Abstract: A vaginal speculum (10) includes a spreading element (12) and at least two electromyographic sensors (16). At least one of the electromyographic sensors (16) is mounted in or on the spreading element (12). The electromyographic sensors (16) generate signals indicative of electromyographic activity in a vagina, cervix, or uterus.
VAGINAL SPECULUM WITH ELECTROMYOGRAPHIC SENSORS

FIELD OF THE INVENTION

The present invention generally relates to vaginal specula, and more specifically to a vaginal speculum with electromyographic sensors.

BACKGROUND OF THE INVENTION

As is well known in the art, a vaginal speculum has two "duck-bill" spreading members which are pivotally interconnected. The vaginal speculum is typically used to dilate the vaginal cavity so that an examination or treatment of the cervix and vaginal tissues may be readily performed.

SUMMARY OF THE INVENTION

The present invention seeks to provide a novel vaginal speculum with electromyographic sensors, as is described in detail further hereinbelow. The invention may be used for direct measurement of the electromyographic activity in the vagina, cervix, or uterus.

The system of the invention has many applications, such as without limitation, determination of a characteristic of uterine contractions, determination of intra-uterine pressure correlated to electromyographic activity, treatment of menstrual-related pain for non-pregnant women, measurement of electromyographic activity in the uterus for IVF re-introduction of fertilized eggs when the uterus is non-active to prevent rejection of fetuses, or monitoring pregnant women during or before birth, such as direct and more accurate measurement of electromyographic activity in the uterus, sensing fetal heartbeat, measurement of efficacy of drugs for increasing or decreasing contractions or for accelerating or decelerating uterine activity.

There is thus provided in accordance with an embodiment of the present invention a vaginal speculum including a spreading element and at least two electromyographic sensors, at least one of the electromyographic sensors being mounted in or on the spreading element, the electromyographic sensors operative to generate signals indicative of electromyographic activity in a vagina, cervix, or uterus.

In accordance with an embodiment of the present invention the electromyographic sensors are in electrical communication with an electromyographic processor.

In accordance with an embodiment of the present invention the spreading element includes more than one spreading element each of which has mounted therein or thereon at least one of the electromyographic sensors.
In accordance with an embodiment of the present invention the spreading element includes more than one spreading element each of which has mounted therein or thereon at least two of the electromyographic sensors.

In accordance with an embodiment of the present invention at least one of the electromyographic sensors includes a surface electromyographic sensor.

In accordance with an embodiment of the present invention at least one of the electromyographic sensors includes an intramuscular electromyographic sensor.

In accordance with an embodiment of the present invention a position sensor may be mounted in or on the speculum.

**BRIEF DESCRIPTION OF THE DRAWINGS**

The present invention will be understood and appreciated more fully from the following detailed description taken in conjunction with the drawing in which:

Fig. 1 is a simplified illustration of a vaginal speculum with electromyographic sensors, constructed and operative in accordance with a non-limiting embodiment of the present invention.

**DETAILED DESCRIPTION OF EMBODIMENTS**

Reference is now made to Fig. 1, which illustrates a vaginal speculum 10 in accordance with a non-limiting embodiment of the present invention.

Speculum 10 may include one or more spreading elements 12, such as blades 12, which may be pivotally interconnected at a pivot 14. However, the invention is not limited to the particular construction of the spreading elements or any adjustment devices used in the speculum; rather the invention is applicable for any type of vaginal speculum.

Speculum 10 includes one or more electromyographic sensors 16, which may be mounted in or on any of the spreading elements 12. In one embodiment, electromyographic (EMG) sensors 16 are surface EMG sensors, such as a pair of Ag/AgCl electrodes mounted at distal portions of spreading elements 12, or alternatively at other portions of the spreading elements 12. (Optional reference electrode(s) may also be used.) The spreading elements 12 come into direct contact with the vaginal, cervical or uterine wall. The signals from the surface EMG sensors 16 are sent to an electrical connector 18 (such as via wired connection 19 or wireless connection, e.g., Bluetooth) which is in electrical communication with an EMG monitor or processor 20, such as the EUM-100 Pro system, commercially available from OB Tools Ltd., Israel. The EMG monitor can determine the presence, effectiveness, frequency and intensity of uterine contractions. The EMG sensors 16 serve as uterine electrical activity sensors. The
combination of the speculum 10, EMG sensors 16 and EMG processor 20 forms a system for direct measurement of the electromyographic activity in the vagina, cervix, or uterus. The information from the EMG sensors can be used to determine other phenomena, such as but not limited to, intra-uterine pressure which is correlated to the electromyographic activity.

In the illustrated embodiment, there is a pair of EMG sensors 16 disposed in or on each spreading element 12. The use of more than one EMG sensor on each spreading element 12 helps reduce noise in the signals from the sensors. Alternatively, only one sensor 16 may be used in the speculum 10 which cooperates with an external sensor or electrode 22 (shown in broken lines in Fig. 1). The external electrode may be used as a reference electrode.

