

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
12 September 2008 (12.09.2008)

PCT

(10) International Publication Number
WO 2008/107902 A2

(51) International Patent Classification:
A61F 13/15 (2006.01)

(21) International Application Number:
PCT/IL2008/000312

(22) International Filing Date: 9 March 2008 (09.03.2008)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/893,387 7 March 2007 (07.03.2007) US
60/950,054 16 July 2007 (16.07.2007) US

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(81) Designated States (*unless otherwise indicated, for every
kind of national protection available*): AE, AG, AL, AM,

AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA,
CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, 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, LY, MA, MD, ME, 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, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL,
NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG,
CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

- *without international search report and to be republished
upon receipt of that report*
- *the filing date of the international application is within two
months from the date of expiration of the priority period*

(54) Title: DEVICES, SYSTEMS AND METHODS FOR SHORTENING MENSTRUAL PERIOD DURATION

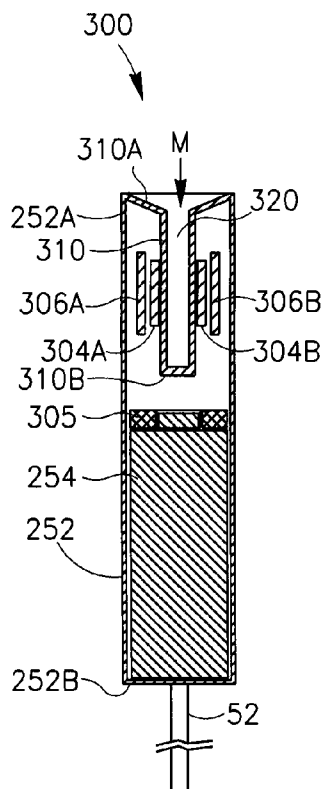


FIG. 24

(57) Abstract: Devices and systems for facilitating the flow of menses through the cervix and for shortening the duration of menstruation include a pressure oscillations generating unit insertable into a vagina and configured for delivering pressure oscillations and/or acoustic waves and/or shock waves to the vagina and cervix to change the flow properties of menses fluid. The pressure oscillations generating unit may include one or more vibratable or movable members for generating pressure oscillations which may be powered by an internal or external power source. The devices may optionally include an absorbing member or a menses collecting member. A method of menstruation duration shortening includes placing the device within the vagina and applying pressure oscillations to the vagina or to a vaginal chamber formed within the vagina for increasing the flow rate of menses and shortening menstruation duration.

DEVICES, SYSTEMS AND METHODS FOR SHORTENING MENSTRUAL PERIOD DURATION

CROSS-REFERENCE TO RELATED US APPLICATIONS

5 This application claims priority from and the benefit of US Provisional Patent Application Serial Number 60/893,387 filed March 7, 2007, entitled "MENSTURATION SHORTENING METHOD AND APPARATUS BY APPLICATION OF VIBRATIONS", and of US Provisional Patent Application Serial Number 60/950,054 filed July 16, 2007, entitled "METHODS AND DEVICES FOR APPLYING VIBRATIONS TO HUMAN
10 NON-NEWTONIAN FLUIDS FOR MEDICAL AND THERAPEUTIC PURPOSES" both provisional applications are incorporated herein by reference in their entirety.

FIELD OF THE INVENTION

The present invention relates in general to medical and therapeutic devices and methods
15 and more specifically to devices and methods for applying pressure oscillations to the female vagina and uterus for shortening menstruation duration.

BACKGROUND OF THE INVENTION

Menstruation in women takes place every 28 days on average, and typically lasts
20 between three to nine days (with an average duration of five days). During this period, the uterus sheds 10 to 80 milliliters of bodily substances, with the average being 35 milliliters. Each individual woman experiences a relatively uniform pattern of menstruation, in time and duration, except while experiencing various physiological changes or dysfunctions.

Menses secretion from the uterus originates in the endometrium layer. When the blood
25 supply to this layer is cut off, following a hormonal signal, the cells undergo natural apoptosis, the blood vessels undergo rupture, and the entire endometrium layer is separated from the myometrium layer. The blood does not clot thanks to the enzyme plasmin.

The vasoconstriction process which causes the shedding of the layer is limited predominantly to the first twenty-four hours of menstruation, and the resulting menses fluid accumulated in the uterus starts to be drained slowly through the cervix. Menses fluid is typically a suspension of non-Newtonian fluid, composed of approximately 50% blood, while the other 50% contains other elastic tissue and various bodily particles and fluids. The menses fluid varies in its viscosity, containing tissue particles of 1-20mm in length (and may be even larger), therefore its flow through the cervix, is restricted and slowed by obstructing the narrow and relatively long uterine cervical lumen and particularly the constrictions in the cervical lumen at the *internal os* and the *external os* of the uterine lumen by such tissue particles. Uterine contractions create a pressure gradient between the uterus and the vagina, thus facilitating the shedding process and flow of menses.

The most common female hygienic absorbents are tampons and pads. The goal of these absorbents is to provide women with a solution for absorbing the menstrual secretions. This enables them to continue their daily routine and activities during menstruation.

As used herein the specification and in the claims section that follows, the term "tampon" and the like refer to a wad of substantially absorbent material introduced into a woman's vagina usually to absorb secretions during menstruation.

Absorbent pads and means for conveniently inserting same into the female vagina are disclosed, among others, in U.S. Patent No. 1,926,900, U.S. Patent No. 2,024,218. Both of these patents are incorporated by reference for all purposes as if fully set forth herein.

The catamenial device, known by the name of "tampon", which has been improving the lives of millions of women around the world for many years, is primarily designated to eliminate all external pads, belts, etc, and is employed internally in the vagina; however it has no effect on the duration of menstruation. Moreover, from their patenting in 1933 until present, only minor changes were introduced in the materials and shape of tampons and pads. To date, of all the different hygiene devices used by women during menstruation, none eliminates or reduce the discomfort, duration, pain and uneasiness of menstruation.

U.S. Patents 5,782,779, and 6,183,428 to Kilgore disclose vibrating tampon apparatus for relieving menstrual pain. The tampon uses an internal mechanical vibrator with the

intent to relieve the user from the menstrual pain as well as to facilitate the insertion of the tampon in the case of a dry vagina. The vibrating tampon comprises a tampon with an embedded electric motor, powered by a miniature battery and an ex-centric weight attached to the motor shaft which generates mechanical vibrations of the tampon which are directly transferred to the vaginal canal walls contacting the tampon.

A description of devices generating acoustic waves that can be used to treat patients with cystic fibrosis (CF), bronchitis and other lung dysfunctional diseases, which use acoustic vibrations to stimulate the evacuation of the secreted mucus (sputum), thus facilitating in the lungs clearance, are described in U.S. Patent No. 5,451,190 to Liardet, U.S. Patent No. 5,829,429 to Hughes, U.S. Patent No. 6,631,721, to Salter et al., and in U.S. Patent No. 7,059,324 to Pelerossi et al., all of which are incorporated by reference in their entirety for all purposes as if fully set forth herein.

U.S. Patent No. 4,141,360 to Lasswell discloses a menstrual extraction device that causes menstrual extraction to achieve a fast depletion of the menses fluid from the uterus. The device reduces the pressure at the end of the cervix creating suction on the menses fluid. However, this device poses several difficulties and dangers to a potential user, including potentially causing a miscarriage, especially if used incorrectly. Due to possible tissue damage, the application of this device has to be supervised and cannot be self-administered.

Thus, there is a widely recognized need for, and it would be highly advantageous to have a device that can efficiently and safely shorten the duration of the menses flow.

SUMMARY OF THE INVENTION

There is therefore provided a device for shortening menstruation duration. The device includes a pressure oscillations generating unit configured to be inserted into a vagina for applying pressure oscillations to a vaginal chamber defined by part of the device, the walls of the vagina and the cervix of the uterus.

Furthermore, in accordance with an embodiment of the device, the device also includes an absorbent member attached to the pressure oscillations generating unit for absorbing menstrual secretions.

Furthermore, in accordance with an embodiment of the device, the absorbent member is a sleeve like absorbent member attached to the pressure oscillations generating unit and the entire device is disposable.

Furthermore, in accordance with an embodiment of the device, the absorbent member is a sleeve-like absorbent member detachably attachable to the pressure oscillations generating unit. The pressure oscillations generating unit is a reusable unit and the absorbent member is a disposable absorbent member.

Furthermore, in accordance with an embodiment of the device, the device also includes a power source for energizing the pressure oscillations generator unit. The power source is selected from an internal power source disposed within the device and an external power source disposed outside the device and coupled to the pressure oscillations generator unit.

Furthermore, in accordance with an embodiment of the device, the power source is an electrical power source.

Furthermore, in accordance with an embodiment of the device, the power source is selected from a battery, an electrochemical cell, a primary electrochemical cell, a rechargeable electrochemical cell, a super-capacitor, a fuel cell, and any combinations thereof.

Furthermore, in accordance with an embodiment of the device, the pressure oscillations are pressure oscillations having a frequency in the range of 0.1Hz-10 kHz, more preferably in the range of 1Hz- 100Hz, and most preferably in the range of 30Hz - 60 Hz.

Furthermore, in accordance with an embodiment of the device, the pressure oscillations generating unit is configured to deliver pressure oscillations having an energy in the range of 0.01-1.0 Watt delivered to the vaginal chamber, but energies larger than 1 Watt may also be used.

5 Furthermore, in accordance with an embodiment of the device, the pressure oscillations are selected from pressure waves, acoustic waves, periodic acoustic waves, sinusoidal acoustic waves, acoustic shock waves, pulsatile acoustic waves and any combinations thereof.

10 Furthermore, in accordance with an embodiment of the device, the pressure oscillations are applied to said vaginal chamber intermittently with a duty cycle in the range of 1%-99%.

15 Furthermore, in accordance with an embodiment of the device, the pressure oscillations generating unit includes at least one movable member coupled to the chamber when the device is disposed in a vagina. The movable member is configured for delivering the pressure oscillations to the chamber.

20 Furthermore, in accordance with an embodiment of the device, the at least one movable member is a single movable membrane wholly or partially comprised of an electrically conducting material, wherein the membrane is disposed adjacent to an electrically conducting coil included in the pressure oscillations generating unit. The movable membrane is configured to oscillate upon application of a periodically varying current to the coil.

Furthermore, in accordance with an embodiment of the device, the at least one movable member is a movable membrane sealingly attached to a rigid housing of the pressure oscillations generating unit and coupled to a linear motor attached to the housing.

25 Furthermore, in accordance with an embodiment of the device, the at least one movable member comprises two movable membranes sealingly attached to a rigid housing. Each membrane has a flat electrically conducting coil attached thereto. The device includes two permanent magnets wherein one permanent magnet of the two permanent magnets is attached to the rigid housing adjacent to each membrane of the two membranes.

Furthermore, in accordance with an embodiment of the device, the at least one movable member comprises two movable membranes sealingly attached to a rigid housing. Each membrane has a flat electrically conducting coil attached thereto. The rigid housing also includes two permanent magnets attached thereto. Each permanent magnet is disposed adjacent to a different movable membrane of the two movable membranes.

Furthermore, in accordance with an embodiment of the device, the at least one movable membrane comprises two elastic movable membranes sealingly attached to a rigid housing. Each membrane has a flat permanent magnet attached thereto. The device also includes two electrically conducting coils. A first coil is rigidly attached to the rigid housing adjacent to the permanent magnet of a first membrane, and the second coil is rigidly attached to the rigid housing adjacent to the permanent magnet of a second membrane.

There is also provided a method for shortening the duration of the menstruation period of a female subject. The method includes applying pressure oscillations to a volume of fluid enclosed within the vagina of the female subject, for increasing the rate of flow of menstrual secretions out of the uterus to shorten the duration of the menstruation period.

Furthermore, in accordance with an embodiment of the method, the volume of fluid is contained in a vaginal chamber defined between part of a pressure oscillations generating unit disposed within the vagina, part of the walls of the vagina and the cervix of the female subject.

Furthermore, in accordance with an embodiment of the method, the volume of fluid includes fluids selected from the group consisting of air, menstrual fluid and a combination of air and menstrual fluid.

Furthermore, in accordance with an embodiment of the method, the pressure oscillations generating unit is configured to deliver pressure oscillations having an energy in the range of 0.01-1.0 Watt delivered to the volume of fluid.

Furthermore, in accordance with an embodiment of the method, the pressure oscillations includes pressure oscillations having a frequency in the range of 0.1Hz-10 kHz, more preferably in the range of 1Hz- 100Hz, and most preferably in the range of 30Hz - 60 Hz.

Furthermore, in accordance with an embodiment of the method, the pressure oscillations are selected from the group consisting of pressure waves, periodic acoustic waves, sinusoidal acoustic waves, acoustic shock waves, pulsatile acoustic waves and any combinations thereof.

5 Furthermore, in accordance with an embodiment of the method, the pressure oscillations are applied to the volume of fluid intermittently with a duty cycle in the range of 1%-99%.

There is also provided in accordance with the methods of the present application, a method for shortening menses duration. The method includes the steps of: introducing into
10 a vagina a device including a pressure oscillations generating unit for applying pressure oscillations waves to a vaginal chamber defined by part of said device, the walls of the vagina and the cervix of the uterus, and activating the device to generate pressure oscillations within the vaginal chamber for increasing the rate of flow of menstrual secretions out of the uterus.

15 Furthermore, in accordance with an embodiment of the method, the step of activating includes providing power to the pressure oscillations generating unit from a power source selected from, an internal power source internally disposed within the device, and an external power source disposed outside the vagina and connected to the pressure oscillations generating unit.

20 Furthermore, in accordance with an embodiment of the method, the step of activating includes activating the pressure oscillations generating unit by remotely actuating an actuatable switching unit included in the device to provide power from the power source to the pressure oscillations generating unit.

25 Furthermore, in accordance with an embodiment of the method, the method also includes the step of absorbing menses fluids flowing into the vagina by an absorbent member attached to the pressure oscillations generating unit.

Furthermore, in accordance with an embodiment of the method, the pressure oscillations include pressure oscillations having a frequency in the range of 0.1Hz-10 kHz,

more preferably in the range of 1Hz- 100Hz, and most preferably in the range of 30Hz - 60 Hz.

Furthermore, in accordance with an embodiment of the method, the pressure oscillations generating unit is configured to deliver pressure oscillations having an energy in the range of 0.01-1.0 Watt delivered to the vaginal chamber.

Furthermore, in accordance with an embodiment of the method, the pressure oscillations are selected from the group including of pressure waves, periodic acoustic waves, sinusoidal acoustic waves, acoustic shock waves, pulsatile acoustic waves and any combinations thereof.

Furthermore, in accordance with an embodiment of the method, the pressure oscillations are applied to the vaginal chamber intermittently with a duty cycle in the range of 1%-99%.

There is further provided in according with an embodiment of the devices of the present application a device for shortening menses duration. The device includes one or more vibration generating units configured to be mechanically coupled to the skin of the body of a menstruating female subject, for directing mechanical vibrations to the region of the uterine cervix of the subject for changing the flow properties of the menses within the uterus of the subject to increase the flow of the menses through the cervix and to shorten the duration of the menstruation period of the female subject. The device also includes a power source for controllably energizing the one or more vibration generating units.

Furthermore, in accordance with an embodiment of the device, the one or more vibration generating units is selected from, one or more piezoelectric transducers, one or more electromechanical transducers, one or more mechanical transducers, and any combinations thereof.

Furthermore, in accordance with an embodiment of the device, the one or more vibration generating units are configured for generating in the tissues of the female subject vibrations selected from pressure waves, shear waves and a combination of pressure waves and shear waves.

Furthermore, in accordance with an embodiment of the device, the one or more vibration generating units are attached to a coupling member selected from a belt-like member, an elastic belt-like member, an adhesive member and any combinations thereof.

There is also provided, in accordance with the present application, a kit for shortening
5 the duration of menstruation period. The kit includes a pressure oscillations generating unit configured to be inserted into a vagina for applying pressure oscillations to a vaginal chamber defined by part of the device, the walls of the vagina and the cervix of the uterus and one or more absorbent members detachably attachable to the pressure oscillations generating unit for absorbing menses.

10 There is also provided, in accordance with an embodiment of the devices of the present application, a device including a pressure oscillations generating unit configured to be inserted into a vagina for applying pressure oscillations to a vaginal chamber defined by part of the device the walls of the vagina and the cervix of the uterus, and a menses collecting member attached to the pressure oscillations generating unit for collecting
15 menses.

Finally, in accordance with an embodiment of the kit of the present application, the one or more absorbent members are one or more sleeve like absorbent members each absorbent member has a hollow passage formed therein for inserting the pressure oscillations generating unit.

20

25

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is herein described, by way of example only, with reference to the accompanying drawings, in which like components are designated by like reference numerals, wherein:

5 Fig. 1 is a schematic perspective view of tampon-like device, in accordance with an embodiment of the menstruation period shortening devices of the present application;

 Fig. 2 is a schematic perspective view of a compressed cotton sleeve of the tampon-like device, of Fig. 1;

10 Fig. 3 is a schematic side view of the tampon-like device, of Fig.1, in position in a vagina;

 Fig. 4 is a schematic side view of the tampon-like device, according to the present invention;

 Fig. 5 is a schematic illustration in view from the edge of the insertion side of the tampon-like device of Fig.1;

15 Fig. 6 is a schematic illustration in view from the bottom of the tampon-like device, of Fig.1;

 Fig. 7 is a schematic cross sectional side view of the tampon-like device of Fig. 5 taken along the line VII-VII;

20 Fig. 8 is a schematic partial cross sectional side view of a flat coil and the elastic membrane of the tampon-like device of Fig.1;

 Fig. 9 is a schematic partial cross sectional side view illustrating an internal electronic compartment casing of the tampon-like device of Fig.7;

 Fig. 10 is a schematic top view illustrating the flat coil of the tampon-like device, of Fig. 7;

25 Fig. 11 is a schematic isometric view illustrating the rigid tube of the tampon-like device, of Fig.7;

 Fig. 12 is a schematic side view illustrating the rigid tube of Fig. 11;

 Fig. 13 is a schematic top view illustrating the rigid tube of Fig. 11;

Fig. 14 is a schematic block diagram illustrating some of the components of a menstruation period duration shortening device having an internal power source, in accordance with an embodiment of the devices of their present application;

5 Fig. 15 is a schematic block diagram illustrating some of the components of a menstruation period duration shortening device having an external power source, in accordance with another embodiment of the devices of the present application;

Fig. 16 is a schematic side view illustrating a pressure oscillations generating unit usable in the tampon-like devices of the present application and including a linear motor;

10 Fig. 17 is a schematic cross sectional view of the pressure oscillations generating unit of Fig. 16 taken along the line XVII-XVII;

Fig. 18 is a schematic cross sectional view illustrating in detail part of the pressure oscillations generating unit of Fig. 17.

15 Fig. 19 is a schematic side view illustrating a pressure oscillations generating unit usable in the tampon-like devices of the present application and including a cup-like elastic member and two coils, in accordance with another embodiment of the pressure oscillations generating unit of the present application;

Fig. 20 is a schematic cross sectional view of the pressure oscillations generating unit of Fig. 19 taken along the line XX-XX;

20 Fig. 21 is another schematic side view illustrating the pressure oscillations generating unit of Fig. 19;

Fig. 22 is a schematic cross sectional view illustrating pressure oscillations generating unit of Fig. 21 taken along the line XXII-XXII and also illustrating in detail part of the pressure oscillations generating unit;

25 Fig. 23 is a schematic side view illustrating a pressure oscillations generating unit usable in the devices of the present application and including a box-like elastic member having two coils and also including two permanent magnets, in accordance with another embodiment of the pressure oscillations generating unit of the present application;

Fig. 24 is a schematic cross sectional view of the pressure oscillations generating unit of Fig. 23 taken along the line XXIV-XXIV;

Fig. 25 is another schematic side view illustrating the pressure oscillations generating unit of Fig. 23;

Fig. 26 is a schematic cross sectional view illustrating the pressure oscillations generating unit of Fig. 23 taken along the line XXVI-XXVI;

5 Fig. 27 is a schematic top view of the pressure oscillations generating unit of Fig. 26 as seen from the direction represented by the arrow M of Fig. 24;

Fig. 28A is a schematic illustration of a woman wearing an active belt around her pelvis, according to another embodiment of the devices of the present application;

10 Fig. 28B is a schematic cross sectional side view of the woman and the active belt of Fig. 14 taken along the line XXVIII B-XXVIII B;

Fig. 29 is a schematic isometric diagram illustrating the components of an experimental setup used for performing EXPERIMENT 1;

Fig. 30 is a schematic isometric view of an experimental setup used for applying acoustic pressure waves *in-vivo* to a vagina of a menstruating female subject;

15 Fig. 31 is a schematic graph illustrating the results of an *in-vivo* experiment measuring the flow of menses in the presence of acoustic pressure waves applied to the vagina of a menstruating female;

Fig. 32 is a schematic graph illustrating the results of an *in-vivo* experiment comparing the menses flow of a menstruating female with and without application of pressure oscillations to the vagina;

20 Fig. 33 is schematic isometric view illustrating a system for shortening menstruation period duration having a reusable pressure oscillations generating unit and disposable tampon-like absorbent sleeves configured to be detachably attached to the pressure oscillations generating unit, in accordance with an embodiment of the menstruation period shortening systems of the present application;

25 Fig. 34 is a schematic perspective view illustrating a vaginal pressure oscillations generating unit including a menses collecting member, in accordance with another embodiment of the menstruation period duration shortening device of the present application;

Fig. 35 is a perspective view of the vaginal pressure oscillations generating unit of Fig. 34 folded within an insertion device usable for introducing the pressure oscillations generating unit into a vagina;

5 Fig. 36 is a schematic perspective view illustrating a vaginal pressure oscillations generating unit including a menses collecting member, in accordance with yet another embodiment of the menstruation period duration shortening device of the present application;

10 Fig. 37 is a schematic cross sectional view illustrating a vaginal pressure oscillations generating unit without an absorbing member disposed within a vagina, in accordance with still another embodiment of the menstruation period duration shortening device of the present application;

Fig. 38 is a schematic cross sectional view illustrating a vaginal pressure oscillations generating unit disposed within a vagina and useful in understanding the theoretical analysis of **APPENDIX A**; and

15 Fig. 39 is a schematic graph illustrating the menses excitation amplitude as a function of the pressure oscillation frequency, as theoretically computed in **APPENDIX A** for nominal parameters and an assumed pressure oscillation power of 0.1 Watt.

