Innovation, Sciences et Développement économique Canada
Office de la Propriété Intellectuelle du Canada

Innovation, Science and Economic Development Canada
Canadian Intellectual Property Office

CA 3222966 A1 2013/08/08

(21) 3 222 966

(12) DEMANDE DE BREVET CANADIEN
CANADIAN PATENT APPLICATION

(13) A1

(22) Date de dépôt/Filing Date: 2013/01/30

(41) Mise à la disp. pub./Open to Public Insp.: 2013/08/08

(62) Demande originale/Original Application: 2 862 928

(30) Priorité/Priority: 2012/01/30 (US61/592,092)

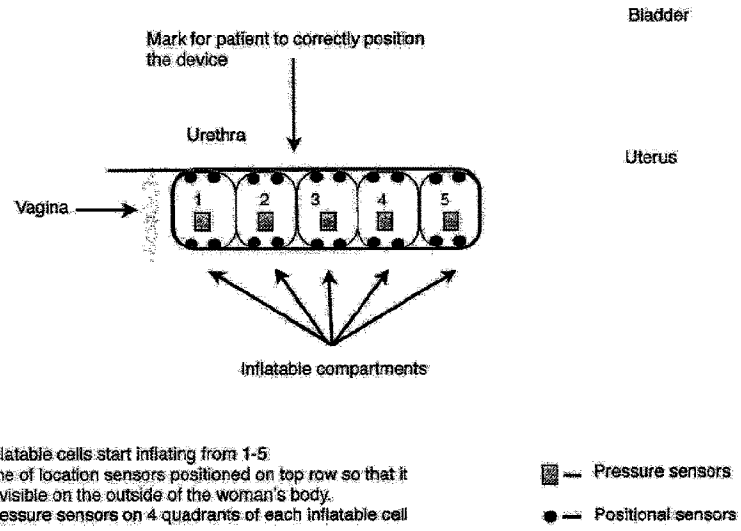
(51) Cl.Int./Int.Cl. *A61F 2/00* (2006.01),
A61B 5/00 (2006.01), *A61B 5/22* (2006.01)

(71) Demandeur/Applicant:
AXENA HEALTH, INC., US

(72) Inventeur/Inventor:
IGLESIAS, RAMON JOSE, US

(74) Agent: ROBIC AGENCE PI S.E.C./ROBIC IP AGENCY LP

(54) Titre : TRAITEMENT D'UN PROLAPSUS GENITAL
(54) Title: TREATMENT OF PELVIC ORGAN PROLAPSE



(57) Abrégé/Abstract:
The present invention relates to the diagnosis and treatment of pelvic floor prolapse. The diagnosis and treatment may involve the use of a multiple sensor-enabled device for vaginal insertion capable of providing real-time data regarding the patient's physiology, the position and movement of the urethra, and the muscular strength of the patient's vagina and pelvic floor. The methods and devices of the invention may also be useful to addressing other medical issues, including urinary incontinence, sexual health, and fecal incontinence, as well as facilitate patient home wellness activities.

ABSTRACT

The present invention relates to the diagnosis and treatment of pelvic floor prolapse. The diagnosis and treatment may involve the use of a multiple sensor-enabled device for vaginal insertion capable of providing real-time data regarding the patient's physiology, the position and movement of the urethra, and the muscular strength of the patient's vagina and pelvic floor. The methods and devices of the invention may also be useful to addressing other medical issues, including urinary incontinence, sexual health, and fecal incontinence, as well as facilitate patient home wellness activities.

Date Reçue/Date Received 2023-12-13

TREATMENT OF PELVIC ORGAN PROLAPSE

BACKGROUND OF THE INVENTION

[0001] The present invention relates to the diagnosis and treatment of pelvic organ prolapse and related conditions. The diagnosis and treatment may involve the use of a multiple sensor-enabled device for vaginal insertion capable of providing real-time data regarding the patient's physiology, the position and movement of the urethra, and the muscular strength of the patient's vagina and pelvic floor.

