INTRAVAGINAL MONITORING DEVICE AND NETWORK

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U.S. Cl. .......... 600/304; 600/591; 600/476; 600/588; 600/511

ABSTRACT

Various types of intravaginal monitoring devices (IMD) along with various supporting medical and computing devices within a communication network service pluralities of femal reproductive systems. An IMD alone or with assistance from one or more supporting systems assists in detection, monitoring, therapy delivery and efficacy evaluations of various types of physiological conditions of the various female reproductive systems. Exemplary conditions include those related to pregnancy, premature birth, fertility, ovulation, diseases, infections, fluids, flora, pre-cancerous conditions, cancer, non-human animal estrus, etc. Various types of IMDs include those with multiple sensors within a housing sized for at least partial insertion into a vaginal channel of a reproductive system. In some IMDs, only a single sensor such as an optical imager might be found, while in others multiple such imagers and as temperature, pH, glucose, electrolyte, sonogram, magnetic resonance, pressure, ultrasound, microphone, etc., sensors can also be included.
Intravaginal Monitoring Device 611

- UV & IR Emitter & Detector 621
- Piezo Mic(s) & Speaker(s) 623
- Electrolyte & EKG I/F 625
- Pressure Transducers 629
- Thermal Contact Assembly 631
- Glucose Sensor 633
- PH Sensor 635
- Sonogram Head Unit 639

Processing Circuitry 641

Memory 681
- Network Management Module 683
- Display Management Module 685
- App. Programming Interface 687
- External Memory Management 689
- IMD Server Module (SM) 691
- Program & Operational Logic 693
- Sensor Data 695
- Workspace 697

Wired-Wireless Communication I/F Circuitry 661
- Display Interface 649
- External Memory Interface 643
- Communication Interface 645
- App. Program I/F 647

Power Regulation 651
- Battery(s) 653
- Display(s) 663

User Input Devices 665
- Normal (IR & UV) Illuminator 667
- (Fixed-Manual-Auto Focus) Lensing 669
- Photodetector Array 673
- Photodetector Array 675
- (F-M-A Focus) Microscope Lensing 679

FIG. 6
FIG. 7
<table>
<thead>
<tr>
<th>Select</th>
<th>Type</th>
<th>Date</th>
<th>Duration</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>LUM-F106</td>
<td>1/1/09 11:15AM</td>
<td>00:13</td>
<td>Video, Image &amp; Temperature Data Collection</td>
</tr>
<tr>
<td></td>
<td>Query: User</td>
<td>12/28/09 7:23PM</td>
<td>N/A</td>
<td>User Symptom Query: Ovulation Related</td>
</tr>
<tr>
<td></td>
<td>LUM-G13A</td>
<td>12/28/09 12:02PM</td>
<td>07:19</td>
<td>Worn: Image &amp; Temperature Data Sampling</td>
</tr>
<tr>
<td></td>
<td>Query: Doctor</td>
<td>12/27/09 11:15AM</td>
<td>N/A</td>
<td>Symptom Evaluation</td>
</tr>
<tr>
<td></td>
<td>Note: User</td>
<td>12/25/09 6:24PM</td>
<td>N/A</td>
<td>Symptom Report</td>
</tr>
<tr>
<td></td>
<td>LUM-F106</td>
<td>12/24/09 6:55AM</td>
<td>00:09</td>
<td>Video, Image &amp; Temperature Data Collection</td>
</tr>
<tr>
<td></td>
<td>LUM-G13A</td>
<td>12/23/09 11:28PM</td>
<td>08:14</td>
<td>Worn: Image &amp; Temperature Data Sampling</td>
</tr>
<tr>
<td></td>
<td>LUM-G13A</td>
<td>12/22/09 11:12PM</td>
<td>07:27</td>
<td>Worn: Image &amp; Temperature Data Sampling</td>
</tr>
<tr>
<td></td>
<td>Lab Results</td>
<td>12/21/09 7:23PM</td>
<td>N/A</td>
<td>STD Test Results - Negative</td>
</tr>
<tr>
<td></td>
<td>Med Support</td>
<td>12/17/09 7:41PM</td>
<td>N/A</td>
<td>Blood Pressure Measurement</td>
</tr>
<tr>
<td></td>
<td>Query: User</td>
<td>12/17/09 7:32PM</td>
<td>N/A</td>
<td>Body Measurement Data</td>
</tr>
</tbody>
</table>

IMD Status: Tethered (or Wireless or Disconnected) | 213

Tools

Client's Browser 225

FIG. 9
### Reproductive Health Management - Medical Support

#### Predefined Queries

<table>
<thead>
<tr>
<th>Select Category</th>
<th>By</th>
<th>Usage</th>
<th>Q#</th>
<th>Description</th>
<th>Q-Triggers</th>
</tr>
</thead>
<tbody>
<tr>
<td>General</td>
<td>Std</td>
<td>9241</td>
<td>120v12</td>
<td>General Patient Query: Waiting Room</td>
<td>108v02, 121v8...</td>
</tr>
<tr>
<td>Abortion</td>
<td>JTM</td>
<td>592</td>
<td>119v1a</td>
<td>Conception dates; previous history; ...</td>
<td>53v11, 198v12...</td>
</tr>
<tr>
<td>Pharma</td>
<td>pha</td>
<td>63</td>
<td>p881</td>
<td>Gynactin Pharma Query</td>
<td></td>
</tr>
<tr>
<td>STD-Gen</td>
<td>JTM</td>
<td>1592</td>
<td>221a</td>
<td>General STD Symptom Query</td>
<td>282a, 282v1b; ...</td>
</tr>
<tr>
<td>STD-HIV</td>
<td>std</td>
<td>172</td>
<td>282v1b</td>
<td>HIV Symptom Query</td>
<td></td>
</tr>
</tbody>
</table>

**Category:** Pharma  **By:** pha  **Date:** 11/1/09 1:45PM  **Query#** p881

**Notes:** Gynactin Pharma Query

**Details:** For ongoing use of Gynactin by all patients. Related preliminary Query# p880 should be used once at initial outset. For completion during office visits and/or at home on at least a weekly repeating schedule.

### IMD Status
Tethered (or Wireless or Disconnected)

**Tools**

**FIG. 10b**
Dear Ms. Thomas,

Please find my comments recorded in the Data View you sent - reattached hereto. Also, I am attaching a Research View and a prior Forum View of a patient with similar concerns.

Dr. Moore

Attachments: Data View-123; Research View-123; and Forum View-113

FIG. 11
<table>
<thead>
<tr>
<th>Topic</th>
<th>Posts</th>
<th>Recent Posts</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Discussions</td>
<td>81393</td>
<td>Boston Area OB Referral Sought by JBD1 11/4/09 3:14PM</td>
</tr>
<tr>
<td>Family Planning</td>
<td>14302</td>
<td>LM Experience by Judy 10/4/09 4:35PM</td>
</tr>
<tr>
<td>Miscarriage</td>
<td>17689</td>
<td>FID Detect &amp; Prevention by Over 11/9/09 9:21PM</td>
</tr>
<tr>
<td>First Trimester</td>
<td>9239</td>
<td>Healthy Cervixx by Jade 10/2/09 8:11PM</td>
</tr>
<tr>
<td>Second Trimester</td>
<td>2893</td>
<td>Abnormal Discharge by TJ-Detroit 11/1/09 9:18AM</td>
</tr>
<tr>
<td>Third Trimester</td>
<td>12957</td>
<td>Back Pain Relief by Momma-Amy 11/5/09 8:11PM</td>
</tr>
<tr>
<td>Sonogram</td>
<td>1298</td>
<td>Girl at Bey 3 by FridaK 11/4/09 7:21AM</td>
</tr>
<tr>
<td>Complications</td>
<td>8219</td>
<td>Greenish Fluids by Nora11 11/4/09 7:21AM</td>
</tr>
</tbody>
</table>

**IMD Status:** Tethered (or Wireless or Disconnected) 12/27
<table>
<thead>
<tr>
<th>Title</th>
<th>Latest Reply</th>
<th>by</th>
<th>Replies</th>
<th>Views</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boston Area OB</td>
<td>Please find my support-view-238 attached for my doctor Mr. Smith. I highly recommend her and her nursing staff. We had three...</td>
<td>xTina</td>
<td>4</td>
<td>13</td>
</tr>
<tr>
<td>Referral Sought</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>by JBB1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Need link for new</td>
<td>All Lumeden IMD supplies can be found at <a href="http://www.lumeden.com">www.lumeden.com</a>, but also via my attached view (Shopping-View-AAA).</td>
<td>ModIA</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>LUM-F106 caps</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>by DarlaB</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I'm having fluid</td>
<td>-- Moved to &quot;Complications&quot; --</td>
<td>ModIA</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>discharge...</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>by TAL198</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How often should I</td>
<td>It depends on what you are trying to measure and your current conditions. Please provide further details and/or ask your OB-DR.</td>
<td>DrTIO1</td>
<td>18</td>
<td>43</td>
</tr>
<tr>
<td>use my IMD...</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>by AlenaQ</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

IMD Status: Tethered (or Wireless or Disconnected) 1253

Client's Browser 1255

FIG. 12b
FIG. 14b
Reproductive Health Management

<table>
<thead>
<tr>
<th>Select</th>
<th>Model</th>
<th>Version</th>
<th>Support Site</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>LUM-G13A</td>
<td>1003A</td>
<td><a href="http://www.lumaden.com/">www.lumaden.com/</a>...</td>
<td>General purpose, wireless, wearable...</td>
</tr>
<tr>
<td></td>
<td>LUM-O112</td>
<td>523.1C</td>
<td><a href="http://www.lumaden.com/">www.lumaden.com/</a>...</td>
<td>Tethered, Obstetrics</td>
</tr>
<tr>
<td></td>
<td>LUM-O201C</td>
<td>O2.001</td>
<td><a href="http://www.lumaden.com/">www.lumaden.com/</a>...</td>
<td>Enhanced support, STD &amp; Cancer...</td>
</tr>
<tr>
<td></td>
<td>LUM-F106</td>
<td>F100.03</td>
<td><a href="http://www.lumaden.com/">www.lumaden.com/</a>...</td>
<td>Enhanced support, Fertility Detection</td>
</tr>
</tbody>
</table>

**LUM-F106**

- Status: Inserted
- Battery: [ ]
- Memory: [ ]
- Reception: N/A
- Operational Modes: Conception Avoidance
- Video Camera Mode: Real Time Viewing, Resolution Setting: Low
- Temperature Mode: Single Stable Measurement
- Wearable Duration: Short Term, Tethered
- Indications: Capture Request: LED; Completion: LED + PC/Phone Display

**IMD Status:** Tethered (or Wireless or Disconnected)

**Online Status:** Connected (or Local)

**FIG. 15a**
### Reproductive Health Management

#### Overview:
- **Find an Obstetrician:** Inform you of obstetricians near you. Inform your selection with specialty areas identified & both patient & peer-based satisfaction rankings & comments.
- **Find a Gynecologist:** Inform your selection with specialty areas identified & both patient & peer-based satisfaction rankings & comments.
- **Find a Local Retailer:** Products and services offering categories, complete with satisfaction rankings & comments.
- **Find a Fertility Specialist:** Products and services offering categories, complete with satisfaction rankings & comments.

#### Categories:
- **IMD Setup**
- **Organizations**
- **Current**
- **Telephone**
- **Email**
- **Reproductive Health Management**
- **Reproductive Records**
- **Queries**
- **PDA**
- **Software**
- **Clinics**
- **Current**
- **Family**
- **Institute**
- **Research**
- **Accounts**
- **IMD**
- **Setup**

---

**Client's Browser (le 1607)**

**IMD Status: Tethered (or Wireless or Disconnected) le 1607**
<table>
<thead>
<tr>
<th>Categories:</th>
<th>Overview:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Introvaginal Monitoring Devices (IMD)</strong></td>
<td>Lumeden IMD offerings including products, cap kits, kegel exerciser packs, carrying cases, prophylactic sleeves, cleaners, douches, and more</td>
</tr>
<tr>
<td><strong>Software Applications</strong></td>
<td>IMD client software for PDA's, PC's as well as Cellular &amp; VoIP Phones can be found here</td>
</tr>
<tr>
<td><strong>Pharmaceuticals</strong></td>
<td>Browse complete selections by category or selected offerings based upon either text searching or anonymous correlation with underlying IMD data, user RHM interaction &amp; related medical info</td>
</tr>
<tr>
<td><strong>Homeopathy</strong></td>
<td>Categorized for browsing, text searching or automatically based on underlying anonymous RHM data as above</td>
</tr>
<tr>
<td><strong>Baby Products</strong></td>
<td>Full line of motherhood, baby clothes and toys, bottles, thermometers to all your infant needs</td>
</tr>
</tbody>
</table>

**IMD Status:** Tethered (or Wireless or Disconnected) 1707

**Client's Browser** 1725

**FIG. 17**
FIG. 18a
FIG. 22
Processing Circuitry (Data Processing/Analysis/Conclusions) 2321

Operational Logic 2323

User's Input Data 2341

Doctor's Input Data 2343

External User Supporting Medical Device Data 2345

External Doctor's Supporting Medical Device Data 2347

Doctor's Diagnosis/Treatment Data 2349

IMD Sensor Data 2351

IMD Prior/Current Sensor Data 2353

Medical Information Data 2355

Analysis Logic Data 2357

Gynaecological Data 2359

Analysis Engine 2311

FIG. 23
Supporting Operations 2421

- Registration/Authentication Management 2423
- Billing/Charge/Payment Management 2425
- Directed Advertisement Management 2427
- Alerts & Other Conclusion Processing 2431
- External User Interaction Support 2433
- Healthcare Professional Interaction Support 2435
- Presentation Management (e.g., Browser Application) 2439
- IMD & Network-Support Communication Processing 2441

Sensor Data Processing 2437

Data/Information Processing 2429

- Gynaecological Data Storage 2453

Analysis Engine Operations 2455

Supporting Server 2411

FIG. 24
FIG. 32
INTERRAVAGINAL MONITORING DEVICE AND NETWORK

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application incorporates by reference herein in their entirety and makes reference to, claims priority to, and claims the benefit of:

[0002] a) U.S. Provisional Application Ser. No. 61/246,375 filed Sep. 28, 2009, entitled “Intravaginal Monitoring Device” by Ziaro et al.;


[0004] c) U.S. Provisional Application Ser. No. 61/246,396 filed Sep. 28, 2009, entitled “Network Supporting Intravaginal Monitoring Device” by Ziaro et al.

[0005] d) U.S. Provisional Application Ser. No. 61/290,792 filed Dec. 30, 2009, entitled “Network Supporting Intravaginal Monitoring Device, Method and Post Harvesting Processing of Intravaginally Processed Data” by Ziaro et al.; and


[0007] Also incorporated herein by reference in their entirety are:

[0008] a) U.S. patent application Ser. No. _____ filed on even date herewith by Ziaro et al., entitled “Intravaginal Monitoring Device” client docket number PUS-L019-001;

[0009] b) U.S. patent application Ser. No. _____ filed on even date herewith by Bennett et al., entitled “Network Supporting Intravaginal Monitoring Device” client docket number PUS-L019-002;

[0010] c) U.S. patent application Ser. No. _____ filed on even date herewith by Bennett et al., entitled “Analysis Engine within a Network Supporting Intravaginal Monitoring” client docket number PUS-L019-003;

[0011] d) U.S. patent application Ser. No. _____ filed on even date herewith by Bennett et al., entitled “Intravaginal Monitoring Support Architecture” client docket number PUS-L019-004;

[0012] e) U.S. patent application Ser. No. _____ filed on even date herewith by Bennett et al., entitled “Intravaginal Therapy Device” client docket number PUS-L019-006;

[0013] f) U.S. patent application Ser. No. _____ filed on even date herewith by Bennett et al., entitled “Intravaginal Dimensioning System” client docket number PUS-L019-007; and

[0014] g) U.S. patent application Ser. No. _____ filed on even date herewith by Bennett et al., entitled “Intravaginal Optics Targeting System” client docket number PUS-L019-008; and

[0015] h) PCT Patent Application Ser. No. _____ filed on even date herewith by Bennett et al., entitled “Intravaginal Monitoring Device and Network” client docket number PWO-L019-001.

BACKGROUND

[0016] 1. Technical Field

[0017] The invention generally relates to intravaginal monitoring devices, methods, and networks, as well as smart phone devices communicating with the intravaginal monitoring devices, and smart phone devices communicating with other nodes on a network.

[0018] 2. Related Art

[0019] Reproductive health covers a wide area of a female’s health and it is of critical importance to be able monitor this aspect of a female’s life. Monitoring of a female’s reproductive health should begin during the teen years and proceed all the way through end of life. However, a shortage of health care professionals and prohibitive costs make it difficult to continuously monitor intravaginal conditions that include conditions that can be monitored via vaginal fluid discharges, discharges from the uterus that are exuded through the cervical canal into the vagina, cervical colors and color changes, ovulation related conditions, menopause related conditions, sexually transmitted diseases related conditions, and child birth related conditions. In addition to all these conditions, treatments and therapies also necessitate constant monitoring to determine their efficacy for various female health problems and events.

[0020] These conditions are typically monitored by a gynecologist or obstetrician by inserting a speculum and examining or inspecting the inside of the vagina, cervix, and uterus for the possibilities of the aforementioned conditions and efficacy of treatments. That is, patients need to visit the gynecologist or obstetrician routinely and these routine checkups needs to be done during visiting hours of the health care professionals (gynecologist or obstetrician). Travel is necessitated, relocation, the effort required to locate a new gynecologist, long lines in waiting rooms, potential embarrassment, all serve to discourage female from routinely having these checkups, and present potential dangers for the female in the event of a quickly deteriorating event or condition, e.g., Chlamydia infection, progression of a cancer to dangerous stages and the like.

[0021] For instance, the fluid discharge (e.g., non colored, colored, opaque, pus) indicates conditions such as normal (small amount of clear or slightly milky vaginal discharge), yeast infections, abnormal vaginal flora, menstrual cycle, menopause, infections or STD—sexually transmitted diseases—(much more discharge than normal, discolored discharge, or abnormal discharge). By way of example, STDs include Chlamydia (increased vaginal discharge), Human Papilloma Virus (HPV—white lesions on the cervix during infection), Gardnerella (grayish, foamy discharge, with a strong fishy smell), Candida (thick creamy whitish discharge, with a yeasty smell), Gonorheea (yellow or greenish discharge with a strong smell), Trichomonas (TV) (a frothy discharge, sometimes a yellow-green color) and so forth. In addition, externally and or internally, cysts, lumps and bumps, conditions related to growing hairs, acne spots, and blocked glands are also observed via inspections. These routine checkups become even more difficult when the female is in a remote location and this is even truer in the developing regions of the world where there are no specialists, medical clinics or medical help located close to the female. These females are forced to proceed to the nearest town or larger city where a female’s health care provider are located. This may involved hours or even days of travel by train or bus further discouraging the female from seeking needed medical care or treatment.

[0022] These and other exemplary limitations and deficiencies associated with the related art are more fully appreciated...
by those skilled in the art after comparing such related art with various aspects of the present invention as set forth herein with reference to the figures.

**BRIEF SUMMARY OF THE INVENTION**

**0023** The present invention is directed to a device, apparatus and methods of operation that are further described in the following Brief Description of the Drawings, the Detailed Description of the Invention, and the claims. Other features and advantages of the present invention will become apparent from the following detailed description of the invention made with reference to the accompanying drawings.

