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(54) Title: AN INTRA VAGINAL DEVICE TO AID IN TRAINING AND DETERMINING MUSCLE STRENGTH

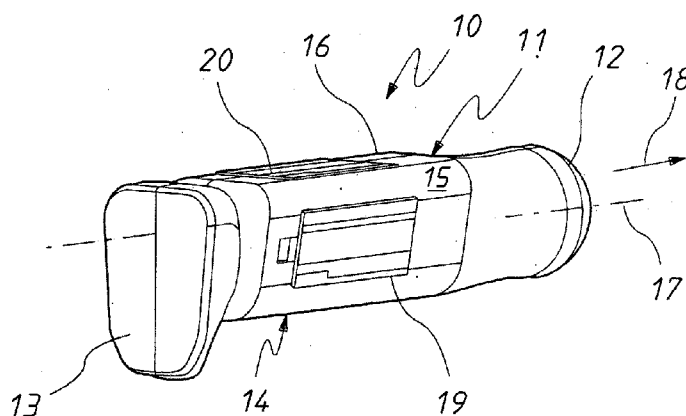


FIG. 1

(57) Abstract: An intra vaginal device (10) including an elongated hollow body (11) with side wall portions (15, 16 and 24). Secured to each wall portion (15 and 24) is a sensor (19), while secured to the wall portion (16) is a sensor (20). The sensors (19) simply measure forces directly applied by the bi-lateral contraction of the pubococcygeus, while the sensor (20) provides an indication of the puborectalis contraction forces.



## AN INTRA VAGINAL DEVICE TO AID IN TRAINING AND DETERMINING MUSCLE STRENGTH

### Technical Field

The present invention relates to intra vaginal devices to aid in determining muscle strength and more particularly but not exclusively to perineometers.

### Background of the Invention

The group of muscles involved in performing a kegel exercise (and hence responsible for continence) is the levator ani. Making up part of the levator ani is the pubococcygeus and the puborectalis. The pubococcygeus arises from pubis (pubic bone) and inserts into the lateral part of the coccyx (sides of coccyx) and so when contracted, presses bilaterally against the walls of the vagina. The puborectalis arises from the superior and inferior pubic rami (front part of pelvis, either side of pubis) and forms a sling around the rectum. Hence when contracted, it "pulls forward" to aid in closing off the canals. The strength of both is essential in maintaining continence.

Many perineometers currently available measure the pressure change inside the vaginal canal upon muscle contract. These devices have the disadvantage that they do not give any indication of the muscle movement or actual contraction force. It may also lead to deterioration of a patient's condition if they are in fact performing the contraction incorrectly – the problem being that "bearing down" using the stomach muscles can also increase the pressure inside the vaginal canal, thus giving an incorrect indication of muscle contraction.

Known perineometers are described in Australian Patent 739990, Australian Patent 780359 and International Patent Publication WO 92/20283.

### Object of the Invention

It is the object of the present invention to overcome or substantially ameliorate the above disadvantage.

### Summary of the Invention

There is disclosed herein an intra vaginal device to aid in determining muscle strength, said device including:

- an elongated body having an end portion, a base spaced from the end portion,
- 5 and a longitudinally extending side wall extending between the end portion and the base;
- a first sensor, the sensor being mounted on the side wall and to provide an indication of pressure applied thereto; and
- a second sensor, the second sensor being mounted on the side wall so as to be spaced angularly about said axis from the second sensor, and to provide an indication of
- 10 the pressure applied to the second sensor.

Preferably, said end portion is convex.

- Preferably, said side wall includes a first side wall portion to which the first sensor is attached, and a second side wall portion to which the second sensor is attached, with the second sensor being angularly displaced about said axis from the first sensor by
- 15 approximately 80° to 90°.

Preferably, said side wall includes a third side wall portion, and the device further includes a third sensor attached to the third side wall portion, with the third sensor being spaced angularly about said axis from the first and second sensors.