[0002] Pelvic organ prolapse (POP) generally relates to a condition where the muscles and ligaments supporting a woman's pelvic organs weaken thereby causing the pelvic organs to slip out of place (prolapse). There are different types of POP, including vaginal vault prolapse, bladder prolapse, rectal prolapse, uterine prolapse, and small bowel prolapse. Some women develop vaginal prolapse, usually after menopause, childbirth or a hysterectomy.

[0003] In certain cases, POP occurs due to the damage of the tissues that support the intra-abdominal contents causing the contents of the abdominal cavity to spill through the weakest support points and extrude through the vaginal walls. This weakness can be at the bladder area, the uterine area or the rectal/enterocele area. The condition can worsen over time, and the patient may need corrective surgery.

[0004] Information regarding the anatomical areas of weakness suspected as contributing to the condition as well as the primary area of weakness can facilitate appropriate corrective surgery at an early stage and in a targeted fashion to repair the herniated abdominal contents through the pelvic floor area. In addition, specially designed patches, for example, could be used to prevent further prolapse.

[0005] Presently, there is no available test that can accurately diagnose POP by localizing and evaluating the herniated areas suspected of giving rise to a patient's POP. The types of diagnostic tests commonly relied upon today include the cotton swab test (where the health care provider inserts a small, cotton-tipped applicator lubricated with anesthetic gel into the patient's urethra, the patient is asked to strain, and the applicator may indicate a loss of support to the urethra); the bladder function test (to measure the ability of the patient's bladder to store and empty urine, which might aid the health care

Date Reçue/Date Received 2023-12-13

provider to determine the most appropriate type of surgery for bladder or urethral prolapse); pelvic floor strength tests (where the health care provider relies upon personal experience to approximate the strength of the patient's pelvic floor and sphincter muscles, and possibly, the strength of muscles and ligaments that support the patient's vaginal walls, uterus, rectum, urethra and bladder); and imaging tests (which include magnetic resonance imaging (MRI) to obtain a three- dimensional image of the pelvis; ultrasound to visualize the patient's kidneys, bladder or the muscles around the patient's anus; cystoscopy to evaluate symptoms of urinary urgency, frequency, bladder pain or blood in the urine by insertion of a thin tube with a light and camera on the tip (cytoscope) into the patient's urethra to view the urethra and bladder. None of these techniques, however, alone or collectively, can provide the positional and pressure data to yield as detailed and accurate POP diagnosis as possible through the instant invention.

[0006] Furthermore, there is evidence that pelvic floor training can strengthen the pelvic floor muscles to remedy or otherwise alleviate urinary incontinence (UI) and POP, and thereby avoid surgery. Present methods for pelvic floor training, however, do not offer a way for the health care provider or the patient to measure improvement, confirm that such exercises are being performed correctly, or to accurately monitor the amount of time the patient is doing the exercises and amount of exertion the patient is using in order to improve or prevent UI or POP.

[0007] The multiple sensor-enabled device disclosed here can assist the health care provider and the patient to assess whether the patient is properly performing Kegel exercises and otherwise achieving the therapeutic goals.

[0008] Physical therapists today employ certain electronic devices to help the patient perform Kegel exercises. In these cases, a vaginal insert with sensors may be viewed as electrical impulses on a screen. But these devices cannot reflect what muscles the patient is contracting, indicate whether the patient is contracting the appropriate muscles, or monitor the patient's progress. Essentially, the only information readout is a tracing that reflects the discharge of electrical stimuli, but which offers no assurance to the health care provider or patient that the needed

Date Reçue/Date Received 2023-12-13

strengthening of the pelvic floor muscles is occurring. Electrical stimulation might provide temporary relief of UI if the electrical impulses happen to be engaged and placed correctly. However, because it is difficult, if not impossible, to know the amount of electrical discharge needed and the correct positioning, these methods do not work effectively or long-term. The electrical stimulation might allow the patient to recognize their own muscles, but falls short of facilitating the strengthening of the patient's muscles to result in an improvement, because the patient must also contract the particular muscles properly.