**BRIEF DESCRIPTION OF THE DRAWINGS**

**0024** FIG. 1 is a schematic block diagram illustrating a gynaecological analysis engine incorporated into the intravaginal monitoring devices and its supporting network infrastructure; wherein the gynaecological analysis engine, having a database that has association with various gynaecological conditions, makes a first preliminary analysis of possible gynaecological conditions;

**0025** FIG. 1b is a schematic block diagram illustrating an intravaginal monitoring device and its supporting network infrastructure; wherein the intravaginal monitoring device communicates via a communication interface to external devices and/or external servers via wired and/or wireless network pathways;

**0026** FIG. 2 is a schematic block diagram illustrating various powering schemes for intravaginal monitoring devices, of FIG. 1b;

**0027** FIG. 3 is a schematic block diagram illustrating various sensor placement schemes for intravaginal monitoring devices of FIG. 1b;

**0028** FIG. 4 is a schematic block diagram illustrating fluid flush cleaner on the surface of the cap, that cleans both the surface of the cap and the target area of intravaginal monitoring devices of FIG. 1b;

**0029** FIG. 5 is a schematic diagram illustrating placement of the intravaginal monitoring device of FIG. 1b, placed so as to face the outer surface of the cervix in which the device’s cap or head takes images of the outer surface of the cervix as well as sensor readings via many other built-in electronic sensors, to monitor the well being of a female (and developing fetus in case of the female being pregnant);

**0030** FIG. 6 is a schematic diagram illustrating the components of the intravaginal monitoring device of FIG. 1b (that may be found in exemplary intravaginal monitoring devices such as those found in FIGS. 1-5);

**0031** FIG. 7 is a schematic diagram illustrating data flow between intravaginal monitoring device and various systems or devices within the supporting network infrastructure;

**0032** FIG. 8 is a schematic diagram illustrating a snapshot of one of the health care management web pages or system interfaces of FIG. 1b wherein the snapshot depicts user’s data view page;

**0033** FIG. 9 is a schematic diagram illustrating a snapshot of one of the health care management web pages or system interfaces of FIG. 1b wherein the snapshot depicts user’s record page;

**0034** FIG. 10a is a schematic diagram illustrating a snapshot of one of the health care management web pages or system interfaces of FIG. 1b wherein the snapshot depicts user’s queries page;

**0035** FIG. 10b is a schematic diagram illustrating a snapshot of one of the health care management web pages or system interfaces of FIG. 1b wherein the snapshot depicts user’s forum page;

**0036** FIG. 11 is a schematic diagram illustrating a snapshot of one of the reproductive health care management web pages or system interfaces of FIG. 1b wherein the snapshot depicts user’s mail page;

**0037** FIG. 12a is a schematic diagram illustrating a snapshot of one of the health care management web pages or system interfaces of FIG. 1b wherein the snapshot depicts user’s account page;

**0038** FIG. 12b is a schematic diagram illustrating a snapshot of one of the health care management web pages or system interfaces of FIG. 1b wherein the snapshot depicts user’s support page;

**0039** FIG. 13 is a schematic diagram illustrating a snapshot of one of the health care management web pages or system interfaces of FIG. 1b wherein the snapshot depicts user’s IMEI setup page;

**0040** FIG. 14a is a schematic diagram illustrating a snapshot of one of the health care management web pages or system interfaces of FIG. 1b wherein the snapshot depicts user’s support page;

**0041** FIG. 14b is a schematic diagram illustrating a snapshot of one of the health care management web pages or system interfaces of FIG. 1b wherein the snapshot depicts user’s account page;

**0042** FIG. 15a is a schematic diagram illustrating a snapshot of one of the health care management web pages or system interfaces of FIG. 1b wherein the snapshot depicts user’s shopping page;

**0043** FIG. 15b is a schematic diagram illustrating a snapshot of one of the health care management web pages or system interfaces of FIG. 1b wherein the snapshot depicts user’s account page;

**0044** FIG. 16 is a schematic diagram illustrating a snapshot of one of the health care management web pages or system interfaces of FIG. 1b wherein the snapshot depicts a health care professional’s patients page;

**0045** FIG. 17 is a schematic diagram illustrating a snapshot of one of the health care management web pages or system interfaces of FIG. 1b wherein the snapshot depicts a health care professional’s account page;

**0046** FIG. 18a is a schematic diagram illustrating a snapshot of one of the reproductive health care management web pages or system interfaces of FIG. 1b wherein the snapshot depicts a health care professional’s patients page;

**0047** FIG. 18b is a schematic diagram illustrating a snapshot of one of the reproductive health care management web pages or system interfaces of FIG. 1b wherein the snapshot depicts a health care professional’s patients account page;

**0048** FIG. 19a is a schematic diagram illustrating a snapshot of one of the reproductive health care management web pages or system interfaces of FIG. 1b wherein the snapshot depicts a health care professional’s patients account page;

**0049** FIG. 19 is a schematic diagram illustrating a snapshot of one of the reproductive health care management web pages or system interfaces of FIG. 1b wherein the snapshot depicts a health care professional’s account view page;
[0050] FIG. 20 is a perspective diagram illustrating an exemplary support architecture configuration wherein the service involves use of real-time analysis engine functionality;

[0051] FIG. 21 is a schematic and perspective block diagram illustrating a support architecture employing gynaecological analysis engine operations that may reside in one or more of a plurality of supporting devices and systems such as diagnostic equipment located at a health care facility;

[0052] FIG. 22 is a schematic block diagram illustrating analysis engine operations within an intravaginal monitoring device (IMD), built in accordance with various aspects of the present invention;

[0053] FIG. 23 is a schematic block diagram illustrating components of an analysis engine that is found in whole or in part within one or more of the various devices and systems of a network supporting intravaginal monitoring wherein the analysis engine illustrates various aspects of the present invention;

[0054] FIG. 24 is a schematic block diagram illustrating an analysis engine such as that of FIG. 23, placed at least in part within a server to illustrate server based analysis engine functionality along with other server operations related thereto, the server and underlying functionality;

[0055] FIG. 25 is a schematic block diagram illustrating another embodiment of analysis engine integration within a network supporting intravaginal monitoring;

[0056] FIG. 26 is a cross-sectional diagrams illustrating one of many possible variations in dimensions, contour, and orientations, i.e., form factors, of a cap and optics assembly of an IMD sized to correspond to various "form factors" of intravaginal and cervical regions. Therein, the IMD is inserted via a mostly axial direction of a vaginal channel;

[0057] FIG. 27 is a diagram illustrating three different wearable forms of the intravaginal monitoring device that are part of a kit, each possessing varyingly angled cap and adjustable angles of the cap;

[0058] FIG. 28 is a schematic diagram illustrating four different wearable forms of the intravaginal monitoring device that are part of a kit, possessing multi-sized caps;

[0059] FIG. 29 is a diagram illustrating two different wearable forms of the monitoring device;

[0060] FIG. 30 is a schematic diagram illustrating hermetically sealed intravaginal monitoring device in which the illustration depicts a flexible cap that opens upon proper placement of intravaginal monitoring device and then pushing the bottom half of the stem;

[0061] FIG. 31 is a schematic diagram illustrating hermetically sealed intravaginal monitoring device wherein the illustration depicts a flexible cap that opens upon proper placement of intravaginal monitoring device and then pushing the bottom half of the stem, which is another variation of the intravaginal monitoring device of FIG. 30;

[0062] FIG. 32 is a schematic diagram illustrating intravaginal and cervical regions of a woman’s body along with an intravaginal monitoring device (hereinafter “IMD”) to be inserted into place; wherein the intravaginal monitoring device is capable of guiding inside the optics cap to capture images of large portions of intravaginal and cervical regions that come in a wide ranging variation in dimensions;

[0063] FIGS. 33a through 46 are schematic diagrams illustrating construction of one of the embodiments of the intravaginal monitoring device, along with typical dimensions, having manually adjustable optics encased with a (flexible) transparent optics cap;

[0064] FIGS. 34a-e are schematic diagrams illustrating construction of two embodiments of an intravaginal monitoring device along with typical dimensions, thereof, and having an actuator-controlled optical system and built in accordance with and to illustrate several aspects of the present invention;

[0065] FIGS. 35a-d are perspective diagrams illustrating further details regarding the adjustable optics assembly that supports two imager assemblies;

[0066] FIG. 36 is a perspective and cross-section diagram illustrating a wearable snake-like intravaginal treatment device (ITD) inserted into the cervical channel for capturing imager data, delivering light treatment, and wirelessly communicating to deliver such imager data and, in some embodiments, to receive control signals, e.g., regarding treatment delivery;

[0067] FIGS. 37a-b are perspective diagrams that illustrate a structure of a snake like intravaginal treatment device (ITD) with a segmented stem that is flexible to support guidance deep into uterus, fallopian tube, and ovarian region and carries an imager and light source assembly for capturing images and video, selectively delivering light therapy, and, in FIG. 37b, a fluid delivery nozzle, all in accordance with various aspects of the present invention;

[0068] FIG. 38 is a perspective diagram illustrating a fluid delivery embodiment for an intravaginal treatment device (ITD) with a fluid nozzle and an imager and light source assembly, both disposed within a cervical cap, that selectively deliver fluids and light therapies, respectively, and wherein squeezer ball and tube for manual fluid injection via the nozzle;

[0069] FIG. 39 is a perspective diagram illustrating another embodiment of an intravaginal treatment device (ITD) having a built-in fluid reservoir, a fluid nozzle and dual imager and light source assemblies, and built in accordance with various aspects of the present invention, to capture imager data and deliver fluid and light source therapy;

[0070] FIG. 40 is a perspective diagram of an embodiment of an optics assembly having a stem, mounting structures and two mounted imager and light source assemblies that may be used in some embodiments of an intravaginal treatment device (ITD) in accordance with the present invention to delivery light therapy and capture imager data;

[0071] FIG. 41 is a schematic block diagram illustrating exemplary components and circuitry that may be found in whole or in part within the many embodiments of an intravaginal treatment device (ITD) of the ITDs set forth herein and built in accordance with various aspects of the present invention; and

[0072] FIG. 42 is a perspective and cross-sectional diagram illustrating an inserted ITD having a radial illumination mechanism to support delivery of light therapy along the length of the vaginal canal.

DETAILED DESCRIPTION OF THE DRAWINGS

[0073] FIG. 1 is a schematic block diagram illustrating gynaecological analysis engine 135, 165, 175, 185 incorporated into the intravaginal monitoring devices 105 and its supporting network infrastructure 167, 177, 187 (communicatively coupled via wired and wireless communication pathways 151 that includes 153, 155, 157 and 159), wherein the gynaecological analysis engine 135, 165, 175, 185, having a
database that has association with various gynaecological conditions, makes a first preliminary analysis of possible gynaecological conditions. In specific, based upon correlations with prior known results of various conditions that include normal, sexually transmitted diseases and pregnancy related conditions, the gynaecological analysis engine 135, 165, 175, 185 conducts preliminary analysis and arrives at preliminary conclusions. Once the preliminary conclusions are arrived at, the gynaecological analysis engine 135, 165, 175, 185, via systems it is incorporated into (such as the supporting server 177), intimates to the respective healthcare professionals and user. This allows the healthcare professionals (who cannot afford to inspect minute by minute data from the intravaginal monitoring devices 105, because of having not enough time) to arrive at a final diagnosis very quickly and proceed with treatment procedures thereafter.

[0074] The supporting server 177, in conjunction with the gynaecological analysis engine 135, 165, 175, 185, also provides a forum with which a user can join a community of users, pharmaceutical professionals and even doctors. To facilitate this functionality as well as increase the probability of arriving at accurate conclusions, the intravaginal monitoring devices 105 and its supporting network infrastructure 167, 177, 187 also utilize general medical information 131, 161, 171, 181 and incorporate (possibly, health care professional prescribed treatments) information from supporting medical systems 133, 163, 173, 183. The supporting medical systems 133, 163, 173, 183 may include blood testing, blood pressure, temperature, electrocardiogram results and so forth, of the user.

[0075] To further increase the probability of arriving at accurate conclusions, during analysis, the gynaecological analysis engine 135, 165, 175, 185 also utilizes data collected via a questionnaire that is specifically designed to determine the patient’s history (that, in part, may also be obtained via general medical information 131, 161, 171, 181 and supporting medical systems 133, 163, 173, 183). The questionnaire may be in a tree structure that helps narrow down possible conditions, in addition to having access to sensor data. Then, the gynaecological analysis engine 135, 165, 175, 185 provides referral to different gynaecologists (to choose from), and options of call back, email and so forth, for appointment scheduling.

[0076] In automatically arriving at conclusions, statistical analysis and conclusions on statistical bases are also provided. For instance, 95% chances that it is not serious, 2% chances that it is one type of condition and 3% another condition. To arrive at conclusion, the gynaecological analysis engine 135, 165, 175, 185 may also utilize all of the available abovementioned information, at once. For instance, one particular color of the image and high temperatures for more than three days (in conjunction with patient’s personal history, questionnaire information, other sensor data and so forth) is likely to indicate one particular condition. These analyses are completely done by gynaecological analysis engine 135, 165, 175, 185; while in other cases, it might be done by some gynaecologists (doctors); such as in menstrual cycles and menopause (which have their own symptoms).

[0077] Once such conclusions are arrived at, the gynaecological analysis engine 135, 165, 175, 185 intimation both the user and the corresponding gynaecologist (doctor) via email/SMS/MMS and/or by logging into the supporting server 177 website. This intimation may include a color or numbered importance scheme, for instance, the higher the number, the more is the importance of severity of a gynaecological condition. The color codes may include yellow or 8 to 10 (an immediate scheduling with healthcare professional is essential), red 6 to 8 (severe, but the user may schedule with doctor within a week’s times), and so forth. Moreover, gynaecological analysis engine 135, 165, 175, 185 also allows the user to ask questions, such as “What is the state of art kind of treatment available for this condition?” and so forth.

[0078] Similarly, a gynaecologist’s display shows: (a) Ability to see the images 5 years back and correlate it with that of today; (b) Generate an image with every month one image in a play forward, backward, slow motion movement; (c) Video showing graphs with the sensor data; (d) Different color along with image; (d) Markers that gives ability to go anywhere in the timeline and expand over a region over a week, month, year; (e) Provisions for digital zoom in or zoom out) and so forth.

[0079] Moreover, when logging into the web pages of the supporting server 177, the gynaecologist (doctor) may look at the color or number code and determine which users should be given priority based on their case details. For instance, the gynaecologist may see a list of patients with yellow or 8 to 10 (at the top of the list) and may first wish to go through their cases immediately. Then, the gynaecologist may turn the attention towards other users (with yellow or green color coded) whose cases may not be of urgency.

[0080] To make the analysis and arriving at conclusions fast, the gynaecological analysis engine 135, 165, 175, 185 also utilizes the opinion of the user (and also that of the gynaecologists/healthcare professionals). The opinions of the user may come from personal knowledge, knowledge databases and encyclopedias available in book forms or the websites (including that in the support servers 177), or via forums and discussions with other users (that are supported by the support servers 177). To generate such a database, the gynaecological analysis engine 135, 165, 175, 185 uploads, stores and utilizes the images, sensor readings and prior healthcare professional’s (gynaecologist’s) diagnosis based upon these uploaded and stored data. In addition, where the images do not seem to correlate well (based upon an indication of changes that occurred), the gynaecological analysis engine 135, 165, 175, 185, makes a best judgement call (against prior known good condition of the user or even good condition of other people); and informs so to the user and gynaecologist.

[0081] The components of gynaecological analysis engine 135, 165, 175, 185, supporting medical systems 133, 163, 173, 183 and/or general medical information 131, 161, 171, 181 may in part or whole may be distributed anywhere between intravaginal monitoring device 105 to supporting network infrastructure 167, 177, 187 (such as intravaginal monitoring systems 105, iPods, cell phones, personal computers 167, central support server 177, gynaecologist’s servers 187).

[0082] In all these, a nominal charge may be billed during registration by the user, rest of the revenues are collected via billing user and gynaecologist (doctor) upon a successful appointment is done. Revenues are also collected by ways of targeted advertising to the user and doctors, for instance, from the pharmaceutical companies. The following additional functionalities, billing and advertising scheme are also applicable.

[0083] The device and the nodes on the network described include functionality or modules to process and correlated
intravaginal and extravaginal physiologic or persona use information with advertising related information such as cost per click (CPC) or cost per thousand impressions. Two primary models for determining cost per click: flat-rate and bid-based are used by way of example in the invention contained herein. In both cases the advertiser (e.g. a woman's consumer product marketer, a baby food vendor, a diaper's vendor), considers the potential value of a click from a given source. This value is based on the type of individual the advertiser is expecting to receive as a visitor to his or her website, (who's advertising is made directly on a remote device itself or intravaginal device) and what the advertiser can gain from that visit, e.g. revenue, product visibility. By way of example, an advertisement for baby diapers appears on a smart phone or computer of an expectant mother or expectant father, this information is presented simultaneously with physiological (or other information from the device) on the smart phone or computer in a separate window. In another variant, the advertising information is presented for a time out period and charged to the advertiser based upon the amount of time that the advertisement window appears on the target's remote device. The device itself communicates with one or more nodes on the network to communicate the time the advertisement appeared on the expectant mother or father's smart phone or computer. Based upon the viewing time, or cost per click or cost per thousand impressions, the advertiser then gets billed for the advertising using a billing module based on one or more nodes of the network.

[0084] In another variant of the invention, the flat-rate model module is used. A fixed charge is entered on one or more computers connected to nodes of the module that establish what will be paid for each click. This information, in one variant of the invention take from rate card database that lists the CPC within different areas of a website presenting data from the intravaginal device. These various amounts are often related to the content on pages displayed.

[0085] In another variant of the invention, the bid-based model module is used on one or more nodes of the network to which data from the intravaginal device is communication. By way of example, the a software module is used to permit a first advertiser to compete against other advertisers in a private auction hosted by a website associated with said intravaginal device data or data collected from a plurality of intravaginal devices or, more commonly, an Internet based advertising network. Data on the network for each advertiser informs the host of the maximum amount that the advertiser is willing to pay for a given ad spot. The auction plays out in an automated fashion every time a visitor triggers the ad spot on the network to which the intravaginal device is communicatively linked.

[0086] In another variant of the invention, the major advertising networks are connected to the network of a plurality of intravaginal devices are communicatively linked. Contextual ad data is placed on the web properties of a 3rd-party to which the intravaginal devices are communicatively linked. Publishers electronically sign up to host ads on behalf of the network. In turn, they receive a portion of the ad revenue that the network generates, which can be anywhere from 50% to over 80% of the gross revenue paid by advertisers. These properties are often referred to as a content network and the ads on them as contextual ads. Advertisers are automatically and electronically billed and pay for each click they receive, with the actual amount paid based on the amount bid. It is common practice amongst auction hosts to charge a winning bidder just slightly more (e.g. one euro cent) than the next highest bidder or the actual amount bid, whichever is lower.

[0087] To maximize success and achieve scale, automated bid management systems are deployed on the intravaginal device network of the present invention and include method steps to implement automated bid management and advertising systems on one or more nodes on the intravaginal device network. These systems can be used directly by the advertiser, though they are more commonly used by advertising agency computer systems that offer PPC bid management modules as a service. These tools generally allow for computerized and automated bid management at scale, with thousands or even millions of PPC bids controlled by a highly automated system. The system generally sets each bid based on the goal that has been set for it, such as maximize profit, maximize traffic at breakeven, and so forth. The system is usually tied into the advertiser's website and feed the results of each click, which then allows it to set bids.

[0088] By way of further example, a targeted advertising module is used in the present invention. Intravaginal device detects a female condition, e.g. a pregnancy, a sexually transmitted disease (STD), a precancerous condition, a cancer, a medical abnormality. This information is communicated to one or more nodes on the network. Advertising data for the treatment of the STD, e.g. for a drug used to treat the STD or other condition, from a particular pharmaceutical company or one or more companies, is then sent to the intravaginal device or other remote device on the network, for a user or doctor to review. Treatment option data are also communicated in another variant of the invention to the intravaginal device and/or remote device. With respect to pregnancy data, baby gift data or products used with babies are displayed on the intravaginal device or remote device. In yet another aspect of the invention, a module is provided to provided to mask, conceal or render anonymous the identity of a user of the intravaginal device while still permitting the information concerning the treatment for the users condition, state or intravaginal event to be used to direct advertising to the user needing a particular drug or treatment regimen.

[0089] In yet a further aspect of the invention (optionally using GPS functionality for locating or placing the intravaginal device at a geographic location, e.g. or a remote device, (e.g. mobile phone communicating the intravaginal device), patient candidate and drug recipient candidates data is collected. User specific condition or event data is collected on one or more nodes on the network and correlated to treatment advertising data, and or medical specialist, or hospital data. It is appreciated that drug companies will be able to provide targeted advertising data or their therapies and/or drugs to exactly the users who are suffering from conditions or events which their products provide beneficial treatments, e.g. drugs that treat STD’s, drugs that treat cancers, etc.

[0090] In yet other aspects of the invention a user profile module is provided, and a method of monitoring and controlling the spread of sexually transmitted diseases. The user enters personal information, medical information, condition information, social information, e.g. the names of sex partner data, date and times of intercourse with specific partners, etc. This information is correlated with data collected from the intravaginal device. By way of further example, a sexually active female takes baseline data with the intravaginal device of the present invention. The data is time and date stamped, a record of the health or condition of her cervix is recorded on the device or one or more nodes of the network. She then has
intercourse with a sex partner. In one scenario, if the partner is free of STDs a follow up record of the cervical or vaginal condition can be compared with the baseline data and archivally recorded. In another scenario, if the sex partner had an STD, then the user uses the device and notices that there are abnormal cervical and or vaginal changes, and these are archivally recorded and or an alert is sent to a remote device, e.g. the user’s or doctor’s, and one or more of the advertising modules above is activated. Similarly, the sex partner is notified early of the STD condition. It is appreciated that the early notification of the condition for the user and the sex partner can stop the spread of the disease to other sex partners that may occur, e.g. in the case of HPV transmission.

[0091] There are various types of support architectures that can be found operating within the supporting network infrastructure of FIG. 1. For example, the IMD 105 may operate entirely independent from all other supporting computers or devices, e.g., when out of range or when otherwise detached. As such, the IMD 105 would be the only source of analysis engine operations. When in attached, the IMD 105 (or any other of the various IMDs that may be operating in the network infrastructure) might interact with any selected computing device located anywhere within the infrastructure (e.g., a computing device selected from one of the supporting personal computing devices 167, the supporting servers 177, and the medical supporting computing devices 187). Together, the selected computing device and the IMD form a support architecture to service a female reproductive system via a communication link. The communication link can be a direct point to point link or comprise a network routed pathway, both as illustrated by the communication pathways 151.

[0092] A two device support architecture through which analysis engine functionality is provided might involve, for example, the IMD and a single one of the supporting personal computing devices 167. It might also involve only the IMD and one of the supporting servers 177. Similarly, a two device support architecture might involve the IMD and one of the systems/devices 187. With any of these support architectures, the functionality of the analysis engine may be fully disposed solely within one of the two devices or distributed across both of the devices. For example, an IMD captures raw image data. It may also pre-process the data to generate measurement data. Lastly, after some initial analysis engine operations, the final processing by the analysis engine of the supporting device might take over with further analysis engine functionality.

[0093] In other words, at a stage 1, raw sensor data from an IMD along with, perhaps, other medical data produced by other medical systems, and manual input data is collected regarding a patient and their underlying physiology. At a stage 2, the raw sensor data from the IMD and, possibly, from other raw data from other medical devices, is pre-processed if necessary to generate measurement data therefrom. At stage 3, the analysis engine (or portions thereof) receives and processes the raw sensor data, retrieved data from other sources, manual input data, and measurement data, to either reach at least an intermediate assessment regarding the status of the reproductive system under service, or to reach a determination that further or supplemental input is needed. If needed, the analysis engine can either direct further operations of any supporting computing devices, IMD, etc., to automatically gather such needed information, automatically request delivery of further information or data from supporting systems or devices, or make requests (via supporting computing devices) to the patient, medical staff, or third parties therefor. After receiving any supplemental input, the analysis engine generates the at least the intermediate assessment (or again makes supplemental request cycling until it is able to make such assessment).

[0094] After the at least intermediate assessment of a status relating to the reproductive system under service, various actions can take place. For example, medical staff might further interact with the analysis engine to verify or redirect the analysis engine operations to generate yet other assessment results. Alternatively, only a “human’s” (medical staff or patient’s) verification might be applied. Either way, once the stage 3 cycling ends, at a stage 4, automated actions based on such assessment can be carried out. Such automated actions might involve, for example, sending immediate notifications (along with underlying and relevant identification of the underlying female) to medical staff, ambulances, patient, patient’s relatives (e.g., baby is on the way!), pharma salespersons and other third parties. Such automated actions may involve human confirmation, and may be related to scheduling, transport, pharma or other treatment regime selection, etc. Automated actions may also involve sending control signals to the IMD or other medical equipment. Automated communications may take any of a variety of forms such as email, sms/inms, voice generation from text that is delivery via telephony networks to phones, letters, etc., and via the various visual working environments on the corresponding various supporting computing devices.

