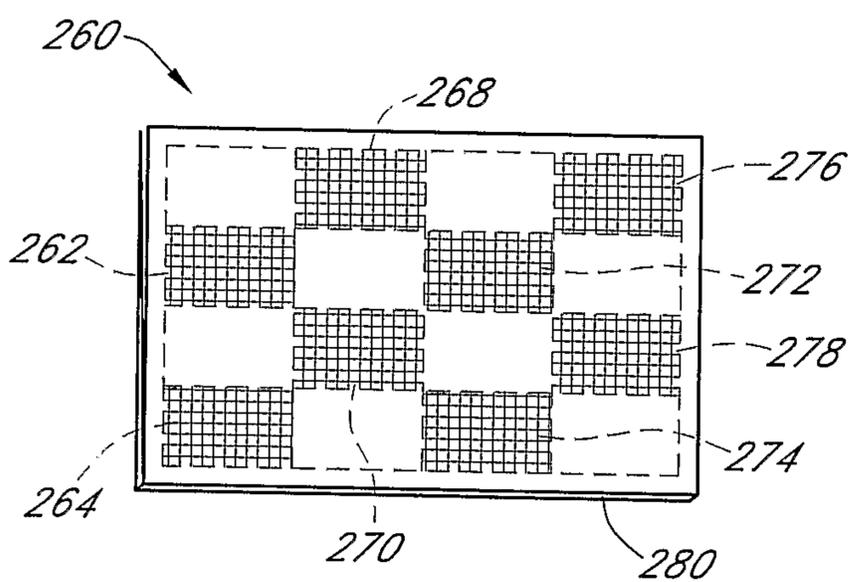


FIG. 22

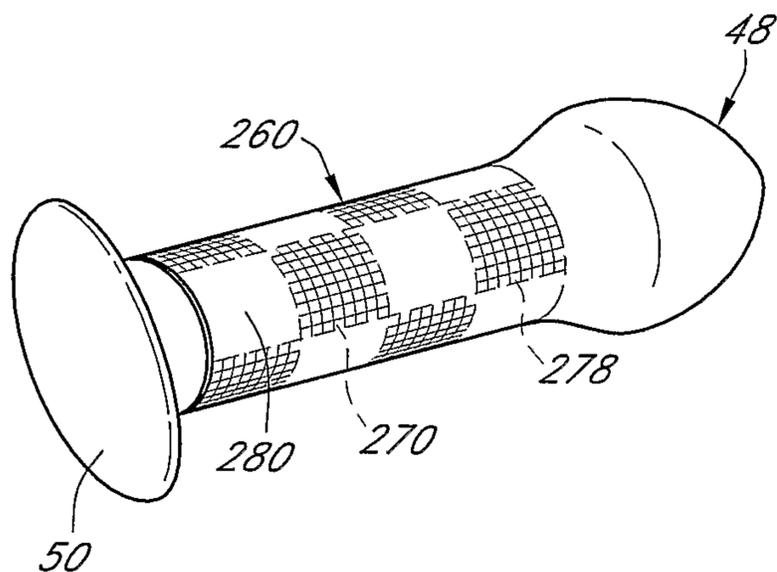


FIG. 23

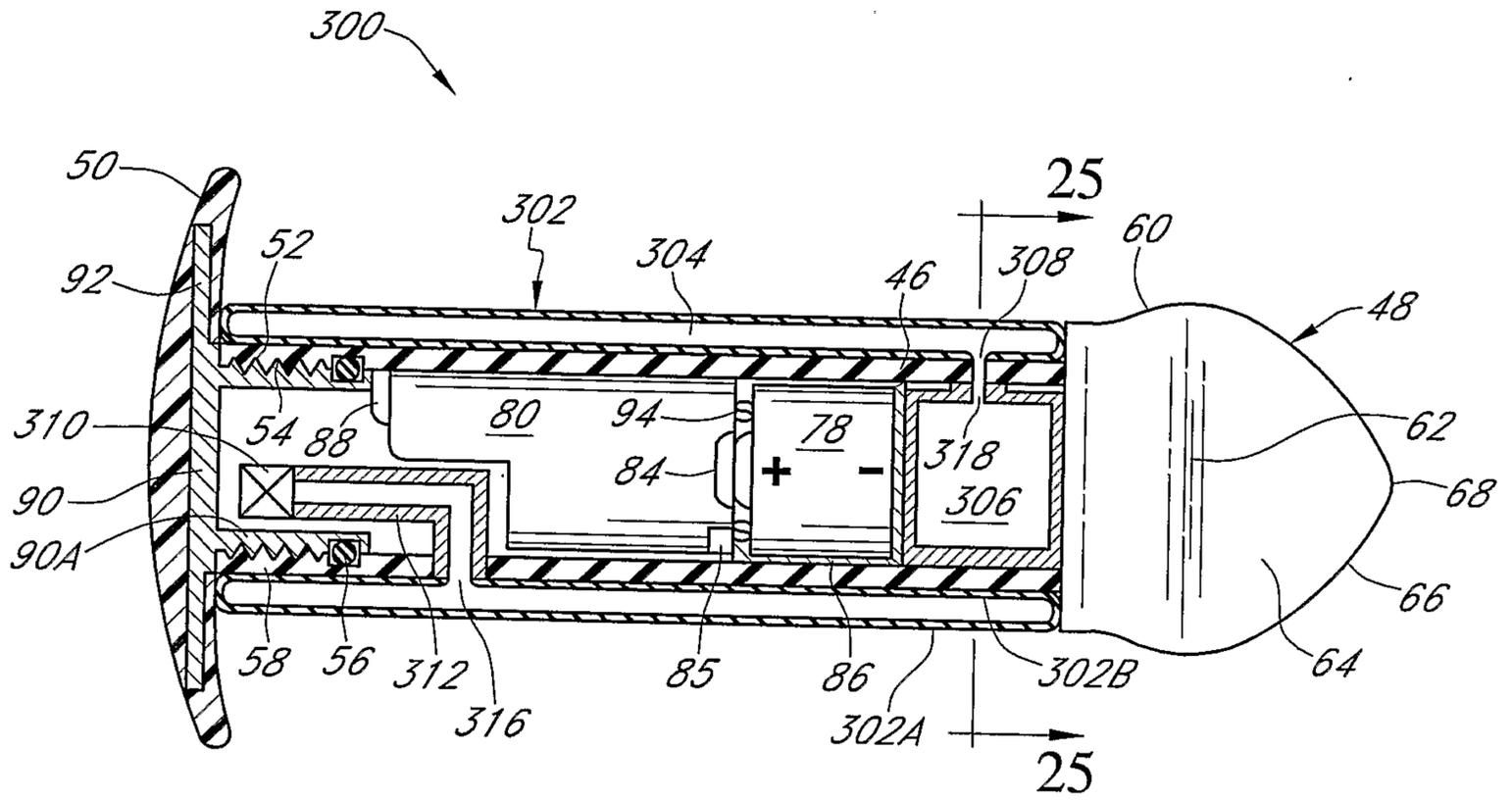


FIG. 24