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25

DETAILED DESCRIPTION OF THE INVENTION

Notation Used Throughout

The following notation is used throughout this document.

Term	Definition
AC	Alternating current
cm	Centimeter
DC	Direct current
Hz	Hertz
kHz	Kilohertz
ml	Milliliter
mm	Millimeter
Mpa	MegaPascal
mWhr	Milliwatt hour
PCB	Printed circuit board
PET	Polyethylene Terephthalate
PVC	Polyvinyl Chloride
W	Watt

5

The devices, systems and methods disclosed in the present application are medical and therapeutic devices and methods that apply vibrations to non-Newtonian fluids, which facilitate and induce streaming behavior on various fluids within various cavities and lumens of the human body.

10

One of the therapeutic effects according to the present invention is the acceleration of the menses flow leading to the shortening of the duration of the menstruation period.

15

Shear and vibrational viscosity thinning are both well-known physical phenomena that take place when non-Newtonian suspension type fluids are subjected to oscillatory waves. The two main used forms of waves are pressure waves and shear waves. Cyclic energy applied to a suspension type fluid causes the breakup of flow obstructing aggregations of the different elements in the fluid and possible streamlined re-aggregation. The result of this behavior is a reduction of the effective dynamic viscosity of the fluid. Thus, in essence the waves applied to the fluid cause a significant reduction in the fluid's resistance, therefore, the non-Newtonian fluid can flow significantly faster than without the applied energy.

The devices, systems and methods disclosed herein use a powered device for directly assisting women in shortening the menstrual flow period. The device may be self administered in a simple and safe manner to spare its user lengthy menstrual flow. Such devices maybe convenient for the user to wear and do not impede the user's mobility.

5 The duration of draining of menses fluid is shortened by means of reducing its effective viscosity. This is achieved by acoustically vibrating the menses fluid and the adjacent tissue, which by nature has the flow qualities of non-Newtonian fluids, such that it achieves flow qualities of, or similar to, newtonian fluid with reduced effective dynamic viscosity.

10 As used herein the specification and in the claims section that follows, the term "Newtonian fluid" and the like refer to a fluid whose stress at each point is linearly proportional to its strain rate at that point.

15 Some of the devices described herein may be pressure oscillations generating unit remotely (electronically, magnetically or otherwise) activated prior to their insertion into the vagina; the activation is by means of a magnetic switch or any other suitably remotely actuatable switching unit or switching mechanism, as is known in the art. This is done in order to ensure the absolute sealing of the electronic compartment from the exterior environment. The device can be inserted into the vaginal cavity through the use of a conventional tampon cardboard applicator.

20 In another embodiment of the present invention, oscillators or vibrating units are worn externally and are fitted on a belt placed around the abdomen, or otherwise attached to the abdominal region of the body (such as, but not limited to by the use of adhesive pads, or the like). The vibrating units are aimed towards the center of the abdomen where the uterus and/or cervix is located, where geometric focusing and constructive interference result with large oscillations. The power unit may also attached to the belt. In this embodiment, the
25 vibrating units can generate two different types of waves. One type is the regular pressure wave at a frequency in the range of 1 Hz to 10 kHz, with an oscillator membrane maximum amplitude which is typically 0.1mm to 2mm. The generating mechanism in the vibration generating units can be a simple ex-centric motors or any other suitable other oscillating or vibration generating unit and/or mechanism or device, as is known in the art. The second

type of wave is the shear waves. The vibration generating mechanism for that type of wave is a shear wave generating unit at similar amplitudes and frequencies as the pressure emitters.

As used herein the specification and in the claims section that follows, the term "pressure wave" and the like refer to a longitudinal wave for which the particle displacement is parallel to the direction of wave propagation.

As used herein the specification and in the claims section that follows, the term "shear waves" and the like refer to transverse waves in which the particle displacement is perpendicular to the direction of wave propagation.

The present invention may be better understood with reference to the following scientific papers:

1. Boris N Ouriev, and Naum B Uriev, *Influence of vibration on structure-rheological properties of a highly concentrated suspension*, Meas. Sci. Technol. 16 1691–1700, (2005);

2. Boris Ouriev, *Rheology and Rheometry of Aluminum alloys: influence of shear and vibration on aluminum flow properties*, Solid State Phenomena Vols. 116-117 pp. 558-564 (2006);

3. Youbing Li, Kaizhi Shen, and Jie Zhan, *Improving Rheological Property of Polymer Melt Via Low Frequency Melt Vibration* Journal of Applied Polymer Science, Vol. 102, 5292–5296 (2006);

4. J. Bear, *Dynamics of Fluids in Porous Media*, sec. 5.10. American Elsevier Pub. Co., (1972);

5. Yingzi Chen, Huilin Li, *Effect of Ultrasound on the Viscoelasticity*, The State Key Laboratory of Polymer Materials Engineering, Polymer Research Institute of Sichuan University, Chengdu 610065, People's Republic of China, received 13 November 2003; accepted 13 April 2004, DOI 10.1002/app.20831, published online in Wiley InterScience (www.interscience.wiley.com);

6. N B Uriev, and I V Kuchin, *Modelling of the dynamic state of disperse systems*, #2006 Russian Academy of Sciences and Turpion Ltd
Russian Chemical Reviews 75 (1) 31 ± 55 (2006);

7. Y. J. Liu, *Rheological equation for polymer melt under the action of vibration*, Plastics, Rubbers and Composites VOL 34 NO 2 (2005);

8. TA Scherer, J Barandun, E Martinez, A Wanner and EM Rubin, *Effect of high-frequency oral airway and chest wall oscillation and conventional chest physical therapy on expectoration in patients with stable cystic fibrosis*, CHEST / 113 4 April, 1019 (1998);

9. FDA Approval, *High-Frequency Ventilator*, PMA Number P890057/S14, September 24, (2001);

All of the above cited eight papers are incorporated herein by reference in their entirety for all purposes as if fully set forth herein.

In the specific applications adapted for shortening the duration of menses, the devices, systems and methods disclosed herein may use pressure oscillations, and/or acoustic waves and/or shock waves, and/or shear waves to vibrate the vaginal cavity, uterus, the uterus cavity, and the menses fluids.

The devices, systems and methods disclosed herein use and apply a physical principle called 'streaming'. The waves of the device cause streaming of the menses fluids. The streaming effect of suspension, non-Newtonian fluids is well known and applied in different industrial applications. Ref [1] demonstrates the effect of vibrations on chocolate and finds the range of amplitudes and frequencies in which the non-Newtonian fluid flows as a Newtonian fluid. Ref [2] compares the changes in the rheological properties of aluminum suspension flow with and without vibrations. Ref [3] shows the effect of vibrations during the manufacturing extrusion process of a polymer. In the above mentioned scientific literature, the vibrations are used to lower the effective viscosity of the suspension liquid.

The reduced effective viscosity is the combined result of two important physical processes taking place in the flow of a suspension fluid. First, the effect of vibration is to phase separate the medium and allow the aggregation of the suspension component. Once aggregation takes place, the fluid part of the medium can flow more easily as it is on average further away from obstructions. General models of a flow in porous media give, for

example, an effective dynamic viscosity which is inversely proportional to the squared size of the structures (i.e., aggregates in the present case) (e.g., Ref [4]). The effect is generally temporary and completely reversible. It stops once the vibrations cease. Note however, that the effect can still be present several seconds later, due to a possible memory effect.

5 According to the present invention, the generated pressure oscillations (and/or acoustic waves and/or shock waves) waves for applying the streaming effect in menses vibrate the tissue as well as the menses fluid and can be optimized for the reduction of the effective viscosity of menses fluid.

Reference is now made to Figs. 1-13. Fig. 1 is a schematic perspective view of a
10 tampon-like device, in accordance with an embodiment of the menstruation period duration shortening devices of the present application. Fig. 2 is a schematic perspective view of a compressed cotton sleeve of the tampon-like device, of Fig. 1. Fig. 3 is a schematic side view of the tampon-like device of Fig.1, disposed in position in a vagina. Fig. 4 is another schematic side view of the tampon-like device of Fig. 1. Fig. 5 is a schematic top view of
15 one end of the tampon-like device of Fig. 4 viewed from the edge of the insertion side of the tampon-like device of Fig.1. Fig. 6 is a schematic bottom view of the tampon-like device of Fig. 4 illustrating the bottom part of the tampon-like device. Fig. 7 is a schematic cross sectional side view of the tampon-like device of Fig. 5 taken along the line VII-VII. Fig. 8 is a schematic partial cross sectional side view of a flat coil and an elastic membrane
20 of the tampon-like device of Fig. 1. Fig. 9 is a schematic partial cross sectional side view illustrating an internal electronic compartment casing of the tampon-like device of Fig.7. Fig. 10 is a schematic top view illustrating the flat coil of the tampon-like device of Fig. 7. Fig. 11 is a schematic isometric view illustrating the rigid tube of the tampon-like device of Fig.7. Fig. 12 is a schematic side view illustrating the rigid tube of Fig. 11, and Fig. 13 is a
25 schematic top view illustrating the rigid tube of Fig. 11.

Turning to Fig.1, a tampon-like device **500**, in accordance with an embodiment of the active devices of the present application, is illustrated. Fig. 1 illustrates three external components of the tampon-like device **500**. A compressed cotton sleeve **51**, which is an absorbent member constructed and operative like the absorbent part of a standard tampon, a

pulling cord **52** attached to the battery compartment **58** of Fig. 7 (or alternatively to the cotton sleeve **51**), which may be used for pulling and removing tampon-like device **500** from the vagina, and an elastic membrane **53**, which may be operated for producing pressure oscillations and/or acoustic waves and/or shock waves as disclosed in detail hereinafter.

The insertion side end **55** of the tampon-like device **500** has rounded corners in order to facilitate insertion to the vaginal cavity. The exterior surface **56** of the compressed cotton sleeve **51** can have a multi-lobed shape having small circular curves which resembles a top view of a flower, as shown in the present figure, but any other suitable shapes may be used.

The purpose of this shape is to increase the outer surface of the absorbent part, compressed cotton sleeve **51**, or any other material which could be used for absorption, thus increasing the absorbance capability of the highly viscous substances that are part of the menses fluid and do not penetrate compressed cotton.

For the purpose of the following descriptions, we will define the side on which the membrane **53** is disposed in the tampon-like device **500**, as shown in the illustration, as the insertion side (or top side), and the opposite side, to which the pulling cord **52** is attached, as the bottom side of the tampon **500**.

Turning to Fig. 2, the compressed cotton sleeve **51** of the tampon-like device **500**, is viewed from the bottom side. A recess **29** is formed within the bottom part of the compressed cotton sleeve **51**. The recess **29** is used to house a battery compartment (not shown in Fig. 2), as described in detail hereinbelow with respect to Fig. 7. At the center of the cotton sleeve **51**, there is a longitudinal generally cylindrical passage **54** longitudinally passing through the cotton sleeve **51**. The passage **54** which is configured to contain a rigid tube, (the rigid tube is not shown in Fig. 2 for the sake of clarity of illustration, but is described in Fig. 7 hereinafter). The passage **54** has a first end opening at the side of the recess **29**, and the other end opening at the top side (the insertion side as defined hereinafter) of the tampon **500**.

Turning to Fig. 3, the tampon-like device **500** is illustrated disposed in a vagina **101**. The illustration also shows the cervix **102**, and the uterus **103**. When the tampon-like

device **500** is placed within the vagina **101**, as shown in Fig. 3, an enclosed vaginal chamber **40** is formed and defined between the walls of the vagina **101**, the cervix **102** and part of the insertion side **55** of the tampon **500**.

Turning now to Fig. 4, the tampon-like device **500** includes the compressed cotton sleeve **51**, for absorbing menses secretions, as is well known in the art. The tampon-like device **500** also includes a pulling cord **52**, which may be used for pulling out and removing the tampon-like device **500** from the vagina **101**. The insertion side end **55** of the tampon-like device **500** is shown. The illustration also shows the pulling cord **52**, and the elastic membrane **53**.

Turning to Fig. 6, the bottom end of the tampon-like device **500**, of Fig. 4 is illustrated. The illustration also shows the pulling cord **52** attached to a battery compartment **58** disposed within the recess **29** (see Fig. 2) of the compressed cotton sleeve **51**.

Turning to Fig. 7, a cylindrical tube **57** is disposed within the passage **54** formed within the cotton sleeve **51**. The tube **57** may be made from a preferably biocompatible suitable plastic or polymer based material or any other suitable rigid material known in the art, such as, but not limited to polypropylene, polyethylene terephthalate (PET), polyethylene and the like. The tube **57** is sealingly attached at a first end **57A** thereof to a battery compartment **58**. The battery compartment **58** may be any type of sealable housing made from a suitable polymer base material or any other suitable structural material known in the art for sealingly holding a battery **59** or other suitable power source therewithin.

A flat electrically isolated, electrically conducting coil **60** (best seen in Figs. 8 and 10) is attached to the end **57B** of the tube **57**. The coil **60** may be a planar spirally formed coil made from any suitable electrically conducting material such as but not limited to, copper, aluminum, an electrically conducting polymer and the like. The coil **60** may be electrically isolated by a suitable thin isolating material (not shown in the figures for the sake of clarity of illustration), such as Teflon®, or any other suitable isolating material such as an electrically isolating varnish, an elastomer, plastic, and the like.

The circumferential end **60C** of the coil **60** is suitably sealingly attached (by a suitable sealing glue, or by any other attachment method known in the art) to the (open) end **57B** of the tube **57**. An elastic membrane **53** is suitably circumferentially and sealingly attached to the part **60C** of the coil **60** such that the electronic compartment **47** formed within the tube **57** is a sealed compartment. The elastic membrane **53** is a thin flat membrane which is made from an electrically conducting material. For example, the elastic membrane may be a thin elastic foil made from aluminum, copper or any other suitable electrically conducting elastic material, such as but not limited to an elastic electrically conducting polymer.

Preferably, the elastic membrane **53** is an elastic, thin, electrically isolating membrane made from Mylar®, Polypropylene, or any other suitable plastic or polymer or the like and is coated or painted with a layer of electrically conducting material such as a metal or electrically conducting polymer or the like (The electrically conducting layer is not shown in the Figures). In this case, the electrically conducting layer is coated or painted or deposited only on the side **53B** of the membrane **53** facing the coil **60** and not on the side **53A** of the membrane **53** which faces the external side of the tampon **500**. For example, the elastic membrane **53** may be a disc-like shaped piece of Mylar® Aluminized on one side only, as is known in the art.

It is noted that all of the internal electronic and mechanical parts disposed within the sealed compartment **47** and within the battery compartment **58** are sealingly protected from the fluids with which the tampon-like device **500** may come into contact.

The electronics compartment **47** includes electronic circuitry, such as the printed circuit board (PCB) **45**. The PCB **45** includes all the circuitry necessary for forming a frequency generating unit configured for generating an oscillatory or periodically varying electrical current as is described in detail hereinafter. The theory and practice of electronic circuits for generating oscillating currents is well known in the art, is not the subject matter of the present invention and is not described in detail, hereinafter.

Briefly, any suitable oscillating and/or periodically varying current generating unit or circuitry known in the art may be implemented on the PCB **45** or other circuitry disposed in the sealed electronics compartment **47**, such as a simple RC circuit(s), RLC circuit(s), or

any other oscillating circuit known in the art that receives direct current as input and outputs an oscillating current (or oscillating voltage) having one or more frequencies or a periodically varying current. It noted that the PCB 45 may include analog circuit(s) and/or components, and/or Digital circuits and/or components and/or any combinations of analog and digital circuits and/or components. The PCB 45 may also include any suitable combination of multiple oscillator circuits which may be used to generate current oscillations having different frequencies or periodic current waveforms having different frequencies and wave-shapes.

Turning to Fig. 8, the coil 60 has coil terminals 60A and 60B. The coil terminals 60A and 60B of the coil 60 are electrically connected to two isolated electrical wires 43A and 43B (best seen in Fig. 7) which are also electrically connected to the PCB 45 for providing the oscillating current and/or a periodically varying current to the coil 60.

When a periodically varying current (or an oscillating current, such as, but not limited to a sinusoidal current) is applied to the coil 60, the currents flowing through the coil 60 induces eddy currents in the metal forming the elastic membrane 53 or deposited in a layer thereupon (depending on the type of membrane being used). These induced eddy currents cause a periodically varying force pushing the elastic membrane away from the surface of the coil 60. As the elastic membrane 53 is attached only partially to the coil 60 only at the narrow circumferential part 60C as disclosed hereinabove, most of the surface 53B of the elastic membrane 53 is not permanently attached to the surface of the coil 60 and may move away from and/or towards the surface of the coil 60 when a suitable force is applied thereto.

Thus, as long as the oscillating and/or periodically varying currents are applied to the coil 60, the part of the elastic membrane 53 which is not attached to the circumference 60C of the coil 60 will mechanically oscillate along the general direction of the longitudinal axis of the tampon 500 represented by the double headed arrow 35. When the tampon 500 is disposed in the vagina 101 as illustrated in Fig. 3, and the power is switched on to energize the circuitry of PCB 45, the oscillations and/or periodic movement of the elastic membrane 53 push the air adjacent to the side 53A of the elastic membrane 53 generating pressure oscillations and/or acoustic waves and/or shock waves (depending, *inter alia*, on

the particular waveform of the periodically varying currents flowing through the coil **60**) in the vaginal chamber **40**.

The advantage of applying pressure oscillations (and/or s and/or shock waves) to the vaginal chamber **40** is that a large portion of the oscillation energy is used to generate a varying pressure gradient across the uterine cervical canal connecting the internal space of the uterus **103** with the vaginal air chamber **40**. The inventor of the devices disclosed herein surprisingly and unexpectedly found that the application of such pressure oscillations and/or acoustic waves and/or shock-waves to the vaginal air chamber **40** significantly assists and accelerates the flow of menses secretions from the uterus **103** through the cervical canal leading to a very substantial shortening of the menstrual period duration, as disclosed in detail in the experiments described hereinafter.

The PCB **45** may also include a remotely actuatable switching unit, such as a magnetic field actuatable switch that may control the flow of current from the power source (such as, for example, the battery **59** of Fig. 7) to the oscillating and/or periodic current generating circuitry included in the PCB **45**. Thus, when the tampon **500** is in storage or not being used, the switch is (by default) in the "off" state and no power is supplied to the PCB **45**. The switch (not shown) may then be activated (turned to the "on" state) by the user, (for example by placing a magnet close to the tampon **500** to turn on the switch and energize the circuitry of the PCB **45**).

When the switch is turned on, power is supplied to the PCB **45** and the circuitry of the PCB **45** outputs an oscillating and/or periodically varying current through the wires **43A** and **43B** to the coil **60**.

It is noted that the tube **57** functions as a rigid support holding the coil **60** and the elastic membrane **53** attached to the circumference **60C** of the coil **60**. The tube **57** also seals the internal electronics compartment **47** formed within the tube **57** from any liquids present in the exterior environment. The battery compartment **58** similarly functions to hermetically isolate and seal the battery **59** from the external environment, in order to prevent any electrical discharge to the body.

Turning to Fig. 9, the tube **57** and the battery compartment **58** are attached together forming an internal electronic compartment casing **61** of the tampon-like device **500**. The cross-section illustrated in Fig. 9 is taken along the line VII-VII of Fig. 4. The internal electronic compartment casing **61** includes the rigid tube **57**, and the battery compartment
5 **58**. All the electronic components of the tampon-like device **500** are disposed within the internal electronic compartment casing **61** which provides sealing to the electronic compartment from the external environment.

Turning to Figure 10, the flat coil **60** of the tampon-like device **500** is illustrated viewed from the top side. It is noted that the details of the flat coil **60** as shown in this
10 exemplary-non-limiting illustration, such as the number of turns, are not meant to be limiting in any way and other coils having a different number of turns and cross-sectional shape may also be used.

In another embodiment of the devices of the present application, the pressure oscillations and/or acoustic waves and/or shock waves may be generated by using a small
15 motor attached to a suitable piston. In each case the frequency of the vibrations may be between 1Hz and 10kHz, and the amplitude of the vibrations may be between 0.1mm to 2mm.

Usable pressure oscillations may be as follows:

- a. a symmetrical subsonic wave in the range of 10Hz to 1kHz.
- 20 b. a superposition of the two waves into a 1Hz saw-tooth shaped wave where a higher wave of the range of 10Hz to 1kHz is added to its second part.

It is noted that the oscillation frequency range, frequency combinations, and vibration amplitudes mentioned hereinabove while found to be practical, are not intended to limit the scope of the oscillation parameters usable with the various embodiments of the present
25 invention. Other different ranges of oscillation frequency or frequency combinations lower than 1Hz or higher than 10kHz may also be used in the devices of the present invention. For example the oscillation frequency may be in the range of 0.1Hz-10 kHz, more preferably in the range of 1Hz- 100Hz, and most preferably in the range of 30Hz - 60 Hz.

However, other different oscillation frequencies or frequency combinations may also be used.

Similarly, vibration amplitudes lower than 0.1 mm or higher than 2 mm may be used , depending, inter alia, on the particular type, structure and dimensions of the pressure oscillation generating unit being used.