[0095] The IMD may be configured to both provide the preprocessing of the raw sensor data it captures to generate measurement information (before analysis engine operations), and a beginning portion but not all of the analysis engine functionality. With the raw sensor data, measurement information and output from the beginning portion of the analysis engine functionality, a supporting device may then take over analysis engine operations and perform yet other portions or all of the analysis engine operations, i.e., produce a conclusive status assessment or provide information on through which a human can complete or verify the task. Likewise, the IMD may only send the raw sensor (including imager) data to the single supporting device which performs the entire sequence of the analysis system operations, without assistance from the IMD.

[0096] Of course, three or more devices within a support architecture are also possible, and analysis engine operations can be spread across all of such devices or handled by one or a sub-group thereof. For example, in a three device configuration, an IMD and two computing devices, such as one of the supporting servers and a supporting personal computing device, might interact to carry out the servicing of a female reproductive system. Over a series of sessions (insertion events on differing dates or times), the IMD might collect and forward to a supporting server for full analysis engine operations. A patient using the supporting personal computing device interacts with the supporting server to not only view the sensor data (e.g., images and video and temperature charts), but also to view resultant analysis engine output such as measurement information, rates of change, colorization analysis results, comparisons with such patients prior sensor data, prior analysis engine results, physiological condition profiles, alerts, etc.

[0097] Final conclusions regarding the physiological status of the reproductive system under service may be entirely provided by one or more of the IMD and other computing
devices in the network illustrated via analysis engine operations. In addition, medical staff or the patient themselves may provide manual input (via typing, etc.) into the process and either confirm or make the final determination regarding the physiologic status. To support this process, a visual working environment, via software application definition, is provided on all of the devices in the illustrated network. Through such a visual working environment presented by one of the medical computing devices 187, a doctor can interact to view the sensor data collected over the sessions along with output from the various stages of analysis engine operations to verify and supplement such operations, if needed. As a result, the analysis engine with or without doctor verification and input yields status information regarding the reproductive system under examination which is displayed in the visual working environment. Similarly, such a working environment may be provided to the patient and even other third parties for viewing the sensor data and analysis engine operation output, and may allow such persons an opportunity to assist and possibly enhance the analysis engine’s performance.

More particularly, the servicing of the female reproductive system in part involves capturing, exchanging, and displaying images generated from the various types of raw sensor data and pre-processed measurement data, along with related “support information”, e.g., information from the supporting medical systems 133, 183, 163, 173, supporting information from the medical information 181, 161, 171, 131 and manual input by the patient, medical staff and third parties. In addition, the servicing of the female reproductive system involves analysis engine operations which are based on such raw sensor data, pre-processed measurement data, and such “support information”. The analysis involves functionality such as: a) extracting usable information from the raw sensor data and pre-processed measurement data, changes over time, colorization information, etc.; b) identifying, gathering and applying selections from the “support information”; c) comparing prior session data received (that is, image and other sensor data received on perhaps a different day and from that produced by the same patient in the current day’s session, and including multiple sensor data groupings for comparisons with such and other information where beneficial); d) comparisons of such sensor data (including imager data) and “support information” along with intermediate stage results of the analysis engine operations with corresponding known status profiles and thresholds; and e) production of visual information (related to any of the previous elements) for use in various computing devices throughout the network.

In other words, the analysis engine output in some limited situations, e.g., such as when used with an IMD with limited functionality in a point to point link with a hand-held computer (perhaps both off-line from other device and 3rd party assistance), might involve a few preliminary steps or operations of the analysis engine only. Even so, such analysis system output, does provide better information than that of merely viewing a representation of the raw sensor data and, perhaps, pre-processed measurement data, and, as such, provides greater assistance in the drawing of conclusion regarding the physiologic condition or status of a reproductive system under examination.

The raw sensor data is often in a form that is not easily understood even when presented in a visual form. By pre-processing to generate measurement information, e.g., scaling or dimensioning information, such raw sensor data and measurement information can be used to produce more readily understood visual presentations. In addition, together they support a more detailed analysis by a human or the analysis engine in any attempt to draw conclusions (intermediate or final) regarding the status of the reproductive system under service.

FIG. 1b is a schematic block diagram illustrating an intravaginal monitoring device 1 and its supporting network infrastructure wherein the intravaginal monitoring device 1 communicates via a communication interface 21 to local external devices 71 and/or external servers 51, 61 via wired and/or wireless network pathways 31. In specific, the depiction shows flow of data between the intravaginal monitoring device 1 and the supporting network infrastructure 71, 51, 61 via communication pathways 33, 35, 37, 39 and/or 41. Essentially, this flow of data is meant to look into the image (or sensor) data collected within the memory (are be a built-in memory, flash memory, memory cards, and or one or more memory stick) of the intravaginal monitoring device 1 and then deliver themes, for inspection, suggestions, annotations, readings, recommendations, discussions and/or as a basis for a treatment or therapy, to the user, health care professionals, user Internet or Intranet discussion forums, social networking sites where female share their experiences related to their reproductive health, or for secure storage at a data archive farm located externally from a plurality of intravaginal monitoring devices in the field, back up storage servers, and databases, private storage devices, AmazonSM storage device, EC2SM storage servers, alone or in combination. The data is sent in an encrypted form so as to be able to maintain the privacy of the female, that is, without the female’s (user’s) permission the data cannot be seen by anyone within the support network infrastructure. The data is decrypted at one or more nodes of the network. The system, network and nodes on the network serve to protect the privacy of the medical data in one mode of operation. Privacy is protected via a third party interception of the data, which can include the female’s private medical history, images of the female’s cervix and other parts of her anatomy, et al.

The data is reviewed by the user, health care professionals, and or user forums only with the user permission, in one variant, and the support infrastructure provides facilities to choose one or more user forums (to be able to discuss a reproductive health related problem, for instance), health care professionals (gynecologist or obstetrician) to receive treatments or for general checkups. The users are also wish to see the images (or sensor readings) for one’s own routine inspections and checkups of reproductive health, possibly in conjunction with health care professionals. Exemplary forums used in the invention include FacebookSM, a private forum associated with a manufacturer of the intravaginal device, alone or in combination.

For instance, the image and other sensor readings, of the intravaginal device, of an external electronic, wireless, monitoring patch applied to the skin of a female, alone or in combination (taken remotely from a medical facility, in one variant, and or taken within a medical facility or clinic, in another variant) allow the female, users of the forums, health care professionals, to inspect, suggest, annotate, create reports from the data, create electronic medical records, update electronic medical records, annotate the data, recommend, discuss and/or treat one or more of conditions and events related to: (a) Routine reproductive health; (b) Menstrual cycles, both normal and abnormal; (c) Menopause, and
therapies related thereto, including but not limited to hormonal therapies; (d) Sexually transmitted diseases, and the efficacy of therapies therefore, e.g. drug therapies, cryotherapy; (e) Pregnancy checkups, and or (f) pre and/or post coitus periods. All of these checkups otherwise would necessitate the presence of the female in question at the health care professional's office, consuming valuable time and adding to needless health care costs. Using the intravaginal monitoring device 101 and knowledge of reproductive health and well being (which is provided on a smart phone node or computer node of the network described herein) transferred over the Internet to the user, the female are herself observe the cervix, her vagina (and the vaginal and or cervical discharges therefrom) and be able to use sensor readings taken by the intravaginal device or associated external device (and hence be able to judge health conditions and events, possibly, in conjunction with health care professionals). It is appreciated that early notification of an abnormal condition by the female herself or a health care professional leads to early treatment of the event, e.g. cervical incompetence via suture therapy or cervical ring therapy, and a positive health outcome for the female. In variants of the invention, the intravaginal device and network provided herein provide early notification in patient pools at risk for a premature birth event or a threshold event, prior to which therapy or effective treatment can be provided, and an adverse event, e.g. premature birth, can be prevented.

It is appreciated that the method of extending the term of a gestation cycle is provided herein. The method consists of providing early notification of an event associated with a probably premature birth using the intravaginal monitoring device and network described herein, and providing a therapy to extend the term of gestation of a being in a womb. The therapy is selected from the group consisting of a drug therapy, a medical device therapy, e.g. cervical ring, a surgical therapy, e.g. suturing the cervix shut, alone or in combination. In yet a further variant, post therapy monitoring is also provided by the device to determine the efficacy of the treatment or therapy. In one variant, a kit is provided comprising an intravaginal monitoring device and a therapy to extend the gestation period of a being in the womb. It is appreciated that extending the gestation period of a being in a womb, e.g. by weeks or months, has significant short term and long term benefits for the being in the womb, e.g. organ development proceeds further, increasing the likelihood of survival of the being in the womb, and the long term prognosis should the being in the womb be born.

By way of further example, the method, system and network includes a female utilizing intravaginal monitoring device and network described herein. The device monitors and tracks intravaginal physiologic conditions (e.g. whether there has been a release or waters (e.g. detecting a fast rush of anterior waters and or detecting a slow release of posterior waters), position of the cervix and or cervical channel (e.g. if it is anterior, posterior, or center (positioned for birth)), whether the cervix is ready for birth or not yet ready for birth, cervical dilatation (e.g. absolute opening size of the cervical channel), the three dimensional shape of the cervix, e.g. cervical effacement, and optionally using an ancillary electronic measuring device externally measures other parameters, e.g. fetal heart rate, female’s heart rate, tonus, e.g. uterine muscle contraction and or relaxation, provides data for a trace or digital indication of fetal EKG over time on a first graph, and provides data measuring contraction intensity (e.g. either using the intravaginal device, the external wirelessly communicating monitoring device, alone or in combination), (the graphs of EKG and contraction intensity are positioned one above another in one variant), and other sensor data described herein. An alert is sent to a remote device, e.g. the female’s or the doctor’s iPhon™ or computer over the Internet or cell phone network, once one or more of the parameters measured, alone or in combination, indicate a premature or normal birth condition or that a series or cascade of events detrimental to the gestation of the being in the womb have happened or are about to happen. In one variant, a doctor reviews the data collected calls the female to advise her to rush to a clinic for therapy or treatment. The female does so. The doctor or medical professional provides the female therapy, e.g. cervical suturing, drug therapy, bed rest, or application of a cervical ring. The therapy results in a longer gestation time of the being or fetus in the womb. The fetus continues fetal development, improving its chances at survival and normal in womb development. The intravaginal device is continued to be used post therapy to monitor the efficacy of the therapy in one variant. Should other abnormal events occur post therapy, the intravaginal device, network and method is again used to monitor events and conditions in one variant.

Fluid discharge monitoring observed via a small moving image video clip (taken at distinct points in time and over a period of time) allows the female, users of the forum or health care professionals to identify reproductive health based upon one or more of: (a) Small amount of clear or slightly milky vaginal discharge (considered to be normal); (b) Menstrual cycle discharges; (c) Menopause discharges; (d) Infections or STD—sexually transmitted diseases—(much more discharge than normal, or discolored discharges). And in case of any observable discrepancies observed by the sensors or image comparison, during pregnancy or during normal occurrences of pre and post coitus (due to concerns about STD) or at all other periods, or upon periodic request by a health care specialist (gynecologist or obstetrician) (the device is remotely activated or placed into a mode of operation), the sensor readings and images obtained via the intravaginal monitoring device 1 are be utilized in taking precautionary actions or advise the female to seek medical professional intervention.

The intravaginal monitoring device 1 can communicate with the supporting infrastructures such as user’s MID (Intravaginal Monitoring Device) client systems 71, supporting server(s) 51 and/or supporting MID (Intravaginal Monitoring Device) client systems and devices 61 in many different ways: (a) A memory stick intravaginal monitoring device 1 and USB and or mini USB port within the client module (inside the personal computer 77 or mobile phone or smart phone) assist in viewing the data contents on the personal computer 77 and deliver directly to the supporting server(s) 51 and viewed through web pages. To enable this, the intravaginal monitoring device 1 contains a unique network ID; (b) The intravaginal monitoring device 1 are be plugged directly to a television 73 (or communicate with a wireless connection through an intranet wireless network connection or Internet connection) or personal computer 77 display using display management 10 and display driver (all of the software is driven by the display management 10); (c) The intravaginal monitoring device 1 are be plugged it into a personal computer 77 (and the personal computer 77 considers it as a memory device and copies all of the files and data from the
intravaginal monitoring device 1 to the personal computer (and optionally this can happen from the personal computer to the device 1 in another variant), the personal computer 77 uses memory device interface 85 to do this; (d) The browser goes on to query mode and the website or server 51 connects to the intravaginal monitoring device 1 and pulls out information data (female subject data with time and date stamped data, unit data, software version data, etc.); and (e) A served up web page, real server module 65 or locally populated server module to the female's name browser (without connecting to the supporting server 51) extracts information from the intravaginal monitoring device 1 (the client module 83 are not detect intravaginal monitoring device 1, it are be turned off). The data is pushed from device 1 in one variant onto the servers. In another variant, the data is pulled from the device 1 upon interrogation of the device.

[0108] These supporting local personal computing devices 71 are include cell phones 75, personal computers 77 and video recorder 79, or simply an access point, for instance. Exemplary phones include the Apple brand, iPhone, the Google brand, Android, and Blackberry branded phones. The intravaginal monitoring device 1, while inserted in place (inside the vaginal channel) or after usage and removal, allows an authenticated supporting personal computing device 71 to send control signals (as well as firmware and other logistical program codes) and receive images/video clips/sensor data and so forth from the intravaginal monitoring device 1. In one variant, the device 1 transfers and stores data in memory on the device 1 and has the wireless chip in standby mode or disabled mode. Once the device 1 is removed from the vaginal channel, the device 1 senses the removal of the device therefrom and once the device is outside the vaginal channel communication of the data via a wireless communication communicates the data from the device to remote devices. The data transfer mode of operation is also manually activated by the user once the device is outside the female’s body. In another variant, device 1 includes a sonogram mode of operation for imaging the position of the uterus head or other body parts. It is appreciated that periodic images are taken by device 1. These images provide useful data selected from the group consisting of the size and dimensions of the head or body parts of the body of the uterus, the location of the fetal head or other body part in relation to the female’s anatomy: etc.

[0109] In other words, the communication be initiated by the intravaginal monitoring device 1, upon removal from the vaginal channel, upon switching off the intravaginal monitoring device 1, upon memory full, upon emergency situations, and upon communication button press (if there exists one) by the user. These logistical codes are built into the intravaginal monitoring device 1; however, they might also be received from supporting servers 51, by request. The receiving of images/video clips/sensor data are also be initiated remotely by supporting servers 51 (as per certain logistics) or supporting intravaginal monitoring device client systems and devices 61 (as per health care professional’s instructions or commands from a device used by a health care professional, for instance).

[0110] To make all of the aforementioned functionality and flow of data possible, the intravaginal monitoring device 1 contains a head or cap 5, stem 3, 7 (that contains many of the electronic components including a display 13, some or all of the sensors and batteries), bottom cap 9 (that allows insertion and removal or recharging of batteries and exposes mini USB port for wired communications) and an on/off switch 15. The on/off switch 15 also allows independent selections of modes, wireless on/off, wired on/off (by keeping on clicking 15 until the mode is selected). It also contains a server module (SM) 11 and display management 10 unit.

[0111] The user’s IMD (Intravaginal Monitoring Device) client systems 71, in addition, contain server module 81, client module 83, memory device interface 85 and application programming interface 87. Similarly, the supporting IMD (Intravaginal Monitoring Device) client systems and devices 61 also contain server module 91, client module 93, memory device interface 95 and application programming interface 97. The supporting IMD (Intravaginal Monitoring Device) client devices 61, for instance, be a blood pressure monitor or thermometer, which could be in the patient’s or health care professional’s hands. Moreover, the sensor data can be supported by supplemental data, and the sensor data itself can be stored remotely from the support server(s) 51, a supporting management company such as 53, 55, 57 or supporting IMD (Intravaginal Monitoring Device) client systems and devices 61.

[0112] For instance, a female are purchase intravaginal monitoring device 1 kit, consisting of intravaginal monitoring device 1 as well as a dock where the intravaginal monitoring device 1 can be placed for charging and for communications (alternatively, communication are also occur while in vaginal channel). The female are also sign up with supporting server(s) 51, 53, 55 or 57 and in addition are also sign up for service from local/regional/remote health care professionals (which is possible via the supporting IMD (Intravaginal Monitoring Device) client systems and devices 61).

[0113] Then, to use the intravaginal monitoring device 1, the female are begin to follow the instructions provided within the intravaginal monitoring device 1 kit, from the supporting servers 51 and/or supporting IMD (Intravaginal Monitoring Device) client systems and devices 61 (via the health care professionals from whom the female has requested service). The instructions are be streamlined for various specific circumstances that include routine checkups, menstrual cycles, menopause, sexually transmitted diseases and pregnancy checkups (are also include pre and/or post coitus periods).

[0114] During the usage (while on continuously wearing) or after usage, depending upon the aforementioned specific circumstances, based upon the permission given by the female, the intravaginal monitoring device 1 are transmit the captured images/video clips/sensor data to the supporting server(s) 51 (via user’s IMD client systems 71 such as an access point, cell phone 75 or computers 77, for instance). Alternatively, the female are also opt to watch these images/video clips/sensor data all by herself and decide whether to send them to the support server(s) 51 (and then to the health care professionals via the supporting intravaginal monitoring device client systems and devices 61), make her own personal decisions, or discard the images/video clips/sensor data. These options are always available to the individual female.

[0115] Later, the female logs into her account in the supporting servers 51, selectively upload images/video clips/sensor data of interest to her or the health care professionals and then give permission to the supporting IMD (Intravaginal Monitoring Device) client systems and devices 61 of the health care professionals for further investigation (of a routine occurrence or a specific condition, for instance). Alternatively, the female are opt to access suggestions from other users, from another server (user forum servers, such as 53, 55, 57).
or 57, for instance) by sending certain information stored in her account in the supporting server(s) 51 (for no fees at all, for instance).

Once the health care professionals gain access to the images/video clips/sensor data, they are able to provide recommendations/treatments options via the same supporting server(s) 51 back to the female. These recommendations/treatment options are be informed via emails or directly via the supporting server(s) 51 (which is more secured). These cycles of monitoring and recommendations/treatments can be done routinely during routine checkups, menstrual cycles, menopause, sexually transmitted diseases and pregnancy check-ups (are also include pre and/or post coitus periods), thereby saving the time of the female and the health care professionals.

Note that in all cases of the female, the very same processes are applicable to female animals; in that case instead of female, the case would be that of a female animal in conjunction with its caretaker and the health care professional are be a veterinarian or artificial insemination technician.

FIG. 2 is a schematic block diagram illustrating various powering schemes for intravaginal monitoring devices, of the FIG. 1b. A typical intravaginal device 205 consists of a head or cup 207, a stem 209 and a bottom cap. Near the bottom cap, there would be an on/off switch that assists the user to switch on and off the intravaginal monitoring device 205 and also selects various modes. The modes are include WiFi on/off, WiMax on/off, various sensors on/off selections, so forth.

As depicted in the intravaginal monitoring device 225, the bottom most part of the stem contains batteries 227. Batteries 227 can be inserted or removed by unscrewing the stem bottom cap 229 (that also contains on/off and mode switch 231), or be rechargeable batteries. Still further down the bottom most part is an unscrewable cap 233, which when unscrewed exposes a mini USB communication port or other suitable communication port. This port assists in communicating with local external devices or external servers via an access point. Alternatively, the bottom part are also consist of a WiFi port, in which case the bottom cap 233 acts as a battery 227 insertions or removal opening.

The depiction 245 shows a rechargeable battery 247 variant of intravaginal monitoring device 245 that comes with a cord 253 to charge the battery 247. The depiction shows a WiFi communication variant (other exemplary variants include WiMax communication functionality and circuitry, cellular phone communication functionality, Bluetooth communication functionality, etc.), but the unit are also have a mini USB port (which exposes itself when the bottom cap 249 is unscrewed). The depiction also shows an on/off or mode selection switch 251.

Finally, the depiction 265 shows another variety of intravaginal monitoring device 265 that comes with a recharging dock 283. When the intravaginal monitoring device 265 is not in use, it can be docked in the recharging dock 283 and after few hours of charging of the batteries 271, the intravaginal monitoring device 265 is ready for use again. The depiction 265 also shows placements of few of sensors 267, 269, 279 and recharging plugs 281.

FIG. 3 is a schematic block diagram illustrating various sensor placement schemes for intravaginal monitoring devices, of the FIG. 1b. In specific, the depictions of 305, 325, 345 and 365 show placements of (video) camera 309, 347, sonogram 315, 335, electrocardiogram 331, pressure 329 and temperature 327, 349, 367 sensors and user interfaces that includes an on/off/mode selection switch 313, 333, 353, 373.

In other words, the illustrations 305, 325, 345 and 365 show placement of electronic components, as they appear externally. The electronic components that appear from one side of the wearable (used for longer term monitoring) or non-wearable (in another variant) intravaginal monitoring devices 305, 325, 345 and 365 include conductive rings 331 (the top one being on the surfaces of the cup or head 307 or 337; through which electrical potential can be measured, for instance, in case of pregnancy, baby’s EKG), electrolyte, PH, glucose sensors 311 (these sensors, in reality, are not co-located), infrared temperature sensor window, plate for thermal temperature sensing 327, 349, 367, microphone 315 (for instance, piezo) affixed to either the inside or the outside of the cap (such that cap amplifies mother-fetus heartbeats or infant movement sounds), hermetically sealed on/off switch with fingertip texture 313, 333, 353, 373, light emitting display (for instance, indicating green on ready; red on servicing required—battery, storage full, etc.; no light indicating power off and so forth), and mini-liquid crystal display. Also note that all sensor positions illustrated are merely illustrative; any sensor could be located anywhere on intravaginal monitoring device housing or there within (if operational), or externally thereof. The depiction 345 also show bottom cap 359 that can be sealed while screwing back 355 (with a washer 357 that makes the intravaginal monitoring device 345 water resistant/proof).