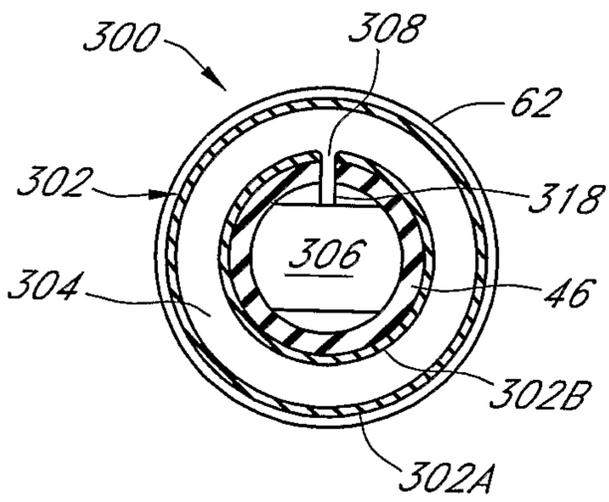


FIG. 25

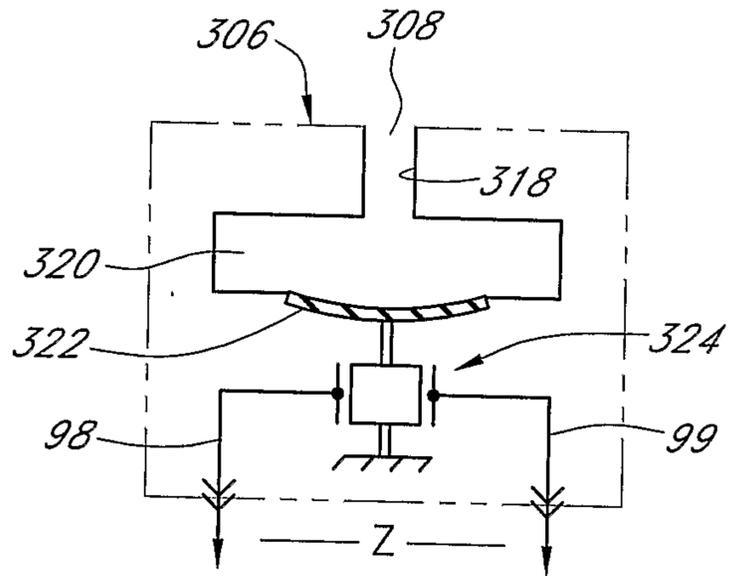


FIG. 27

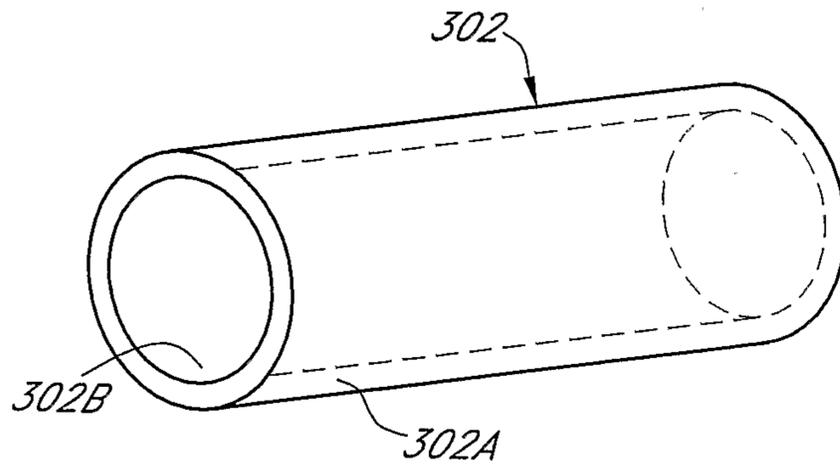


FIG. 26

170