The tampon-like device **500** may be activated by using a small magnet not shown in the illustrations to activate a magnetically actuatable switch (not shown) included in the device **500**. Once the tampon-like device **500** is ready to be used, the oscillator is activated by the exterior magnet. Once the oscillator is in operative mode its action will be stopped only upon the depletion of the batteries. The oscillator can be active between 20 minutes to one hour.

However, it is noted that in other embodiments of the devices of the present application the power source may be switched on and off at the user's discretion, such as, for example in devices having an external switchable power source (see, for example the power source **358** of the system **380** of Fig. 33 hereinafter). When such a larger external power source is being used, the duration of activation of the oscillator may be greatly extended as the batteries or other power sources used may have much greater capacity.

Additionally, even in devices having a small internal capacity, the duration of oscillator activation may be extended beyond one hour by activating the oscillator of the device intermittently (in a pulsatile manner) with a duty cycle between smaller than 100% (such as for example with a duty cycle in the range of 1%-99%).

Turning to Figs. 11, 12 and 13, the tube **57** of the tampon-like device **500**, are illustrated in perspective view, side view and top view, respectively.

It is noted that the exemplary pressure oscillations generating unit disclosed hereinabove and illustrated in Figs 7-13 is not limited to the particular embodiment described with respect to Figs. 7-13.

Reference is now made to Figs. 14-15 which are schematic block diagrams illustrating two different embodiments of the tampon-like device of the present application. Fig. 14 is a schematic block diagram illustrating some of the components of a menstruation period

duration shortening device having an internal power source, in accordance with an embodiment of the devices of the present application, and Fig. 15 is a schematic block diagram illustrating some of the components of a menstruation period duration shortening device having an external power source, in accordance with another embodiment of the devices of present application;

Turning to Fig. 14, the device **200** includes a frequency generating circuit **212** which may be any type of electrical or electronic circuit configured for providing oscillating electrical current (or an oscillating voltage) at the frequency or frequencies disclosed herein. The frequency generating circuit **212** is connected to an electrical power source **209** through a controllable switching unit **210**, and may receive electrical power from the Power source **209** when the switching unit **210** is actuated to the "ON" state (which may be performed remotely if the switching unit is of the remotely actuatable type as disclosed in detail herein).

The electrical power source **209** is an internal power source disposed within the device **200** and may be any suitable compact electrical power source known in the art, such as but not limited to, a battery, an electrochemical cell, a primary electrochemical cell, a rechargeable electrochemical cell, a super-capacitor, a fuel cell and any combinations thereof. The Frequency generating unit **212** may be any type of electrical circuit for generating time varying electrical signals and or periodically oscillating electrical signals, as disclosed in detail hereinabove.

The frequency generating unit **212** is also connected to a pressure oscillations generating unit **214** by suitable electrical conductors (not shown in detail in Fig. 14). When the power is switched on, the frequency generating unit **212** supplies appropriate oscillating or periodically varying electrical signals to the pressure oscillations generating unit **214** which generates pressure oscillations and/or acoustic waves and/or shock waves within the vagina **101** as disclosed in detail hereinabove.

Turning to Fig. 15, the device **220** includes the frequency generating circuit **212**, controllable switching unit **210**, and the pressure oscillations generating unit **214** disclosed hereinabove. The device **220** includes an external power source **227**. The external power

source **227** is a power source disposed outside the device **220** and may be any type of electrical power source known in the art such as but not limited to a DC power source an AC current source (with or without a transformer), a battery, an electrochemical cell, a primary electrochemical cell, a rechargeable electrochemical cell, a super-capacitor, a fuel cell and any combinations thereof. The external power source **227** may be suitably connected to the switching unit **210** (as shown in Fig 15) but may also (optionally) be a switchable external power source directly connected to the frequency generating unit **212**. in the latter case the internal switching unit **210** is replaced by a switching unit (not shown) included in the external switchable power source.

Reference is now made to Figs 16-18. Fig. 16 is a schematic side view illustrating an pressure oscillations generating unit usable in the devices of the present application and including a linear motor. Fig. 17 is a schematic cross sectional view of the pressure oscillations generating unit of Fig. 16 taken along the line XVII-XVII. Fig. 18 is a schematic cross sectional view illustrating in detail part of the pressure oscillations generating unit of Fig. 17.

The pressure oscillations generating unit **250** includes a housing **252** which is a cylindrical housing having an opening at one end **252A**. The housing **252** may be made from any suitable biocompatible rigid structural material such as, plastic or a polymer based rigid material or any other suitable rigid material known in the art, such as, but not limited to polypropylene, polyethylene terephthalate (PET), polyethylene and the like. A power source such as a battery **254** is disposed within the housing **252**. The power source may be any suitable type of compact power source as disclosed in detail hereinabove. In the exemplary embodiment illustrated in Figs. 16-17, the battery **254** is a standard N type battery, but any other type of battery may be used. The pressure oscillations generating unit **250** also includes a linear motor **256** having a motor shaft **257** which is movable along the directions indicated by the double headed arrow **258**. The shaft **258** is mechanically coupled to a movable member **260**. The movable member includes a rigid conical portion **260A** which is sealingly attached to the opening at the end **252A** of the housing **252** (such as, for example by suitable gluing or welding or any other method known in the art). The

movable member **260** also includes a preferably rigid bottom portion **260B** to which the motor shaft **257** is attached. The movable member **260** also includes a corrugated (accordion-like) flexible portion **260C** which may elastically be elongated and shortened in the direction of movement of the motor shaft **257**.

5 A printed circuit board (PCB) **245** is disposed in the housing **252**. The PCB **245** is suitably electrically connected to the battery **254** to receive electrical power from the battery **254** (the electrical connections are not shown for the sake of clarity of illustration). The PCB **245** may include a remotely actuatable switch (such as, for example the switching unit **210** of Fig. 14) that may be implemented as a magnetically actuated switch as disclosed
10 hereinabove, however, any other type of remotely actuatable switching device may be used, as is known in the art. The PCB **245** also includes a controller (not shown in detail) which controls the movement of the shaft **257** of the linear motor. The controller is configured for moving the shaft **257** to push or pull the rigid portion **260C** such that the corrugated flexible portion **260C** is shortened and extended periodically. The movements of the motor
15 shaft **257** may thus be controlled by the controller included in the PCB **245** such that the movable member **260** may generate any desired type of pressure oscillations, and/or acoustic waves, and/or shock waves, and/or pressure waves of a desired frequency or frequencies as disclosed in detail hereinabove and hereinafter. The PCB **245** is electrically
20 connected to the linear motor **256** (the electrical connections are not shown in Fig. 17 for the sake of clarity of illustration) for providing suitable electrical signals to the motor **256** for controlling the movements of the shaft **257** and the frequency and wave shape and (optionally) the duty cycle of the pressure oscillations generated by the moving member **260**.

25 A pulsing cord **52** (see also Fig. 7) may be attached to the bottom end **252B** of the housing **252** for assisting the removal of the pressure oscillations generating unit from the vagina **101** as disclosed hereinabove. The pressure oscillations generating unit **250** may be inserted into the vagina **101** (see Fig. 3) with the end **252A** inserted first into the vagina **101** until a vaginal chamber is defined between the end **252A**, the walls of the vagina **101** and the cervix **102**. When the pressure oscillations generating unit **250** is activated, pressure

oscillations and/or acoustic waves and/or shock waves are generated within the vaginal chamber as disclosed in detail hereinabove to effect the change of flow rate of menses effectively shortening the duration of the menstruation period.

Reference is now made to Figs 19-22. Fig. 19 is a schematic side view illustrating a pressure oscillations generating unit usable in the devices of the present application and including a cup-like elastic member and two coils, in accordance with another embodiment of the pressure oscillations generating unit of the present application. Fig. 20 is a schematic cross sectional view of the pressure oscillations generating unit of Fig. 19 taken along the line XX-XX. Fig. 21 is another schematic side view illustrating the pressure oscillations generating unit of Fig. 19. Fig. 22 is a schematic cross sectional view illustrating the pressure oscillations generating unit of Fig. 21 taken along the line XXII-XXII and also illustrating in detail part of the pressure oscillations generating unit.

The pressure oscillations generating unit **270** includes a housing **252** which is a cylindrical housing having an opening at one end **252A**. The housing **252** may be made from any suitable biocompatible rigid structural material such as, plastic or a polymer based rigid material or any other suitable rigid material known in the art, such as, but not limited to polypropylene, polyethylene terephthalate (PET), polyethylene and the like. A power source such as a battery **254** is disposed within the housing **252**. The power source may be any suitable type of compact power source as disclosed in detail hereinabove. In the exemplary embodiment illustrated in Figs. 19-22, the battery **254** is a standard N type battery, but any other type of battery may be used.

The pressure oscillations generating unit **270** also includes a cup-like movable member **280**. The movable member **280** is shaped like a flaring cup, but other suitable shapes may also be used. The movable member **280** may be a thin elastic membrane made from a suitable biocompatible elastic material, such as but not limited to Milar® or any other type of elastic biocompatible plastic or polymer based material known in the art or the like. The open end **280A** of the movable member **280** is sealingly attached to the opening at the end **252A** of the housing **252** (such as, for example by suitable gluing or welding or any other method of sealably attaching method known in the art).

Two flat thin electrically conducting plates **272A** and **272B** are attached to or glued on opposite sides of the movable member **280**. The plates **272A** and **272B** are rectangular in shape but may also be shaped as elliptical plates or as plates having other suitable shapes. The plates **272A** and **272B** may be made from any suitable electrically conducting material such as but not limited to a metal, aluminum, copper, silver, an electrically conducting polymer and the like. Two rectangular coils **274A** and **274B** are rigidly attached to the housing **252** such that the coil **274A** is adjacent to the plate **272A** and the coil **274B** is adjacent to the plate **272B**. The coils **274A** and **274B** are preferably planar coils, but other types of non-planar coils may also be used. The coils **274A** and **274B** are preferably wound from thin insulated electrically conducting wires (not shown in detail), but may also be planar or non-planar coils printed on a thin printed circuit board (PCB) as is known in the art, or any other type of suitable coils). It is noted that the windings of the electrical wires or conductors included in the coils **274A** and **274B** are not shown in detail in Figs. 19-22 for the sake of clarity of illustration.

Preferably, the surface of the plates **272A** and **272B** which face the coils **274A** and **274B**, respectively, are electrically isolated by a thin layer of non-electrically conducting material or paint (not shown), to ensure that the conducting material of the plates **272A** and **272B** does not electrically short circuit the coils **274A** and **274B** if there is contact between the coil and the plate. It is noted that this isolating material may not be necessary if the conducting wires or conducting elements of the coils are isolated electrically by a suitable material. When a time varying electrical current is passed in the coils **274A** and **274B**, eddy currents are generated in the electrically conducting plates **272A** and **272B** and a force is generated pushing the plates away from the coils. If the electrical current in the coils **274A** and **274B** periodically changes, the plates vibrate or oscillate and the elastic walls of the moving member **280** also vibrate. When the pressure oscillation generating unit **270** is disposed within a the vagina **101** such that the cavity **278** is directed towards the cervix **102** (see Fig. 3), pressure oscillations are generated in the vaginal chamber defined by the cavity **278**, part of the walls of the vagina **101** and the cervix **102**. The pressure oscillations act to change the flow properties of menses which results in increase menses flow rate out

of the uterus **103** through the cervical canal, resulting in increase menses flow and the shortening of the duration of the menstruation period.

A printed circuit board (PCB) **275** is disposed in the housing **252**. The PCB **275** is suitably electrically connected to the battery **254** to receive electrical power from the battery **254** (the electrical connections are not shown for the sake of clarity of illustration). The PCB **275** is electrically connected to the coils **274A** and **274B** (the electrical connections are not shown in Figs. 19-22 for the sake of clarity of illustration) for providing suitable electrical signals to the coils and for controlling the movements or vibrations of the walls of the movable member **280** and the frequency and wave shape and (optionally) the duty cycle of the pressure oscillations generated within the vaginal chamber by the movable member **280**. The PCB **275** may include a remotely actuatable switch (such as, for example the switching unit **210** of Fig. 14) that may be implemented as a magnetically actuated switch as disclosed hereinabove, however, any other type of remotely actuatable switching device may be used, as is known in the art. The PCB **275** also includes a controller or a frequency generating unit (not shown in detail), such as for example the frequency generating unit **212** of Fig. 14 which controls the parameters of the electrical signals applied to the coils **274A** and **274B**, such that the movable member **280** may generate any desired type of pressure oscillations, and/or acoustic waves, and/or shock waves, and/or pressure waves of a desired frequency or frequencies as disclosed in detail hereinabove and hereinafter.

A pulsing cord **52** (see also Fig. 7) may be attached to the bottom end **252B** of the housing **252** for assisting the removal of the pressure oscillations generating unit **270** from the vagina **101** as disclosed hereinabove.

It is noted that the wiring of the connections of the coils **274A** and **274B** to the PCB **275** is arranged such that the polarity and phase of the currents flowing in the coils **274A** and **274B** are suited to optimize the displacement of air and/or fluids included in the vaginal chamber and the resulting pressure oscillations.

Reference is now made to Figs 23-27. Fig. 23 is a schematic side view illustrating a pressure oscillations generating unit usable in the devices of the present application and including a box-like elastic member having two coils and also including two permanent

magnets, in accordance with another embodiment of the pressure oscillations generating unit of the present application. Fig. 24 is a schematic cross sectional view of the pressure oscillations generating unit of Fig. 23 taken along the line XXIV-XXIV. Fig. 25 is another schematic side view illustrating the pressure oscillations generating unit of Fig. 23. Fig. 26 is a schematic cross sectional view illustrating the pressure oscillations generating unit of Fig. 23 taken along the line XXVI-XXVI. Fig. 27 is a schematic top view of the pressure oscillations generating unit of Fig. 26 as seen from the direction represented by the arrow **M** of Fig. 24.

Turning to Fig. 23, the pressure oscillations generating unit **300** includes a housing **252** which is a cylindrical housing having an opening at one end **252A**. The structure of the housing **252** is as described in detail hereinabove. A power source such as a battery **254** is disposed within the housing **252**. The power source may be any suitable type of compact power source as disclosed in detail hereinabove. In the exemplary embodiment illustrated in Figs. 23-27, the battery **254** is a standard N type battery, but any other type of battery may be used.

The pressure oscillations generating unit **300** also includes a movable member **310**. The movable member **310** is shaped like a rectangular box flaring at an open end **310A** thereof, and closed at another end **310B** thereof. However, other suitable shapes may also be used. The movable member **300** may be a thin elastic membrane made from a suitable biocompatible elastic material, such as but not limited to Milar® or any other type of elastic biocompatible plastic or polymer based material known in the art or the like. The flaring end **310A** of the movable member **300** is sealingly attached to the opening at the end **252A** of the housing **252** (such as, for example by suitable gluing or welding or any other method of sealably attaching method known in the art). An open cavity **320** is formed within the movable member **310**.

Two flat thin electrical coils **304A** and **304B** are attached to or glued on opposite sides of the movable member **310**. The coils **304A** and **305B** are rectangular in shape but may also be shaped as elliptical coils round coils or as coils having other suitable shapes. Two permanent magnets **306A** and **306B** are rigidly attached to the housing **252** such that the

magnet **306A** is disposed adjacent to and facing the coil **304A** and the magnet **306B** is disposed adjacent to and facing the plate **272B**. The coils **304A** and **304B** are preferably planar coils, but other types of non-planar coils may also be used. The coils **304A** and **304B** are preferably wound from thin insulated electrically conducting wires (not shown in
5 detail), but may also be planar or non-planar coils printed on a thin printed circuit board (PCB) as is known in the art, or any other type of suitable coils. It is noted that the windings of the electrical wires or conductors included in the coils **304A** and **304B** are not shown in detail in Figs. 19-22 for the sake of clarity of illustration.

When a time varying electrical current is passed in the coils **304A** and **304B**, a
10 magnetic field is generated in the coils having a polarity depending on the current direction and the coil geometry and windings direction and a force is generated pushing the coils **304A** and **304B** towards or away from the permanent magnets **306A** and **306B**, respectively (the direction of the force may depend , inter alia, on the polarity of the magnetic field of the permanent magnets **306A** and **306B**, and on the direction of current flow in the coils
15 **304A** and **304B**. If the electrical current in the coils **304A** and **304B** periodically changes, the side walls of the movable member **310** to which the coils **304A** and **304B** are attached vibrate or oscillate. When the pressure oscillation generating unit **300** is disposed within the vagina **101** such that the opening of the cavity **320** is directed towards the cervix **102** (see Fig. 3), pressure oscillations are generated in the vaginal chamber defined by the cavity
20 **320**, part of the walls of the vagina **101** and the cervix **102**. The pressure oscillations act to change the flow properties of menses which results in increase menses flow rate out of the uterus **103** through the cervical canal, resulting in increase menses flow and the shortening of the duration of the menstruation period.

A printed circuit board (PCB) **305** is disposed in the housing **252**. The PCB **305** is
25 suitably electrically connected to the battery **254** to receive electrical power from the battery **254** (the electrical connections are not shown for the sake of clarity of illustration). The PCB **305** is suitably electrically connected to the coils **304A** and **304B** (the electrical connections are not shown in Figs. 23-27 for the sake of clarity of illustration) for providing suitable electrical signals to the coils **304A** and **304B** and for controlling the movements or

vibrations of the walls of the movable member **310** and the frequency and wave shape and (optionally) the duty cycle of the pressure oscillations generated within the vaginal chamber by the movable member **310**. The PCB **305** may include a remotely actuatable switch (such as, for example the switching unit **210** of Fig. 14) that may be implemented as a magnetically actuated switch as disclosed hereinabove, however, any other type of remotely actuable switching device may be used, as is known in the art. The PCB **305** also includes a controller or a frequency generating unit (not shown in detail), such as for example the frequency generating unit **212** of Fig. 14 which controls the parameters of the electrical signals (electrical currents) applied to the coils **304A** and **304B**, such that the movable member **310** may generate any desired type of pressure oscillations, and/or acoustic waves, and/or shock waves, and/or pressure waves of a desired frequency or frequencies as disclosed in detail hereinabove and hereinafter.

A pulsing cord **52** (see also Fig. 7) may be attached to the bottom end **252B** of the housing **252** for assisting the removal of the pressure oscillations generating unit **300** from the vagina **101** as disclosed hereinabove.

It is noted that the wiring of the connections of the coils **274A** and **274B** to the PCB **305** is arranged such that the polarity and phase of the currents flowing in the coils **304A** and **304B** are suited to optimize the displacement of air and/or fluids included in the vaginal chamber and the resulting pressure oscillations.

It is also noted that in accordance with another embodiment of the pressure oscillations generating unit of the present application, the permanent magnets **306A** and **306B** may be replaced with two coils (not shown) attached to the walls of the movable member **310**. These coils which may be fed with suitable electrical currents by connecting them to current generating circuitry disposed on the PCB **305** such that they function as an electromagnet to generate a magnetic field (optionally) similar to the magnetic field of the permanent magnets **306A** and **306B**. However, when such a configuration having four coils is implemented, the current passed in the coils replacing the permanent magnet need not necessarily be a DC current, rather oscillating currents or other types of time varying (or

pulsatile) currents may be passed through all four currents to optimize current consumption and to optimize the pressure oscillations amplitude.

It is noted that while the tampon-like devices disclosed hereinabove (such as for example the device **500** of Fig.1) which include an absorbent element sleeve or pad, (such as, for example, the compressed cotton sleeve **51** of Fig. 1) are convenient for use, they are not intended to limit the devices of the present application. For example, any of the pressure oscillations generating units disclosed in the preset application may be used to achieve the intended desired menses period duration shortening effect without including any absorbent member or sleeve or pad as part of the device placed in the vagina **101**.

In accordance with another embodiment of the menses duration shortening devices of the present application, the dimensions of any of the pressure oscillations generating units disclosed herein may be modified such they are within the range of dimensions which may be conveniently and comfortably inserted into the vagina **101**. For example, any of the pressure oscillations generating units illustrated in Figs. 16-27 may be adapted for convenient insertion inserted into the vagina **101**. In such a case, the menstruation period duration shortening device may be a pressure oscillations generating unit, such as but not limited to any of the pressure oscillations generating units **250**, **270** and **300** (of Figs. 17, 20, and 24, respectively) which is adapted in it's dimensions for convenient insertion into a vagina. It is noted that the dimensions of such pressure oscillations generating units may be similar to the dimensions of typical regular tampons known in the art, but they may be made from a non-absorbent material and configured to be hermetically sealed to prevent entry of any vaginal fluids or menstrual secretions into the pressure oscillations generating unit to prevent any electrical circuitry shorting effects and/or the delivering of electrical currents to the vagina (an exemplary embodiment of such a tampon-less device is disclosed in detail in Fig. 37, hereinbelow).

Reference is now made to Figs. 28A-28B. Fig. 28A is a schematic illustration of a woman wearing an active belt around her pelvis, according to another embodiment of the devices of the present application, and Fig. 28B is a schematic cross sectional side view of the woman and the active belt of Fig. 28A taken along the line XXVIII B-XXVIII B.

Figs 28A-28B illustrate several anatomical details, such as the cervix **102**, rectum **104**, and bladder **105**. The woman **100** wears an active belt **700** around her pelvis, according to another embodiment of the active menstruation duration shortening devices of the present application. The active belt **700** includes several vibration generating units **72** that are attached to an elastic belt **71**. The vibration generating units **72** are designed to generate the following vibrational waves:

- a. Pressure waves.
- b. Shear waves.

The frequency and amplitude of each of the wave types is preferably between 0.1Hz to 10kHz and 0.1 to 2 mm, respectively, but other different vibration frequencies and amplitudes may also be used in the active belt of the present application. The vibration generating units **72** are all directed towards the cervix **102** thus enabling the transfer of sufficient energy through the tissue giving rise to the vibration of the cervix.