FIG. 4 is a schematic block diagram illustrating fluid flush cleaner on the surface of the cap that cleans both the surface of the cap and the target area of intravaginal monitoring devices, of the FIG. 1b. Specifically, the illustration depicts typical placement of few of the electronic components 419, 423, 425, 427, 457 within the hermetically sealed transparent cap 413, 453 and stem 421 that includes camera, an infrared thermometer and other sensors, processing circuitry and memory, communication and user interfaces and batteries 425, and a fluid flush cleaner 415, 455 on the surface of the cap 413, 453. The electronic components are placed over one or more circuit boards, such as the 419. The circuit boards 419 hold most of the electronic components that capture images and take sensory readings (from the front side of the outer surface of the cervix).

The illustration also shows a fluid tube 427, 459 for lens cleaning or sperm injection; whereas the depicted fluid tube 427 is built internal to the intravaginal monitoring device 443, the fluid tube 459 is built removable outside of the intravaginal monitoring device 473. Note that the squeeze rubber bulb/ball 429 are either be filled with vinegar and water type solutions; alternatively, a syringe containing cleaning solution (or, sperm injection) as well is used. Moreover, the syringe attachment could also be used to deliver drugs. Likewise, instead of the exterior tube 427 cleaning solution/sperm/drag could be stored in interior intravaginal monitoring device 473 cavity (for instance, within the stem 421), with an injection grommet for initial delivery and pumping (or a pressurized cavity and valve). In addition, drain holes (when the cleaning system 429, 427, 459 and 415, 455 is not used as a sperm delivery device) can be added to the cap 411 for cleaning fluid delivery and vaginal-uterus discharges. Also note that the tube 427 can assist in device insertion-removal.
FIG. 5 is a schematic diagram illustrating placement of the intravaginal monitoring device 511 of FIG. 1b, placed so as to face the outer surface of the cervix 543; wherein the device’s cap or head 513 takes images of the outer surface of the cervix 543 as well as sensor readings via many other built-in electronic sensors, to monitor the well being of a female (and developing fetus in case of the female being pregnant).

Including during pregnancy, a female person’s reproductive health is observed using the intravaginal monitoring device 511, directly or indirectly (by a gynecologist or obstetrician, to determine the health conditions), include Vulva 521, Vaginal Channel 531, Exterior Portion of Vaginal Channel 533, Interior Portion of Vaginal Channel 535, Cervix 541, Outer Surface of Cervix 543, Exterior Orifice (opening) of Cervix 545, Interior Orifice 547, Cervical Channel 549, Uterus 551, Fallopian Tube 561, and Ovary 571.

The intravaginal monitoring device 511 itself contains a cap or head 513 (that contains most of the built in electronics), stem 515 (that aids in user insertion/removal and stabilization/orientation during wear) and bottom cap (or, finger ring) 517 that assists insertion/removal. The stem 515 are, in some configurations, also contain built in electronics. The cap 513 and stem 515 are include one or more of camera and illumination system, sensors, user interfaces, power management system, communication interfaces. The sensors include temperature sensors, pressure sensor, glucose sensor, pH sensor, EKG sensor, and somogram sensor. Other sensor systems that assist in determining other gynecological conditions (and in cases of other needs for physiological reproductive data) are also contemplated. The intravaginal monitoring devices 511 are inserted in one variant by applying some lubricant on the surface of the cap 513.

Features that are incorporated in various embodiments of the intravaginal monitoring device 511 of the present invention include: (a) a Camera unit containing wide angle lensing as well as “fish eye” lensing and image recovery; (b) Transparent latex or other biocompatible material is used to cover the device for use and to protect the lensing cap of some of the designs (this also extends the life of the medical grade rubber device); (c) Time stamping sensor data capture (to be able to follow up and investigate the vaginal conditions by a health care professional) is also provided in another variant; (d) Live video is used for guidance of the device into place and proper orientation for imaging desired anatomy; and (e) Linear, symmetric device with a very flexible neck and stem to assist in fitting the space; and (f) Making the intravaginal monitoring device able to bend and face toward cervix (straight ahead, in a line of sight; note that a female moves the intravaginal monitoring device 511 to orient it properly, in an optional audible or visible alert is given to the user once the device detects it in a mode of operation that provides device assisted positioning—this can also be accomplished by viewing the images in an external device or with an algorithm on the device indicating to the user the device is properly imaging).

In addition, there are two exemplary variants of the intravaginal monitoring devices 511, the first one that is wearable (for continuously wearing during night or other periods, and for long term monitoring) and the second one is non-wearable (for shorter term monitoring and quick assessments at the gynecologist’s presence, for instance). These two types come in different shapes and sizes, depending upon their applications and the anatomy or events to be monitored in the female. One or more portions of the device are composed of medical grade silicon for flexibility and adjustability of the cap or head or other suitable metal biocompatible material or plastic, material, to snugly but comfortably fit into the cervix area 543. Other types of plastics or rubber are also used herein, including hypoallergenic materials. Moreover, the cap 513 (or head 513, shaped like a bulb) appear to be made of a flexible, medical grade silicon rubber cap, with most of the electronics located in the bottom of the cap or inside of the stem and in one variant, the user interfaces are visible externally (for the images and sensor readings to be transmitted to a video system such as phone, camera, television, computer and so forth, or transmitted to a health care center via Internet and a server). All of the electronics and user interfaces are placed within the hermetically sealed areas of the intravaginal monitoring device 511, so as to be able to handle vaginal discharges, and then be able to wash and clean after use.

FIG. 6 is a schematic diagram illustrating the components of the intravaginal monitoring device of FIG. 1b (that may be found in exemplary intravaginal monitoring devices such as those found in FIGS. 1-5). The intravaginal monitoring device 611 contains wired or wireless communication interfaces 661 as well as firmware and program & operational logic codes 693 that makes it possible for the intravaginal monitoring device 611 to communicate with the local external electronic devices as well as receive control signals via (immediate) external electronic devices. Moreover, the intravaginal monitoring device 611 also contains memory 681, processing circuitry 641, displays 663 and user input devices 665. The memory 681 additionally contains network management module 683, display management module 685, application programming module 687, external memory management module 689, 1MD server module (SM) 691, sensor data 695 and workspace 697.

Firmware and program & operational logic codes 683 allow the intravaginal monitoring device 611 to perform in accordance with specific logic that includes: (a) Receiving and/or executing instructions, in case of wearable intravaginal monitoring device 611, as to when to switch on and off functionality on the device, when and at what points in time to take images/video clips/sensor data, and at what interval they should be taken; (b) Receiving and/or executing instructions to vibrate/beep, and then, switch off and transfer data to an external device or external servers (such as after enough data to make diagnosis has been taken and it is time to switch off until some other time or in emergency situations such as sometime before delivery of a baby); (c) Receiving and/or executing instructions that involves exceeding limits in cases of sensor data; and/or (d) Monitoring the battery operations and informing the user to recharge batteries, if need be, and so forth.

The sensors and devices that are incorporated into the intravaginal monitoring device 611 include components of one or more of: (a) UV and IR emitter and detectors 621, to monitor temperature; (b) Piezo microphones and speakers 623, to monitor heartbeat sounds of fetus, for instance; (c) Electrolyte and EKG interfaces 625, to take electrocardiogram graphs of heartbeat of a fetus, for instance; (d) Pressure transducers 629, to make pressure measurements within the intravaginal channel, to monitor dilations, for instance; (e) Thermal contact assembly 631, to take temperature measurements in cases of wearable intravaginal monitoring device.
611, for instance; (f) Glucose sensor 633, to take glucose measurements; (g) PH sensor 635; and/or (h) Sonogram head unit 639.

[0134] In all of the above-mentioned sensor cases, a processing circuitry 641 executes, as mentioned above, the operational logics, and takes measurements at appropriate intervals and also verifies if the limits are exceeded and precautionary actions should be taken. Other components of the intravaginal monitoring device 611 depicted include normal (infrared and ultraviolet) illuminators 667, fixed-manual-auto focus lensing 669, a bunch of photodetector arrays 673, 675 (or one or more arrays positioned at predetermined locations on the device) and fixed-manual-auto focus microscopic lensing 679. The wired and wireless communication interface circuitry 661 also contains: (a) Display interface 649, to support on-screen displays on external monitors, for instance (on a smartphone or other mobile communications device, e.g., two-way); (b) External memory interfaces 643, to interface with external computers and deliver the memory contents; (c) Communication interface 645; and/or (d) Application program interface 647, alone or in combination.

[0135] Although the intravaginal monitoring devices 611 show a variety of basic types of functionalities, a variety of other intravaginal monitoring devices 611 (shown FIGS. 1 through 5, for example) may also be built with all of those functionality or some portions of them, still others may also be built with further functionalities, such as having more sensors, more photo sensor arrays, or illuminators and so forth.

[0136] The intravaginal monitoring device 611 is used to gather sensor information from the variety of sensors illustrated when the intravaginal monitoring device is at partially inserted into the vaginal channel. For example relating to an imager (i.e., the photodetector array 673), the processing circuitry 641 receives user input from the user input devices 665 and responds by (i) delivering power from the batteries 653 to at least one of the illuminators 667, and (ii) producing a control signal delivered to the photodetector array 673 directing that imager data (still images and/or video data) is to be captured. The photodetector array 673 responds by capturing reflections of the illumination from the target area (e.g., a cervix), and delivers such imager data captures to the processing circuitry 641. Also, in addition to performing the above behavior in response to the user input, the processing circuit 641 can also do so in response to control signals received via the communication interface 645 from external devices. Although described in reference to the photodetector array 673, such operations performed by the processing circuit 641 apply equally to all other sensors of the IMD 611.

[0137] The processing circuitry may a) send the imager data (or a processed version thereof) to the display 663; b) store the sensor data along with previously captured imager data within the sensor data 695 of the memory 681; c) forward the captured imager data via the communication interface 645 (in real time during the capture process or otherwise) to external supporting devices; d) process the imager data to produce measurement information for use in the above a-c; and e) perform at least a portion of the analysis engine functionality. Whether or not the processing circuit 641 performs such elements a-e above depends on the particular configuration of the IMD 611, and may vary pursuant to configurable modes of setup that is maintained by the operational logic 693. Such modes can be set via the user input devices 665 or via control signals originating, for example, from an external supporting computing device via the communication interface 645. Although described in reference to the imager data captured by the photodetector array 673, such operations performed by the processing circuitry 641 apply equally to all sensor data captured by the various other sensors of the IMD 611.

[0138] Thus, the IMD 611 can operate in an independent mode and under control of the processing circuitry 641 pursuant to the program and operational logic 693 within the memory 681. All control signaling in such mode originate within the IMD 611 and, at times, in response to the user input devices 665. However, the IMD 611 as shown can operate in a dependent mode wherein various control signals originating from other supporting devices outside of the IMD 611.

[0139] Switching between independent and dependent modes can occur automatically or require further control signals that direct the switch. For example, in one mode of operation (via configuration or setup), the IMD 611 begins operating in the independent mode. During such independent operations, an external control signal is received via the communication interface 647. In response to the receipt, the IMD 611 enters a controlled mode to carry out the underlying task. After such task is completed, the IMD 611 returns to the independent mode to continue locally directed operations. Alternatively, the IMD 611 can be placed in a slave mode wherein no functionality is performed without direction from externally originating control signals. That is, the IMD 611 can wait (e.g., in a low power, idle state) for external control signals. Upon receipt, underlying procedures are carried out and, once completed, the IMD 611 returns to the idle state awaiting further instructions (i.e., awaiting further control signals from an external supporting device).

[0140] The program and operational logic 693 (of the memory 681) consist of operating instructions that direct the processing circuitry 641 in carrying out the various independent and dependent modes of operation. Moreover, the program and operation logic 693 defines processes for the selection from the plurality of modes and switching there between. As mentioned, such definition involves, for example, responding to the user input devices 665 and to incoming control signals from external supporting computing devices. In addition, the IMD 611 can be placed in various initial modes of operation (either via the user input devices 665 or via externally originating control signals) in advance of input or at any time thereafter by, for example, setting parameters within the memory 681 that are used to configure the operating instructions of the program and operational logic 693 for use by the processing circuitry 641.

[0141] Thus, the program and operational logic 693 may have a plurality of operational procedures from which a user of the IMD 611 or a user of a supporting external device can select and configure. Some of the operational procedures may be tuned to service particular physiological aspects of the specific reproductive system under service. One procedure, for example, might involve using a first type of illuminator and corresponding imager, while another might involve a different group of sensors entirely and so on.

[0142] FIG. 7 is a schematic diagram illustrating data 755 flow between each of the plurality of intravaginal monitoring devices 719 and various systems or devices 711, 713, 715, 717, 721 within the supporting network infrastructure. Within the supporting infrastructure, there are various entities such as the 711, 713, 715, 717, 721, all of which in a centralized or distributed form hold sensor data (sensor information/query
information) from a plurality of intravaginal monitoring devices 719. Also note that each IMD of the plurality of IMDs 719 is used to monitor a corresponding one of a plurality of female reproductive systems under service. The

In addition, the data/information 755 also contains data generated via queries, as remedies to various reproductive health related issues or as data collected from auxiliary devices (such as blood pressure, heart rate, blood chemistry, physiological parameter inputs), IMD systems/devices inputs 713, user IMD support systems/devices 717, practitioner’s supporting systems/devices 715, pharmaceutical computing systems/devices 721 and central supporting systems 711 (or in another variant distributed computing systems including but not limited to cloud networks).

Each of these entities is responsible for dissemination of information/data 755 and they flow with permission from the respective entities 711, 713, 715, 717, 721, 719 in an encrypted form. These data or information flow in turn assist IMD systems/devices inputs 713 develop new medicines, user IMD support systems/devices 717 to take care of the data and avail user forum suggestions and recommendations, practitioner’s supporting systems/devices 715 to provide treatments to the users of IMD 719, pharmaceutical computing systems/devices 721 to develop or recommend medicines and central supporting systems 711 to possibly govern and control all of the movements of data and information in a secured manner.

The supporting devices, e.g., the devices 711, 713, 715, 717, 721 establish communication with each of the plurality of IMDs 719, for example, to retrieve sensor data therefrom. Such retrieved data can be stored, analyzed (analysis engine functionality) and displayed along with any reproductive system status generated. The communication between such supporting devices can be direct point to point links or involve network routing, both via wired and/or wireless infrastructures. The sensor data retrieval and storage can be repeated to cover the many sessions (e.g., insertion sessions) carried out by each of the plurality of IMDs 719. The display presented can illustrate differences by merely simultaneously presenting data from, for example, a first session and a second session that is perhaps gathered weeks later. Moreover to assist in detecting the differences, analysis engine functionality can be applied and resulting output can be also presented so that a viewer can easily and fully appropriately appreciate the underlying changes. Such presentations may involve historical tracking of features, overlays, highlighting, etc.

FIG. 8 is a schematic diagram illustrating a snapshot of one of the reproductive health care management web pages or system interfaces of FIG. 1b, wherein the snapshot depicts a user’s data view page. The snapshot of the user’s data view page of the reproductive health management system 811 depicts data view page of the current registered user. Additionally, all of the available user’s pages include records, queries, electronic mail, forum, research, accounts, IMD setup, support, educational, tutorial and shopping, among others (depicted in the FIGS. 9 through 17). All these user’s pages assist in making the intravaginal monitoring device functional in very specific ways that are designed to assist follow up of routine reproductive health care or a specific reproductive health care related condition.

The snapshot depicts, in all four major windows. The right side window, named as “Time Position Status”, shows various sensor boxes as applicable to the current device. Hence, the Time Position Status window are consist of temperature, viscosity, acidity-PH, electrolytes, heart rate, fetal rate, dilation, cervical face, vaginal channel, user symptoms and so forth (along with a notes text box). Any of these selected sensor data/information is pictured in the left side graphical window (which are show live sensor data or select group of sensor data in a time lapse sequence) and/or image window (which are show live video or select group of images in a time lapse sequence). These windows appear on a smart phone or phone in one variant, in full or condensed format, and on various tabs or pages that are opened on the smart phone.

A chronological time line chart bar/marker (shown as a dashed straight line in the graphical window) shows the data/information about the selected sensors at the Time Position Status window. The corresponding image or video clip is shown on the top-left window. Shown on the top of this image window is the time limit, that is, begin and end times as well as the current position. This current position is selected by using marker at the bottom graphical window (chart bar/ marker shows exact time line and allows user to drag left or right).

Moreover, the snapshot also shows a tool box, containing various tool icons, that includes magnify, mark, select, notes for the current image and general notes, mail, database storage and so forth. A small tool bar at the top of these icons is associated with the video and image displays and allows the user to playback, start, stop, pause, fast forward, fast reverse the displayed video images.

Additionally, all of the available user’s pages, such as the records, queries, mail, forum, research, accounts, IMD setup, support and shopping, among other pages (depicted in the FIGS. 9 through 17) also contain tool boxes that are enabled by clicking on the “Tools” icon. The client’s browser 825 (which can be the user, third party or the health care professional, for instance) also shows a status bar indicating current IMD status 813 and on line status 815. For instance, the current data points of the graphical window, shown in dashed lines are for normal female data, e.g., normal within medical ranges, along with the current user data. Similarly, the tool bar allows zoom in or out a select area, cut and mark a select area to show gynecological or obstetrics notes add notes to them, and then, store those images in the database and mail them if necessary (the user are write a small note such as “Is this normal?!” and send the current image via email). A small button or icon or tab on the right side of the graph allows the graphical window to be collapsed.

FIG. 9 is a schematic diagram illustrating a snapshot of one of the reproductive health care management web pages or system interfaces of FIG. 1b, wherein the snapshot depicts user’s record page. This simple records page 911 contains listing of all of the various types of available intravaginal monitoring devices (such as LUM-F106, LUM-G133A) as well as other work records of the current user (such as query: user or query: doctor). All these records are listed in the current record page. Again, these web pages appear on a standard PC or laptop in one variant, or in another variant appear on a smart phone screen, alone or in combination with the same views or views created or adjusted for presentation on the appropriate remote device, e.g. PC or smart phone.

The record page also is provided with many buttons (displayed at the bottom) that allows the user to view, search, delete, select all or clear selections. Each of these displayed records contains date, duration (if applicable, as in the case of video clippings), description and a select check box fields. These fields assist the user in remembering the contents as...
appropriate and to select a relevant record for detailed viewing (shown in FIGS. 10a and 10b).

[0153] To view any of the records, the user is click on the select box on the left side of the record and then click on the view button, which takes the user to the next pages depicted in FIGS. 10a and 10b. Additionally, all of the available user’s pages, such as the records, queries, mail, forum, research, accounts, IMDb setup, support and shopping, among other pages (depicted in the FIGS. 9 through 17) also contain tool boxes that can be enabled by clicking on the “Tools” icon such as 927. The client’s browser 925 also shows a status bar indicating current IMDb status 913.

[0154] FIG. 10a is a schematic diagram illustrating a snapshot of one of the reproductive health care management web pages or system interfaces of FIG. 1b, wherein the snapshot depicts a user’s queries page. The queries page provides all the data records listed in rows, each containing the fields of select, category, subcategory, last (sensor readings), due (date of sensor readings), and estimate (sensor reading take time). The query pages permit a user of health care professional to augment data from the intravaginal monitoring device, with other data relevant to a diagnosis or tracking of a female medical event or condition, and provide for more facts upon which a diagnosis or tracking of a condition of an event can be made by the user or medical professional. The device and method herein are used to create or augment an electronic medical record for a user which can be stored on the device, on a smart phone communicatively linked to the device, or at a remote database to which this electronic medical record data is sent.

[0155] These fields allow the user to select a particular record (such as an ovulation electronic medical record data) and then communicate the data to whichever server/systems that the user intends to send queries to. The major categories are predefined such as ovulation, coitus, impregnation, 1st, 2nd, 3rd trimester, postpartum, STD-detect, cervix-artifact, measurement, background and so forth, in one variant of the invention. Similarly, a subcategory is also predefined, to assist the user to quickly determine the query to be sent, for instance, to a health care professional. The last date of the sensor reading taken and due date of sensor readings to be taken are also preprogrammed, with the help of a health care professional for instance, to further assist the user.

[0156] At the bottom of the queries page, buttons are provided to initiate a query, view last query, delete, select all and clear selection. These buttons allow the user to further the proceedings from the listing toward reading and communicating with the relevant health care professional, a user forum, R&D of a medical device manufacturer computer system, or pharmaceutical manufacturer computer system, or pharmaceutical personnel. All of the available user’s pages, such as the records, queries, mail, forum, research, accounts, IMDb setup, support and shopping, among other pages (depicted in the FIGS. 9 through 17) also contain tool boxes that can be enabled by clicking on the “Tools” icon. The client’s browser 1025 also shows a status bar indicating current IMDb status 1013.

[0157] FIG. 10b is a schematic diagram illustrating a snapshot of one of the reproductive health care management web pages or system interfaces of FIG. 1b, wherein the snapshot depicts user’ queries page. This query page 1051 allows the client (which can be anyone who has the access to these queries, including the user, users of a forum, health care professional, R&D and pharmaceutical personnel) to read query messages and reply to them (in the next mail window of the FIG. 11), if necessary. Query pages include entry pages regarding a history of sexual activity, the name of the patient, insurance information, week of pregnancy information, consulting physician information, primary health care provider information, IMDb information, social security number information, national health care information, method of payment information, credit card information, family member information, insured information, type of insurance policy information, number of pregnancy information, date of last menstruation information, allergy information, allergy to drug information, previous abortion information, number of children information, the ability for the patient to take a photo icon and include it in the electronic medical record profile, electronic medical record information, the ability to download electronic medical record information from a remote source connected to the Internet, information about a woman’s moods or feelings, information about the tenderness of a woman’s breasts, information about the sensitivity of a woman’s nipples, bloating information, history of see partner information, name of sex partner information, marital status, history of sexually transmitted disease information, history of therapy information, current drug intake information, history of and sex information, number of sex partner information, history of previous gynecological or obstetrics events or conditions, history of endometriosis information, and an relevant information that would assist a physician to make a diagnosis, and or provide a treatment for a condition or event. The query page answers are stored on a smart phone described herein, on a memory of said intravaginal device, on a remote database communicatively linked to these devices, alone or in combination.