[0009] The multiple sensor-enabled device of the instant invention would allow the health care provider and the patient to visualize whether the patient is actually doing the pelvic floor exercises correctly. Moreover, educating the patient on the correct way of using the device would allow the patient to take the device with her, and in the privacy of her home, visualize her exercise regimen through a convenient display, such as a computer or smart phone application. The patient may also benefit from inserting, removing and cleaning the device at her convenience. Furthermore, the patient can monitor and record her progress and send her information back to the health care provider to assure her compliance. The convenience and privacy of home training and progress monitoring can enhance patient compliance with the therapeutic regimen, and facilitate a more efficient achievement of therapeutic goals.

BRIEF SUMMARY OF THE INVENTION

[0010] The present invention relates to the diagnosis and treatment of pelvic organ prolapse (POP). In an embodiment of the invention, this diagnosis and treatment involves the use of a multiple sensor-enabled device for vaginal insertion capable of providing real-time data regarding the patient's physiology, the position and movement of the urethra, and the muscular strength of the patient's vagina and pelvic floor. In one embodiment, the device may be inflatable.

[0011] The multiple sensor-enabled device may include at least one sensor capable of providing real-time data of one or more types selected from the group consisting of position, movement, pressure, and flow. In this regard, a sensor may have a single measurement and reporting capability, or may have multiple measurement and reporting capabilities.

Date Reçue/Date Received 2023-12-13

[0012] The present invention also includes a method for the diagnosis or treatment of urinary incontinence (UI) or POP comprising providing a multiple sensor-enabled device in a patient and determining the anatomical state of the patient capable of relieving the incontinence. The device can indicate the position of the patient's urethra and vagina, and allow the health care provider or patient to visualize the relative movement of these anatomical organs, and thus, show the patient whether her efforts at performing Kegel exercises are being performed correctly.

[0013] Often, the proper performance of Kegel exercises is difficult to explain and difficult for the patient to understand how to achieve. If the patient misunderstands how to perform such exercises, she can perform them wrong, usually by performing a valsalva maneuver and consequently causing more damage to the pelvic floor by causing the abdominal contents to be pushed down through the pelvic floor.

[0014] The multiple sensor-enabled device of the present invention would also enable the health care provider and patient to view quantitatively what vaginal pressure is being exerted by the patient at any time, to recognize the vaginal muscular strength, and to facilitate the patient's performance of muscular exercises in a precise manner. The position and pressure of the posterior vaginal wall as well as that of the lower intestines and rectal area can be determined using the device.

[0015] In an embodiment of the present invention, where the device includes Inflatable components as shown in Figure 1 as an example, POP could also be alleviated or prevented by placing the device into the vagina and inflating each section from farthest to the most proximal. The most proximal inflatable section may be inflated to prevent spillage of the vaginal contents. In this mode of operation, the device offers advantages over devices, such as pessaries, used today. Every month, rather than the patient having to return to the health care provider to extract the pessary and clean it for reinsertion, the patient would be able to withdraw the instant device and clean it for reinsertion in the convenience and privacy of her own home, which may include any location outside the health care provider's office or facility. In this regard, the device disclosed here may be used to improve a woman's vaginal muscular strength by performing vaginal strengthening exercises (VSE) to achieve

Date Reçue/Date Received 2023-12-13

her desired sexual health as well as to address any UI or POP conditions.

[0016] The present invention contemplates the real-time position and movement tracking described in International Patent Application PCT/US2010/053712, and the multiple sensor-enable device described in U.S. provisional patent application Serial No. 61/563,889, which are hereby incorporated in their entirety by reference. In this regard, the real-time position and movement tracking may include sensing the position of the anatomical organ of interest to an anatomical reference point, such as the patient's pubic bone, the coccyx or the vagina, or to an external reference point, such as a target on a patient's garment or in the patient's surroundings. The method may be performed in real-time, for example, during a medical examination, procedure, or surgery. In another embodiment, the method may be performed at multiple time intervals. The multiple time intervals may occur, for example, pre- and post-event, wherein the event may be pregnancy or menopause.

[0017] The multiple sensor-enabled device may also provide pressure data, which reflects muscular strength, and provide a health care provider a detailed map of where the weakest anatomical points are for purposes of POP diagnosis and treatment. Where vaginal strengthening exercises are inadequate to prevent or relieve UI or POP, a surgeon would be able to use this information to target corrective procedures appropriately.