- Preferably, the third sensor is spaced approximately 80° to 90° from the first
- 20 sensor.

Preferably, the wall portions are generally planar.

In an alternative preferred form, the wall portions are convex.

Preferably, at least one of the sensors provides an electrical resistance that diminishes with an increase of pressure applied thereto.

- 25 Preferably, the sensors are elongated longitudinally of said body.

Preferably, said base is elongated in a direction transverse of said direction.

Preferably, said base is adapted to engage the vaginal entrance to aid in correctly locating the sensors.

### Brief Description of the Drawings

A preferred form of the present invention will now be described by way of example with reference to the accompanying drawings wherein:

Figure 1 is a schematic isometric view of a intra vaginal device to aid in  
5 measuring muscle strength;

Figure 2 is a schematic top plan view of the device of Figure 1;

Figure 3 is a schematic side elevation of the device of Figure 1;

Figure 4 is a schematic diagram of an electronic circuit employed in the device  
of Figure 1; and

10 Figure 5 is a schematic end elevation of the device of Figure 1.

### Detailed Description of the Preferred Embodiment

In the accompanying drawings there is schematically depicted a device 10 to be inserted in a woman's vagina to aid in measuring muscles operatively associated with the women's vagina.

15 The device 10 includes an elongated hollow body 11 having an end portion 12, a base 13 and a longitudinally extending side wall 14. The side wall 14 includes side wall portions 15, 16 and 24. Preferably, the side wall portions 15, 16 and 24 are generally planar (or convex) and the portion 12 generally convex.

The device 10 has a longitudinal axis 17.

20 Secured to each wall portion 15 and 24 is a sensor 19, while secured to the wall portion 16 is a sensor 20. Each of the sensors 19 and 20 is adapted to provide an indication of the pressure applied thereto. As a particular example, the sensors 19 and 20 could provide an electrical resistance that increases or decreases with pressure applied thereto, preferably decreases.

25 Preferably, the sensor 20 is spaced angularly about the axis 17 by an angle of approximately 80° to 90° from each of the sensors 19.

Preferably, the sensors 19 are spaced from the base 13 by the said distance. The sensor 20 is placed at a desired distance from the base 13, that may be the same or smaller distance from the base 13 than the sensors 19. Preferably, the sensors 19 and 20 are  
30 elongated longitudinally relative to the body 11.

Preferably, the base 13 is transversely elongated to aid a user to manipulate the device 10 and to aid in correctly positioning the device 10 by having the base 13 engage the vaginal entrance.

Preferably, the device 10 includes an electronic circuit 21 incorporating the sensors 19 and 20. The circuit 21 includes a processor 22 that interrogates the sensors 19 and 20 to determine their resistance, and then to provide a signal for a read out 23 that provides information in respect of the muscles associated with the user's vagina. The read out 23 may be remote from body 11 and communicates via wireless with the processor 22.

10 The sensor 20 provides an indication of the puborectalis contraction forces, the sensors 19 provide an indication of the pressure applied by the pubococcygeus.

The device 10 is shaped in such a way that once inserted into the vagina, it is able to measure both modes of contraction. The device 10 is inserted in the direction 18. The sensor 20 is preferably on top of the device 10 and measures the force applied to the device 10 by the urethral wall – thus capturing the contraction strength contributed by the puborectalis.

The sensors 19 are on the sides of the device 10.

The base 13 is spaced from the sensors 19 and 20 so that the base 13 upon engaging the entrance of the vagina, correctly locates the sensors 19 and 20.

20 The sensors 19 are able to separately measure the force directly applied by the bilateral contraction of the pubococcygeus.

The force measurements can also be combined to give an average contraction strength output.

This separation of the measurements enables a more thorough understanding of the overall contraction and may lead to easier diagnosis of incontinence problems, as well as an invaluable teaching aide. There are many factors involved in incontinence, and this may enable clinicians to identify the muscle group that is contributing to incontinence in different case studies.