The query information as well as information harvested by the intravaginal device, e.g. all or select portions thereof, are selectively, on any one of these devices and databases, alone or in combination.

[0158] The listing in this page have the columns of select, category, by (sent by), usage, Q# (query number), description and Q-Trigger (that is, in response to which query). The client can read these short messages on the window at the bottom along with any attached notes. At the top of the page, many links are also available that assist the user in searching, sorting and also quickly find the messages. These links include predefined queries, query builder, reports, database chart and display. The query page also provides buttons at the bottom that includes view, add, search, delete, edit, initiate and hide detail. Among other actions (similar to those in the query page of the FIG. 10a), the buttons also allow the user to initiate a new query via the next mail page of FIG. 11. All of the available user’s pages, such as the records, queries, mail, forum, research, accounts, IMDb setup, support and shopping, among other pages (depicted in the FIGS. 9 through 17) also contain tool boxes that can be enabled by clicking on the “Tools” icon. The client’s browser 1055 also shows a status bar indicating current IMDb status 1053.

[0159] FIG. 11 is a schematic diagram illustrating a snapshot of one of the reproductive health care management web pages or system interfaces of FIG. 1b, wherein the snapshot depicts user’s mail page. The client’s mail page is a typical mail page that contains an inbox, and categories of sent, draft, trash, compose, select all, clear all and search. These assist in performing any of the mentioned tasks that includes searching through the inbox or other groupings.

[0160] The mail page contains the columns of select, from: category (such as gynecologist, obstetrician, pharmaceutical,
R&D and so forth), from (the name of the sender), regarding (subject of the communication sent), date, views, query, other.

The user are view any of the messages by selecting them and the bottom window displays the corresponding message. These messages are be general, sent for instance by a gynecologist or obstetrician to all of the patients or be specific, sent only to the client. The message window also shows attachments, if there are any (such as an image of a healthy reproductive parts to a patient who would like to know whether a particular condition is normal or not). These attachments also include word processed documents, electronic digital photos (e.g. historically taken images by the intravaginal device), etc. The intravaginal device, and or smart phone then processes real time or near real time data with historical data, e.g. images, and displays the images, e.g. or other sensor data, side by side on a display of the smartphone or PC. The algorithms described herein can perform a comparison and highlight discrepancies or changes in the images and sensor data automatically in one variant of the invention. All of the available user’s pages, such as the records, queries, mail, forum, research, accounts, IMD setup, support and shopping, among other pages (depicted in the FIGS, 9 through 17) also contain tool boxes that can be enabled by clicking on the “Tools” icon. The client’s browser 1225 also shows a status bar indicating current IMD status 1107.

FIG. 12a is a schematic diagram illustrating a snapshot of one of the reproductive health care management web pages or system interfaces of FIG. 1b, wherein the snapshot depicts user’s forum page. The forum page 1205 of the user or client is meant for the clients (which includes users of the IMD) to read the contents of the postings by other users as well post one’s own messages (and read responses for those postings).

The forum page is designed on the basis of categories such as news, obstetrics, gynecology, support, IMDS, shopping, account, search (and logout, once the reading and/or posting is accomplished). Each of these categories come with their own subcategories such as general discussions, family planning, abortions, the physiological effects of abortions, adoption options, miscarriage, first, second, third trimester, sonogram and complications. These postings are arranged in rows, each row containing the above mentioned subcategories, while the columns are arranged by contents such as obstetrics (a main category) and posts (that is, number of posts) and recent posts (most recent relevant posts that might be of interest to the user; displayed with subject head, date/time of posting). Clicking on one of the subcategory entry such as general discussions takes the user to a next page depicted in the FIG. 12b. All of the available user’s pages, such as the records, queries, mail, forum, research, accounts, IMD setup, support and shopping, among other pages (depicted in the FIGS, 9 through 17) also contain tool boxes that can be enabled by clicking on the “Tools” icon. The client’s browser 1225 also shows a status bar indicating current IMD status 1207.

FIG. 12b is a schematic diagram illustrating a snapshot of one of the reproductive health care management web pages or system interfaces of FIG. 1b, wherein the snapshot depicts user’s forum page. The depiction shows a page that the user arrived into, by clicking the general discussions subcategory in FIG. 12a and the current page provides facilities to search, go back to forum home page or logout. The general discussion entries are arranged in rows, each row having columns such as title (or, subject head), latest reply (are in response be to the user’s own postings previously), by (those who responded), replies (number of replies), views (number of people who viewed the corresponding posting). All of the available user’s pages, such as the records, queries, mail, forum, research, accounts, IMD setup, support and shopping, among other pages (depicted in the FIGS, 9 through 17) also contain tool boxes that can be enabled by clicking on the “Tools” icon. The client’s browser 1225 also shows a status bar indicating current IMD status 1207.

FIG. 13 is a diagram illustrating a snapshot of one of the reproductive health care management web pages or system interfaces of FIG. 1b, wherein the snapshot depicts user’s research page. The research page 1305 of the client is reserved for the clients to read the contents of latest research postings by research establishments. This is of particular interest to those users who are undergoing treatments for a certain condition, for which new research and developments by various institutions and organizations (that includes medical schools, for instance) have been going on. Hence, the user is able to get all these research and developmental information in one convenient place. This information is optionally displayed on the smartphone screen in one or more pages permitting the user or medical professional to truly be informed about the best and most innovative options of therapy for a given event or condition, long prior to coming to the doctor for consultation. It is appreciated the device and system described herein creates a truly knowledgeable female about her own body and the events and conditions that are affecting it, including infectious diseases in obstetrics and gynecology.

The research page contains categories such as professional publications, peer reviewed journals news, obstetrics publications, gynecology publications, pharma publications, IMD data, accounts functionality, account functionality, search functionality (and logout, once the reading and/or posting are accomplished). Each of these categories come with their own subcategories such as a published medical database data and information, rapid research notes, obstetrics today, pregnancy magazines, mothering magazines, STD related magazines, and newsletters (e.g. published magazines), British medical journal (are be published magazine), webmd.com (are be an on line publication organization) and so forth. These postings are arranged in columns, each column is arranged by contents such as obstetrics (a main category) and overview (that is, brief explanation of the subcategory). Clicking on one of the subcategory entry such as general discussions takes the user to a next page containing detailed entries from the same institutions or organizations. This information is displayed on a PC related device or on a smartphone in an appropriate format. It is appreciated that the intravaginal device sends data to a remote node on the network regarding the female’s particular condition or event. This data is then used to select the appropriate return information feed so that only relevant information and or website links for the female is transmitted back to the smart phone or laptop to educate the female or the medical professional as to the condition. Similarly, in another variant, where the user of the methods and system described herein is a medical professional, information or web site links regarding current treatment protocols, drug therapies, complication information for the condition or event are sent to from a node on the network and provided to the medical professionals.
smart phone or PC for display thereon. It is appreciated that the medical professional and the female has access to state of the art drug therapies, new treatment technologies, treatment protocols approved by professional organizations, IVF procedures, costs and the like.

[0167] All of the available user's pages, such as the medical records, queries, mail, forum, research, accounts, IMD setup, support and shopping, among other pages (depicted in the FIGS. 9 through 17) also contain tool boxes that can be enabled and/or disabled by clicking on the “Tools” icon. The client's browser 1325 also shows a status bar indicating current IMD status 1390.

[0168] FIG. 14a is a schematic diagram illustrating a snapshot of one of the reproductive health care management web pages or system interfaces of FIG. 1b, wherein the snapshot depicts user's account page. The user accounts page 1405 maintains user's personal information, some of which are be made available to health care professionals (in case of treatments for a condition is sought) and other login information to various user forums, R&D pages, shopping, mail and VoIP phone facilities. These web pages are presented on a smart phone, PC, workstation to appropriate users, e.g. a female, a sex partner, a medical professional, an obstetrician, a gynecologist, a hospital administrator, an insurance company employee or consultant, a researcher, an engineer, a medical device company individual, etc. The web pages permit a female or other party described to manage the woman's gynecological and/or obstetrics health throughout her lifetime, e.g. from early years of life through end of life.

[0169] The user information itself, e.g. as input on a query page (e.g. on a smart phone or PC) contain name (first, middle, last), address, city, state/country, zip codes or postal codes, phone numbers and email addresses, e.g. including the female patient, the doctor, the midwife, the hospital admissions staff, a nurse, an insurance company. This information, with user permission, are be made available to other entities (such as health care professional nodes, R&D establishment nodes, pharmaceutical company nodes, insurance provider nodes, National Health Care System nodes on the network described herein and so forth; described with reference to the FIG. 7). In addition, user information and data also include login information that assists the user to quickly login without entering user name (handle) and password each time. The login information and data contain a login handle (user name or userID), a password, website (to which the user has subscribed) or which is entered automatically by the smart phone or intravaginal device, and include a select box that lets the reproductive health care management software and node know and interpret whether an auto login mode of functionality is enabled.

[0170] A “Related Medical Information” button allows the user to enter personal medical information (described with reference to the FIG. 14a) that is made available to health care professional nodes, R&D establishment nodes, pharmaceutical company or supplier nodes and so forth, as well. All of the available user's pages, such as the records, queries, mail, forum, research, accounts, IMD setup, support and shopping, among other pages (depicted in the FIGS. 9 through 17) also contain tool boxes that can be enabled by clicking on the “Tools” icon. The client's browser 1425 also shows a status bar indicating current IMD status 1407 and on line status 1409.

[0171] FIG. 14b is a schematic diagram illustrating a snapshot of one of the reproductive health care management web pages or system interfaces of another variant of FIG. 1b, wherein the snapshot depicts user's account page. The Current user accounts page contains same personal information as in the case of FIG. 14a, such as the name (first, middle, last), address, city, state/country, zip codes, phone numbers and email addresses; and in addition also contains related medical information about the IMD user, identifier data of the specific intravaginal device, e.g. serial number, user profile, etc.

[0172] The related medical information are includes but is not limited to, age, height, weight, prior known related conditions, cholesterol, other information, blood group, blood pressure, lower waist line circumference, belly button waist circumference, under breast circumference, breast- chest circumference, week of pregnancy, and so forth, including the other information described herein; any or all of which are gathered from queries (by the health care professionals, for instance) or extracted from a remote medical records archive node on the network described herein.

[0173] All of the available user's pages, such as the records, queries, mail, forum, research, accounts, IMD setup, support and shopping, among other pages (depicted in the FIGS. 9 through 17) also contain tool boxes that can be enabled by clicking on the “Tools” icon. The client's browser 1457 also shows a status bar indicating current IMD status 1453 and on line status 1455.

[0174] FIG. 15a is a schematic diagram illustrating a snapshot of one of the reproductive health care management web pages or system interfaces of FIG. 1b in another variant of the system and network, wherein the snapshot depicts user's IMD setup page. IMD setup page 1505 can be exhaustive, nonetheless, many of the information are be filled in automatically by auto detect and remotely by health care professionals opting for a follow up of a particular medical condition (by downloading a condition follow up firmware, for instance). The user then onwards are simply have to follow up the instructions provided in the data view, records or queries pages. In yet another mode of operation of the invention, the system and network include a mode of operation in which historical female health condition information, e.g. electronic medical records of different medical professionals are harvested from many different nodes on the network where they reside in databases so as to provide a complete profile of the female from the medical records point of view.

[0175] A typical IMD set up page contains columns such as select (to select a particular model and version or firmware), model, version, support site (where additional help and firmware are be available) and description (of the follow up firmware, connection type—wireless or wired, type—wearable or non-wearable and so forth). This information also comes up with auto detect, add and delete buttons and modes of operation to take appropriate actions.

[0176] Once selected or auto detected, the bottom half of the page provides various configurations. As mentioned above, these are also be automatically opted by the user or remotely by a support server, based upon the type of usage (such as pregnancy-follow-up, for instance). The depiction shows the configuration information for a particular model such as LUM-F106 and IMD status (inserted), battery levels, memory available, wireless reception (in this case of tethered wiring, it is N/A—not available). It is appreciated that the system, methods and network of the present invention provide for an automatic set up mode for the user, e.g. on the smart phone or PC, that is a function of the condition or event the female is currently being treated for or experiencing.
Other configuration modes include operational modes, video camera mode, temperature mode, wearable duration and indications (along with buttons that assist in settings, update, visit support, order kits, manual and test the device). The settings button or icon takes the user to a next IMD setup page. All of the available user’s pages, such as the records, queries, mail, forum, research, accounts, IMD setup, support and shopping, among other pages (depicted in the FIGS. 9 through 17) also contain tool boxes that can be enabled by clicking on the “Tools” icon. The client’s browser 1525 also shows a status bar indicating current IMD status 1507 and on line status 1509.

[0177] FIG. 15b is a schematic diagram illustrating a snapshot of one of the reproductive health care management web pages or system interfaces of FIG. 1b, wherein the snapshot depicts user’s IMD setup page. The current (depicted) page allows various specific configuration modes to be set up (based upon the selection made in the IMD setup up page of FIG. 15a, LUM-F106, for instance). The preset modes (on the right window of the page) allow the user (or remotely, by professionals) various settings as follows: (a) General Health—a routine checkup mode set by the user, without expecting any assistance by external servers or professionals, for instance; (b) Cancer Detect/Monitor mode—that allows the auto enabling many particular sensors on the left side of the window, in conjunction with health care professional’s assistance—that are include routine images taken by the Main camera, IR camera, UV camera, Microscope and temperature sensors, drug dispenser (a compartment within the IMD that delivers drugs to the correct area—e.g., cervix—or delivery over time when worn), for instance, and moreover enabling Dye Douche Kits—assisting detection of cancer; (c) STD Detect/Monitor—an under “Light Treatment”, including certain blue frequencies that are used to minimize bacterial/fungal growth—it should be noted here that such blue frequency is a common acne treatment today; all UV causes DNA/RNA damage to both the virus/bacteria/fungus and the patient so low doses and correct UV is used herein; it also noted that this can be used to reduce the amount of normal female yeast; some female have excessive amounts and yeast infections commonly (also, enabling Dye Douche Kits—assisting detection of fluids, bacteria, fungus, etc.); (d) Fertility Cycling; (e) Conception Avoidance—are necessitate monitoring and certain treatments or fluid delivery and PH Douche—Environment Promoting Gender+Ovulation Sync via Douche Kit; (f) Pregnancy Promotion—are necessitate monitoring and certain seminal fluid delivery—to promote impregnation using “cap” containment with automatic or manual alerts (audible, vibrating, LEDs, phone call, phone/pc display indications to user to use a syringe attachment, rubber ball squeeze injection, etc.); (g) Pregnancy Follow-up—an enabled microphone, that allows measurement of mother’s heart rate, fetal heart rate, fetal activity detection on trimester basis, so forth. It is appreciated that the system and mode of operation provides for an intravaginal device that can be used to treat undesirable vaginal flora and infections, e.g. yeast infections and the like, as well as track the progress of the disease, inflammatory state of the female organs, and the like. All of the available user’s pages, such as the records, queries, mail, forum, research, accounts, IMD setup, support and shopping, among other pages (depicted in the FIGS. 9 through 17) also contain tool boxes that can be enabled by clicking on the “Tools” icon. The client’s browser 1557 also shows a status bar indicating current IMD status 1553 and on line status 1555.

[0178] FIG. 16 is a schematic diagram illustrating a snapshot of one of the reproductive health care management web pages or system interfaces of FIG. 1b, wherein the snapshot depicts user’s support page. The user’s support page 1605 is intended to provide the user assistance in searching for a gynecologist, obstetrician, other doctors (such as fertility specialists) and find retailers (who sell products other than the ones provided by reproductive health management). In this variant of the invention, it is appreciated that the system, e.g. the smart phone or PC, node in the network automatically provides the female with data, e.g. name, appointment calendar, location, of a medical professional that can address the medical needs of the female. A register of medical professionals is provided on a database. The system selects appropriate specialists in the vicinity of the user, e.g. through GPS functionality, displays their information and data to the user on the smart phone, and their availability for an appointment. This reduces the stress on the user and the need to wait to obtain a therapy or treatment for the condition they have of the event they are experiencing. This reduces the amount of psychological physical suffering the female experiences by reducing the time from an indication of an abnormal condition to the time that actual treatment or therapy is administered.

[0179] The support page 1605 contains several main links (all of which are meant to provide assistance to the user) such as referral (e.g., doctoral referral), IMD (provide IMD related support, for instance), site (provide reproductive health management site related support, for instance), PC-software (such as latest firmware), phone-PDA software (that is, firmware for supporting phones or PDAs), clinical(s) (provide assistance with latest clinical stages research and developments), organizations and logout. The smart phone and or intravaginal device also has a mode of operation that communicatively links (with appropriate access authorization and security functionality) to a medical records node on the network to transmit appropriate data from the intravaginal device directly. The medical records node on the network, in another variant, is a medical records archive node that stores electronic medical records data from a multiplicity of female users located in remote locations globally. The archive receives and processes several terabytes of data from remote nodes on the network, e.g. including by way of example, millions of intravaginal devices communicating with smart phones and PCs, alone or in combination.

[0180] Each of these main links provides their own categories to help in getting assistance in a quickly and in a very efficient manner, automatically without or with very little human intervention. For instance, the referrals main link, as depicted, contains several categories such as find an obstetrician, gynecologist, local retailer, on line retailer and so forth (along with overview or descriptions for each of the category). Each main link has a sub link, provided automatically or selected manually by a user of sub-specialists or other medical professionals. All of the available user’s pages, such as the records, queries, mail, forum, research, accounts, IMD setup, support and shopping, among other pages (depicted in the FIGS. 9 through 17) also contain tool boxes that can be enabled by clicking on the “Tools” icon. The client’s browser 1625 also shows a status bar indicating current IMD status 1607.
FIG. 17 is a schematic diagram illustrating a snapshot of one of the reproductive health care management web pages or system interfaces of FIG. 1b, wherein the snapshot depicts user’s shopping page. The user’s shopping page 1705 is designed to provide the user assistance in shopping for IMDs, software applications, pharmaceuticals and so forth. The shopping pages or tabs are provided on a smartphone node on the network, a PC node on the network, a laptop node on the network, and other nodes on the network described herein. For example, a link to the Pampers web site is provided, a link to a vendor is provided, an advertisement, is provided.

The shopping page 1705 contains main links (all of which are meant to provide quick and easy shopping interfaces to the user) such as referral, IMD (provide IMD related shopping), site (provide reproductive health management site related shopping, for instance), PC-software, phone-PDA software (for example, shopping firmware and software for the IMD supporting phones or PDAs), clinical(s), support organizations and logout. It is appreciated that other nodes on the network provide for billing, shipping and payment functionality, e.g. credit or debit card functionality, as well as a node on the network providing functionality to obtain a percentage of each sale of product or service as well as referral fees for professional services, returning to a commercial enterprise node on the network, e.g. including but not limited to a medical device manufacturer node on the network.

Each of these main links come with their own categories, tabs, sub-tabs, that makes shopping an easy experience, such as, IMD, software applications, pharmaceuticals, homeopathy and baby products (along with overview or descriptions for each of the category) under referral. Included on the smartphone is a mode of functionality that permits the selection of applications both for the smartphone and also for the intravaginal device. These applications are paid for by the user and or insurance carrier and or by a national health care system automatically or via payment screens and functionality on the smartphone node of the network. By way of further example, applications include a pregnancy monitoring application, a premature birth monitoring application, an ovulation monitoring application, an STD detection application, a birth control application, a therapy monitoring application, a cervical health monitoring application, a genit catching management application, and an HPV monitoring application. All of the available user's pages, such as the records, queries, mail, forum, research, accounts, IMD setup, support and shopping, among other pages (depicted in the FIGS. 9 through 17) also contain tool boxes that can be enabled by clicking on the “Tools” icon. The client's browser 1725 also shows a status bar indicating current IMD status 1707.

FIG. 18a is a schematic diagram illustrating a snapshot of one of the reproductive health care management web pages or system interfaces of FIG. 1b, wherein the snapshot depicts health care professional’s patients page 1805. The health care professional’s patients page 1805 contains a list of patients (all of whom are associated with one of several models/versions of the IMDs that are available for shopping and with a concerned gynecologist, obstetrician or any other specialist), each of the patients having associated with certain codes and relative importance in terms of seeking medical care/advice. It is appreciated that the smartphone node also serves to manage a medical professional's time by automatically alerting a medical professional as to the medical condition of a patient under his or her care. In another variant, the patient data sent to the medical professionals' smartphone node is queued as a function of the immediacy of the need of the medical professional's intervention, e.g. several pregnant patients are ranked by the system on a node of the network, and the women who are at the point of giving birth or needing an epidural or other therapy or treatment are presented first to the medical professional's smartphone node of the network on a tab, e.g. which can flash different colors, e.g. red, yellow, and green, according to their immediacy of the need of the intervention. This functionality permits the medical professional or clinic or birthing center with an accurate way to provide efficient and timely medical services. The list of patients in this health care professional’s patients page 1805 is arranged in rows, with each column containing a list of patient’s names, ID# (identity number of the patient), due, time (due date and time for any of the IMD related procedures, such as taking sensor readings at one instant or for a prolonged period), regarding and code. The regarding column includes reminder notes to the doctor such as a first visit-general or routine examination, annual checkup, repeat: fertility treatment, monthly checkup.

The health care professional’s patients page 1805 also comes with a select column and many buttons such as view, search, delete, select all, clear selection (all of which have similar functions as that of the user’s records page 911 of the FIG. 9). For instance, when the health care professional selects a patient and click on the view button, the page of FIG. 18b appears (which provides an overview and billing aspects with regards to the selected patient). In another variant, these pages permit searching of archived medical records and images, and comparison of archived data with current day data harvested from the intravaginal device. This permits ready tracking of disease conditions, therapies and the like, as well as an electronic medical record of the state of the female’s sex organs over the course of her life.