BRIEF DESCRIPTION OF THE DRAWINGS

[0018] Figure 1 depicts a lateral view of an embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0019] When used in the claims, the terms "a" and "an" and "the" and similar references in the context of describing the invention (especially in the context of the following claims) are to be construed to cover both the singular and the plural, unless otherwise indicated herein or clearly contradicted by context. Also when used in the claims, the terms "comprising," "having," "including," and "containing" are to be construed as open- ended terms (i.e., meaning "including, but not limited to,") unless

Date Reçue/Date Received 2023-12-13

otherwise noted. To the extent used, the recitation of ranges of values herein are merely intended to serve as a shorthand method of referring individually to each separate value falling within the range, unless otherwise indicated herein, and each separate value is incorporated into the specification as if it were individually recited herein. All methods described herein can be performed in any suitable order unless otherwise indicated herein or otherwise clearly contradicted by context. The use of any and all examples, or exemplary language (e.g., "such as") provided herein, is intended merely to better illuminate the invention and does not pose a limitation on the scope of the invention unless otherwise claimed. No language in the specification should be construed as indicating any non-claimed element as essential to the practice of the invention. Variations of the embodiments may become apparent to those of ordinary skill in the art upon reading the description. Accordingly, this invention includes all modifications and equivalents of the subject matter recited in the claims appended hereto as permitted by applicable law. Moreover, any combination of the described elements in all possible variations thereof is encompassed by the invention unless otherwise indicated herein or otherwise clearly contradicted by context.

[0020] For purposes of the present invention, the term "urethra" may be defined as the canal leading from the bladder, discharging the urine externally. See STEDMAN's MEDICAL DICTIONARY, at page 2072 (28th ed). In females, the urethra is a canal about 4 centimeters long passing from the bladder, in close relation with the anterior wall of the vagina and having a long axis that parallels that of the vagina opening in the vestibule of the vagina posterior to the clitoris and anterior to the vaginal orifice. *Id.* The term "urinary bladder" refers to a musculomembranous elastic bag serving as a storage place for the urine, filled via the ureters and drained via the urethra. *Id.* at page 226. The term "bladder neck" is defined as the smooth muscle of the bladder neck is histologically, histochemically and pharmacologically distinct from the detrusor muscle proper and so the bladder neck should be considered as a separate functional unit. *See* GRAY's ANATOMY, at page 1290 (39th ed.). The arrangement of smooth muscle in this region is quite different in males and females, and therefore each sex is described separately. In females, the bladder neck consists of morphologically distinct smooth muscle. The large diameter fasciculi characteristic of the detrusor is replaced in the region of the bladder neck by small diameter fasciculi which extend obliquely or longitudinally into the urethral wall. *Id.* In the normal

Date Reçue/Date Received 2023-12-13

female the bladder neck which above the pelvic floor supported predominantly by the pubovesical ligaments, the endopelvic fascia of the pelvic floor and levator ani. These support the urethra at rest; with elevated intra-abdominal pressure the levators contract increasing urethral closure pressure to maintain continence. This anatomical arrangement commonly alters after parturition and with increasing age, such that the bladder neck lies beneath the pelvic floor, particularly when the intra-abdominal pressure rises. The mechanism described above may fail to maintain continence (incontinence as a result of urethral hypermobility).

[0021] As commonly understood, the term "vagina" refers to an elastic muscular canal that extends from the cervix to the vulva. Although there is wide anatomical variation, the length ofthe unaroused vagina of a woman of child-bearing age is approximately 6 to 7.5 cm (2.5 to 3 inches) across the anterior wall (front), and 9 cm (3.5 inches) long across the posterior wall (rear). The vagina connects the superficial vulva to the cervix of the deep uterus. In a typical woman standing upright, the vaginal tube points in an upward-backward direction and forms an angle of slightly more than 45 degrees with the uterus. The vaginal opening is at the caudal end of the vulva, behind the opening of the urethra. The upper one- fourth of the vagina is separated from the rectum by the recto-uterine pouch.