This specific feedback is also essential in encouraging and maintaining consistency with patients using the device.

This ability to distinguish between the specific muscles and modes of contraction may also be helpful in addressing a common issue of over-clenching of the pelvic floor. Many women suffer from this condition and need to be taught how to relax these muscles. The device 10 would be able to offer a more accurate picture of the clenching problem by  
5 measuring the full input of each muscle, and possibly pinpointing which area to focus on.

Preferably in use of the device 10, the device 10 is covered by a sheath. As a particular example, the sheath may be of a synthetic rubber.

**CLAIMS:**

1. An intra vaginal device to aid in determining muscle strength, said device including:
  - an elongated body having an end portion, a base spaced from the end portion, and a longitudinally extending side wall extending between the end portion and the base;
  - a first sensor, the sensor being mounted on the side wall and to provide an indication of pressure applied thereto; and
  - a second sensor, the second sensor being mounted on the side wall so as to be spaced angularly about said axis from the first sensor, and to provide an indication of the pressure applied to the second sensor.
2. The device of claim 1, wherein said end portion is convex.
3. The device of claim 1 or 2, wherein said side wall includes a first side wall portion to which the first sensor is attached, and a second side wall portion to which the second sensor is attached, with the second sensor being angularly displaced about said axis from the first sensor by approximately  $80^{\circ}$  to  $90^{\circ}$ .
4. The device of claim 3, wherein said side wall includes a third side wall portion, and the device further includes a third sensor attached to the third side wall portion, with the third sensor being spaced angularly about said axis from the first and second sensors.
5. The device of claim 4, wherein the third sensor is spaced approximately  $80^{\circ}$  to  $90^{\circ}$  from the first sensor.
6. The device of claim 3, 4 or 5, wherein the wall portions are generally planar.
7. The device of claim 3, 4 or 5, wherein the wall portions are convex.