The specialist sees a photograph or video of the patient by clicking on a face icon 1827 (which pops up an image or small video—of a first visit, for instance). The entire available health care professional’s patients pages, such as the records, queries, mail, forum, research, accounts, IMD setup, support and shopping, among other pages (depicted in the FIGS. 18 through 19) also contain tool boxes that can be enabled by clicking on a “Tools” icon. The health care professional’s browser 1825 also shows a status bar indicating current IMD status 1807. Similarly, there appears on the page a photo of the woman taken at different points in her life, allowing the medical professional to associate the data for the female with her current electronic medical record information, some or all of which was harvested by the intravaginal monitoring device. The same digital photo of the woman appears on the medical professional’s smartphone node on the network.

FIG. 18b is a schematic diagram illustrating a snapshot of one of the reproductive health care management web pages or system interfaces of FIG. 1b, wherein the snapshot depicts a health care professional’s patient’s accounts overview page 1851. The depiction shows another of the health care professional’s patients page 1851, which is also a patient’s records page. Similar to the conventional files of a
patient that contains several personal and medical details as pertaining to the selected patient, the current depicted page and that of the FIG. 18c also contain many of the personal overview, medical and billing details as pertaining to the patient. Similarly, the medical professional smart phone network nodes provides the physician billing and commercial information about specific users so that he or she can manage his or her business aspects of the practice of medicine.

The patient personal information/overview contains patient ID, name (first, middle, last), address, city, state/country, zip codes or postal code, phone numbers, age, email addresses, mobile phone numbers, electronic medical record information, and a photo or small video. In addition, a button or icon for emailing, messaging or contacting the patient and another button for VOIP or direct phone call is also available. It is appreciated that another node on the network (including appropriate links, icons and tabs) includes a Skype™ node on the network, an instant messaging node on the network, a Facebook™ node on the network, a Google™ node on the network, a National Health Care system node, an insurance company node on the network, an HMO node on the network, a PPO node on the network, a hospital node on the network, a physicians practice group node on the network, a Twitter™ node on the network, an emergency first responder node on the network, a social networking node on the network, a drug company node on the network, a medical device company node on the network, and a birth control vendor node on the network to facilitate communication between users of various nodes on the network, and other data transmission modes of operation. The health care professional’s patient’s page 1855 also comes with many buttons such as view, search, delete, select all, clear selection. For instance, when the health care professional clicks on the view button, the page of FIG. 18c appears (which provides a billing aspects with regards to the patient, among other information).

Also, at this time of attending to the patient, a timer (or, a time counter) also goes on in one variant, indicating how much time the doctor/health care specialist has spent on the patient. This information is used to bill for the doctors time, and produce an invoice to the patient, National Health Care system, private insurance carrier, etc. (described further with reference to the FIG. 18c). Reimbursement code data is also correlated with other data and electronic medical records and other data harvested from the intravaginal monitoring device and transmitted therefrom to other nodes on the network. The current health care professional’s patient’s accounts overview page 1851 also provides a brief medical summary of the patient’s medical history along with a provision to annotate the medical records or information harvested from the intravaginal device, and write further notes base upon the current status of the patient, derived from the new IMD data. The health care professional’s patients pages, such as the records, queries, mail, forum, research, accounts, IMD setup, support and shopping, among other pages (depicted in the FIGS. 18a through 19) also contain tool boxes that can be enabled by clicking on the “Tools” icon. The health care professional’s browser 1851 also shows a status bar indicating current IMD status 1853.

FIG. 18b is a schematic diagram illustrating a snapshot of one of the reproductive health care management web pages or system interfaces of FIG. 1b, wherein the snapshot depicts health care professional’s patient’s records view and invoicing page 1871. The health care professional arrives at the current health care professional’s patient’s records view and invoicing page 1871 by clicking on the view button in the page of FIG. 18b. Here, the health care professional is allowed to select on the type of the interaction, professional advise, medical diagnosis, therapy performed with reference to the current patient (whose name, user ID and phone numbers appear on the top of the page; and if unable to remember the patient, the health care professional is allowed to see a digital photograph or video clip of the patient by clicking on a face icon on the bottom-right of the page). In another variant, a digital record of an examination of the female is also archived and correlated with the patients other electronic medical records, including data harvested by the intravaginal device. The selections for the health care professional (in the current health care professional’s patient’s records view and invoicing page 1871) include type of the interaction, date and time, duration (based upon the timer) and description (based upon the notes left by the specialist, for instance). The depiction shows the IMD LUM-F106 being selected and the description includes video image and temperature data collection (upon which the health care specialist deliberated, analyzed, reported on, and wishes to produce an invoice).

The bottom of the page contains the type of billing (such as based upon hourly rate, flat fee, reimbursement code or fixed rate), timer duration, invoice description and notes and annotations. The entire available health care professional’s patient’s pages, such as the records, queries, mail, forum, research, accounts, IMD setup, support and shopping, among other pages (depicted in the FIGS. 18a through 19) also contain tool boxes that can be enabled by clicking on the “Tools” icon. The health care professional’s browser 1875 also shows a status bar indicating current IMD status 1873. It is appreciated that with the smart phone network node the medical professional has global access to patient data and can work from anywhere in the world in real time given the patient data access. For example, a physician can be at a medical conference in Hawaii while simultaneously reviewing in real time patient medical records, and providing analysis, feedback and even making phone consultations with patients and other medical professionals. By way of further example, medical consultation with world thought leaders can be obtained using the network nodes of system described herein. For example, a world thought leader specialist in premature birth in Switzerland can be consulted by a doctor in Ukraine regarding a patient with an unusual condition or rare condition. The Swiss expert can review on his smart phone network node and or his or her PC, in real time the patient data and provide a consultation.
and shopping, among other pages (depicted in the FIGS. 18a through 19) also contain tool boxes that can be enabled by clicking on the “Tools” icon. The health care professional’s browser also shows a status bar indicating current IMD status. During billing or any other times, if the health care specialist is unable to remember the patient, the health care professional is allowed to see a photograph or video of the patient by clicking on a face icon on the bottom-right of the page.

Fig. 20 is a perspective diagram illustrating an exemplary support architecture configuration for servicing a female reproductive system, wherein the service involves use of real-time analysis engine functionality in accordance with various aspects of the present invention. Therein, an IMD 2017, a wearable IMD, has been inserted via a vaginal channel 2015 into a female reproductive system 2005. The IMD 2017 has a plurality of sensors disposed therein, including, for example, an axial optical imager, a radial optical imager, a pair of imagers, a temperature sensor, a microphone, a glucose sensor, an EKG sensor, etc. While inserted and operating to capture sensor data during an insertion session, the IMD 2017 maintains wireless communication one or more various supporting devices, such as a laptop computer 2045, support systems 2093, and a smart phone 2041. The IMD 2017 may maintain such communication either directly in a point to point fashion or via an access point 2043 and a communication network 2001. Some of such communication can also be maintained with some of the supporting devices via others of the supporting devices.

The supporting devices illustrated may be located at the same premises or that of the female reproductive system 2005 or located at an entirely different location. Either way, the real time sensor data from the IMD 2017 is delivered so as to support a real-time display (based on such sensor data) in a visual working environment on each of the supporting devices. In addition, analysis engine operations (within one or more of the various illustrated elements of the support architecture) also receive such sensor data such that output from the analysis engine can also be displayed in virtually real time along with the representations of the sensor data within such visual working environments. Additional input into the analysis engine operations is received from the various supporting devices, the IMD or third party sources (not shown). Such input involves (i) sensor data or test data from other types of supporting medical systems 2007, and (ii) general medical information 2005, 2051, 2071. All input is either automatically or manually (via patient, medical staff, or third party input) delivered into the analysis engine.

Based on the input, various intermediate and final conclusions regarding a particular status of the reproductive system 2005 can be generated by analysis engine operations and output for visual display and storage, or to other systems such as the supporting medical systems 2007, 2053, 2073 (or another medical device local to the reproductive system 2005) for their own further processing. Control signals and alerts based on such conclusions may also be generated. For example, control signals might be delivered to a supporting medical system 2007 or to the IMD 2015 to adjust one or more characteristics or operations thereof. They may also comprise requests for further capture. As mentioned, the overall analysis engine functionality can be placed on one or more of the devices as illustrated by the gynecological analysis engine blocks 2009, 2075, 2055. Note also that the blocks 2051, 2053, 2055, 2057 are merely representative of counter-parts that may be found within the laptop computer 2045, the IMD 2017, the smart phone 2041 and perhaps an additional type of IMD or other type of medical device 2021.

Fig. 21 is a schematic and perspective block diagram illustrating another possible support architecture employing gynecological analysis engine operations that may reside in one or more of the plurality of supporting devices and systems such as diagnostic equipment located at a health care facility. Therein, an intravaginal monitoring device (not shown) may be inserted within a vaginal channel within the health care facility or be located remote therefrom. Either way, the intravaginal monitoring device is in communication via the communication network 2191 with the various supporting architecture shown. As with the particular support architecture of Fig. 20, general medical information 2195, 2113, 2131, 2105, 2115, 2133, and analysis engine operations 2199, 2117, 2135 can be found within any one or more of the elements of the present support architecture 2105. Such elements include a communication network 2191, an access point 2111, mobile phones 2123, 2151, laptops 2121, 2153 and even within supporting diagnostic equipment illustrated within a block 2157.

Within such a support infrastructure vast pluralities of IMDS and associated other patient medical devices can be supported, even when the patient has no supporting computing devices of their own. Within the visual working environments of a medical staff system 2125 or a doctor’s systems 2155, a patient can be selected from a plurality of patients under care can be made. Such selection changes the visual working environment to one directed at the selected patient’s reproductive system by accessing (i) previously retrieved sensor information, related data and notes, and (ii) generated analysis output based thereon. If currently active, the sources of sensor data and real time analysis engine output can be fielded to provide a virtually real time visual working environment for review, evaluation and analysis.

Fig. 22 is a schematic block diagram illustrating analysis engine operations within an intravaginal monitoring device (IMD), built in accordance with various aspects of the present invention. More specifically, IMDS can be built without any analysis engine functionality. They may merely deliver raw sensor data (which includes optical imager sensor data) with or without measurement pre-processing performed thereon or related thereeto. They may also only perform a selection of the overall analysis engine operations found in a support architecture, or may perform all such operations. The IMD illustrated does perform at least part of the overall analysis engine functionality.

Within the illustrated IMD, the firmware and program & operational logic codes 2265 allow the intravaginal monitoring device to perform in accordance with specific logic, in one variant, that includes: (a) receiving and/or executing instructions, in case of wearable intravaginal monitoring device, as to when to switch on and off, when to take images/video clips/sensor data, and at what interval they should be taken; (b) receiving and/or executing instructions to vibrate/beep, and then, switch off and transfer data to an external device or external servers (such as after enough data to make diagnosis has been taken and it is time to switch off until some other time or in emergency situations such as sometime before delivery of a baby); (c) receiving and/or executing instructions that involves exceeding limits in cases
of sensor data; (d) monitoring the battery operations and informing the user to recharge batteries, if need be; and so forth.

[0200] In fact, the illustrated IMD may operate in one of a plurality of modes based on: (i) input via a user input device of the user input devices and displays 2255 and (ii) control signals originating outside of the IMD from a supporting device. For example, in a wearable mode of operation, the device can be worn by the user continuously, but its functionality is turned on or off at different times during the wearing session per mode settings to save battery power and conform to session measurement goals. Similarly, a mode can specify when specific functionality within the IMD becomes active or in an idle state, when communications should be sent and to which supporting systems, the type of analysis operations to perform (if any) and when, etc.

[0201] In addition to one or a plurality of optical imager sensors, other sensors and components that may be incorporated into the IMD may include components of one or more of: (a) IR emitter and detectors 2221 used perhaps to monitor temperature or blood flow; (b) piezo microphones 2223, to monitor heartbeat sounds of a female and/or her fetus, for instance; (c) EKG contacts 2225, to take electrocardiogram graphs of heartbeat of a fetus, for instance; (d) piezo speaker 2227, to produce a soothing sound for the fetus, for instance; (e) pressure transducers 2229, to make pressure measurements within the intravaginal channel, to monitor dilations, for instance; (f) thermal contact assembly 2231, to take temperature measurements in cases of wearable intravaginal monitoring device, for instance; (g) glucose sensor 2233, to take glucose measurements; (h) pH sensor 2235; (i) electrolyte sensor 2237; (j) fetal brain activity monitors; and/or (k) Sonogram head unit 2239.

[0202] In all of the above-mentioned sensor cases, a processing circuit 2261 executes, as mentioned above, the operational logics, and gathers sensor data and performs preprocessing to extract consumable, measurement information based thereon. From the raw sensor data, the related measurement information produced, historical counterparts thereof stored within a memory 2273, and any of a plurality of types of other sensor data or information (medical information, historical data, human input, etc.) received via the communication interfaces from supporting devices outside thereof, operations, the processing circuit 2261 performs various analysis engine operations pursuant to analysis engine instructions 2269 retrieved from the memory 2273. All of the analysis engine operations mentioned throughout this application with reference to various figures herein, or a subset thereof, can be performed.

[0203] Other components of the IMD depicted include displays 2255, user interface devices and displays 2255, normal (infrared and ultraviolet) illuminators 2251, fixed-manual-auto focus lensing 2247, a plurality of photodetector arrays (i.e., imager arrays) 2245, 2243, fixed-manual-auto focus microscopic lensing 2241, and lens zoom capability (mechanical and/or digital).

[0204] The analysis engine 2255 functions as an automatic servicing entity, that is to provide service to the clients as well as the healthcare professionals in assisting to come to a conclusion on the bases of the measured and quantized parameters that emerge from the intravaginal monitoring device, not only at the present time, not only based upon the historical data emerged from that intravaginal monitoring device but also based upon the data emerged from a plurality of intravaginal monitoring devices.

[0205] Lastly, as constructed, the illustrated IMD may operate in an entirely self-contained mode, or under control of one or more external supporting devices. In the latter case, all or part of the functionality defined within the analysis engine instructions 2269 can be turned on or off or replaced or supplemented by such supporting device or devices. In other words, like other controllable modes of operation, the illustrated IMD can be placed in an independent and various controlled modes of operation. Such placement can be via the user input devices and displays 2255 or via external control signals originating from such support device(s).

[0206] FIG. 23 is a schematic block diagram illustrating components of one embodiment of an analysis engine that may be found in whole or in part within one or more of the various devices and systems of a network supporting intravaginal monitoring, wherein the analysis engine illustrates various aspects of the present invention. That is, the various blocks of the analysis engine can correspond to software instructions and/or dedicated hardware depending on the design of the particular device in which such blocks are found. They and other components of the analysis engine 2311 may be found in whole or in part, for example, on a supporting server, further medical systems and computers, a patient’s supporting computing device, a medical staff member’s computing device, etc.

[0207] In particular, processing circuitry 2321 pursuant to the operational logic 2323 (firmware or software) carries out various analysis engine operations based on a variety of input data such as: a) a user’s or patients input data 2341; b) doctor’s or medical staff data 2334; c) data 2345, 2347 from external supporting medical device of a user or a doctor; d) diagnosis and treatment information, conclusions and data 2349; e) IMD sensor data 2351, 2353 from a current and prior sensor data gathering session; f) medical information data 2355; g) analysis logic data 2357 (which can be modified via external control signals as can the operational logic 2323). With such data which may be interactively gathered via automated requests or through automatic direction by control signals and preprocessing.

[0208] The operational logic 2323 and the analysis logic data 2357 together define the various operations of the analysis engine 2311, including how and when to abort one to all operations, for example, in response to control or direction originating outside of the analysis engine 2311. The term “outside” as used above may still be within the particular device in which the analysis engine 2311 resides, or may be outside of such device entirely and within a different supporting device or IMD.

[0209] FIG. 24 is a schematic block diagram illustrating an analysis engine such as that of FIG. 23, placed at least in part within a server to illustrate server based analysis engine functionality along with other server operations related thereto, the server and underlying functionality built in accordance with various aspects of the present invention. Therein, a supporting server 2411 contains analysis engine operations 2455 and other supporting operations 2421. Such operations 2411, 2455 are carried out pursuant to application software tailored for support operations and hardware typically found in a conventional servers.

[0210] Within the analysis engine operations 2455 all or a portion of the analysis engine operations mentioned within
this specification, for example, may be included. For example, analysis of sensor data 2437 and related various types of supporting data and information 2429 (some retrieved from a data storage 2453 and other received via the communication processing functionality 2441) can be utilized to produce either intermediate or final status conclusions about a plurality of reproductive systems serviced by the supporting server 2411 via, at least in part, a corresponding plurality of IMDs.

[0211] The supporting operations 2421 include: a) registration management 2423, account management 2423; b) directed advertising 2427 (based on revealed characteristics of a particular female being serviced); c) alert and other conclusion processing 2431; d) third party (non patient and non medical staff) interaction support 2433 (e.g., pharmaceutical or research organizations); e) doctor and patient interaction support 2435, 2433; f) the communication processing 2441; and g) presentation management associated with the various visual working embodiments found in the corresponding various supporting computing devices within the overall support network. Regarding the latter, the supporting server 2411, using typical web servering or “app” serving approach, may deliver conclusion information, gather further information from patients, doctors and third parties or their computing systems, and otherwise at least assist in creating tailored visual working environments for a patient’s supporting computer, a doctor’s computer or phone, etc.

[0212] As before, although the entirety of possible analysis engine operations are illustrated within the supporting server 2411, they can be distributed in whole or in part throughout the various other possible network components. To support the many configurations of support architectures, IMD capabilities and supporting system capabilities, the analysis engine operations 2455 use of particular analysis operations can be selected to best conform to such configurations. In other words, for a first patient with a relatively simplistic IMD design and no supporting devices beyond the server 2411, only those analysis operations that apply to such IMD are performed by the server 2411. Yet in another embodiment with a relatively advanced IMD and a plurality of other supporting systems, a more full set of analysis options becomes available for use by the supporting server. Even so, less that the “more full set” might be employed if such other supporting devices or such more advanced IMD is designated to carry out all or a portion of such analysis operation “set.”

[0213] FIG. 25 is a schematic block diagram illustrating another embodiment of analysis engine integration within a network supporting intravaginal monitoring, and build in accordance with and illustrative of various aspects of the present invention. Therein, within the network infrastructure 2505, central support servers 2591 service various supporting operations to support a plurality of IMDs of differing levels of functionality (some of which relates to analysis engine operations). Each of the plurality of IMDs are used by a corresponding plurality of females via intravaginal insertion into their reproductive system. Regional and remote health care servers 2551, 2539 and remote health care servers also provide support to each other, the central support servers 2591 and, of course, to the plurality of IMDs. Such support is provided via wired/wireless, point-to-point, Internet/Intranet network pathways 2513, 2511. The support server 1209, in conjunction with the regional and remote health care professional servers 1259, 1239, enables many of the functionalities including the analysis engine operations and support for presenting visual working environments for various supporting computer systems.

[0214] In particular, at the remote server(s) 2539, perhaps located within a doctor’s office, local supporting medical information 2521 can be retrieved in an automatic, automated or manual fashions (depending on the underlying infrastructure) from supporting medical systems 2529, and can be used along with other general medical information 2527 as input to an analysis engine function 2531. Other input for the analysis engine function 2531 includes for example, IMD sensor information 2525 and medical personnel data (extracted via the interface 2523). Therefrom, all, none or portions of the overall analysis engine functionality can be performed.

[0215] Similarly, corresponding infrastructure supporting analysis engine operations within the regional and central servers 2551 and 2591 can be found. Overall, it can be appreciated that the servers 2591, 2551, 2539 together contain a vast amount of analysis engine operations and data. Such data can be exchanged there between as needed such that the servers can each carry out their designated and available analysis engine operations. Designation may involve not only the selection of which server will handle a particular operation, but also includes whether a non-server supporting device (not shown) or IMD (not shown) will have such responsibility.

[0216] By way of further example, a targeted advertising module is used in the present invention. Intravaginal device detects a female condition, e.g. a pregnancy, a sexually transmitted disease (STD), a precancerous condition, a cancer, a medical abnormality. This information is communicated to one or more nodes on the network. Advertising data for the treatment of the STD, e.g. for a drug used to treat the STD or other condition, from a particular pharmaceutical company or one or more companies, is then sent to the intravaginal device or other remote device on the network, for a user or doctor to review. Treatment option data are also communicated in another variant of the invention to the intravaginal device and remote device. With respect to pregnancy data, baby gift data or products used with babies are displayed on the intravaginal device or remote device. In yet another aspect of the information, a module is provided to provided to mask, conceal or render anonymous the identity of a user of the intravaginal device while still permitting access to the treatment for the users condition, state or intravaginal event to be used to direct advertising to the user needing a particular drug or treatment regimen.

[0217] In yet a further aspect of the invention (optionally using GPS functionality for locating or placing the intravaginal device at a geographic location, e.g. or a remote device, (e.g. mobile phone communicating the intravaginal device), patient candidate and drug recipient candidates data is collected. User specific condition or event data is collected on one or more nodes on the network and correlated to treatment advertising data, and or medical specialist, or hospital data. It is appreciated that drug companies will be able to provide targeted advertising data or their therapies and or drugs to exactly the users who are suffering from conditions or events which their products provide beneficial treatments, e.g. drugs that treat STD’s, drugs that treat cancers, etc.

[0218] In yet other aspects of the invention a user profile module is provided, and a method of monitoring and controlling the spread of sexually transmitted diseases. The user enters personal information, medical information, condition
information, social information, e.g. the names of sex partner
data, date and times of intercourse with specific partners, etc. This information is correlated with data collected from the
intravaginal device. By way of further example, a sexually
active female takes baseline data with the intravaginal device
of the present invention. The data is time and date stamped, a
record of the health or condition of her cervix is recorded on
the device or one or more nodes of the network. She then has
intercourse with a sex partner. In one scenario, if the partner
is free of STDs a follow up record of the cervical or vaginal
condition can be compared with the baseline data and
archivally recorded. In another scenario, if the sex partner had
an STD, then the user uses the device and notices that there
are abnormal cervical and or vaginal changes, and these are
archivally recorded and or an alert is sent to a remote device,
e.g. the user’s or doctor’s, and one or more of the advertising
modules above is activated. Similarly, the sex partner is noti-
fied early of the STD condition. It is appreciated that the early
notification of the condition for the user and the sex partner
can stop the spread of the disease to other sex partners that
may occur, e.g. in the case of HPV transmission.