The external vibration of the cervix achieves the desired change of the effective viscosity of the menses fluid as explained hereinabove by changing the flow properties of the non-Newtonian menses secretions. This accelerates the flow of menses through the cervical lumen and thus effectively shortens the duration of menstruation.

The vibration generating units **72** may be any type of vibrating elements configured for delivering mechanical vibrations to the tissues of the woman **100** (including, but not limited to, piezoelectric transducers, mechanical and/or electromechanical vibrating elements and/or transducers, and the like) are disposed in contact with the skin of the woman **100** and are all directed towards the cervix **102**, enabling the transfer of sufficient vibrational mechanical energy through the tissue to cause or induce vibrations of the cervix **102**. The vibration emitters **72** may be operated by a regular switch, which may be connected to a power supply (not shown) through a transformer (not shown) or to a battery pack (not shown). For example, a control unit **75** attached to the elastic belt **71** may include a power source (not shown) such as any of the electrical power sources disclosed in detail hereinabove, an activating switch (not shown) for controlling power application from the power source included in the control unit **75** to the vibration emitters

It is emphasized that active belt **700**, with the necessary changes and modifications, may also be put on other places of the human body for reducing the effective viscosity of liquids or fluids in other body parts.

Besides the theoretical analysis of the physical behavior and operational parameters of the devices required and vaginal chamber physical behavior, the inventor has also performed *in-vitro* and *in-vivo* experiments which are disclosed in detail hereinafter.

EXPERIMENT 1

The *in- vitro* experiment was aimed at carry out an initial optimization study of the shape, amplitude and frequency of the pressure oscillations usable in the devices of the present application. In addition, the characteristics of the tissue debris within the menses were analyzed, as was the effect of the pressure oscillations on the debris characteristics.

Reference is now made to Fig. 29 which is a schematic diagram illustrating the components of an experimental setup used for performing **EXPERIMENT 1**.

The experimental setup **400** includes a transducer **403**, a vaginal applicator **406**, a cervical model **408**, a uterus model **410** and a controller **412**. The pressure oscillation transducer **403** includes a sub-woofer **402** and a funnel coupler **404** sealingly attached to the subwoofer **402**. The sub-woofer **402** was a "PSB alpha subsonic 5 sub-woofer". The subwoofer **402** comprises a 378 x 314 x 419 mm sized wooden box. All outlets of the box were sealed through the use of rigid materials and glued into place using a commercial silicone sealing compound. The circular speaker, located on the side of the box of the subwoofer **402** is 25cm in diameter, and includes a polypropylene cone, a rubber surrounded 38mm diameter voice coil and both a 794gr magnet and a shielding magnet. The total internal volume of the sub-woofer **402** is 28.6 liter and it is rate at 150 Watt nominal power.

The speaker port of the sub-woofer **402** was covered with a 27cm diameter funnel coupler **404** and sealed using a silicon sealing compound. The narrow outlet of the funnel coupler **404** was connected to a PVC tube (commercially available from Reshafim, Israel)

having 16 and 19 mm inner and outer diameters, respectively.

A vaginal applicator **406** is sealingly attached to the funnel **404** on one end and is sealingly attached to the uterus model **410**. The cervical model **408** is fluidically coupled to the uterus model **410** as shown. The uterus model **410** was implemented as a syringe (10ml
5 volume from PLASTIPAK. The syringe plunger was removed and discarded and the resulting rigid tube of the syringe opens to the atmosphere at one end, and was connected at the other end **410B** to a needle connecting port (not shown) with an inner diameter of 3.5mm. The outer diameter of the syringe was 16mm and the length of the syringe was 10cm.

10 The cervix model **408** was a tube with an inner diameter 3mm. The Young modulus is typically 1Mpa. In the associated literature the cervix muscle tissue is described as similar to cartilage. The cervix model **408** was connected to the needle port (not shown in detail) of the syringe used as the uterus model **410**. The tube implementing the cervix model **408** is suspended in the inner cavity of the vaginal applicator **406**. The cervical model **408** was a
15 rigid tube with small bending capabilities. The tube was 4cm long and had a 3mm inner diameter. The vaginal applicator **406** was implemented by a rigid tube made from polyvinyl chloride (PVC) which had 16mm and 19mm inner and outer diameters, respectively and a length of 20 cm. The tube was sealingly coupled connected to the syringe simulating the uterus model **410** as illustrated in Fig 29.

20 The pressure oscillations were generated by the sub-woofer **402** and were controlled by the controller **412** which was implemented on a laptop computer (Macintosh 2.16GHz Intel Core 2 Duo running Mathematica® software used to generate the required wave shapes and frequencies) The headphone port of the laptop computer was connected to the low level input jacks of the subwoofer **402** . The frequency and amplitude of the electrical
25 signals delivered to the subwoofer **402** were controlled through the use of the laptop computer implementing the controller **412**. Real menses fluid and debris were freshly collected from a menstruating female subject and were used in the model by placing the menses within the syringe used as the uterus model **410**.

Anatomical and Physiological Simulation:

The anatomical simulation model is divided into three components: the uterus, the cervix, and the menses. The uterine cavity is a potential cavity, i.e., the uterine inner walls normally touch each other. The endometrial layer slowly grows in the inner part of the uterus. During menstruation, two types of forces affect the menses flow: the uterine thick muscle layer contractions and gravitational forces. According to literature, the inner pressure inside the uterus during menstruation is in the range of 50-200mmHg.

In order to simulate accurately the uterine cavity, the above physiological and anatomical properties of the uterus must be taken in to account. Nevertheless, since the natural contractions of the uterus facilitate the flow of menses through the cervix, the pressure oscillations effect, if shown without the contractions will evidently work with the contractions as well. Hence, the naturally applied contractions by the uterus and the inner uterine changes in pressure can be neglected and only the gravitational forces are considered.

The experimental procedure was used for characterizing the tissue particles before and after applying pressure oscillations, and for examining the effects of application of different pressure oscillations on the tissue fragments included in the menses.

Characterizing the tissue fragments:

The menses fluid was pre-collected from a female volunteer. The fluid was divided to liquids and tissue fragments by the use of a sieve having a pore size of approximately 1mm by 1mm. The pieces of tissue were measured. The average size of tissue pieces was found to be 1cm. Therefore, the pieces of tissue were manually ordered and cut if needed to approximately 1cm in length when the rest was discharged. The goal of this procedure was to create a somewhat standard base line.

In total 6 tissue fragments were used. Each was taken separately and placed gently on the bottom of the syringe (uterus model 410) near the inlet of the cervical model 408. Real menses fluids with no tissue particles was then purred into the syringe slowly, so the

elevation of static pressure would be very slow and controlled. The menses added moved the tissue into its location at the inlet of the cervical model **408**. As a result, the tissue pieces blocked the 3mm diameter opening of the cervical model **408** and the menses fluid was accumulated in the syringe.

5 Two tests were then preformed on the system: 3cm height of menses fluid was purred in the syringe and left to stand for fifteen minutes. This showed that without any external force the tissue fragments completely block the cervix model **408** preventing any fluids from flowing.

10 The second test was to examine, what static pressure is needed in order to force the tissue through the cervical model **408**. For this part, fluid was added into the syringe to increase the static pressure applied to the tissue pieces. The expression “drain pressure” is used hereinafter to refer to the static pressure which was measured when the tissue fragment was forced out from the cervical model **408**. Each experiment was carried out five times on each tissue fragment. In addition the same tests were preformed on each one of the used
15 tissue fragments after they were exposed to pressure oscillations, and their drain pressure was measured again after exposure of these tissue fragments to pressure oscillations.

Examining the effect of different pressure oscillations

20 The tissue fragments that were used in the experiments were taken in the same manner as described hereinabove and placed inside the syringe of the uterus model **410**. Menses was then poured into the syringe to a height of 1cm lower then the average “draining pressure” height found previously. This was done to make sure that the tissue fragment is placed in the cervical model **408** in such a way that sufficient amount of pressure is needed to open it. Then, the menses fluid level in the syringe of the uterus model **410** was reduced to a height gravitationally equivalent to 3cm of water. This was
25 done with the use of a pipette without touching the tissue fragment or changing its position. The reduction in static pressure was performed in order to make sure that the pressure oscillations applied to the cervical outlet are the cause of “opening” the cervix and not the static pressure applied by the liquids.

After the particle and the menses fluid were ready inside the syringe of the uterus model **410**, different pressure oscillations were applied using the sub-woofer **402**. The pressure oscillations were applied through the PVC tube of the vaginal applicator **406** to the outlet of the cervical model **408**. The tested range of pressure oscillations was 10Hz to 300Hz with 10Hz jumps.

Six different pressure oscillation waveforms were applied: a sine wave, a sawtooth wave with a slow rising phase and a fast falling phase, a sawtooth wave with a fast rising phase and a slow falling phase, a sine wave which was amplitude modulated by a 1Hz sawtooth with slow rise and fast fall, and a sine wave which was amplitude modulated by a 1Hz sawtooth wave with a fast rising phase and a slow falling phase, and a square wave with a 50% duty cycle.

The signal peak amplitude which was fed to the input terminals of the sub-woofer **402** was constant and was set to the maximum amplitude possible for the sub-woofer **402**. For each individual particle and each individual waveform used, a range was found where the particle was affected by the pressure oscillations and the tissue has undergone a "drainage pressure" event.

Results of Characterizing the tissue particles:

The total amount of tissue particles used in this experiment was six particles.

Each particle was tested five times to examine its resistance to static pressure.

The results are summarized in **TABLE 1** below:

TABLE 1

particle No.	Drainage pressure (cmH ₂ O)	Particle length	Particle width	Mean pressure (cm H ₂ O)
1	4	1cm	3mm	5.3
1	6			
1	4			
1	9			

particle No.	Drainage pressure (cmH ₂ O)	Particle length	Particle width	Mean pressure (cm H ₂ O)
1	3.5			
2	7	1cm	5mm	6.4
2	5			
2	6			
2	7			
2	7			
3	7	5mm	5mm	6.4
3	4			
3	7			
3	7			
3	7			
4	18	1cm	5mm	14.9
4	14			
4	14			
4	14			
4	14.5			
5	5.5	8mm	4mm	6.4
5	6			
5	7.5			
5	5			
5	8			
6	4	6mm	4mm	4.8
6	5			
6	2.5			
6	8			

particle No.	Drainage pressure (cmH ₂ O)	Particle length	Particle width	Mean pressure (cm H ₂ O)
6	4.5			

The results of determining the particle characteristics after exposure to the series of pressure waves are summarized in **TABLE 2**. The parameters of the pressure wave types used on specific particles are summarized in **TABLE 3** below

5

TABLE 2

Particle No.	Drainage Pressure (cmH ₂ O)	Mean Pressure (cmH ₂ O)
1	1	4.5
1	8	
1	4	
1	0.5	
1	9	
2	0	3.8
2	2	
2	6	
2	7	
2	4	
3	10	4.2
3	2	
3	1	
3	8	
3	0	

Particle No.	Drainage Pressure (cmH ₂ O)	Mean Pressure (cmH ₂ O)
4	5	7.1
4	10	
4	11	
4	3	
4	6.5	
5	0	3.0
5	1	
5	7	
5	2	
5	5	
6	1	2.5
6	4	
6	2.5	
6	2	
6	3	

TABLE 3

Particle no.	Wave shape	Frequency range draining the tissue	Max Duration
1	Sine	10-230 Hz	3sec
2	Sawtooth (slow rise fast fall)	10-260Hz	5sec
3	Sawtooth (fast rise slow fall)	10-250Hz	2sec

4	Sine + Sawtooth (slow rise fast fall constant 1Hz)	20-230Hz	10sec
5	Sine+Sawtooth (fast rise slow fall constant 1Hz)	10-220 Hz	3sec
6	Square	50-150Hz	20sec

As may be seen from **TABLES 1-3** above, the resistance to pressure was reduced, moreover, the particles were observed to have different color and their three dimensional shape has changed following pressure application but these observed effects could not be quantified without the proper measurement tools.

While **EXPERIMENT 1** described above is an exploratory preliminary experiment, the following conclusions may be drawn:

The static pressure resistance of tissue fragments depends on to the fragments' position inside or at the cervical model inlet. Particles that are more round are more likely to have consistent pressure resistance characteristics. After the tissue particles were exposed to pressure oscillations above 100Hz, their measured resistance to static pressure was reduced at certain positions.

Pressure oscillations are shown to create "drainage pressure" conditions on the tissue fragments. As shown, pressure oscillations cause tissue fragments to flow through the cervix model. This may possibly be the result of the following effects on menses flow: (a) The effective viscosity of the suspension fluid is reduced due to the "streaming" effect applied by the fluid vibrations induced by the oscillatory pressure gradient across the cervix model. (b) The vibration of the fluid allows for resettling of the tissue debris in the cervical inlet, which may also facilitates the menses flow through the cervix model used.

In order to extend the present study of the effects of pressure oscillations on menses

flow, an additional *in-vivo* experiment was performed as disclosed hereinafter.

EXPERIMENT 2

In this experiment, the menses flow of a female volunteer was compared, with and without the application of pressure oscillations to the vagina.

- 5 In the first part of **EXPERIMENT 2**, a normal menstruation period of a 36 years old parous female volunteer, who experiences regular menstruations but does not normally experiences dysmenorrhea was followed by measuring the amount of menses fluid at time intervals of about six hours by using a commercial menstrual cup inserted into the vagina. The parameters determined during the normal menstrual period (the control period)
- 10 included, for each measurement, the total volume of menses collected in the single measurement (in ml) and the menses flow rate in ml/hour (computed from the collected menses volume divided by the collection period duration for each single measurement).

The results of the first part of the experiment (normal menses control) are summarized in **TABLE 4** below.

15 **TABLE 4**

Sample number	Date	Hr.	Time (hours)	Amount Of collected menses (ml)	Menses Flow Rate (ml/hr.)	Remarks
1	3.11.07	22:00		1		First day
2	4.11.07	8:00	10	0.5	0.05	Night
3	4.11.07	12:00	4	1	0.25	
4	4.11.07	18:00	6	0.5	0.083	
5	5.11.07	6:00	12	2	0.167	Night
6	5.11.07	12:00	6	1.5	0.25	
7	5.11.07	20:00	8	8	1	
8	6.11.07	7:00	11	11	1	Night
9	6.11.07	13:00	6	7.5	1.25	
10	6.11.07	18:00	5	5	1	
11	7.11.07	6:00	12	2.5	0.21	Night
12	7.11.07	12:00	6	1	0.167	
13	7.11.07	18:00	6	0.5	0.083	

In the second part of the in-vivo experiment, pressure oscillations were introduced into the vagina of the same volunteer at different times during menstruation, such that an oscillatory pressure gradient was induced on the cervix. The second part of the experiment was performed two menses cycles apart from the first part of the experiment. The first part of the experiment was conducted starting on November 3, 2007 and the second part of the experiment using pressure oscillations was conducted starting on December 28, 2007.

Reference is now made to Fig. 30 which is a schematic isometric view of an experimental system used for applying pressure oscillation *in-vivo* to a vagina of a menstruating female subject.

The experimental system 450 includes the same transducer 403, controller 412, funnel coupler 404 and vaginal applicator 406 as described in detail hereinabove for **EXPERIMENT 1**. The parts representing the uterus model 410 and cervical model 408 of **EXPERIMENT 1** were disconnected from the end 406A of the vaginal applicator 406. The open end 406A of the vaginal applicator 406 was inserted into the vaginal cavity of a 36 years old parous female volunteer, who experiences regular menstruations but does not normally experiences dysmenorrhea, and pressure oscillations were applied to the vaginal chamber formed between the end 406A of the vaginal applicator 406 the vaginal walls and the cervix of the volunteer.

Different sinusoidal pressure oscillations were applied at different times. The pressure oscillations were applied for time periods of 10 minutes or 15 minutes. The menses drained into the vagina and were collected through the use of a commercial menstrual cup. The amount of menses was then measured using a 1.0 ml measuring syringe.

TABLE 5 below summarizes the amount of menses measured at different times and the application of various oscillatory pressure waves as described above. The onset of menstruation was marked as time zero.

TABLE 5

DAY	Hr (hours)	Minute	Flow from previous entry (ml)	Pressure oscillations
28/12/07	0	0	1	0
29/12/07	6	10	0.1	40Hz
29/12/07	6	20	0.1	80Hz
29/12/07	6	40	0.1	100Hz
29/12/07	7	0	0	0
29/12/07	11	10	5	0
29/12/07	11	20	0	80Hz
29/12/07	12	30	0.5	0
29/12/07	12	45	0.2	0
29/12/07	15	43	1.80	0
29/12/07	15	53	0.1	80Hz
29/12/07	16	5	0.05	100Hz
29/12/07	16	18	0.05	40Hz
29/12/07	16	24	0	1Hz
29/12/07	16	32	0.01	60Hz
29/12/07	16	41	0.4	80Hz
29/12/07	17	0	0.01	0
29/12/07	17	15	0.02	0
29/12/07	17	35	0.25	0
29/12/07	18	0	0.4	0
29/12/07	18	15	0.3	0
29/12/07	18	30	0.25	0
29/12/07	18	48	0.3	80Hz
29/12/07	18	5	0.4	0
29/12/07	18	23	0.6	0
29/12/07	18	46	0.5	0
29/12/07	19	0	0.25	80Hz
29/12/07	19	7	0.25	80Hz
29/12/07	19	22	0.25	0
29/12/07	19	41	0.35	0
29/12/07	20	0	0.25	0
29/12/07	20	16	0.25	0
29/12/07	20	50	0.25	0
29/12/07	22	30	0.75	0
29/12/07	22	45	0.25	0

DAY	Hr (hours)	Minute	Flow from previous entry (ml)	Pressure oscillations
29/12/07	23	15	0.25	0
29/12/07	25	30	0.5	0
30/12/07	32	45	1.75	0
30/12/07	34	35	0.25	0
30/12/07	36	17	0.4	0
30/12/07	36	25	0.2	80Hz
30/12/07	36	40	0.5	80Hz
30/12/07	37	5	0.2	0
30/12/07	38	45	0.7	0
30/12/07	38	52	0.25	80Hz
30/12/07	39	4	0.35	80Hz
30/12/07	40	5	0.05	0
30/12/07	42	30	0.15	0
30/12/07	51	0	0.7	0
31/12/07	57	30	0.5	0
31/12/07	61	30	0.5	0
31/12/07	67	30	0.5	0

A comparison between the results summarized in **TABLE 4** and **TABLE 5** reveals a clear physiological effect to the application of the pressure oscillations of the present invention.

5 Reference is now made to Figs. 31 and 32. Fig. 31 is a schematic graph illustrating the results of the *in-vivo* experiment measuring the flow of menses in the presence of acoustic pressure oscillations applied to the vagina of a menstruating female. Fig. 32 is a schematic graph illustrating the results of an *in-vivo* experiment comparing the menses flow of the same menstruating female with and without application of acoustic pressure waves to
10 the vagina.

In Fig. 31, the horizontal axis represents time in hours, the left vertical axis represents the menses rate of flow in ml/hour and the right vertical axis represents the applied pressure oscillation frequency in Hz. The open rhombus symbols **3** represent individual menses flow rate data points, and the curve **5** represents a spline curve fit
15 computed for the data points **3** (represented by the open rhombus symbols) representing the

menses flow rate of **TABLE 5** and the multiple filled circles **2** in the graph each represent the time of application of vaginal pressure oscillations and the frequency of the applied pressure oscillations in Hz.

In Figs. 31-32, the dashed vertical line **8** represent the time of application of the last pressure oscillations (at forty hours from the beginning of menstruation) in the second part of the experiment, after which no more pressure oscillations were applied for the remaining time of the menstruation (but menses flow rate measurements were continued).

In Fig. 32, the horizontal axis represents time in hours and the vertical axis represents the menses rate of flow in ml/hour. The curve **4** represents a spline curve fit computed for the data points representing the menses flow rate of **TABLE 4**.

Normal menses flow is known to follow a typical "crescendo-decrescendo" behavior. see , for example, the article found in :

http://www.ultimatehealthguide.com/guide/womens_health/menstruation/articles_menstrual_cycle/), that is, the normal menses flow typically starts with a moderate flow rate, it then progressively increases, and then slowly tapers off. This exact behavior can be seen in the normal menstrual flow represented by curve **4** of Fig. 32. On the other hand, the menstrual flow measured in the second part of the experiment (in which pressure oscillations were applied to the vagina) represented by the curve **5** of Figs. 31-32 has a shape and time course notably different than those of curve **4**. Apparently, the peak (maximal) flow rates in the presence of pressure oscillations application are reached much earlier in the menstruation as compared to the normal menstruation, such that the bulk of the outflow under pressure oscillation application ends relatively early.

As may be clearly seen from comparing the curves **4** and **5**, the total amount of hrs with any menses flow is roughly similar (about seventy two hours for curve **5** and ninety hours for curve **4**). However, it is noted that no pressure oscillations were applied after forty hours in the second part of the experiment. Irrespectively, it is clear that the pressure oscillations are effective at quickly evacuating the uterus already in the early phase of the menstrual flow.

The clear evidence of the early evacuation of the uterine under pressure oscillation

application does not prove that dysmenorrheic pain will be reduced, it does however strongly suggest so, since it implies that the uterus is kept free of menses and the prostaglandins they contain which are believed to cause the cramps and uterine contraction which are experienced by dysmenorrheic women.

5 Although the small pressure oscillation generating devices disclosed hereinabove and the large subwoofer **402** used in the experiments appear to be remarkably different, based on calculations performed by the inventor, the energy available to the small pressure oscillation generating devices from a standard N-sized battery is sufficient to produce pressure oscillations in the inner vaginal cavity that are similar to those produced by the
10 large subwoofer used in the experimental system of Fig. 30, and for the necessary duration.