[0022] In the present invention, for example, a device for vaginal insertion may be equipped with at least one sensor capable of providing real-time data of one or more types selected from the group consisting of position, movement, pressure, and flow. In this regard, a sensor may have a single measurement and reporting capability, or may have multiple measurement and reporting capabilities. The data obtained by the multiple sensor-enabled device may be reported in any number of ways known in the art, including the transmission to, and visualization on, a graphical user interface wirelessly.

[0023] The device would be inserted into the vagina until the patient feels her cervix. The distal section of the device, in an inflatable embodiment, would be filled with air, gel, liquid, or other appropriate material suitable for inflation and deflation of a compartment, to fit the patient's vagina. In an embodiment with multiple inflatable sections, the rest of the compartments could be filled from distal to proximal (vaginal opening). In this way, a patient with POP not only would strengthen her vaginal muscles but could also use the device as a pessary that can be easily removed at home and would

Date Reçue/Date Received 2023-12-13

not have the complications currently associated with pessaries, such as pressure point problems and vaginal infections.

[0024] When the device is properly inserted and inflated, the health care provider or patient can visualize the device on a display screen. When the patient is asked to perform Kegel movements, the vaginal pressure or strength of the vaginal musculature will also be visualizable on the screen. The health care provider could then go through the exercises with the patient to ensure that she is performing the exercises optimally and has understood how to interpret the information and otherwise use the equipment properly.

[0025] The multiple sensor-enabled device would be invaluable as a study or rehabilitation tool for the health care provider as well as the patient who is considering a pregnancy. The health care provider may be able to provide the patient with an exercise regimen that could strengthen her vagina and urinary musculature at home before she had her baby, helping her prevent urinary incontinence in the future and strengthening her pelvic floor, before the possible damage may occur during pregnancy and delivery.

[0026] The multiple sensor-enabled device could aid various diagnoses that rely upon data concerning the position, strength and pressures of the vaginal space. By combining pressure sensors along the multiple sensor-enabled inflatable vaginal insert along with the positional sensors, objective measurements relating to vaginal pressure and positional location can be evaluated and correlated to aid in the diagnosis and treatment of UI or POP and the rehabilitation of the vaginal muscles and pelvic floor.

[0027] In yet another embodiment of the present invention, the multiple sensor-enabled device can provide data, which is transmitted and recorded in a manner to create and maintain historical patient information for medical and/or fitness purposes, such as a pelvic floor muscle strengthening exercise calendar.

[0028] Another use for a multiple sensor-enabled device would be to correct fecal incontinence, which is often another sequela of pregnancy and childbirth. For example, if a rectocele or enterocele is diagnosed, a multiple sensor-enabled device could be inserted into the rectum. With this information the health care provider would be able to properly diagnose the etiology of the fecal incontinence whether that is due to muscle weakness of the pelvic floor, a rectal sphincter deficiency, or a combination of the two. The health care provider could target the surgical repair, in real-time if preferred, to correct the fecal incontinence.

Date Reçue/Date Received 2023-12-13

[0029] The multiple sensor-enabled device may incorporate at least one sensor capable of measuring and/or reporting data of various types including position, movement, pressure and flow. A multiple sensor-enabled device with more than one individual sensor may be arrayed as depicted in Figure 1. However, a multiple sensor-enabled device may incorporate a single sensor capable of multiple measurement and reporting capabilities.

[0030] The position and movement data may be of the sort measured and/or reported by any number of sensor devices, including an accelerometer, gyroscope, inductive non-contact position sensor, string potentiometer, linear variable differential transformer, potentiometer, capacitive transducer, Eddy-current sensor, Hall effect sensor, optical proximity sensor, piezo-electric transducer and photodiode array. The position and movement data may also include magnetic, electromagnetic, microelectromechanical, radio frequency, ultrasound and video.

[0031] The pressure and flow data may be of the sort measured and/or reported by any number of sensor devices, including force collector types, such as piezo-resistive, capacitive, electromagnetic, piezo-electric, optical, potentiometric, or other types, such as resonant, thermal, ionization, ultrasonic, and density (mass and index of refraction). In addition, sensor technology that recognizes movement and touch may be incorporated, which includes the types such as resistive, surface acoustic wave, capacitive (surface capacitance, projected capacitance, mutual capacitance, and self-capacitance), infrared, optical imaging, dispersive signal technology, and acoustic pulse recognition.