[0219] FIG. 26 is a cross-sectional diagrams illustrating one of many possible variations in dimensions, contour, and
orientations, i.e., form factors, of a cap 2609 and optics
assembly 2613 of an IMD 2605 sized to correspond to various
“form factors” of intravaginal and cervical regions. Therefore,
the IMD 2605 is inserted via a mostly axial direction of a
vaginal channel 2601. Within the vaginal channel 2601 at a
mostly radial angle therein, a cervical region 2603 is illus-
trated. The insertion of the IMD 2605 proceeds until the cap
2609 falls within an area near the cervical region 2603.

[0220] The insertion process may benefit from visual guid-
ance of the process via the display of live imager data on an
associated display (not shown), and wherein the live imager
data is captured by the mostly axially oriented imager 2611.
When reaching the illustrated position, the cervical region
2603 falls within a field of view of a mostly radial imager
assembly 2607. The mostly radial imager assembly 2607 can
thus be used to provide further imager data for a more detailed
evaluation of various aspects of the cervical region 2603.

[0221] That is, the imager assembly 2611 captures only a
portion of the cervical area, but such capture can be used: a)
to assist in the guidance process by allowing the user to find
and target the cervical region 2603 for image and video cap-
ture by the imager assembly 2611; b) along with the image and
video capture from the imager assembly 2607 to con-
struct a panorama, 3D information, etc.; c) to support analysis
and viewing of other artifacts, events or conditions outside of
the cervical region 2603 but within the vaginal channel 2601;
and d) to support pre-processing measurements of the cervical
region 2603 such as the height, length, width, etc., of the cervix
or associated cervical opening portions of the cervical area—an
important indication during pregnancy. The optics
assembly 2613 of the IMD 2605 is inserted within a main
housing stem 2614. The optics assembly 2613 supports the
imager assemblies 2611, 2607. The cap 2609 may be made
with a firm but compressible material (such as silicone rub-
er) that permits installation, removal and replacement. This
may be accomplished by feeding the optics assembly into the
inner chamber of the cap 2609. Radial tension of the opening
portion of the cap 2609 due to elasticity of the cap 2609
supports at least a partial hermetic seal and mechanical con-

[0222] As illustrated, the field of view and underlying
mounting angle of the radial imager assembly 2607 is
adequately matched to the illustrated reproductive system’s
orientation and size. Exemplary fine tuning adjustment, how-
ever, might involve one or more of: a) installation of a differ-
ent sized and shaped optics cap; b) relocating the radial
imager assembly 2607 to provide better field of view cover-
age of the present cervix; c) changing the angle of the radial
imager assembly 2607 to provide view more normal to the
surface of plane of the cervical region 2603; d) extending or
retracting the axial imager assembly 2611 directly (or rela-
tively via use of a longer cap) to (i) minimize having the radial
imager assembly 2607 within the field of view of the axial
imager assembly 2611, (ii) minimize having the axial imager
assembly 2611 within the field of view of the radial imager
assembly 2607, and (iii) attempting a better lateral image of
the cervical region 2603 by relocating the axial imager assembly
2611. Moreover, further imager assemblies (not shown)
could be added to the optical imager assembly, or one of the
imager assemblies 2607 or 2611 can be removed. An imager
assembly may have integrated illumination lighting and lens-
ing, or other optical elements supporting an imager array
installed therein.

[0223] The illustrated cap is termed an asymmetric cap as it
does not maintain symmetry in the radial direction. Of course
fully symmetric caps can be used, such as that illustrated in
FIG. 1. Similarly, to maximize the target coverage area for
a field of view 2615 of the imager assembly 2607, the imager
assembly 2607 is oriented off center and in the opposite radial
direction from that of the cervical region 2603 (the intended
target). Similarly, the imager assembly 2607 having a field of
view 2607 is positioned with a significant distance to the end
of the cap 2615. With such positioning, it is more likely that a
reasonably large target coverage area for capturing imager
data (by the imager assembly 261) can be maintained. In
addition, the extended axial length of the cap 2615 can help in
positioning the imager assembly 2607 in its mostly axial
position that orients fairly well with the opposing orientation
and axial location of the cervical region 2603. If for example,
a female’s cervical region is much smaller than that illustrated
and located closer to the entrance to the vaginal channel, the
cap 2609 might be replaced with a longer counterpart. If the
cervical region of another female is located in a normal ori-
entation as viewed from the axial direction, a centrally
located axial imager assembly only might be used with a
symmetric cap of perhaps narrower dimensions.

[0224] If installation of a replacement for the cap 2609 is
insufficient to address a mismatch between the optical assem-
by and the desired target, e.g., the cervical region 2603
(which varies greatly from female to female), the optics
assembly 2613 might be swapped with another via an elec-
trical and mechanical mating engagement, e.g., a connector
within the stem 2614 which matingly engages with a coun-
terpart connector on the base of the optics assembly 2613.

[0225] However, note that although larger optics assem-
blies and caps may be optimal, they may give rise to more
difficult and uncomfortable insertion of an IMD. Thus, where
these “fitting” processes are limited by comfort and insertion
concerns, other cap and optics assembly selections may still
prove useful as a compromise under the given reproductive
system.

[0226] FIG. 27 is a schematic diagram illustrating three
different wearable forms of the intravaginal monitoring
device 2751, 2753, 2755 that are part of a kit, each possessing
varyingly angled caps 2711, 2721, 2731 and some others having adjustable angles of the cap. The illustration shows three different types (of course, more or less than three different types are also provided) of wearable intravaginal monitoring devices 2751, 2753, 2755 (that can be used over a short period of time or prolonged period of time) that consists of a stem 2715, 2725, 2735 and a finger ring 2717, 2727, 2737 (to be able to insert and remove the intravaginal monitoring device 2751, 2753, 2755). The electronics that is part of the intravaginal monitoring device 2751, 2753, 2755 is not shown in this figure; nonetheless they are incorporated within the cap 2711, 2721, 2731, the stem 2715, 2725, 2735, or combination thereof with appropriate connectors (e.g. mechanical, optical or electrical).

[0227] Each of the designs of the intravaginal monitoring devices 2751, 2753, 2755 vary slightly and are applicable for different conditions, events, situations and circumstances, which include vaginal anatomy (for ease of use and comfortable wearing) and intended period of usage. For instance, the intravaginal monitoring device 2751 has an angled cap 2711 and has a shorter stem 2715 that can only accommodate a small battery 2713 (e.g. standard or rechargeable) and is intended for short term usage. The intravaginal monitoring device 2753, on the contrary, has a slightly lesser angled cap 2721 and has a larger stem 2725 that can only accommodate a large battery 2723 and is intended for long term usage and better comfort.

[0228] The intravaginal monitoring device 2755 has an angle adjustable cap 2731 and has a larger stem 2735 that can only accommodate a large battery 2733 and is intended for long term usage and better ease of use. Some of these hermetically sealed intravaginal monitoring devices 2751, 2753, 2755 have the same cap 2711, 2721, 2731 size (with rear mounted stem, for optics assembly) and are designed in sizes and dimensioned to fit comfortably to varieties of vaginal anatomies.

[0229] FIG. 28 is a schematic diagram illustrating four different wearable forms of the intravaginal monitoring device 2851, 2853, 2855, 2857 that are optionally part of a kit, possessing multi-sized caps 2811, 2831, 2841, 2821. The illustration shows four different types of wearable intravaginal monitoring devices 2851, 2853, 2855, 2857 (that comes in different cap sizes) that consists of a stem 2815, 2835, 2845, 2825 and a finger ring 2847 (to be able to insert and remove the intravaginal monitoring device 2851, 2853, 2855, 2857—shown only in case of the intravaginal monitoring device 2855). The electronics that is part of the intravaginal monitoring device 2851, 2853, 2855, 2857 is not shown; nonetheless they are incorporated within the cap 2811, 2831, 2841, 2821 and the stem 2815, 2835, 2845, 2825.

[0230] Each of the three designs of the intravaginal monitoring devices 2851, 2853, 2855, 2857 vary slightly (in specific, the cap 2811, 2831, 2841, 2821 sizes) and are applicable for different vaginal anatomies, for ease of use and comfortable wearing, and intended period of usage. Each of the hermetically sealed intravaginal monitoring devices 2851, 2853, 2855, 2857 is made up of medical grade silicon rubber (or other medical grade plastics) that are adjustable at the neck and the cap 2811, 2831, 2841, 2821 itself is flexible so as to fit snugly at the face of outer surface of the cervix. The neck is flexible so that the angle between the cap and the stem flexes and conforms the natural angles between the lower vaginal canal and the upper part of the vaginal canal. It is appreciated that this flexible or pivoting neck contributes to the level of comfort for the female user and also provides for adjustment of the imaging angle between the image capture components of the device and the target cervix or other part of the vagina which is a desired target capture image. The neck can flex through a variety of angles in a planar dimension or can rotate freely across 360 degrees in another variant.

[0231] FIG. 29 is a schematic diagram illustrating two different wearable forms of the intravaginal monitoring device 2951, 2953, 2955, possessing multi-sized caps 2911, 2921, 2931 and stems 2915, 2925, 2935; the cap 2911, 2921, 2931 being perforated to allow flow of any vaginal discharges. Various natural or abnormal vaginal discharges are created by various cells or fluid within the vagina, in the cervical canal, or up further in the female anatomy. It is appreciated that detection of discharges assists in the analysis of the health of the female reproductive anatomy. Detection, imaging and sensing of the type of discharge (e.g. color, texture, opacity, consistency, is a feature of the device, and provides a method for determining abnormal pathologies of the female reproductive system.

[0232] The illustration shows three different types of wearable intravaginal monitoring devices 2951, 2953, 2955 (which comes in three different perforated cap 2911, 2921, 2931 sizes) that consists of a stem 2915, 2925, 2935 and a finger ring 2917, 2927 (to be able to insert and remove the intravaginal monitoring device 2951, 2953, 2955—shown only in case of the intravaginal monitoring devices 2951, 2953). The electronics that is part of the intravaginal monitoring device 2951, 2953, 2955 is not shown in this figure; nonetheless they are incorporated within the cap 2911, 2921, 2931 and the stem 2915, 2925, 2935. As is illustrated, various form factors that permit detection of various intravaginal conditions are used herein.

[0233] Each of the three designs of the intravaginal monitoring devices 2951, 2953, 2955 vary slightly (in specific, the cap 2911, 2921, 2931 sizes) and are applicable for various vaginal anatomies, for ease of use and comfortable wearing, and intended period of usage. Each of the optionally hermetically sealed intravaginal monitoring devices 2951, 2953, 2955 is made up of medical grade silicon rubber (or other medical grade plastics, glass, acrylics, biocompatible material, biocompatible carbon coated materials, biocompatible metals, or combinations thereof) that are flexible at the neck 2919, 2929, 2939 and the cap 2911, 2921, 2931 itself is flexible so as to fit snugly at the face of outer surface of the cervix. The cap 2911, 2921, 2931 spreads the vaginal tissue to provide line of sight and perforations (openings) allow fluid flow.

[0234] It is further appreciated, that one or more components of the device described herein are reusable and or disposable in one or more combinations. By way of example, caps are disposable. In this variant, replacement disposable caps are provided in cap kits. By way of further example, sheaths are provided for the device that are transparent and or translucent. For example, materials from which condoms are constructed are used for the disposable components of device and system. Use of the kits provides for hygienic conditions to be provided to a user, and to keep various parts of the device free of bodily fluids. A user may simply insert a sheath over one or more components of the device in the same manner as a condom is placed over a penis. The sheath conforms snugly over one or more components of device and or cap, and is constructed of a very thin elastic, hypoallergenic material. By virtue of the elasticity of the material, a watertight or water
proof seal with made between the elastic covering and the device. The device is used, the sheath removed and discarded. By way of further example, the top portions of the caps described herein, in another variant, include a thin clear plastic film (tensioned or non tensioned) covering the top portion thereof, or open area. This plastic film can come in direct contact with the cervix. When spotting occurs the spotting will be visible on the thin plastic film and imaged by the camera. It is appreciated that these variants of the invention provide both hygienic benefits as well as the benefits of keeping the lens assembly (and indeed where the sleeve covers the entire device) free from bodily fluids and microbes. Typical types of materials used include biocompatible shrink wrap material, and other medical grade plastics. Of course, the sheath in different variants covers all of the device, substantially all of the device, part of the device, and the top portion of the sheath or plastic film can have markings thereon (e.g. cross hairs, and other measurement markings such as circumferential measurement markings, quadrant markings, grid pattern markings) so that the imager images both the markings and the markings in relation to the cervix itself. This feature also assists in visually positioning the device in relation to the cervix, e.g. the cross hairs can be positioned over the opening of the cervical canal. Where the film is elastic it can also provide a three dimensional topography of the cervix including contours. It is appreciated that the device of the present invention includes a reusable member and also a kit including one or more disposable members.

[0235] FIG. 30 is a schematic diagram illustrating hermetically sealed intravaginal monitoring device 3051, 3053, 3055, 3057 wherein the illustration depicts a flexible cap 3011, 3021, 3031, 3041 that opens up upon proper placement of intravaginal monitoring device 3051, 3053, 3055, 3057 and then pushing the bottom half of the stem 3015, 3025, 3035, 3045. Specifically, the illustration shows wearable intravaginal monitoring device 3051, 3053, 3055, 3057 that provides the female an expanding cap (that expands only after insertion; somewhat like tampon insertion—something wearers would be familiar and comfortable with). In one variant, the cap is self expanding and biased outward to expand and move the tissue of the vagina out to expose the cervix for imaging. The different wearable intravaginal monitoring device 3051, 3053, 3055, 3057 contains a stem 3013, 3023, 3033, 3043 and finger ring 3049 (to be able to insert and remove the intravaginal monitoring device 3051, 3053, 3055, 3057—shown only in case of the illustration 3051, upon proper placement). In addition to or in place of the finger ring a string or looped string is provided to assist in removal of the device from the vagina. The string is constructed of a biocompatible material that is microresistant. The electronics that is part of the intravaginal monitoring device 3051, 3053, 3055, 3057 is not shown; nonetheless they are incorporated within the cap 3011, 3021, 3031, 3041 and the stem 3015, 3025, 3035, 3045.

[0236] In yet another variant of the invention the body of the devices described herein is constructed of a material that kills microbes upon surface contact. Alternatively, a lubricant that contains microbe killing properties is used with the device described herein. The lubricant assists women who do not have adequate moisture in their vaginas to properly and comfortably insert the device.

[0237] This particular design of the intravaginal monitoring device 3051, 3053, 3055, 3057 employs a telescopic bottom half of the stem 3015, 3025, 3035, 3045 (that is hermetically sealed by screwing up the bottom cap 3017, 3027, 3037, 3047), so that the entire intravaginal monitoring device, as depicted in 3051, appears to be sized and dimensioned like a tampon. Upon insertion, as shown in illustrations 3053, 3055, 3057, the intravaginal monitoring device 3051, 3053, 3055, 3057 opens up to provide line of sight view of the outer surface of the cervix, to the camera which is built in the device. Then, as depicted in the illustration 3057, 3059 the bottom half of the stem 3015, 3025, 3035, 3045 is removed and kept in a safe place. The intravaginal monitoring device 3051, 3053, 3055, 3057 then can be used for short term or long period of time, depending upon the needs. Moreover, other expansion schemes may also be employed, for instance, a spring release cap, screw out cap and so forth. The intravaginal monitoring device 3051, 3053, 3055, 3057 can also be non wearable and usually is made up of medical grade silicon rubber.

[0238] FIG. 31 is a schematic diagram illustrating hermetically sealed intravaginal monitoring device 3151, 3153, 3155 wherein the illustration depicts a flexible cap 3111, 3121, 3131 that opens up upon proper placement of intravaginal monitoring device 3151, 3153, 3155, and then pushing the bottom half of the stem 3115, 3125, which is another variation of the intravaginal monitoring device of FIG. 30. The illustration shows wearable intravaginal monitoring device 3151, 3153, 3155 that provides the female a folding 3111, 3121 within the cap 3113, 3123, 3131 (that expands only after insertion). The wearable (that can also be a non wearable) intravaginal monitoring device 3151, 3153, 3155 illustrations also show a telescopic stem 3115, 3125 and a finger ring 3135 (to be able to insert and remove the intravaginal monitoring device 3151, 3153, 3155—shown only in case of the illustration 3155, that detaches upon proper placement). The electronics that is part of the intravaginal monitoring device 3151, 3153, 3155 is not shown; nonetheless they are incorporated within the cap 3113, 3123 and the stem 3115, 3125.

[0239] In one variant of the invention, the stem is totally within the female body. It is appreciated that in this configuration, there is little risk of accidental displacement of the device so that is presses unintentionally up and into a woman’s body in an abnormal fashion. Moreover, when totally within the vaginal cavity, it is not noticeable that the user is using the device and that the device is harvesting data. In yet another variant, the device is sized and dimensioned to be wholly contained, enclosed, or hidden within the vaginal cavity so that the outside world does not know the device is within the user. In a variant, a string may hang outside the vagina to remind the user that the device is still inserted.

[0240] This design of the current illustration of the intravaginal monitoring device 3151, 3153, 3155 uses a telescopic bottom half of the stem 3115, 3125 (that is hermetically sealed by screwing up the bottom cap 3117, 3127), so that the entire intravaginal monitoring device, as depicted in 3151, appears like a tampon. Upon insertion, the intravaginal monitoring device 3151, 3153, 3155 opens up to provide line of sight view of the outer surface of the cervix, to the camera built in. The intravaginal monitoring device 3151, 3153, 3155 then can be used for short term or long period of time, depending upon the needs. Moreover, other expansion schemes may also be employed, for instance, a spring release cap, screw out cap and so forth. Moreover, although not shown in the figures, note that the bulb, cage or any other type folding for placement within the insertion housing may also be employed. The
intravaginal monitoring device 3151, 3153, 3155 can also be non-wearable and made of medical grade silicon rubber.

[0241] FIG. 32 is a schematic diagram illustrating a vaginal channel 3213 and cervical regions 3217, 3221 of a woman’s body along with an intravaginal monitoring device 3291 to be inserted into place; wherein the intravaginal monitoring device 3291 is capable of guiding inside the optics cap 3271 to capture images of large portions of vaginal channel 3213 and cervical regions 3217, 3221 that comprise a wide ranging variation in dimensions. The current illustration depicts an introitus 3223 of a vaginal channel 3213, cervix 3221, outer surface 3217 of the cervix 3221, interior 3219 of the uterus 3207 in a normal orientation, fallopian tube 3211, and ovary 3209. Also, depicted is an exemplary overlay of a tilted uterus 3215. As can be appreciated, the cervical orientation depends on, among other factors, the orientation of the uterus 3207 (or cervix 3215) under the various situations. Typical angular orientations in relation to the axial direction 3295 of the vaginal channel 3213 include normal orientations 3251 and tilted orientations 3225. Wide ranging variations in the vaginal channel 3213 and the cervical regions 3217, 3221 are important factors in design considerations of the Intravaginal Monitoring Device (IMD) 3291. Considerations include, for example, focal lengths, fields of views, comfort and targeting with or without guidance assistance.

[0242] Multiple studies show that variations in the vaginal channel 3213 and the cervical regions 3217, 3221 of a woman’s reproductive system involve: (a) length between the introitus 3213 and posterior fornix within the cervical regions 3217, 3221 (variations may range up to sixty one percent); (b) length between the introitus 3213 and anterior fornix (may vary up to thirty seven percent); (c) size of the introitus (variations may be up to seventy seven percent); (d) straight line length between anterior to posterior fornices (may vary up to seventy two percent); (e) straight line widths between lateral fornices (variations may be up to eighty percent); and (f) widths and heights of the vaginal channel 3213 (significant variations typically exist through the entire length). In addition, studies show significant variations across spectrum of women and within the same woman that occur due, for example, to: (a) natural orientation of uterus; (b) alignment of the vaginal channel 3213 during stages of pregnancy; (c) reorientation with full or empty bladder; (d) retraction during arousal; and (e) relocation post birthing (especially evident after cesarean procedures).

[0243] In addition to the abovementioned factors, an intravaginal monitoring device 3291 should also account for cervical orientation and insertion depth. Insertion depth of the intravaginal monitoring device 3291 to the posterior fornix may not be easy across the spectrum of all women due to: (a) abnormal anatomical configurations; (b) cervical impact being misinterpreted as the posterior fornix; (c) anterior fornix being misinterpreted as the anterior fornix; or (d) insufficient nerve feedback of successful positioning. Moreover, for some women based on their current anatomical configurations, full insertion into the posterior fornix may not be optimal for capturing images and further information about the cervix or other areas within the vaginal channel 3213. For a variety of reasons, including abnormal anatomical configurations and other reasons mentioned above, insertion by a particular woman over time may involve insertion to differing depths.

[0244] The cervical orientation may be referred to as an angular measurement between the cervical plane & vaginal channel axis. For example, if a cervical plane is parallel to a vaginal axis, cervical orientation would be 0 degrees; a vaginal axis that is normal to a cervical plane would have a cervical orientation of 90 degrees. The cervical orientation exhibits substantial variation not only from woman to woman, but also within the same woman over time (for example, changes occur during pregnancy, based on bladder volume, in response to arousal, etc.). Vaginal axis is not usually a straight line, but typically comprises a bend or two and curvature between vaginal openings to the anterior fornix, complicating image capture.

[0245] In accordance with the present invention, the design considerations of the intravaginal monitoring device’s 3291 guiding procedures, and optics attempt to address all these variations. Such considerations are important whether the IMD comprises a “one size fits all” design or several independent designs (with each of the several designs being directed toward groups of women with relatively similar anatomical configurations). Design considerations also take into consideration the woman’s comfort involving characteristics such as stem flexibility, wear-ability, stem length, overall stem and cap widths and curvatures, and cap lengths and compressibility.