 If we assume that the efficiency of producing pressure oscillations by the small pressure oscillation generating devices and by the subwoofer **402** is similar, then the following scaling may be used. The volume enclosed externally to the speaker membrane is about 2.3 liter. On the other hand, we expect the volume of the vaginal cavity formed next to the
15 small pressure oscillation generating devices disclosed hereinabove to be about 20 ml. Thus, to get a similar pressure oscillation next to the cervix, the small pressure oscillation generating devices disclosed need about 0.01 (one hundredth) of the energy used by the sub-woofer **402**, or about 1.5 Watt. This implies that in order to get an effect similar to that of the subwoofer **402**, assuming the same efficiency, the smaller pressure oscillation
20 generating devices disclosed in the present application with a power rating of a typical 1500 mWhr N-sized battery can operate for about one hour.

 In reality, however, the efficiency of the small pressure oscillation generating devices disclosed herein can be notably higher (as sound fidelity is not an issue in such devices). Moreover, since we expect the device to work with a typical duty cycle of a few 10% (as
25 the subwoofer **402** was used), the small pressure oscillation generating devices disclosed in the present application will be able to operate for several hours until the battery (or other power source being used) runs out.

 Reference is now made to Fig. 33 which is schematic isometric view illustrating a system for shortening menstruation period duration having a reusable pressure oscillations

generating unit and disposable tampon-like absorbent sleeves configured to be detachably attached to the pressure oscillations generating unit, in accordance with an embodiment of the menstruation period shortening systems of the present application.

The system **380** includes a pressure oscillations generating device **350** which may be implemented as any of the devices **220**, **250**, **270** and **300** disclosed hereinabove or as any other small efficient device capable of delivering pressure oscillations of the required power to the vagina. The pressure oscillations generating device **350** may be electrically coupled through a suitable, electrically isolated power cord **352** to an external power source **358**, designed to be disposed outside the vagina during use of the system **380**. The power cord **352** may (optionally) have a connector **354** for connecting to a second connector **356** which is electrically connected to the power source **358**. The power source **358** may be a small power source attachable to the skin of the user in the region of the upper thigh or the pelvis of the user by a suitable adhesive patch **360** attached to the power source **358**. Alternatively, the power source **358** may be attached to a belt (not shown) or a garment (not shown) worn by the user, either by the adhesive patch **360** or by a similar patch of Velcro® or the like. The power source **358** may be controlled by a suitable switch **362** as illustrated. The power source may be any suitable electrical power source known in the art, such as but not limited to, a battery, an electrochemical cell, a primary electrochemical cell, a rechargeable electrochemical cell, a super-capacitor, a fuel cell and any combinations of any number of the above described power sources.

The system **380** also includes one or more absorbent members **651**. The specific (non-limiting) illustrated example of the absorbent member **651** is shaped as a tampon-like absorbent member which is sleeve-like. The sleeve-like absorbent member **651** has a hollow passage **654** passing therethrough. In use, the pressure oscillations generating device **350** is inserted into the passage **654** of the sleeve-like absorbent member **651** such that the end **350A** of the pressure oscillations generating device **350** which is configured to generate the pressure oscillations, is inserted in the direction shown by the arrowhead. After the sleeve-like absorbent member **651** is fitted onto the pressure oscillations generating device **350**, and the sleeve-like absorbent member **651** together with the pressure

oscillations generating device **350** attached thereto are inserted into the vagina and the pressure oscillations may be applied by switching on the switch **362**.

The menses will be absorbed by the sleeve-like absorbent member **651**. At any desired time during the use of the system **380**, the user may take the sleeve-like absorbent member **651** and the pressure oscillations generating device **350**, remove the used absorbent member and fit a fresh unused sleeve-like absorbent member **651** onto the pressure oscillations generating device **350**, for reinsertion into the vagina. The pressure oscillations generating device **350**, is configure to be completely impervious to liquids, such that it may be cleaned by washing after being removed from the vagina.

The present application also contemplates a kit which includes the pressure oscillations generating device **350** and several sleeve-like absorbent members **651** packed together. The kit may (optionally) also include the power source **358**.

In accordance with another embodiment of the systems of the present application, the power source **358** may be a large power source with replaceable batteries or electrochemical cell(s) and or rechargeable power source with rechargeable cell(s) which may be attached to a belt (not shown) worn by the user. The power source **358** may be a rechargeable power source which may be conveniently recharged by the user.

Reference is now made to Figs 34-36. Fig. 34 is a schematic perspective view illustrating a vaginal pressure oscillations generating unit including a menses collecting member, in accordance with another embodiment of the menstruation period duration shortening device of the present application. Fig. 35 is a perspective view of the vaginal pressure oscillations generating unit of Fig. 34 folded within an insertion device usable for introducing the vaginal pressure oscillations generating unit into a vagina. Fig. 36 is a schematic perspective view illustrating a vaginal pressure oscillations generating unit including a menses collecting member, in accordance with yet another embodiment of the menstruation period duration shortening device of the present application.

The vaginal pressure oscillations generating unit **430** of Fig 34 includes a cylindrical pressure oscillations generating unit **460** which may be any of the devices **220**, **250**, **270** and **300** disclosed hereinabove or any other small efficient device capable of delivering

pressure oscillations of the required power to the vagina as is disclosed hereinabove. The pressure oscillations generating unit **460** is attached at the closed end of a cup-like menses collecting member **465**. The menses collecting member **465** is similar in shape to commercial menses collecting cups, as is known in the art. The menses collecting member **465** includes a soft thin walled elastic cup-like portion **465B** and a thicker elastic ring-like portion **465A**. For example, the menses collecting member **465** may be made from latex or from any other suitable elastic biocompatible material, such as an elastic polymer, or the like. A suitable pulling cord **52** may be attached at the bottom end of the menses collecting member **465** as illustrated for assisting the pulling out of the device from the vagina.

The vaginal pressure oscillations generating unit **430** of Fig 34 may be inserted into the vagina by using a suitable insertion device **462**. The insertion device **456** may include two disposable cardboard or plastic tubes **464** and **466**. The plastic tube **466** has a smaller diameter and is movably or slidably attached within the larger tube **464**. The vaginal pressure oscillations generating unit **430** is disposed within the tube **464** with the menses collecting member **465** properly folded and the pulling cord **52** is inserted into the lumen of the tube **466**. The entire insertion assisting member **462** is inserted into the vagina and the vaginal pressure oscillations generating unit **430** is then pushed further into the vagina by holding the tube **464** and pushing the narrower tube **466** forward to push the vaginal pressure oscillations generating unit **430** outside the tube **464**. The menses collecting member **465** unfolds and is pushed to fit over the cervix. The tubes **464** and **466** may then be taken out of the vagina and discarded. The application of pressure oscillations to the vagina and/or cervix by the pressure oscillations generating unit **460**, may be done in any of the ways disclosed hereinabove and the menses collects in the menses collecting member **465**. The vaginal pressure oscillations generating unit **430** may be pulled out from the vagina by using the pulling cord **52**.

In accordance with another embodiment of the device including a menses collecting member, the position of the menses collecting member in relation to the pressure oscillations generating unit may be different.

Turning to Fig. 36, the vaginal pressure oscillations generating unit **470** includes the cylindrical pressure oscillations generating unit **460** of Fig. 34. The pressure oscillations generating unit **460** is attached to a cup-like menses collecting member **467**. The menses collecting member **467** is similar in shape to commercial menses collecting cups, as is known in the art but has an opening at its bottom end. The menses collecting member **467** is sealingly attached to the middle portion of the pressure oscillations generating unit **460** by suitable attachment method, such as but not limited to, gluing or sealing with a suitable biocompatible glue or sealant, as is illustrated in Fig. 36. This embodiment of the device **470** increases the distance from the active end of the pressure oscillations generating unit **460** and the *cervical external os*.

Reference is now made to Fig. 37 which is a schematic cross sectional view illustrating a vaginal pressure oscillations generating unit without an absorbing member disposed within a vagina, in accordance with still another embodiment of the menstruation period duration shortening device of the present application.

The device **580** includes a cylindrical pressure oscillations generating unit **550** which may be any of the devices **220**, **250**, **270** and **300** disclosed hereinabove (which are modified such that these devices do not include an internal power source) or any other small efficient device capable of delivering pressure oscillations of the required power to the vagina as is disclosed hereinabove. The device **580** of Fig. 37 is illustrated in a configuration having an external power source. The power source **556** is a small power source such as, but not limited to, any of the compact small power sources disclosed hereinabove, any small battery or electrochemical cell may be used as the power source **556**, but other power sources disclosed hereinabove may also be used. The power source **556** is electrically connected to the pressure oscillations generating unit **550** by a suitable electrically isolated power cord **552**. The power source **556** may be attached to the body of the user by an adhesive patch **558** (for example, the adhesive patch **558** may be attached to the upper thigh or the pelvis region of the user). Alternatively, the power source **556** may be attached to a garment (not shown) or to a belt (not shown) worn by the user. The, pressure oscillations generating unit **550** may be inserted into the vagina **101** of a user as

disclosed hereinabove and the pressure oscillations may be activated remotely using any of the remotely actuatable switches (not shown) which may (optionally) be included in the pressure oscillations generating unit **550**.

5 In accordance with another embodiment of the device **580** described hereinabove, the pressure oscillations generating unit **550** may be configured as a device having an internal power source, such as any of the devices **220**, **250**, **270** and **300** disclosed hereinabove. In the latter case, the power source **556**, the power cord **552** and the patch become redundant and are not included. However, in such a case, the device may include a pulling cord (not shown in Fig. 37) attached at it's rear end (instead of the power cord **552**) which may be
10 similar to the pulling cord **52** illustrated in Fig. 17 and which used to facilitate the removal of the pressure oscillations generating unit **550** from the vagina **101**.

It is noted that the pressure oscillations generating unit **550** of the device **580** may be operated within the vagina **101** without any absorbent member or tampon-like absorbing pad. For example, the user of the device **580** may use any type of commercially available
15 external absorbing pads or other hygienic absorbing members placed outside of the user's vagina to absorb menses. Moreover, it is noted that the use of any absorbent member (whether an sleeve-like, tampon-like, or any other type of extra-vaginal or intra-vaginal absorbent member) is not necessary or obligatory to the successful and efficient operation of the devices and systems disclosed herein and that such devices may be operated
20 effectively without the use of any absorbent member whatsoever.

It is noted that the design and implementations of the various different embodiments pressure oscillations generating units disclosed hereinabove which are designed for producing pressure oscillations within a vaginal cavity arise from theoretical considerations following a detailed mathematical analysis of the physical mechanisms of operation of such
25 devices showing that for typically available energies (as may be supplied by currently available compact batteries or other compact power sources), the pressure gradient oscillation generated by the pressure oscillations generating units described herein is sufficient to trigger the physical effects which increase the rate of menses flow through the cervix, while for other devices such as regular vibrators which rely only on waves

propagating in the vaginal tissues, the energy delivered would be insufficient for obtaining a significant increase in the rate of menses flow through the cervix by an order of magnitude. The theoretical analysis is attached hereinafter as **APPENDIX A**.

It is noted that the devices systems, and methods disclosed herein are not limited to the specific menses duration shortening application described. The devices, systems and methods disclosed in the present application are based on a concept of applying pressure oscillations to non-Newtonian fluids, and pertain to the various medical and therapeutic effects that can be achieved through the application of shear and vibrational thinning to induce streaming on various cavities and lumens of the human body.

The sinuses and their thin long connecting tubes, the intestine, the bladder, the arteries, the veins and the uterus, are all examples of cavities and lumens of the human body that may be affected in various ways by the use of the devices and the methods disclosed herein. The common effect of applying cyclic energy, according to the present invention, to these cavities and lumens, is to eliminate or to evacuate from them naturally occurring or dysfunctionally created obstructions or limiting particles that intervene with the natural flow of bodily substances in that cavities or lumen.

For example, constipation is a well known dysfunction which is treated with a wide variety of medications. The devices systems and methods disclosed hereinabove, may also be adapted with suitable modifications to obtain painless, non-medication related, invasive and easy evacuation of the intestine. This is achieved by creating the vibrational thinning effect.

Similarly, the pressure oscillations generating devices disclosed herein may be used for increasing the rate of removal of any non-Newtonian fluid or secretion from within a body passage which is naturally or pathologically congested with such secretions by using the same devices, principles and methods based on the physical phenomena disclosed hereinabove with respect to the particular non-limiting example with respect to menses in menstruating females. Such body passages may include, but are not limited to, congested nostrils and/or nasal cavities, congested parts of the gastrointestinal tract, constipated colon, any congested parts of the urinary tract of males and females, various parts of the

respiratory canal such as but not limited to lungs, larynx bronchi, trachea, passages within the auditory system, such as but not limited to the external acoustic meatus, the pharyngo-tympanic (auditory) tube, or other passages within the ear and other congested body passages and cavities.

5 It is noted that in principle, it is expected that the shortening of the duration of contact between the menses with the walls of the uterus resulting from the faster removal of menses from within the uterus may also result in reducing the pain, and/or cramps associated with dysmenorrhea in users who do suffer from dysmenorrhea.

10 Although the invention has been described in conjunction with specific embodiments thereof, it would be clear that many alternatives, modifications, permutations and variations of the devices, methods, systems and kits described herein will be apparent to those skilled in the art. Accordingly, it is intended to embrace all such alternatives, modifications, permutations and variations that fall within the spirit and broad scope of the appended claims.

APPENDIX A: ANALYSIS OF THE PHYSICAL MECHANISM OF THE PERIOD SHORTENING DEVICE

1 Goal

5 The aim of this appendix is to analyze the physical mechanism of the device of the present application. In particular, we wish to show that the main effect is achieved by means of an oscillating pressure gradient across the cervix and that under realistic conditions a standard sized battery can supply the necessary energy. On the other hand, vibrating the cervix through waves propagating from vibrating vaginal tissue is negligible when compared with the effects
10 of a variable pressure gradient, and by itself, would have been insufficient to facilitate the flow of menses through the cervix. In other words, the proposed idea of generating pressure oscillations in the device is the sole reason for its efficacy.

2 Background

Before concentrating on the details of the physics behind the device, we begin with a short
15 summary of how the device works.

The device and its setting are described in Fig. 38. The device, denoted by **600** in the figure, is inserted into the vagina. It is held in place by the vaginal tissue, denoted by **101** in the figure (in the same way the tissue holds a menstrual cup or a tampon). This forms an artificial cavity, denoted as **40** in the figure, between the device, the vaginal tissue and
20 the cervix, which is marked as **102**. When the device operates, an oscillating membrane periodically pushes air (or fluid) into and out of the device, as denoted by the double arrow **20**. Because of the finite elasticity of the vaginal tissue, the cavity has a finite compliance implying that the changing amount of air/fluid in the cavity will change the pressure inside of it. The oscillating pressure in the cavity also implies that there is an oscillatory pressure
25 gradient across the cervix, between the uterus, marked **103** and the artificial cavity **40**, as

exemplified by the double arrow **14** in the figure. This will accelerate the menses within the cervix, which are denoted as **18** in the figure. The finite elasticity of the vaginal tissue also implies that the walls oscillate in response to the oscillating pressure. (If the walls would have been totally rigid, then the cavity's pressure would have changed without inducing any wall movement). This generates elastic waves in the vaginal tissue. These waves can propagate through the tissue and reach the cervix. This will cause an oscillatory motion, as exemplified by the double arrow **16** in the figure. This oscillation will too accelerate the menses within the cervix. As shown below, the effects of the latter oscillations is negligible when compared to the direct pressure oscillations across the cervix.

3 The forces on menses within the cervix

From Fig. 38 it is apparent that two forces can operate on the menses.

The first force is due to the pressure gradient ∇p across the cervix. This force *per unit volume* is given by

$$F_{pres} = \nabla p = \frac{\Delta p}{\ell}, \quad (1)$$

where $\ell \sim 4$ cm is the typical length of the cervix, and Δp the total pressure drop across it.

The second force is the fictitious d'Alembert force. That is, we are interested in the motion of the menses relative to the cervix. However, because the cervix is vibrating, its frame-of-reference is constantly accelerating. In this frame, the menses will experience the following effective force (per unit volume):

$$F_{cervix} = -\ddot{x}_c \rho. \quad (2)$$

Here $\rho \approx 1$ gr/cm³ is the density of the menses. x_c is the displacement of the cervix *along the direction of its main axis* such that $\ddot{x}_c$ is its acceleration. Since we assume for simplicity harmonic oscillations, we have $x_c = a_c \cos \omega t$ with a_c being the amplitude. For the harmonic oscillations we also have that $\ddot{x}_c = -\omega^2 x_c$.

To *estimate* the amplitude at the cervix a_c , we can use conservation of energy. If we assume an isotropic distribution, then the energy per unit area at some distance from the source should fall as the area, or distance squared. Since the energy of the harmonic waves is proportional to the amplitude squared, the amplitude of the waves should fall as the distance

from the source. More specifically, we can estimate the ratio between the cervical amplitude and the amplitude at the outer edge of the vaginal cavity, a_v , as:

$$a_c \sim a_v \sqrt{\frac{2\pi R s}{4\pi L^2}}, \quad (3)$$

where $L \sim 5$ cm, is the typical distance between the edges of the cavity and the cervix. The cavity is assumed to be a cylinder of $R \sim 1.5$ cm and length $s \sim 2$ cm. Note that this estimate of a_c is actually an overestimate for two reasons. First, only oscillations of the cervix along its axis are relevant for the facilitation of the flow, thus, we should consider only the oscillatory component in that direction. The second reason is the “impedance mismatching” of the elastic waves going from the vaginal tissue to the harder cervical tissue. That is, the oscillation of the cervix should be somewhat smaller than the oscillation of the vaginal tissue.

To estimate the the amplitude a_v of the vaginal wall displacement: $x_v = a_v \cos \omega t$, we have to model the oscillations of the vaginal walls. To do so, we compare the system to an harmonic oscillator. The mass participating in the oscillations is roughly the tissue mass that would have been in the cylinder forming the cavity, i.e., $M \sim \pi \rho R^2 s$. Note that we assume all tissue to have $\rho \approx 1$ gr/cm³.

Next, if we compress the tissue radially by x_v , then the cost of elastic energy is of order $U_{elastic} \sim V E (x_v/R)^2/2$, where $E \sim 100 - 300$ kPa is the expected elastic modulus for the combined stretching and compressing of the fibromuscular vaginal tissue, and V is the volume participating in the tissue distortion, which is roughly $V \sim \pi R^2 s$. Thus, the elastic force is of order $F_{elastic} = -dU_{elastic}/dx_v \sim -\pi E a_v s$.

We also have to include, however, the force from the pressure within the cavity, which is $F_{cavity} = A \Delta p \sim 2\pi R s \Delta p$ (with A being the cavity’s area). Therefore, if we neglect for a moment the dissipation, then the equation of motion of the mass will be:

$$M \ddot{x}_v = F_{elastic} + F_{cavity} \Rightarrow \pi R^2 s \ddot{x}_v \rho \approx -\pi E s x_v + 2\pi R s \Delta p. \quad (4)$$

If we consider that $x_v = a_v \cos \omega t$, such that $\ddot{x}_v = -\omega^2 x_v$, we obtain

$$a_v \approx \frac{2R \Delta p}{E + \rho R^2 \omega^2}. \quad (5)$$

Note that formally for the undamped oscillator, the sign in the denominator should have been a “−”. This would have meant that at a critical frequency there would be a resonance for the

tissue motion. This would have been an unrealistic artifact of the simple model. In reality, the tissue has a large damping coefficient such that the energy in the oscillation is typically lost over one cycle, from both a hysteresis effect and the generation of elastic waves (see §4 below). Thus, to get a realistic behavior for the amplitude we write a “+” instead.

- 5 Consequently, we can now relate the amplitude of the force due to the pressure gradient to the amplitude of the force due to the vibrations of the cervix, we find:

$$\frac{F_{cervix}}{F_{pres}} \approx \frac{\rho a_c \omega^2}{\Delta p / \ell} \approx \sqrt{\frac{2Rs}{L^2}} \frac{\rho R \ell \omega^2}{\omega^2 \rho R^2 + E}. \quad (6)$$

We see that there are two limits, which cross over at $\omega_{cross} \sim \sqrt{E/\rho R^2}$. For our nominal values $\omega_{cross} \sim 1 \text{ ksec}^{-1}$, or a frequency $f_{cross} \sim 150 \text{ Hz}$.

For low frequencies, we find:

$$\frac{F_{cervix}}{F_{pres}} \approx \sqrt{\frac{2s\ell^2}{L^2 R}} \frac{\rho R^2 \omega^2}{E}. \quad (7)$$

- 10 Since the term under the root sign is of order unity, we have in this limit that:

$$\frac{F_{cervix}}{F_{pres}} \sim \left(\frac{f}{f_{cross}} \right)^2 \sim 0.1 \text{ for } f \sim 50 \text{ Hz}. \quad (8)$$

In the opposite limit we have:

$$\frac{F_{cervix}}{F_{pres}} \sim \sqrt{\frac{2\ell^2 s}{L^2 R}} \sim 1. \quad (9)$$

Namely, for high frequencies, the two contributions to the force are comparable. However, this happens for frequencies where both contributions cannot induce any significant effect in any case (as elaborated in §5 below).

15 4 Amplitudes for a given supplied power

To obtain the oscillation amplitude, we have to consider that the device generates pressure oscillations within the cavity with some given power P_{tot} . This will itself be the device's power multiplied by the efficiency of the device ϵ . From battery constraints, while considering a conservative 10% efficiency, we can typically expect $P_{tot} = 0.1 \text{ Watt}$.

The power going into the pressure oscillations will transfer energy to the tissue and then get dissipated there. There are two primary dissipation methods, one is through elastic waves and the second is through local dissipation (caused by the hysteresis behavior of the tissue).