[0032] Figure 1 depicts a multiple sensor-enable device for vaginal insertion with inflatable compartments. The number and precise placement of an individual sensor may vary depending on the type of positional, movement, pressure or flow measurement and/or reporting system employed. An individual sensor may have a single function or be multifunction (such as positional tracking combined with pressure and flow sensing). The multiple sensor-enabled device may also embody a video observation and/or recording device as well as an illumination source to facilitate such video capture. The precise placement of the sensor(s) and video capture component(s) need not be pre-defined, and may be configured according to the requirements of the desired application.

Date Reçue/Date Received 2023-12-13

SPECIFIC EXAMPLES

[0033] As described earlier, the devices of the present invention may embody at least one sensor capable of measuring and reporting at least one data type, including position, movement, pressure, and flow. These include, but are not limited to, magnetic, electromagnetic, microelectromechanical, radio frequency, ultrasound and video. One example of a multiple sensor-enabled device contains various microelectromechanical (MEMS) sensors: a 3-axis accelerometer, a roll/pitch gyroscope and a yaw rate gyroscope, and a pressure and flow transducer. The sensors may be mounted on a small flexible printed circuit board (PCB) and then attached to, or incorporated within, the device. The 3-axis accelerometer tracks translation of the device in three directions. The gyroscopes are utilized to account for gravitational rotation, allowing real-time movement to be tracked.

[0034] A PCB is prepared with MEMS sensors mounted thereon. Soft leads can trail the MEMS sensors to supporting components, including, for example, a data acquisition card which may be used for transforming analog signals to digital signals. The PCB is set within the wall of the device. The location of the device may be determined by the output signals of the MEMS sensors.

[0035] In an embodiment where the multiple sensor-enabled device contains inflatable compartments, the device may be inserted in the length of the vagina at which point the compartment nearest the cervix is inflated to obtain a stationary and/or comfortable fit within the vagina. Any additional inflatable compartments may be inflated together or in sequence from distal to proximal to the vaginal opening.

[0036] The patient may be asked to perform a Kegel movement, while the health care provider and/or the patient observes the display output to confirm that the patient is performing the exercise optimally. The pressure and muscular strength of the vagina as measured by the multiple sensor-enable device would be displayed to reflect the effectiveness of the therapy. The position of the urethra and bladder neck may also be displayed in real time on a graphical user interface and/or recorded.

[0037] Following the examination using the multiple sensor-enabled device, the health care provider may conclude that rehabilitation is an efficacious option for the patient. In this regard, the measurements provided by the multiple sensor-enabled device

Date Reçue/Date Received 2023-12-13

may be recorded to facilitate appropriate patient instructions on performing Kegel exercises in an optimal manner using the visual (on-screen) information provided by the device in real-time. Once engaging the proper musculature has been successfully communicated to the patient during the medical office visit, the patient may be sent home with the instructions to perform Kegel exercises five to six times daily, for example. Four to six weeks later the patient may return for another examination using the multiple sensor-enabled device to evaluate rehabilitative treatment effectiveness, which may allow the health care provider to advise the patient about the prospects for restoring complete continence with a continued rehabilitation regime and/or a surgical procedure.

[0038] Detailed embodiments of the present invention are disclosed herein; however, it is to be understood that the disclosed embodiments are merely exemplary of the invention that may be embodied in various forms. It will be appreciated that many modifications and other variations that will be appreciated by those skilled in the art are within the intended scope of this invention as claimed below without departing from the teachings, spirit and intended scope of the invention.

[0039] Indeed, other possible item(s), aspect(s), object(s), embodiment(s), variant(s) and/or advantage(s) of the present invention, all being preferred and/or optional, are briefly summarized hereinbelow:

1. An intravaginal device for treating a female subject with a pelvic floor disorder, the intravaginal device comprising a plurality of MEMS sensors positioned along a length of the device and mounted on a flexible PCB attached to or incorporated within the device;

wherein the MEMS sensors are capable of providing real-time position or movement data; and

wherein the device is arranged to transmit the real-time data wirelessly to a graphical user interface; wherein the position data relates to at least one of a position of a vaginal space and a position of an anatomical organ of interest to an anatomical or external reference point.