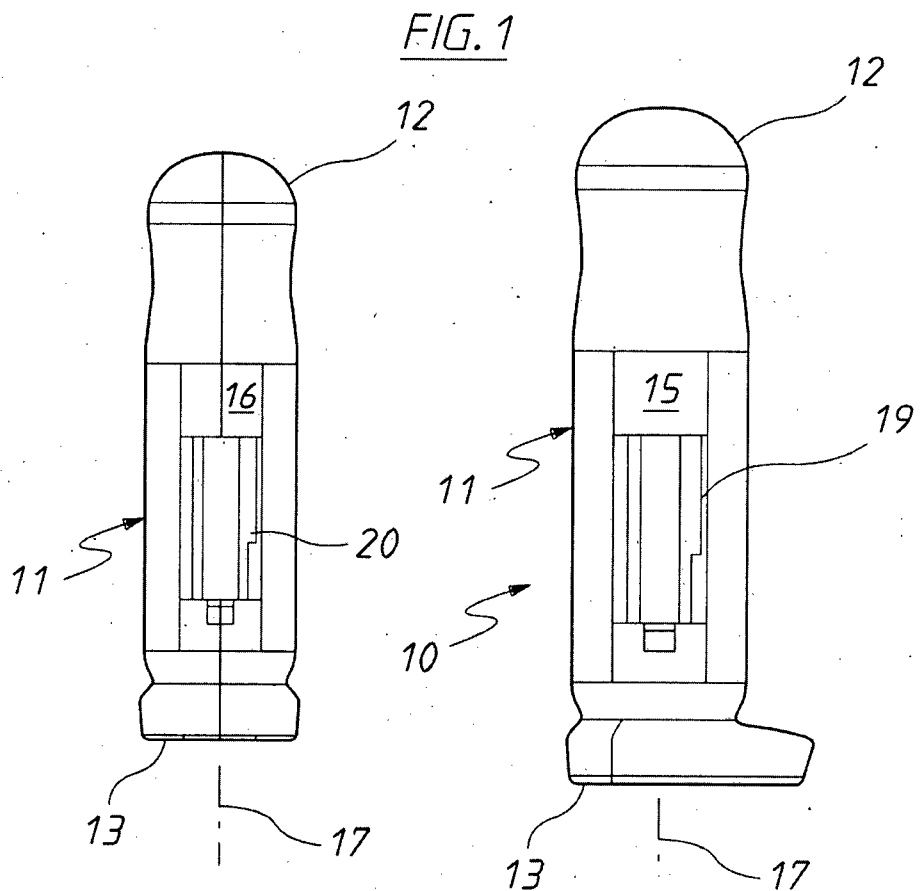
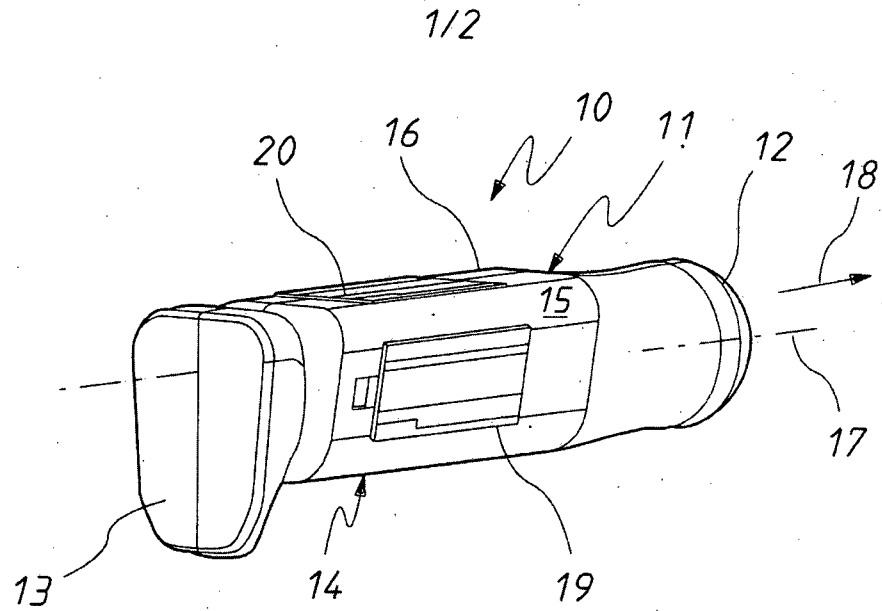
8. The device of any one of claims 1 to 7, wherein at least one of the sensors provides an electrical resistance that diminishes with an increase of pressure applied thereto.

9. The device of any one of claims 1 to 8, wherein the sensors are elongated longitudinally of said body.

10. The device of any one of claims 1 to 9, wherein said base is elongated in a direction transverse of said direction.

11. The device of any one of claims 1 to 10, wherein said base is adapted to engage the vaginal entrance to aid in correctly locating the sensors.





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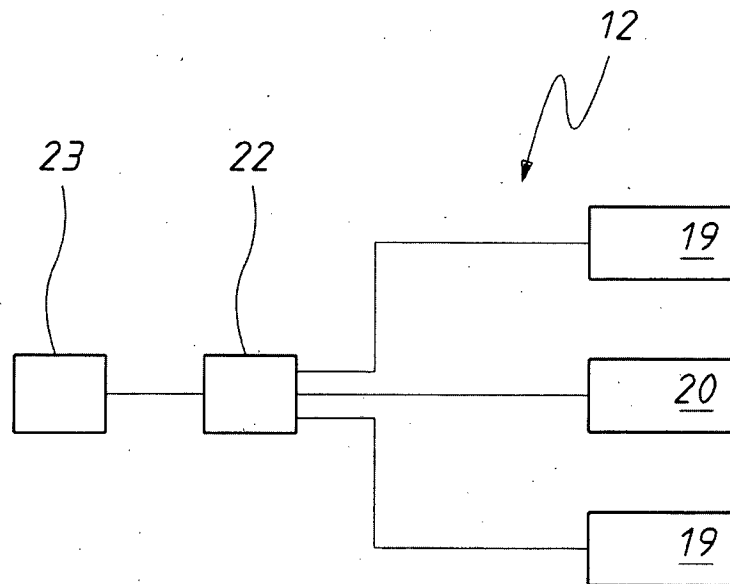