5 The first term is:

$$P_{hyster} = \frac{\alpha U_{elastic}}{T} \approx \frac{\alpha}{4} \omega E s a_v^2 \quad (10)$$

where $U_{elastic}$ is the elastic energy associated with the oscillation, T is the period of oscillation while $\alpha \sim 0.5$ is the fraction of energy lost per cycle.

The second term is:

$$P_{wave} \approx \rho A a_v^2 \omega^2 v_e \approx 2\pi \rho^{1/2} R s \omega^2 E^{1/2} a_v^2. \quad (11)$$

10 Here $v_e \sim \sqrt{E/\rho}$ is the speed of elastic waves, and A is the surface area where the waves are generated.

At about 30 Hz, the two contributions are comparable.

In our system, the power generated by the device becomes the pressure oscillations, which in turn transfer the energy to oscillations of the tissue which is then lost as either waves or in the hysteresis of the tissue. Namely, $P_{tot} = \epsilon P_{device} = P_{wave} + P_{hyster}$.

15 This implies that the amplitude of oscillations of the vaginal walls is

$$a_v \approx \sqrt{\frac{P_{tot}}{2\pi \rho^{1/2} R s \omega^2 E^{1/2} + \alpha \omega E s / 4}}. \quad (12)$$

This allows us to calculate a_c and $\Delta p/\ell$.

For convenience, we can define an amplitude which is the amplitude that the cervix should equivalently have for it to induce the same force as the pressure gradient, that is,

$$a_p \equiv \frac{\Delta p/\ell}{\rho \omega^2}, \quad (13)$$

such that $F_{cervix}/F_{pres} = a_c/a_p$.

20 Using this notation we have:

$$a_p = \frac{F_{pres}}{\rho \omega^2} \approx \frac{\rho \omega^2 R^2 + E}{\ell \rho \omega^2} \sqrt{\frac{P_{tot}}{2\pi \rho^{1/2} R s \omega^2 E^{1/2} + \alpha \omega E s / 4}} \quad (14)$$

and also

$$a_c \approx \sqrt{\frac{Rs}{2L^2}} \sqrt{\frac{P_{tot}}{2\pi\rho^{1/2}Rs\omega^2 E^{1/2} + \alpha\omega Es/4}} \quad (15)$$

5 Threshold amplitudes

Is the amplitude of oscillation sufficient to trigger an effect which will facilitate the flow of menses through the cervix? To answer this question we have to calculate the threshold amplitudes required for the different effects. Here we summarize the threshold amplitudes in terms of the necessary amplitude of oscillation of the cervix or the equivalent amplitude for the pressure oscillations. These results are based on the work of Uriev [1] which is based on both theoretical and experimental analyses.

Following Uriev, it is evident that the viscosity can be reduced as a response to two related effects. One is through the development of shear in the flow and can occur without vibrations, the second is due to vibrations and which can occur without any shear. Either effects can independently reduce the effective viscosity. There is also a threshold amplitude above which the acceleration exceeds that of gravity and allows for the resettling and “unclogging” of the inner cervical os from tissue debris.

Shear reduction of the viscosity - a_γ : Given the results of Uriev [1], a large enough amplitude of oscillation will give rise to a shear (a gradient in the velocity field that is perpendicular to the velocity itself) which will be able to reduce the viscosity of the menses within the cervix. However, because the velocity depends on the flow, we have to consider that there are two types of flow behavior. For low frequencies, the force accelerates the fluid until it reaches a velocity limited by the viscosity. At high frequencies, this limiting velocity cannot be reached because the inertia of the fluid limits it. The two behaviors are encapsulated with the approximate threshold amplitude:

$$a_\gamma \approx \frac{2\dot{\gamma}_c\eta_0}{\rho r\omega^2} \left(1 + \frac{r^2\rho\omega}{\eta_0} \right) \quad (16)$$

where r is the cervical radius, η_0 is the effective viscosity of the fluid, which we measured to be ~ 5 poise, and $\dot{\gamma}_c$ is the threshold shear to get an effect:

$$\dot{\gamma}_c \approx \frac{\eta_f}{\rho d^2} \quad (17)$$

Here $\eta_f \sim 0.1$ poise is the viscosity of the fluid without the debris (i.e., similar to blood). $d \sim 0.1$ cm is the typical smallest debris size.

Vibrational reduction of the viscosity - a_ω, a_d, a_σ : Viscosity reduction can also take place through vibrations. Basically, in the frame of reference of the oscillating fluid, debris particles experience a periodic force. If they can vibrate to distances larger than their typical size, then the fluid viscosity is reduced, as it will allow the debris to self-organize in response to the flow. This has two constraints which capture the two limits whether the debris inertia is important or not. Irrespectively, there is a third constraint that the surface tension will not force the particles to stick together. Thus, for this effect to take place, the vibrational amplitude has to be larger than the following three amplitudes:

$$a_\omega \approx \frac{\eta_f}{\rho d \omega}, \quad a_d \approx d, \quad a_\sigma \approx \frac{f_\sigma \sigma}{\rho d^2 \omega^2} \quad (18)$$

where f_σ is the fraction of the particles's surface area which is actually in contact with other particles. σ is the surface tension.

Gravitational resettling amplitude - a_g : If the acceleration associated with the vibrations is larger than g , then gravitational resettling can occur and "unclog" debris residing in the inner cervical os. This requires that $a_r > a_\sigma$ defined above and also:

$$a_g \approx g/\omega^2. \quad (19)$$

5.1 Amplitude comparison

The different excitation and threshold amplitudes are plotted in Fig. 39 as a function of the applied pressure oscillation frequency, for nominal parameters defined in §3-5 while assuming that the energy going into the pressure oscillations is 0.1 Watt. The amplitudes are a_p , the effective amplitude that the cervix oscillations should equivalently have to give rise to the same acceleration of the menses as the pressure gradient across the cervix, and a_c , which is the actual amplitude of the cervical oscillations from the elastic waves. The other amplitudes are the threshold amplitudes needed to satisfy different criteria. a_γ is the amplitude above which the shear in the flow is sufficient to reduce the effective viscosity. $\max(a_d, a_\omega, a_\sigma)$ is the threshold amplitude above which vibrations can reduce the effective viscosity. It is composed of several thresholds, all of which should be surpassed for the effect to take place.

Last a_g is the amplitude above which the acceleration surpasses g and allows for gravitational resettling. For the nominal parameters, there is an effect only from the oscillatory Δp , up to about 80 Hz. On the other hand, there is no reasonable range of values for which a_c rises above any threshold amplitude unless the input power is about an order of magnitude higher.

5 If we conservatively assume a 10% efficiency, this power implies that a 1000 mWhr battery (or other compact energy source) can operate the device continuously for 1hr, or several hours assuming a finite duty cycle.

6 Summary

- 10 • The device device generates pressure oscillations in the cavity between the device and the cervix and also generates waves in the vaginal tissue as a secondary effect.
- For frequencies below of order 150 Hz, the primary effect of vibrating the menses within the cervix is through the variable pressure drop across the cervix. At 50 Hz, for example it is at least 10 times larger than the effect of elastic waves propagating through the vaginal tissue.
- 15 • An analysis has shown that for the typically available energies, the pressure gradient oscillation is sufficient to trigger the effects modifying the menses flow through the cervix. On the other hand, if the device was to rely only on the waves propagating in the tissue, the energy would have been insufficient by an order of magnitude.
- 20 • Modification of the menses rheology takes place below 50 - 100 Hz (depending on the actual parameters). At very low frequencies, the amplitudes become too large (they would be noticeable by the patient, and also induce nonlinear effects which were hitherto neglected). Thus, the optimal frequencies from this analysis appear to be around 30 - 50 Hz.

References

- 25 [1] N.B. Uriev. Physicochemical dynamics of disperse systems. *Russian Chemical Reviews*, 73:37–58, 2004.

CLAIMS

1. A device for shortening menstruation duration, the device comprising:
a pressure oscillations generating unit configured to be inserted into a vagina for applying pressure oscillations to a vaginal chamber defined by part of said device, the walls
5 of the vagina and the cervix of the uterus.
2. The device according to claim 1 wherein said device also comprises an absorbent member attached to said pressure oscillations generating unit for absorbing menstrual secretions.
3. The device according to claim 2 wherein said absorbent member is a sleeve like
10 absorbent member attached to said pressure oscillations generating unit wherein said device is disposable.
4. The device according to claim 2 wherein said absorbent member is a sleeve like absorbent member detachably attachable to said pressure oscillations generating unit wherein said pressure oscillations generating unit is a reusable unit and said absorbent
15 member is a disposable absorbent member.
5. The device according to claim 1 wherein said device comprises a power source for energizing said pressure oscillations generator unit, said power source is selected from an internal power source disposed within said device and an external power source disposed outside said device and coupled to said pressure oscillations generator unit.
- 20 6. The device according to claim 2 wherein said power source is an electrical power source.
7. The device according to claim 6 wherein said power source is selected from the group consisting of, a battery, an electrochemical cell, a primary electrochemical cell, a rechargeable electrochemical cell, a super-capacitor, a fuel cell, and any combinations
25 thereof.
8. The device according to claim 1 wherein said pressure oscillations comprise pressure oscillations having a frequency in the range of 0.1Hz-10kHz, more preferably in the range of 1Hz- 100Hz, and most preferably in the range of 30Hz - 60 Hz.

9. The device according to claim 1 wherein said pressure oscillations generating unit is configured to deliver pressure oscillations having an energy in the range of 0.01-1.0 Watt delivered to said vaginal chamber.

10. The device according to claim 1 wherein said pressure oscillations are selected from the group consisting of pressure waves, acoustic waves, periodic acoustic waves, sinusoidal acoustic waves, acoustic shock waves, pulsatile acoustic waves and any combinations thereof.

11. The device according to claim 1 wherein said pressure oscillations are applied to said vaginal chamber intermittently with a duty cycle in the range of 1%-99%.

10 12. The device according to claim 1 wherein said pressure oscillations generating unit comprises at least one movable member coupled to said chamber when said device is disposed in said vagina, said movable member is configured for delivering said pressure oscillations to said chamber.

15 13. The device according to claim 12 wherein said at least one movable member comprises a single movable membrane wholly or partially comprised of an electrically conducting material and wherein said membrane is disposed adjacent to an electrically conducting coil included in said pressure oscillations generating unit, said at least one movable membrane is configured to oscillate upon application of a periodically varying current to said coil.

20 14. The device according to claim 12 wherein said at least one movable member comprises a movable membrane sealingly attached to a rigid housing of said pressure oscillations generating unit and coupled to a linear motor attached to said housing.

25 15. The device according to claim 12 wherein said at least one movable member comprises two movable membranes sealingly attached to a rigid housing, each membrane has a flat electrically conducting coil attached thereto, and wherein a permanent magnet attached to said rigid housing adjacent to each membrane of said two membranes.

16. The device according to claim 12 wherein said at least one movable member comprises two movable membranes sealingly attached to a rigid housing, each membrane has a flat electrically conducting coil attached thereto and wherein said rigid housing also

includes two permanent magnets attached to said rigid housing, each permanent magnet is disposed adjacent to a different movable membrane of said two movable membranes.

17. The device according to claim 12 wherein said at least one movable membrane comprises two elastic movable membranes sealingly attached to a rigid housing, each
5 membrane has a flat permanent magnet attached thereto, said device also comprises two electrically conducting coils, a first coil is rigidly attached to said rigid housing adjacent to the permanent magnet of a first membrane and the second coil is rigidly attached to said rigid housing adjacent to the permanent magnet of a second membrane.

18. A method for shortening the duration of the menstruation period of a female subject,
10 the method comprises applying pressure oscillations to a volume of fluid enclosed within the vagina of said female subject, for increasing the rate of flow of menstrual secretions out of said uterus to shorten the duration of said menstruation period.

19. The method according to claim 18 wherein said volume of fluid is contained in a vaginal chamber defined between part of a pressure oscillations generating unit disposed
15 within said vagina, part of the walls of said vagina and the cervix of said female subject.

20. The method according to claim 19 wherein said pressure oscillations generating unit is configured to deliver pressure oscillations having an energy in the range of 0.01-1.0 Watt delivered to said volume of fluid.

21. The method according to claim 18 wherein said volume of fluid comprises fluids
20 selected from the group consisting of air, menstrual fluid and a combination of air and menstrual fluid.

22. The method according to claim 18 wherein said pressure oscillations comprise pressure oscillations having a frequency in the range of 0.1Hz-10kHz, more preferably in the range of 1Hz- 100Hz, and most preferably in the range of 30Hz - 60 Hz.

23. The method according to claim 18 wherein said pressure oscillations are selected
25 from the group consisting of pressure waves, periodic acoustic waves, sinusoidal acoustic waves, acoustic shock waves, pulsatile acoustic waves and any combinations thereof.

24. The method according to claim 18 wherein said pressure oscillations are applied to said volume of fluid intermittently with a duty cycle in the range of 1%-99%.

25. A method for shortening menses duration, the method comprising the steps of:
introducing into a vagina a device comprising a pressure oscillations generating unit
for applying pressure oscillations to a vaginal chamber defined by part of said device, the
walls of the vagina and the cervix of the uterus; and

5 activating said device to generate pressure oscillations within said vaginal chamber
for increasing the rate of flow of menstrual secretions out of said uterus.

26. The method according to claim 25 wherein said step of activating comprises
providing power to said pressure oscillations generating unit from a power source selected
from,

10 an internal power source internally disposed within said device; and

an external power source disposed outside said vagina and connected to said
pressure oscillations generating unit.

27. The method according to claim 25 wherein said step of activating comprises
activating said pressure oscillations generating unit by remotely actuating an actuatable
15 switching unit included in said device to provide power from said power source to said
pressure oscillations generating unit.

28. The method according to claim 25 further including the step of absorbing menses
fluids flowing into said vagina by an absorbent member attached to said pressure
oscillations generating unit.

20 29. The method according to claim 25 wherein said pressure oscillations comprise
pressure oscillations having a frequency in the range of 0.1Hz-10kHz, more preferably in
the range of 1Hz- 100Hz, and most preferably in the range of 30Hz - 60 Hz.

30. The method according to claim 25 wherein said pressure oscillations generating unit
is configured to deliver pressure oscillations having an energy in the range of 0.01-1.0 Watt
25 delivered to said vaginal chamber.

31. The method according to claim 25 wherein said pressure oscillations are selected
from the group consisting of pressure waves, periodic acoustic waves, sinusoidal acoustic
waves, acoustic shock waves, pulsatile acoustic waves and any combinations thereof.

32. The method according to claim 25 wherein said pressure oscillations are applied to said vaginal chamber intermittently with a duty cycle in the range of 1%-99%.

33. A device for shortening menses duration, the device comprising:

one or more vibration generating units configured to be mechanically coupled to the skin of a body of a menstruating female subject for directing mechanical vibrations to the region of the uterine cervix of said subject for changing the flow properties of the menses within the uterus of said subject to increase the flow of said menses through the cervix and to shorten the duration of the menstruation period of said female subject; and

a power source for controllably energizing said one or more vibration generating units.

34. The device according to claim 33 wherein said one or more vibration generating units is selected from, one or more piezoelectric transducers, one or more electromechanical transducers, one or more mechanical transducers, and any combinations thereof.

35. The device according to claim 33 wherein said one or more vibration generating units is configured for generating in the tissues of said female subject vibrations selected from pressure waves, shear waves and a combination of pressure waves and shear waves.

36. The device according to claim 33 wherein said one or more vibration generating units are attached to a coupling member selected from the group consisting of a belt-like member, an elastic belt-like member, an adhesive member and any combinations thereof.

37. A kit for shortening the duration of menstruation period, the kit comprising

a pressure oscillations generating unit configured to be inserted into a vagina for applying pressure oscillations to a vaginal chamber defined by part of said device, the walls of the vagina and the cervix of the uterus; and

one or more absorbent members detachably attachable to said pressure oscillations generating unit for absorbing menses.

38. The kit according to claim 37 wherein said one or more absorbent members comprise one or more sleeve like absorbent member each absorbent member has a hollow passage formed therein for inserting said pressure oscillations generating unit.

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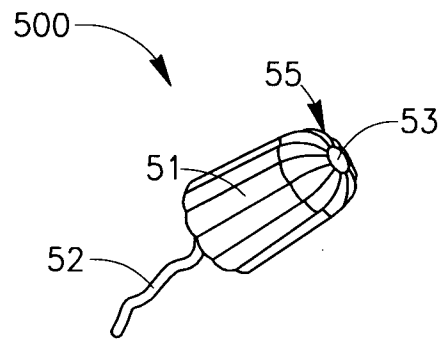


FIG. 1

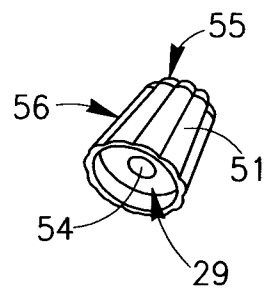


FIG. 2

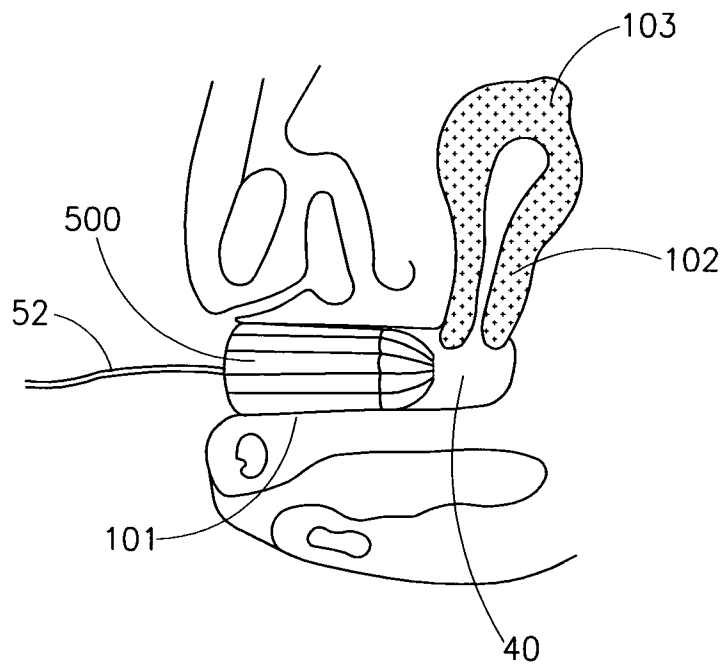
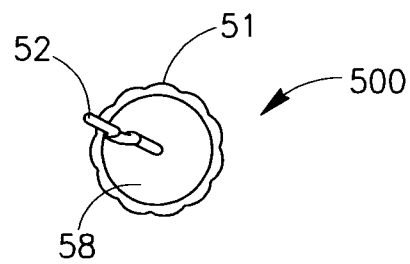
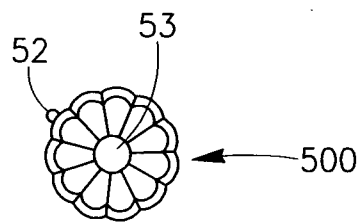
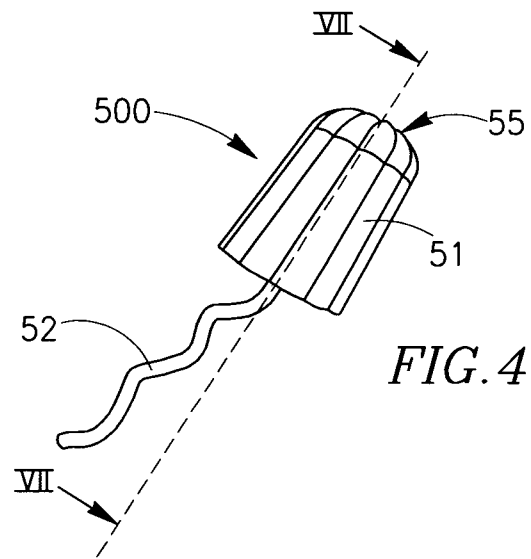


FIG. 3

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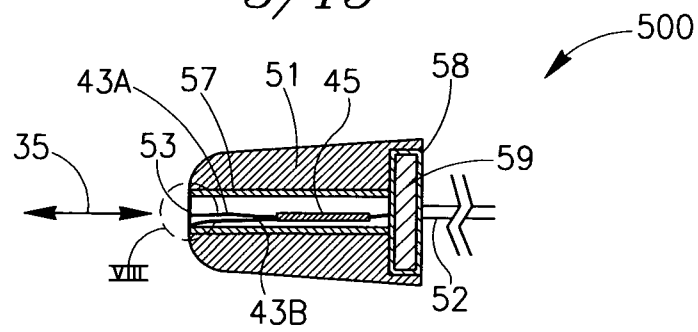