2. The device according to item 1, wherein the position or movement data

Date Reçue/Date Received 2023-12-13

comprises at least one of: magnetic, electromagnetic, microelectromechanical, radio frequency, ultrasound, and video data.

3. The device according to item 1 or 2, wherein the device further comprises one or more additional sensors capable of providing real-time flow data.

4. The device according to item 3, wherein the one or more additional sensors is selected from the group consisting of a gyroscope, an inductive noncontact position sensor, a string potentiometer, a linear variable differential transformer, a potentiometer, a capacitive transducer, an Eddy-current sensor, a Hall effect sensor, an optical proximity sensor, a piezo-electric transducer, a photodiode array, a force collector, a piezo-resistive sensor, a capacitive sensor, an electromagnetic sensor, a piezo-electric sensor, an optical sensor, a potentiometric sensor, a resonant sensor, a thermal sensor, an ionization sensor; an ultrasonic sensor, a density sensor, a resistive sensor, a surface acoustic wave sensor, a capacitive sensor, an infrared sensor, an optical imaging sensor, a dispersive signal technology sensor, and an acoustic pulse recognition sensor.

5. The device according to any one of items 1 to 4, wherein the device further comprises an inflatable component.

6. The device according to item 5, wherein the device comprises a plurality of inflatable components.

7. The device according to any one of items 3 to 6, wherein the device further comprises one or more pressure sensors capable of providing real-time pressure data.

8. The device according to item 7, wherein the position data comprises data relating to the position of a posterior vaginal wall, and the pressure data comprises data related to the pressure of the posterior vaginal wall.

9. The device according to item 7, wherein the pressure data relates to pressure of the vaginal space.

Date Reçue/Date Received 2023-12-13

10. The device according to any one of items 1 to 9, wherein the device comprises twenty MEMS sensors.

11. The device according to any one of items 1 to 10, wherein the device is adapted to be inserted wholly within a vagina.

12. The device according to any one of items 1 to 11, wherein the device comprises one or more accelerometers.

Date Reçue/Date Received 2023-12-13

CLAIMS:

1. An intravaginal device for treating a female subject with a pelvic floor disorder, the intravaginal device comprising a plurality of MEMS sensors positioned along a length of the device and mounted on a flexible PCB attached to or incorporated within the device;

wherein the MEMS sensors are capable of providing real-time position or movement data; and

wherein the device is arranged to transmit the real-time data wirelessly to a graphical user interface; wherein the position data relates to at least one of a position of a vaginal space and a position of an anatomical organ of interest to an anatomical or external reference point.

2. The device according to claim 1, wherein the position or movement data comprises at least one of: magnetic, electromagnetic, microelectromechanical, radio frequency, ultrasound, and video data.

3. The device according to claim 1 or 2, wherein the device further comprises one or more additional sensors capable of providing real-time flow data.

4. The device according to claim 3, wherein the one or more additional sensors is selected from the group consisting of a gyroscope, an inductive noncontact position sensor, a string potentiometer, a linear variable differential transformer, a potentiometer, a capacitive transducer, an Eddy-current sensor, a Hall effect sensor, an optical proximity sensor, a piezo-electric transducer, a photodiode array, a force collector, a piezo-resistive sensor, a capacitive sensor, an electromagnetic sensor, a piezo-electric sensor, an optical sensor, a potentiometric sensor, a resonant sensor, a thermal sensor, an ionization sensor; an ultrasonic sensor, a density sensor, a resistive sensor, a surface acoustic wave sensor, a capacitive sensor, an infrared sensor, an optical imaging sensor, a dispersive signal technology sensor, and an acoustic pulse recognition sensor.

Date Reçue/Date Received 2023-12-13

5. The device according to any one of claims 1 to 4, wherein the device further comprises an inflatable component.

6. The device according to claim 5, wherein the device comprises a plurality of inflatable components.

7. The device according to any one of claims 3 to 6, wherein the device further comprises one or more pressure sensors capable of providing real-time pressure data.

8. The device according to claim 7, wherein the position data comprises data relating to the position of a posterior vaginal wall, and the pressure data comprises data related to the pressure of the posterior vaginal wall.