As is known in the art, surface EMG sensors sense muscle activity on the skin surface above the muscle by sensing the voltage difference between two separate electrodes, or between each electrode and the reference electrode. The sensed data is that of superficial muscle activity to a limited depth.

In another embodiment, EMG sensors 16 are intramuscular EMG sensors. For example, a single EMG sensor 16 may be provided on speculum 10, in which the sensor is a monopolar needle electrode, which cooperates with a surface electrode as a reference. More than one needle electrode may be employed and the system may operate in monopolar, bipolar or combined monopolar/bipolar modes of operation. The needle electrode pierces the skin of the patient and measures the electromyographic activity in the vagina, cervix, or uterus.

In another embodiment, speculum 10 may also include one or more position sensors 24, as described in US Patent 7,447,542 to Calderon et al. The processor 20 processes data of the EMG system and the three-dimensional position information from the position sensors to provide an output of electromyographic activity data in three-dimensional space.
What is claimed is:

1. Apparatus comprising:
   a vaginal speculum (10) comprising a spreading element (12) and at least two
   electromyographic sensors (16), at least one of said electromyographic sensors (16) being
   mounted in or on said spreading element (12), said electromyographic sensors (16)
   operative to generate signals indicative of electromyographic activity in a vagina, cervix,
   or uterus.

2. Apparatus according to claim 1, wherein said electromyographic sensors (16) are
   in electrical communication with an electromyographic processor (20).

3. Apparatus according to claim 1, wherein said spreading element (12) comprises
   more than one spreading element (12) each of which has mounted therein or thereon at
   least one of said electromyographic sensors (16).

4. Apparatus according to claim 1, wherein said spreading element (12) comprises
   more than one spreading element (12) each of which has mounted therein or thereon at
   least two of said electromyographic sensors (16).

5. Apparatus according to claim 1, wherein at least one of said electromyographic
   sensors (16) comprises a surface electromyographic sensor.

6. Apparatus according to claim 1, wherein at least one of said electromyographic
   sensors (16) comprises an intramuscular electromyographic sensor.

7. Apparatus according to claim 1, wherein a position sensor (24) is mounted in or
   on said speculum (10).

8. A method comprising using the vaginal speculum (10) of claim 1 to generate
   signals indicative of electromyographic activity in a vagina, cervix, or uterus.

9. The method according to claim 8, comprising processing said signals to determine
   a characteristic of uterine contractions.

10. The method according to claim 8, comprising processing said signals to determine
    intra-uterine pressure correlated to the electromyographic activity.

11. The method according to claim 8, comprising processing said signals to determine
    treatment of menstrual-related pain for non-pregnant women.

12. The method according to claim 8, comprising processing said signals to measure
    electromyographic activity in the uterus for IVF re-introduction of fertilized eggs when
    the uterus is non-active to prevent rejection of fetuses.
13. The method according to claim 8, comprising processing said signals to monitor pregnant women during or before birth.

14. The method according to claim 8, comprising processing said signals to measure efficacy of drugs for increasing or decreasing contractions or for accelerating or decelerating uterine activity.
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B5/0488 A61B1/32 A61B1/303

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

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)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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<td>Y</td>
<td>2.2. Instrumentation ----- -/-</td>
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X Further documents are listed in the continuation of Box C. X See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"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)
"O" document referred to in oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed

"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

"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

"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

"A" document member of the same patent family

Date of the actual completion of the international search 5 September 2016

Date of mailing of the international search report 16/09/2016

Name and mailing address of the ISA/
European Patent Office, P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk
Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016

Authorized officer Rick, Kai
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<td>US 2005/010127 AI (CALDERON ILAN [IL] ET AL) 13 January 2005 (2005-01-13) cited in the application paragraphs [0002], [0003], [0005] - [0008], [0021] - [0024]; f igure 1 -----</td>
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<td>EP 2 689 724 AI (UNIV CATALUNYA POLITECNICA [ES]; ALTHAIA XARXA ASSISTENCIAL DE MANRESA) 29 January 2014 (2014-01-29) paragraphs [0001], [0011] - [0013], [0016], [0018]; f igure 1 -----</td>
<td>1-7</td>
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**INTERNATIONAL SEARCH REPORT**

**Box No. II  Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. **X** Claims Nos.: 8-14 because they relate to subject matter not required to be searched by this Authority, namely:

   **Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery**

2. □ Claims Nos.: because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. □ Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box No. III  Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

1. □ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. □ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. □ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. □ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

- □ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- □ The additional search fees were accompanied by the applicant’s protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- □ No protest accompanied the payment of additional search fees.

Form PCT/ISA/21 0 (continuation of first sheet (2)) (April 2005)
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