FIG. 7

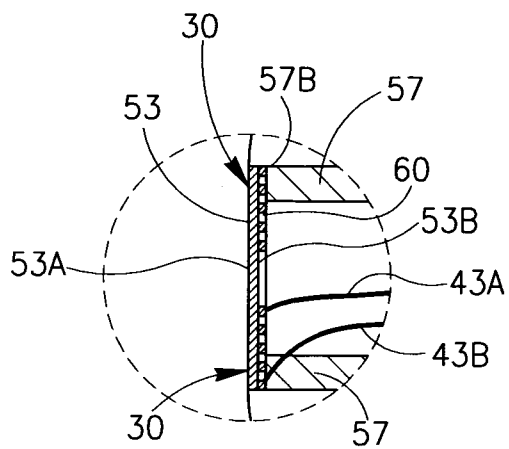


FIG. 8

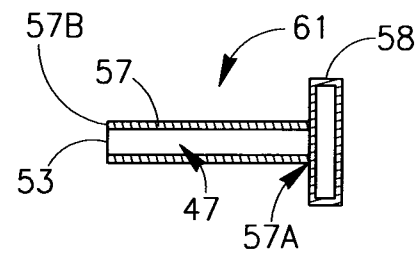


FIG. 9

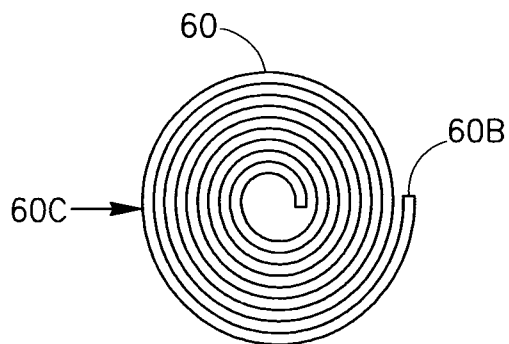


FIG. 10

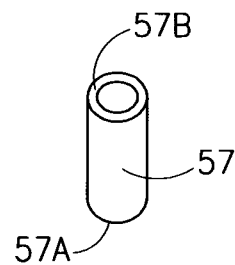


FIG.11

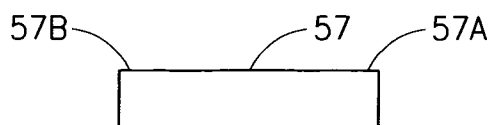


FIG.12

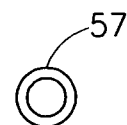


FIG.13

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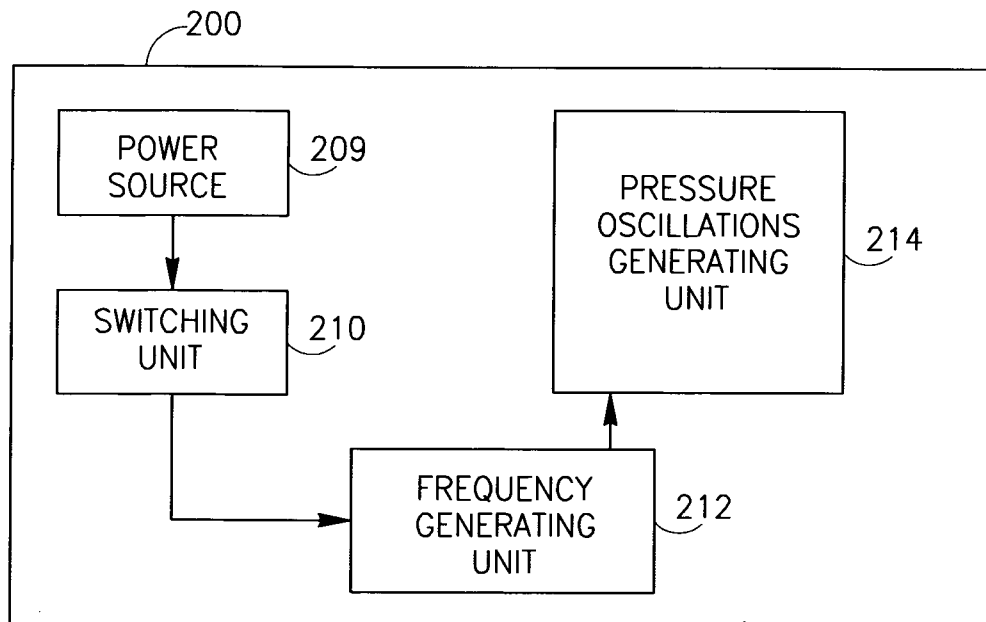


FIG. 14

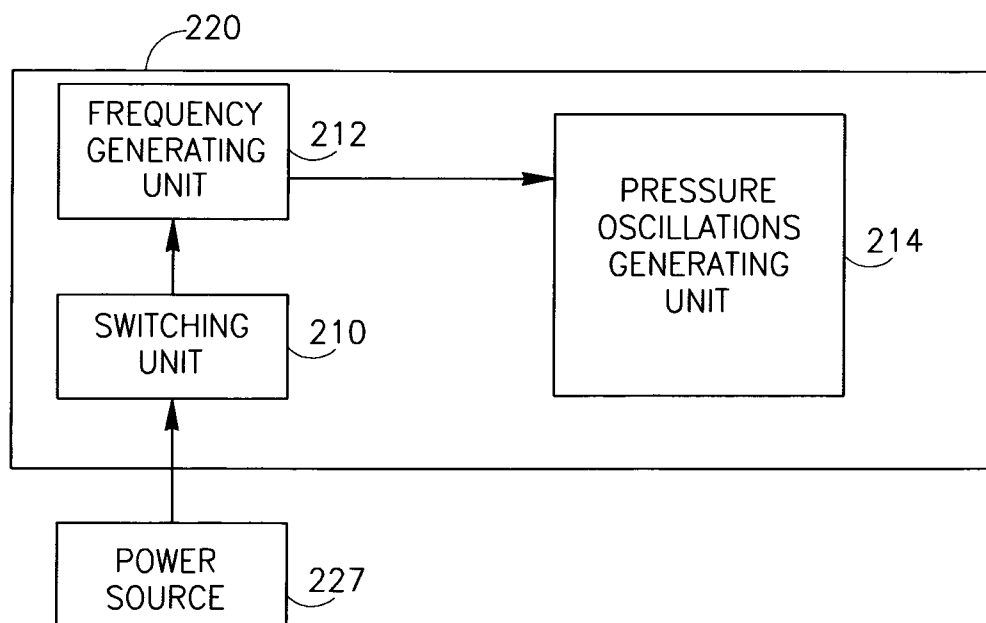


FIG. 15

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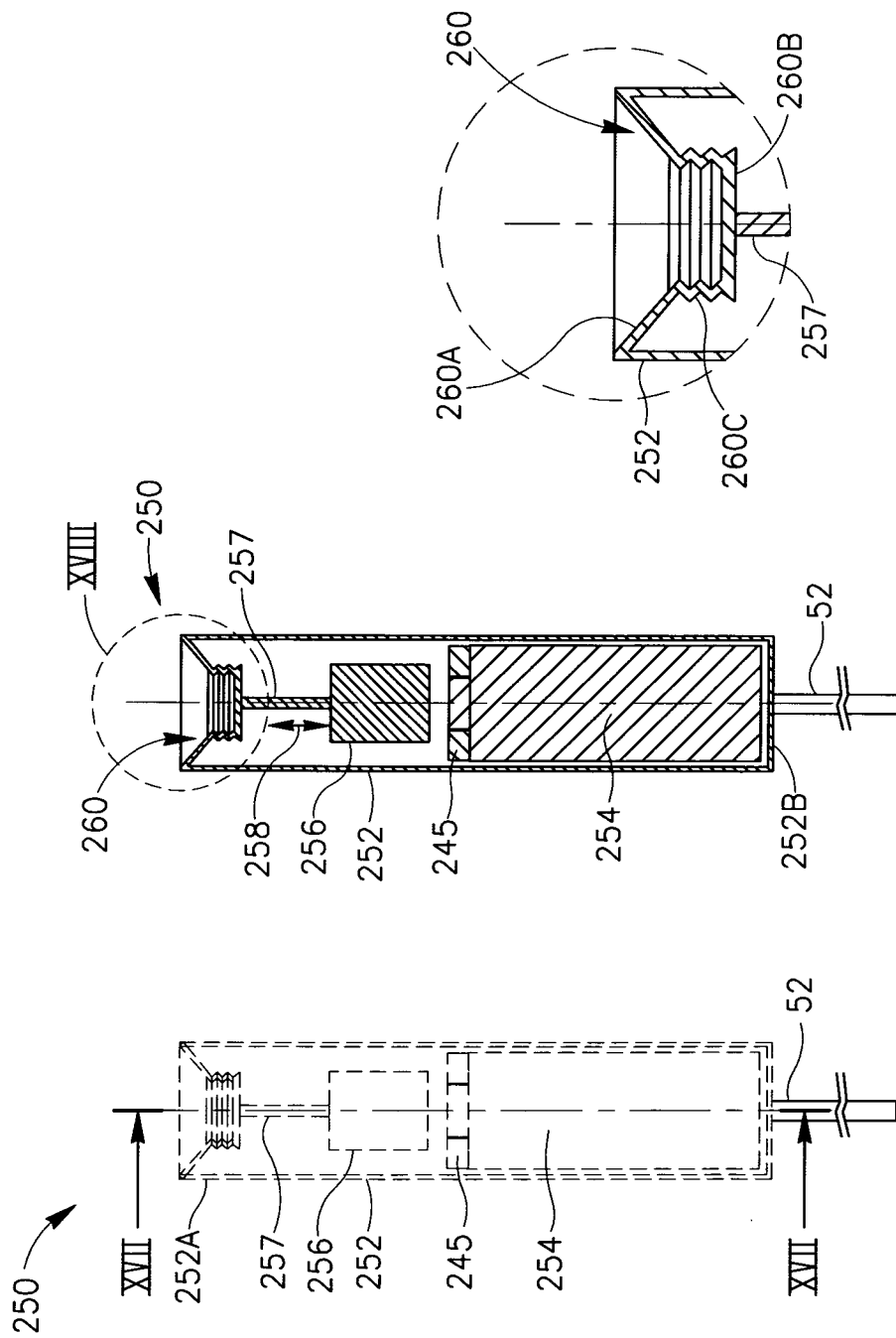


FIG. 18

FIG. 17

FIG. 16

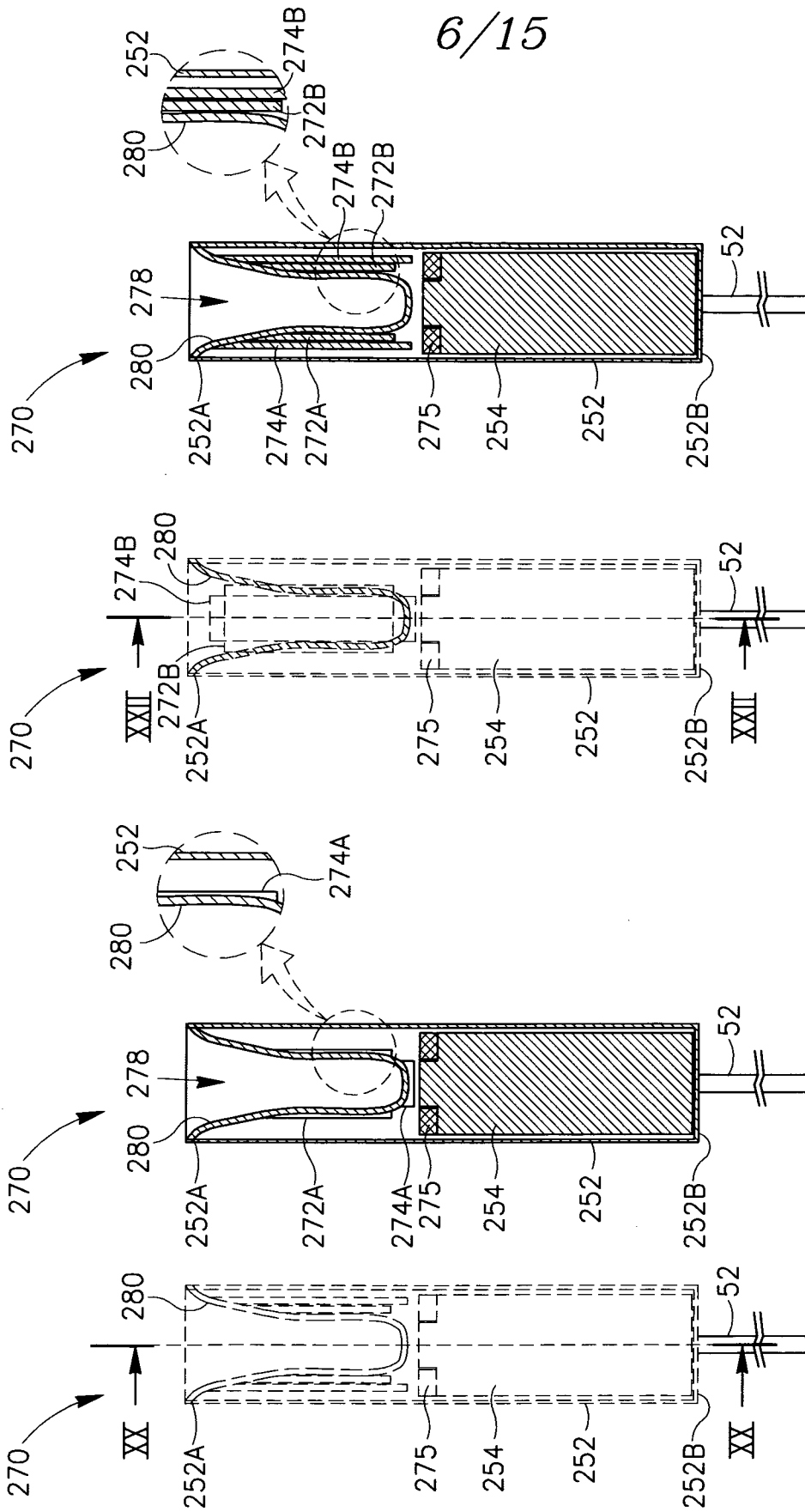


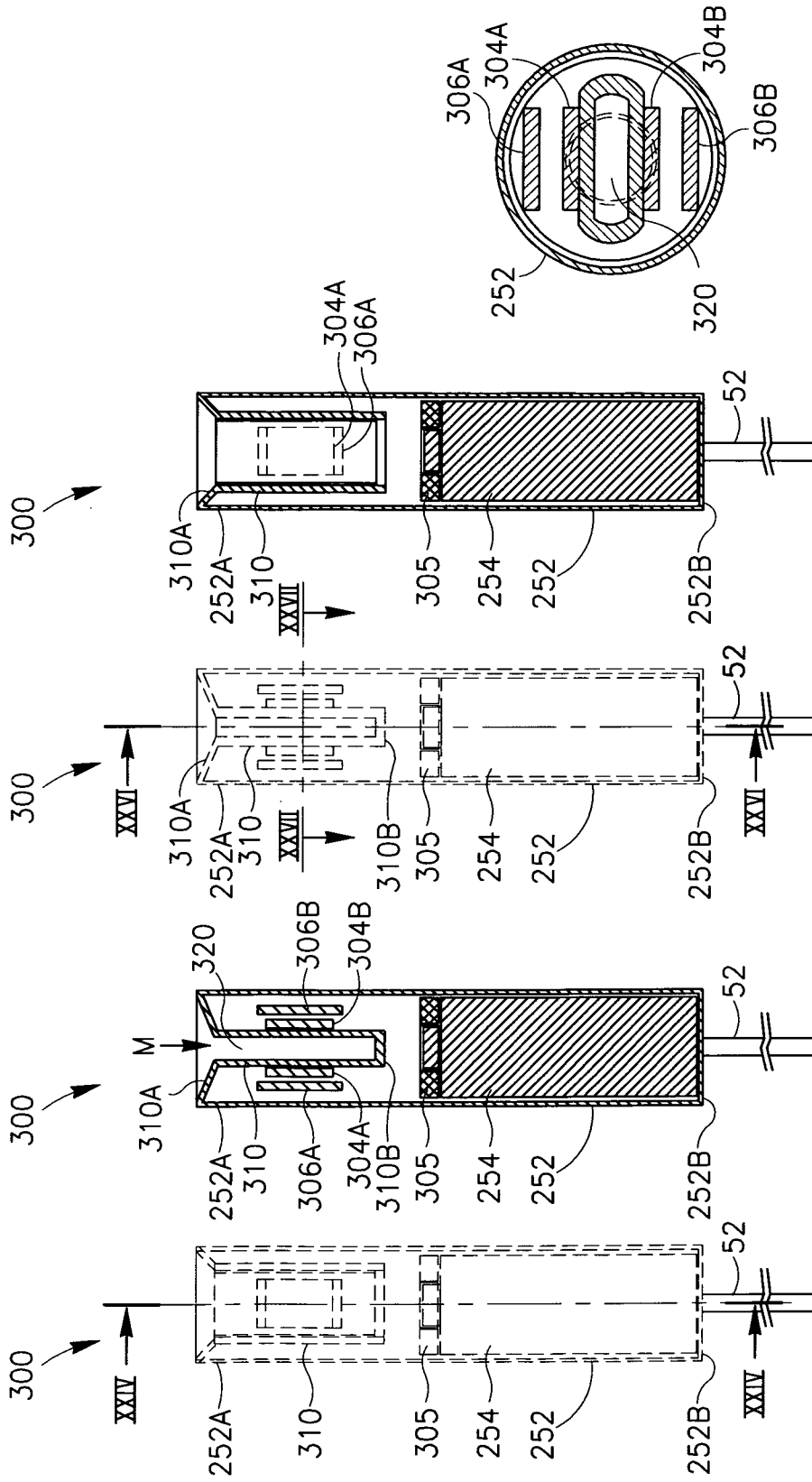
FIG. 22

FIG. 21

FIG. 20

FIG. 19

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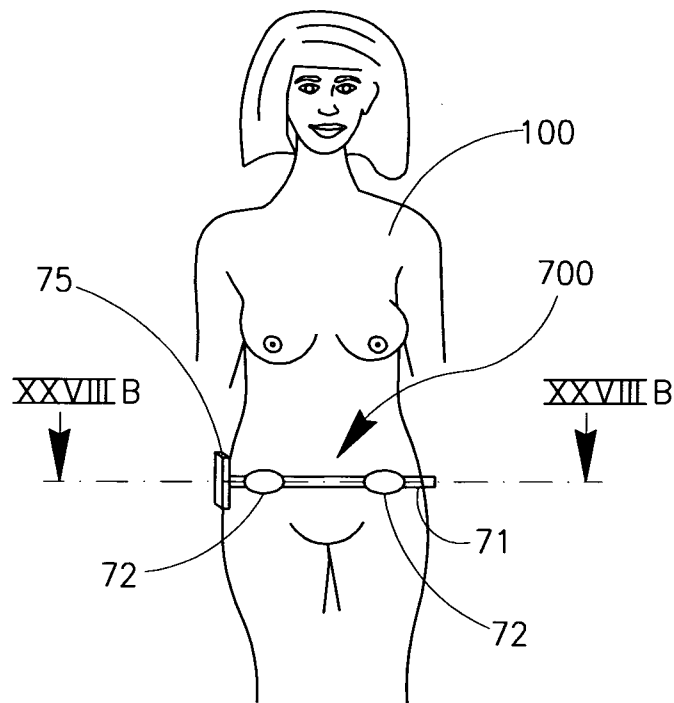


FIG. 28A

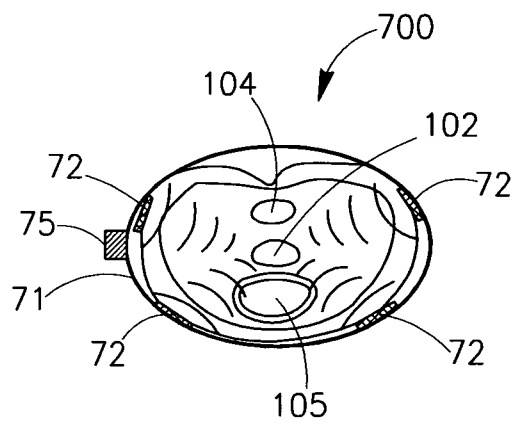


FIG. 28B

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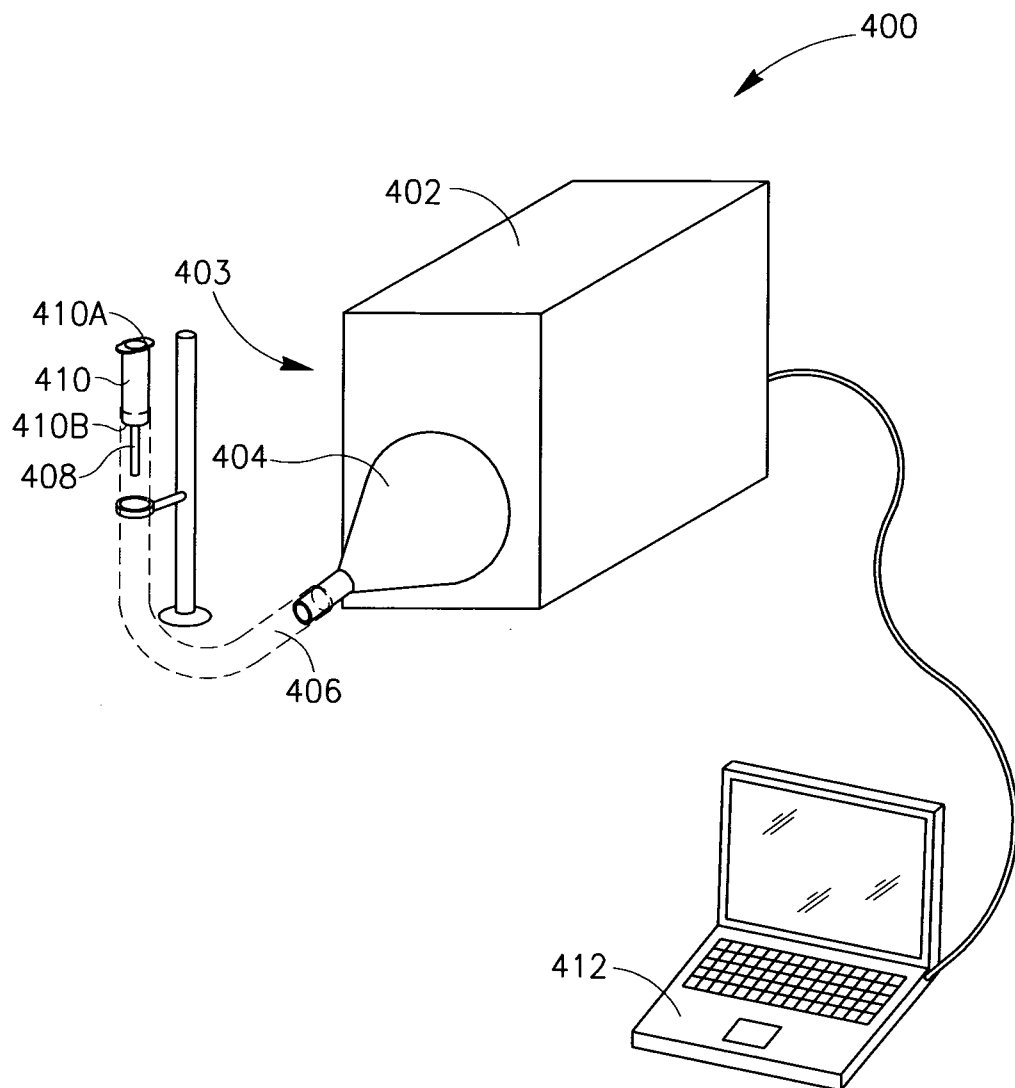