9. The device according to claim 7, wherein the pressure data relates to pressure of the vaginal space.

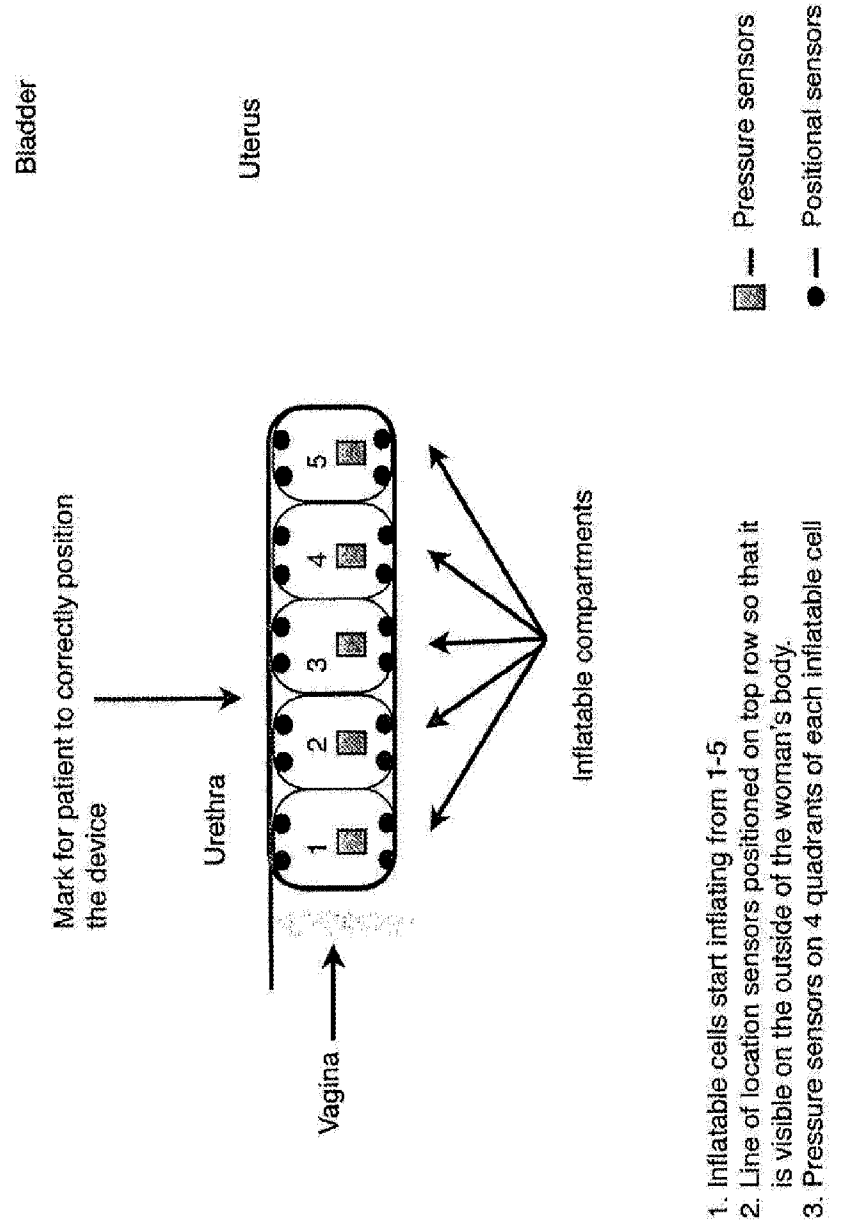
10. The device according to any one of claims 1 to 9, wherein the device comprises twenty MEMS sensors.

11. The device according to any one of claims 1 to 10, wherein the device is adapted to be inserted wholly within a vagina.

12. The device according to any one of claims 1 to 11, wherein the device comprises one or more accelerometers.

Date Reçue/Date Received 2023-12-13

FIGURE 1



1. Inflatable cells start inflating from 1-5
2. Line of location sensors positioned on top row so that it is visible on the outside of the woman's body.
3. Pressure sensors on 4 quadrants of each inflatable cell