FIG.4

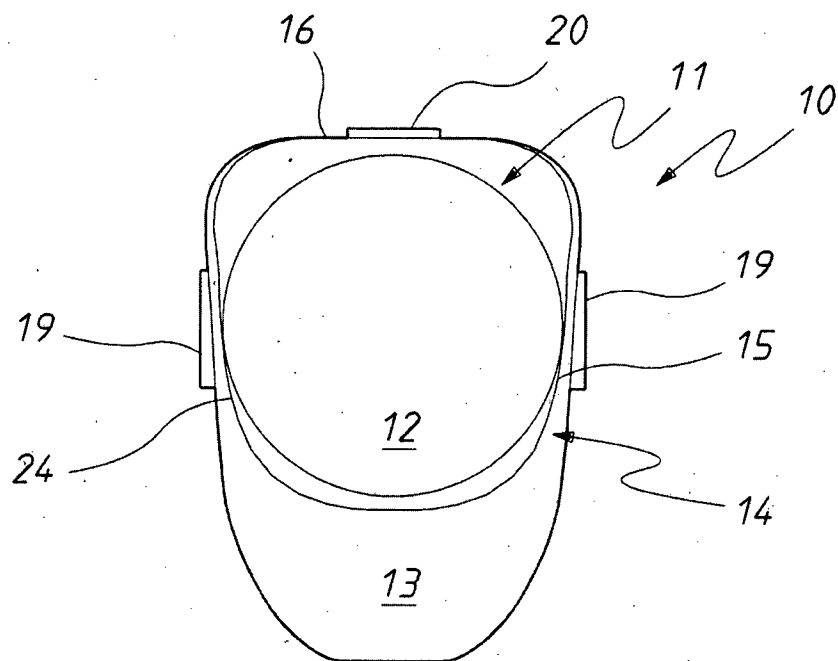


FIG.5

## INTERNATIONAL SEARCH REPORT

International application No.  
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## A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl.

*A63B 23/20* (2006.01)*A61B 5/04* (2006.01)

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPODOC, WPI - keywords: vagina, perineometer, contract, squeeze, sensor, pressure and like terms

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5881731 A (REMES) 16 March 1999 Abstract; Col.2, lines 14-25, 56-63; Col.3 lines 9-13, 25-28; Fig. 3 & 4.	1-11
X	US 4396019 A (PERRY) 2 August 1983 Abstract; Col. 5, lines 51-55; Col. 6, lines 2-8; Figures 1 & 3	1-11
A	US 2006/0036188 A1 (HOFFMAN et al.) 16 February 2006 Paragraphs 54, 57 & 90; Figures 2, 4, 22 & 23.	1-11

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Further documents are listed in the continuation of Box C

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See patent family annex

* "A"	Special categories of cited documents: document defining the general state of the art which is not considered to be of particular relevance	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E"	earlier application or patent but published on or after the international filing date	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O"	document referring to an oral disclosure, use, exhibition or other means	"&"	document member of the same patent family
"P"	document published prior to the international filing date but later than the priority date claimed		

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**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International application No.

**PCT/AU2012/000012**

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report				Patent Family Member			
US	5881731	AU	17098/95	CA	2183427	EP	0749340
		FI	940799	JP	H09508838	US	6289894
		WO	9522378				
US	4396019	CA	1191207	DE	3218938	FR	2507076
		GB	2119516	JP	57211341		
US	2006036188	CA	2628811	GB	2446545	US	2007112284
		US	7628744	US	7645220	US	2010087757
		US	7955241	WO	2007056559		
Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.							
END OF ANNEX							