FIG. 29

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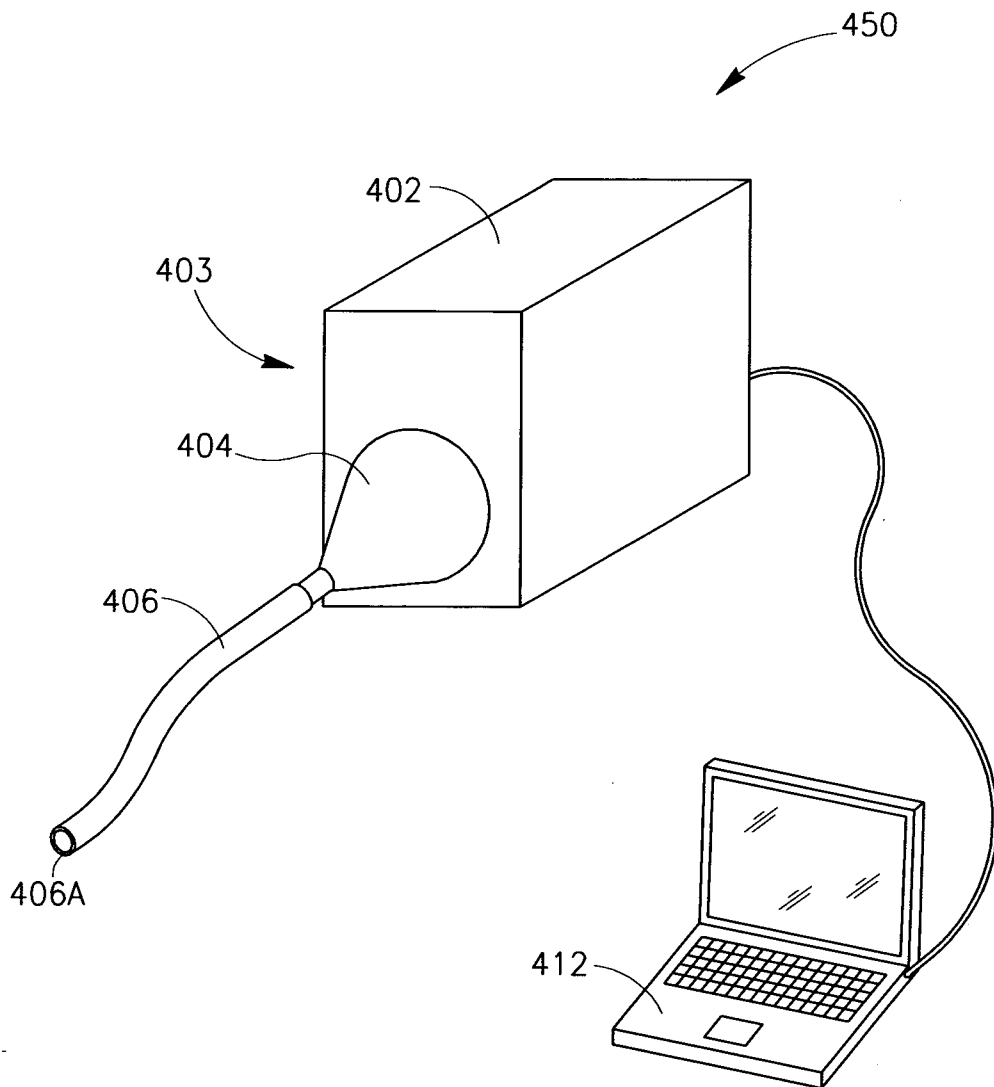


FIG. 30

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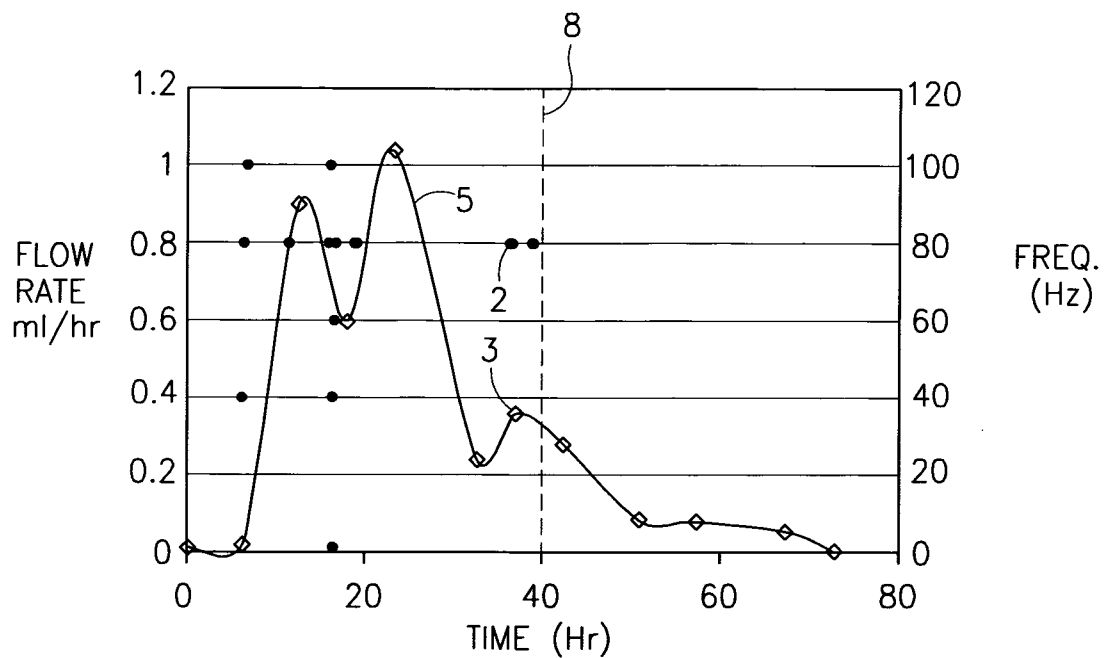


FIG. 31

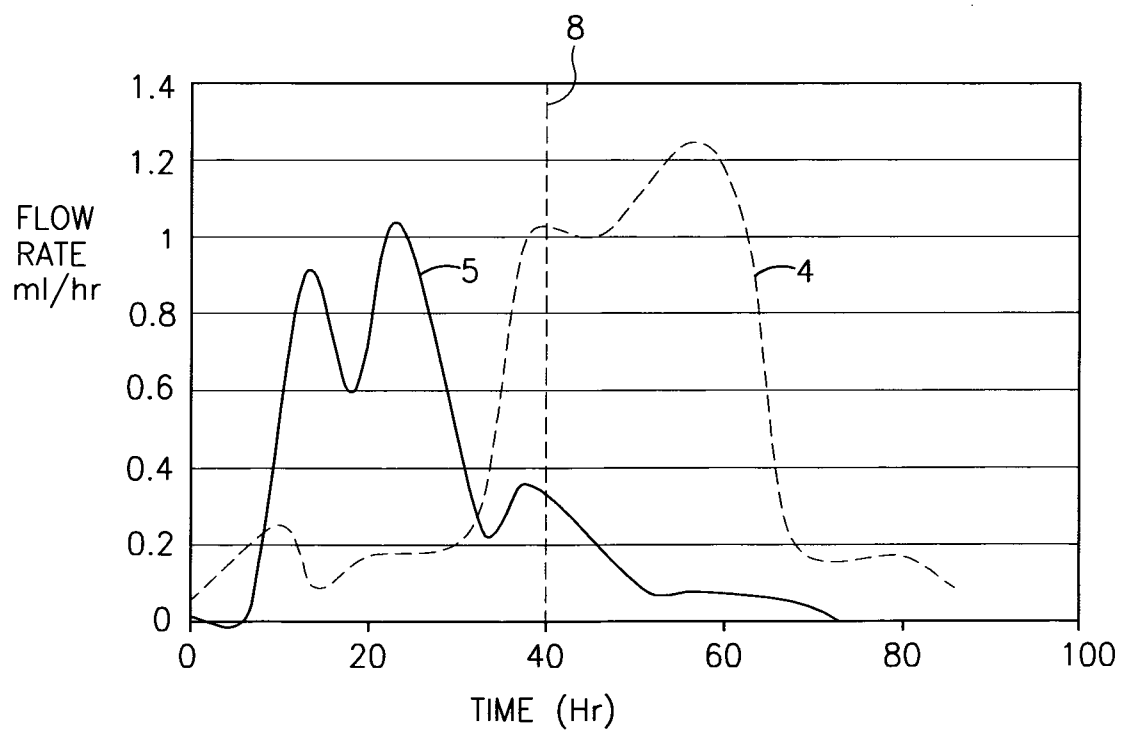


FIG. 32

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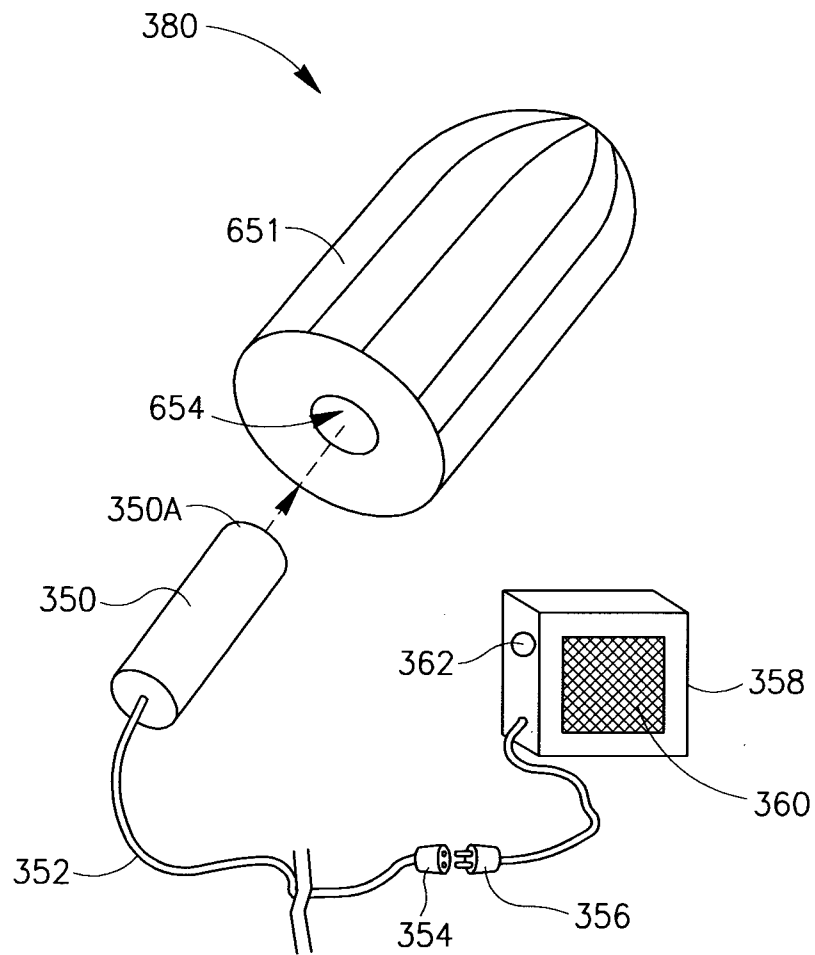


FIG. 33

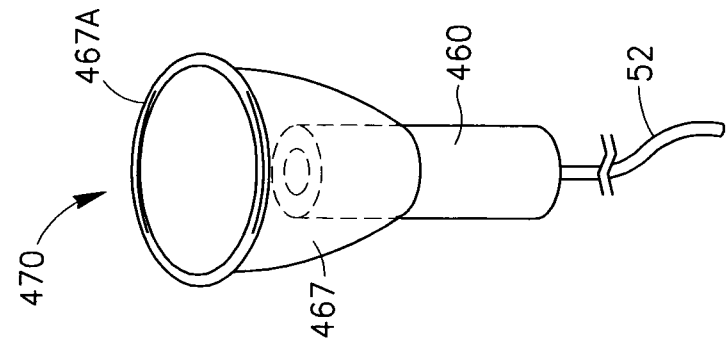


FIG. 34

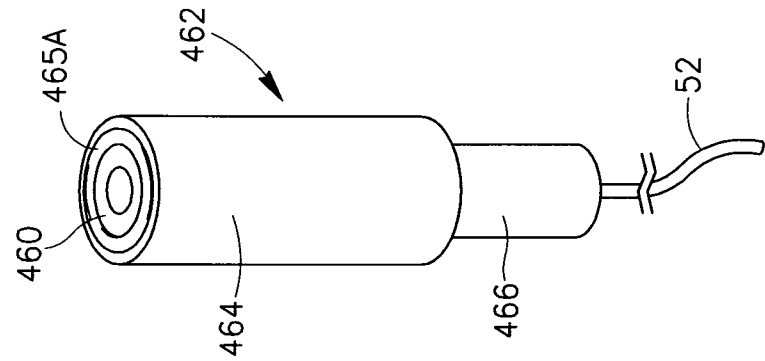


FIG. 35

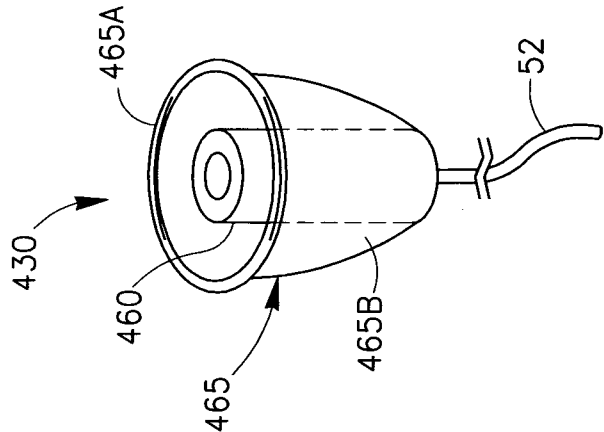


FIG. 36

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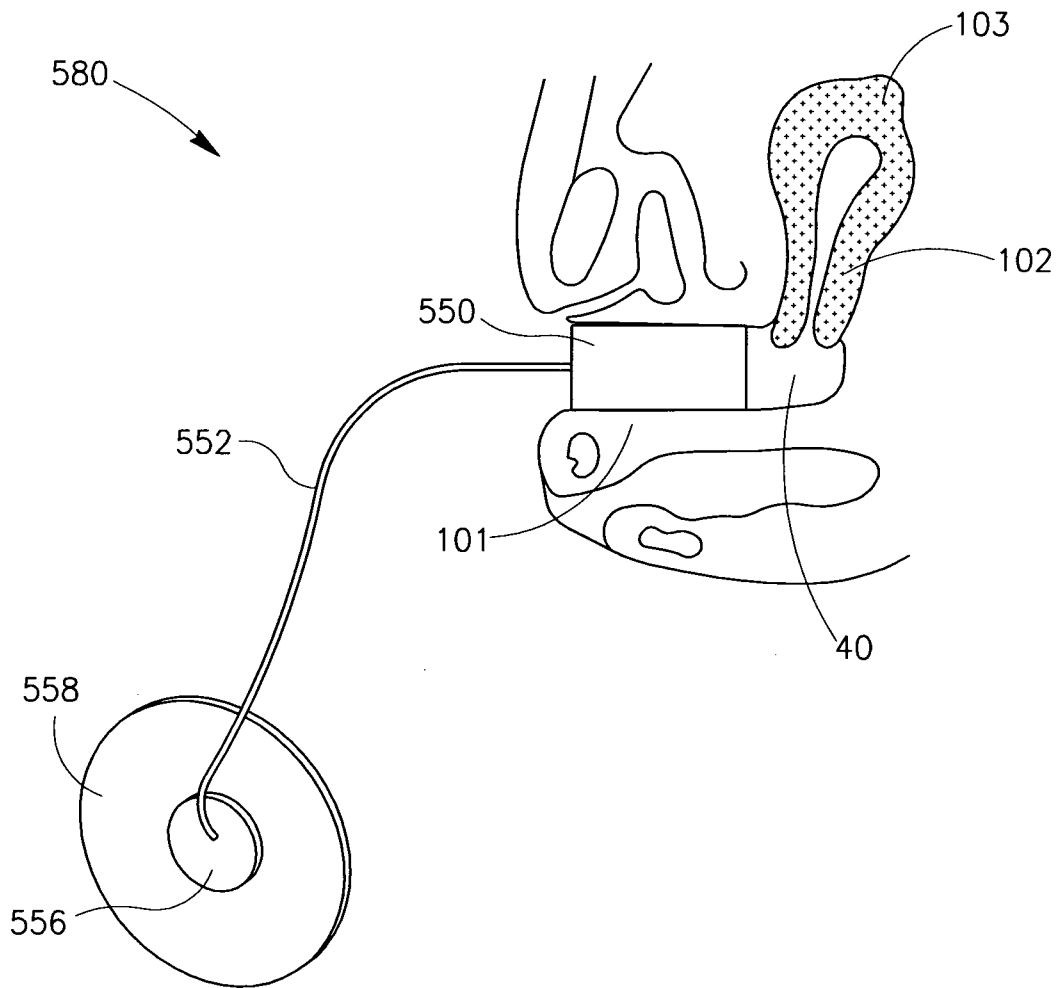


FIG. 37

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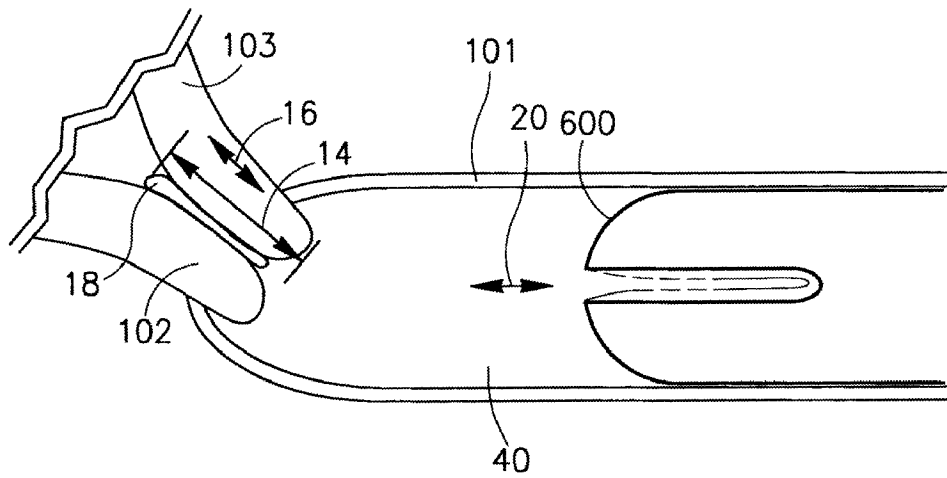


FIG. 38

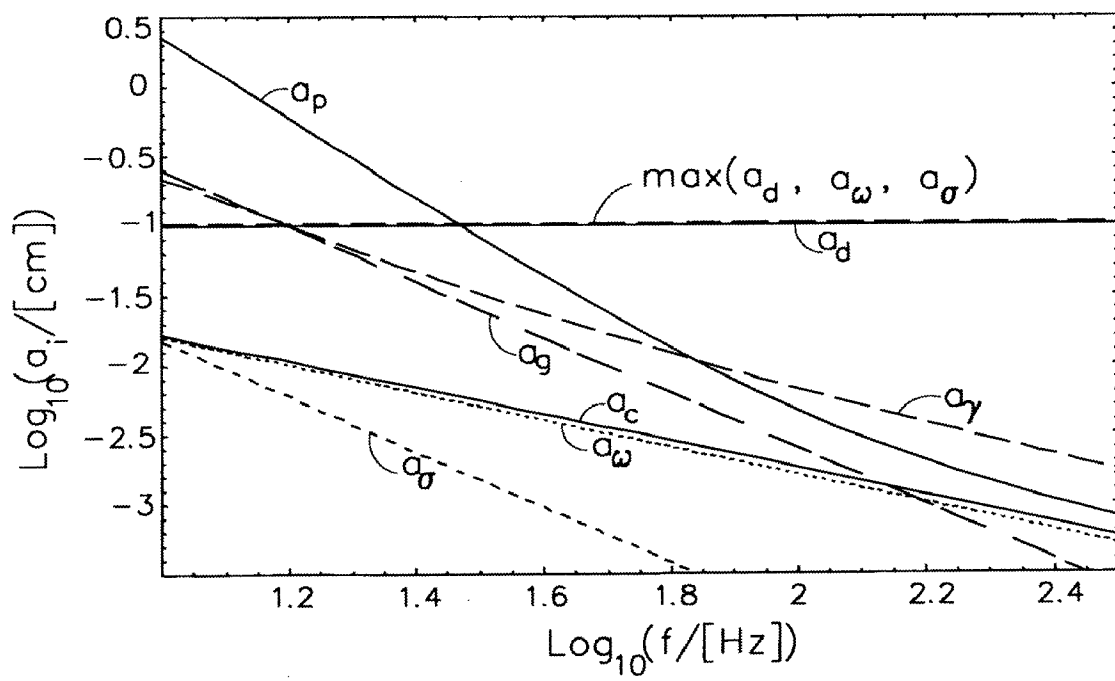


FIG. 39