[0246] Although herein described with reference to human women, the various IMD embodiments within the present application are equally applicable to the reproductive systems of non-human female species. In particular, the IMD 3291 employs a variety of techniques to address the wide variance in reproductive systems usable for all species. In particular, with reference to the human female, the optics and guiding techniques of the IMD 3291 address at least some of the anatomical variations of a female reproductive system. An optics assembly 3277 may be adjusted to various positions within an inner cavity of a cap or optics cap 3271. The optics assembly 3277 includes two imager assemblies 3273 and 3275 to cover a wider field of view than would ordinarily be possible by using only a single imager assembly. The angle of the imager assembly 3273 may also be manually or electromechanically adjusted. For comfort and to maintain rather optimal focal lengths, the optics cap 3271 is relatively transparent, and can be made from a medical grade compressible polymer material, e.g., a soft silicone rubber. Most of these and other features and feature options not only accommodate reproductive system variations but also support comfortable, ease of use.

[0247] As previously mentioned, the optics assembly 3277 may involve manual or electro-mechanical adjustment of both or either of the telescopic optics assembly and the angle of the imager assembly 3273. The electro-mechanical approach involves, for example, the use of miniature piezoelectric actuators. Manual or electro-mechanical rotation of the optics assembly around the axis of the stem of the IMD 3291 may also be employed to address a laterally oriented target such as a laterally situated cervix. Control of the various actuators (controlling tilt, rotation and depth within the optics cap 3271) can be controlled directly via an interface placed on the IMD 3291, remotely by the user via a local computing device, and other computing devices remote from the user. Specifically, for example, such control might involve: (a) an dedicated hand-held device in local communication with the IMD 3291; (b) a multipurpose device (such as a mobile phone, tablet computer or laptop computer) in local communication with the IMD 3291; (c) a remotely located, dedicated or multipurpose device in communication.
with the IMD 3291 via the Internet; (d) manual interaction via a user interface placed on the IMD 3291 (e.g., a button); or (e) via twisting, turning, adjusting insertion depth, and otherwise manually manipulating the IMD 3291 directly and without automation.

[0248] The imager assembly 3275 is adjustable in a mostly radial direction 3297, while imager assembly 3273 is adjustable in a mostly axial direction 3295. The images or video acquired from the imager assemblies 3273, 3275 may be displayed one at a time in a small or full screen window, or, if preferred, at the same time on a remote or local display. For example, upon insertion of the IMD 3291 into the vaginal channel 3213, a first image/video produced via the imager assembly 3273 may be displayed (or primarily displayed) to support “gross” guidance of the IMD 3291 into position. When in such gross position, a second image/video produced via the imager assembly 3275 can be displayed (or become the primary display) to fine tune targeting of a radially located cervix. Primary display may involve replacing the first image/video with the second, but may also involve placing both image/video on the same display screen at the same time (perhaps even with an overlay scheme). Alternatively, in one particular configuration, the first and second image/video may also be stitched together to gain a wide angle image that covers more than 150 degree view of the outer surface of the cervix 3217. Three dimensional imaging/video can also be constructed therefrom.

[0249] For instance, a woman who purchases and adjusts the optics assembly of an intravaginal monitoring device 3291 to fit her present anatomy (possibly with the assistance of a health care professional) may continue to use the imager (with perhaps minor adjustment over the course of pregnancy) using guidance techniques provided by the IMD 3291 and perhaps an external hand-held device. Adjustment is possible in the aforementioned ways, such as via the manually controlled or actuator controlled telescoping, rotation or angular adjustments of and within the optics assembly 3277. Even the optics cap 3271 can be replaced to adjust focal lengths or comfort as the area near the cervix 3217 changes.

[0250] The FIGS. 33a, 33b, 33c, 33d, 33e, and 33f depict individual parts and steps of constructing an intravaginal monitoring device such as that of the FIG. 33g. In particular, an optics assembly 3329 (FIG. 33g) consists of a telescopic stem portion 3315 that has been cut to support a mounting arrangement as shown in FIG. 33b (e.g., a telescopic stem portion 3315 of a width 3365 sized to fit within the housing stem 3331). A platform portion 3313 can be folded and manually adjust and readjusted, see folded platform 3319 of FIG. 33c, to support a desired radial mounting angle for an imager assembly 3321 of FIG. 33d. The axial mounting involves fixing an imager assembly 3323 within a telescopic stem 3325 as shown in FIG. 33d. The optics system 3329 can be adjusted by manually positioning the depth of the telescopic stem within the housing stem 3331 and through clockwise or counterclockwise rotation.

[0251] In an alternate embodiment, the telescopic stem 3328 can be extended and configured for rotation mechanically by a user via the end cap 3333. Similarly, mechanical constructs (not shown) are contemplated to support pivoting of the axially mounted imager assembly. Such configurations would eliminate the need to remove the optics cap to gain access to and to adjust the optics assembly orientation.

[0252] Among other details, the illustration also shows, an optics cap 3335 depicted in the FIG. 33e that is, in this embodiment, shaped irregularly with a bulge on one side so as to maximize focal length to the cervical area while taking advantage of natural elasticity associated with the region of the vaginal channel opposite the cervical surface. Typical dimensions 3351 and 3353 of the outer cap 3335 can typically be 36 mm and 28 mm to serve a variety of types of women’s reproductive systems and the specific underlying optics assembly requirements.

[0253] A battery compartment 3399 contains batteries that are rechargeable or disposable. One or more buttons or other user input devices may be placed on the IMD. For example, a power button is illustrated as being located on the bottom of an end cap 3395. The location of field of views 3373, 3375 of the axially and radially located imager assemblies are adjusted to minimize one imager assembly’s image capture of the other to prevent having to crop or present a perhaps distracting element within each image/video stream captured. Lastly, although only two imager assemblies are shown, many are contemplated so as to provide full or partial 3D coverage of the vaginal space. Such multiple images and video streams can be presented independently or via a 3D merged image (video) viewing environment.

[0254] FIGS. 34a–c are schematic diagrams illustrating construction of two embodiments of an intravaginal monitoring device along with typical dimensions, thereof, and having controllable optical systems built therein accordance with and to illustrate several aspects of the present invention. In each embodiment, the intravaginal monitoring devices use electrically powered actuators (such as miniature piezo actuators) to support the tailoring of an IMD to attempt to comfortably conform to dimensions and orientations of a specific user’s reproductive system. In the IMD of FIG. 34a, in addition to electro-mechanical control, fully mechanical tailoring of some parts of the optical system is also shown.

[0255] In both of the IMDs of FIGS. 34a and 34b, the optics systems can not only be controlled prior to insertion, but also during the insertion process and when fully inserted. As mentioned before, such control and tailoring of the optics system to fit a current user is one purpose of the electro-mechanical and mechanical enhancements. Another is to provide a mechanism for panning, zooming, framing, and otherwise exploring a target area. All of these goals are easily accommodated with electro-mechanical and some mechanical adjustment mechanisms. Specifically, in FIG. 34a, a piezo actuator 3413 controls the angle of a pivoting imager assembly 3411. Beyond “tailoring,” such pivot control can also be used, for example, to assist in the guidance of an IMD 3417 into position to target a cervix, and to pan, zoom, frame during insertion and at the insertion destination. All imager assemblies described throughout this application at a minimum contain an imager, such as, for example, CCD (Charge Coupled Device) or CMOS (Complementary Metal Oxide Semiconductor) varieties. Any other type of imager may be used which captures images and in some cases video are contemplated. In addition, such imagers need not operate in the visible optics range. For example, ultraviolet, infrared or other frequency electromagnetic wave imagers could be employed. Imager assemblies as described herein may also include one or more light (or other frequency) sources, a housing (supporting an optical pathway), lensing, apertures, filters, polarizers, and auto-focus and auto-zoom mechanism. Other imager assemblies mentioned throughout the present application may be similarly constructed. Moreover, throughout this disclosure one or dual imager assemblies are used in
each embodiment presented. Adding further imager assemblies, although not shown, is contemplated. All imagers underlying the imager assemblies herein are capable of capture still images (i.e., “snap shots”), video streams, or both.

[0256] A telescopic stem 3415 may be manually adjusted to accommodate both an optimal radial angle in relation to a power button 3419 (via depth adjustments via threading or tension), and the depth at which the optics assembly fits within an optics cap (shown in FIG. 34c). It can also be adjusted through rotation of the telescopic stem 3415 to accommodate off-center or tilted image/video capture targets. The IMD also uses a flexible stem 3417 (made of a for example silicone rubber) that contains the circuitry and power storage elements (e.g., batteries). A bottom cap 3421 may also screw on or off at least partially hermetically seal or expose or gain access to electrical or optical connectors, batteries, circuitry, etc. Although only a power button 3419 is illustrated, a much more substantial user interface including a display is contemplated for some embodiments.

[0257] A typical example of a procedure for tailoring, guiding and targeting with the IMD of FIG. 34a might first involve a doctor’s measurement of a particular patient’s reproductive system. Thereafter, with or without such information, the doctor or such patient might tailor (adjust) the optics assembly to fit the patient. That is, the doctor or patient may: a) manually adjust the depth of the telescopic stem 3415 within the flexible stem 3417; b) manually adjust (via optical assembly rotation) the pivoting plane with reference to the radial location of the power button 3419; c) select and install a particular one of several sizes and shapes of optics caps (such as the optics cap 3435 of FIG. 34c); d) insert the device with guidance support via an externally viewable display; e) further adjust the angle of the imager assembly during insertion and upon after reaching the target insertion location; and f) remove and readjust the telescopic stem via rotation or insertion extent into the flexible stem 3417 if necessary. The adjustment of the angle of the imager assembly 3411 via the piezo actuator 3413 may not only involve tailoring, but also supports dynamic viewing along with zoom, pan, and framing desires and capabilities of inherent in the imager assembly 3411.

[0258] Guidance support might involve for example using the illustrated axial orientation of the imager assembly 3411 during the insertion process to deliver a streaming video feed to an external viewing screen (not shown) through which guidance and initial positioning can be monitored. Through such screen, a user can determine when the target insertion location has been reached. They can also then control, via an external user input device, the piezo actuator 3413 create a radial angle orientation to support image and video capture of a radially located cervix or artifact. Radial viewing might also be used during the insertion process to better examine vaginal channel walls prior to reaching the target insertion location.

[0259] In FIG. 34b, similar operation can be found with the addition of further electro-mechanical elements that may support control before and after insertion and from external and remote devices. In addition to the electro-mechanical pivoting control of the IMD in FIG. 34a, the IMD of FIG. 34b is configured with automated telescoping and rotation. In particular, an imager assembly 3423 is mounted such that a piezo actuator 3425 can direct the imager assembly 3423 through a wide range of radial angles such as seen there, and including a fully axial position (0 degrees as shown in FIG. 34a). An actuator 3426 is used to not only control the extension of a telescopic stem 3427 into an optics cap, but also controls the rotational position of the pivot plane of the imager assembly 3423 in relation to the power button 3431.

[0260] Specifically, the base of the actuator 3426 is inserted and affixed to the inner wall of a housing stem 3429. The top end of a threaded (or ratcheted) post element of the actuator 3426 connects to the telescopic stem 3427 for raising, lowering, and seeking rotational alignment locations for the entire optical assembly. With this configuration and whether or not fully or partially inserted, using an external display and user interface, the IMD of FIG. 34b can be fully adjusted to assist in insertion guidance, zooming, panning, framing, and tracking interesting intravaginal targets. Depending on the embodiments, a user interface interacting with the IMD’s of FIGS. 34a-b might only support direct and simplistic control commands such as clock-wise/counter clock-wise rotation, in-out telescoping, and up-down pivoting. Other embodiments also support actual angles of rotation and pivoting, and millimeter based telescoping positions with full “go to” functionality. Control may also involve any other three dimensional coordinate relocation as well, and, in any configuration, smooth or fixed movement increments at course and fine tuning speeds are employed. Moreover, the approaches to integrate electro-mechanical and mechanical adjustment techniques underlying the optics assemblies are merely exemplary as many other approaches and configurations are possible and contemplated.

[0261] Any IMD in accordance with aspects of the present invention can be built using various fully or partially automatic and/or manual techniques for best positioning elements thereof in any or all of three dimensions. As illustrated, such positioning elements comprise imager assembly and entire optics systems, but other IMD elements such as other sensors, emitters, drug or fluid delivery or fluid sampling systems that are integrated within an IMD may also benefit from the up to three dimensional mechanical or electro-mechanically driven repositioning systems shown throughout the figures. Thus, all positioning techniques described herein can be used along with guidance techniques and feedback from imagers or any IMD element to assist in its underlying function.

[0262] Manual control can be asserted directly by whom ever inserts the IMD (depth, angles, torque, rotation, etc.) and by the woman’s repositioning of her own body which also effects reproductive system dimensioning. Automatic positioning control over sensors such as an imager assembly, can be made via buttons placed on the IMD itself and monitoring of positioning feedback may be collected via a display disposed on the IMD housing. Positioning control may also be managed via a tethered or wireless link by a local computing device such as a cell phone, tablet computer or laptop. Remote positioning control may also be carried out via a longer distance link such as a wireless cellular network or Internet link to a remote computing device. The remote computing device may also be a phone, tablet computing device, server, or workstation computer through a doctor’s or staffs interaction to analyze and diagnose a remotely inserted IMD.

[0263] Positioning of an optical assembly may also be used to assist in focusing, zooming or otherwise maintaining an adequate focal length to a target such as the cervix or opening of the cervical channel, or some other a gynecological event, artifact or condition. Positioning of other elements of an IMD to assist in their underlying functions is also contemplated as mentioned above for much of the same reasons. Such latter positioning may be carried out via integration with the former
position mechanisms or via separate positioning constructs. For example, further sensors could be attached to a pivoting image assembly and benefit by sharing such pivot even though such sensors have alternate targets than the imager assembly and so the pivoting function could be time-shared. As an alternative, a separate pivoting platform under control via a further actuator would allow simultaneous operation although at the expense of extra materials and volume—which overall should be kept to a minimum for comfort, fitting and other reasons enumerated above.

[0264] In FIG. 34c, among other details, the illustration shows a specific one of a plurality of types and sizes of optics caps, e.g., the optics cap 3435. By being made of a somewhat flexible material such as medical grade, silicone rubber, the optics cap 3435 may conform to sliding over optical assemblies while maintaining a hermetic seal with either or both of the telescopic stems 3415, 3427 or the housing stems 3417, 3429. Such hermetic seal may involve merely elastic tension associated with the diameters of the housing 3417, 3429 versus that of the optics cap 3435. Such hermetic seal may be improved with a bonding agent or glue and/or a mechanical constraint such as ribbing or threading. End caps 3421, 3441 may similarly be attached using tension or with threading and/or other mechanical constraints (e.g., a grommet 3439 of FIG. 34c or glue) to at least provide partial hermetic sealing.

[0265] In one embodiment, the dimensions 3451, 3455, 3457, 3459, 3461, 3463 and 3465 are such that the intravaginal monitoring device is able to accommodate the inner electronics appropriately, while attempting to support comfortable insertion, positioning, and maneuverability for a relatively large percentage of women. For example, the dimensions 3451, 3455, 3457, 3459, 3461, 3463 and 3465 are approximately 235 mm, 16 mm, 25 mm, 16 mm, 35 mm, 15 mm and 10 mm respectively, though the dimensions may vary to accommodate other goals such as fitting within a small carrying case or purse, fully wearable versions, permanently tethered versions, versions supporting groups of females with different reproductive system profiles, to accommodate additional sensors or feature functionality, etc.

[0266] FIGS. 35a-d are perspective diagrams illustrating further details regarding the adjustable optics assembly of FIGS. 9a-b that supports two imager assemblies. Space is at a premium within optics caps. Initially, such cap sizes take into account the need function of spreading the tissues in the target insertion zone so that adequate illumination and image capture can take place. Small form factor on the other hand is a desire for insertion comfort reasons. An optics cap length can also be shortened or lengthened to accommodate targets such as the cervix which may be axially located very close to the vaginal orifice or, alternatively, at the back of the vaginal channel. Overall cap size must also take into account focal lengths, imager and mounting assembly sizes, etc.

[0267] In FIG. 35e, a standard, side-by-side arrangement of two imager assemblies 3513 and 3515 is shown. Through manual or electro-mechanical control, a stem 3517 can be rotated and elevated, and a mounting platform 3511 can be pivoted. FIG. 35g illustrates that a pivot 3520 or other tension based interconnect between imager assemblies 3519, 3521 may further permit an angular adjustment between the two imager assemblies 3519, 3521. To save space yet sacrifice such angular adjustment, FIG. 35e illustrates overlapping cavities of imager assemblies 3523, 3525 to a level that does not cause interference with each optical path. Fully overlapping cavities are also possible yet not shown. In FIG. 35d, although imager assemblies 3527, 3529 appear to be connected, they are merely co-located with separate mounting platforms and separate actuators to provide separate pivot control for each.

[0268] FIG. 36 is a perspective and cross-section diagram illustrating a wearable snake-like intravaginal treatment device (ITD) inserted into the cervical channel for capturing imager data, delivering light treatment, and wirelessly communicating to deliver such imager data and, in some embodiments, to receive control signals, e.g., regarding treatment delivery. The ITD 3609 is intravaginally inserted through the vaginal channel while operating to capture and display imager data in real time on supporting devices. Guidance into the cervical channel and beyond is greatly assisted by such real time imaging.

[0269] In particular, the snake-like portion of the ITD 3609, a segmented section 3607 along with the head end portion 3613, as illustrated is routed into a uterus 3611. A much larger portion relative to the snake-like portion, i.e., a base 3621, includes at least a majority of underlying circuitry and batteries. The base is remains inserted into the cervical channel for light (and, if so configured, with fluid) therapy deliveries, as well as imager data capture support, preprocessing and storage. Via wireless infrastructure, while within the intravaginal regions, the ITD 3609 communicatively couples with external devices. Such coupling involves both the exchange of such imager data as well as any other sensor data captures, and the exchange of control signals relating thereto.

[0270] As such, the segmented section 3607 is designed to be flexible enough to be guided along curvilinear intravaginal channels within the reproductive system 3601. In addition, on the tail-end of the ITD 3609, a finger ring 3615 provides finger grip that assists in insertion, removal and stabilization during wear. The base 3621 of the ITD 3609 may be configured for relatively simplistic or advanced modes of operation, with corresponding functional components and circuits built inside. For example, within the base 3621, signal processing, communication interface, sensor, battery power and user interface circuity and associated components can be found. The cylindrical base 3621, if so configured, also contains a fluid reservoir and pump that injects fluids via the segmented section 3607 and nozzles mounted in the head end portion 3613.

[0271] Herein, often referenced throughout the present application, the female reproductive system of humans can be found. Even so, the present invention and various aspects thereof can be found in ITDs and associated supporting devices and networks designed to service any other species.

[0272] FIG. 37a illustrates a snake like ITD 3701 with a segmented stem 3707 carrying an imager assembly at the head end. The segments 3705 of the stem 3707 makes the ITD of 3701 very flexible. The components of the ITD 3701 are mounted such that they conform to the bending of the stem 3707. A plurality of light source emitters 3717 of the imager assembly 3709 provide illumination and therapy lighting. The imager assembly also contains lensing 3715 and an underlying imager (not shown). The emitters 3717 are LEDs specifically chosen for their illumination or therapeutic performance, e.g., IR, UV, blue, red, and other monochromatic or polychromatic light. Alternatively, some or all of the emitters 3717 may merely comprise optical fiber and dispersion lensing, and wherein such fiber is routed along side of or within the stem 3707 to a lower portion of the ITD 3701 (not shown). Particular light sources of the emitters 3717 can be selected.
depending upon the requirement. For example, to treat a certain infection, perhaps blue LED’s might be turned on continuously, while illumination for image capture occurs once per hour for a snap shot session, and all the while with an infrared LED turned off. The imager assembly 3709 communicates with associated circuitry in a supporting portion of the ITD 3701 (not shown) via wired cabling running within the stem 3707. Such other portion may also be inserted at least in part into the vaginal channel or remain entirely outside thereof. Some circuitry in addition to the present imager may also be embedded in or near the imager assembly 3709.

In FIG. 376, a fluid delivery system has been piggybacked onto an ITD 301 which, other than the fluid delivery components, is identical to the ITD 3701 (FIG. 375). In particular, a fluid delivery head 3723 has a plurality of nozzles 3719 for various fluids to areas within and beyond a vaginal channel via a tube 3721. Such fluids include cleaning solutions and various solutions containing drugs, dyes, bio-markers, or other pharmacological, biological or biochemical fluids. In some embodiments, the tube 3721 routes inside a segmented stem 3727, but in the present embodiment, it runs alongside (and may be affixed to) the segmented stem 3707. The tube 3721 is connected to the nozzle fluid delivery head 3723 on one end, and to fluid reservoirs and a pumping mechanism on the other. The pumping mechanism can be a manual mechanism such as a squeeze ball or syringe. Alternatively, such pumping mechanism can be electro-mechanical, comprising a fluid pump. A fluid pump responds to control signals by deliver all or a fixed amount of the fluid within a reservoir through the tube 3721 and out the plurality of nozzles 3719. The pumping pressure can also be adjusted via such control signaling.

Such pump control signaling can be generated directly via direct interaction with a supporting user interface by the patient, doctor, or other assistants located locally or remotely. Alternatively, pump control signaling can be automatically produced according to preprogrammed settings. Such settings might define parameters for and invoke one or more of: (i) scheduled one time delivery; (ii) periodic repeating deliveries per schedule; (iii) series of unrelated deliveries per schedule; (iv) slow, continuous “drip” delivery; (v) fluid volume per delivery; and (vi) type of fluid (where multiple fluid reservoirs and supporting pumping arrangements are available). For example, via a setup screen associated with a wearable ITD, 10 ml of a first type of fluid might be automatically delivered at a rate of 1 ml per second, once per hour for three days. Alternatively through such setup screen, beginning at midnight, a 30 ml of a first cleaning fluid is delivered at a 3 ml per second rate, followed 30 minutes thereafter by delivery of a second fluid in a continuous, 3 hour “drip.”

[0275] Fluid delivery may also automatically initiate in response to detected conditions. For example, via a setup screen, pump initiation of fluid delivery may be tied to sensor data. If for example, a pH sensor determines that the acidity level is beyond a desired threshold, a pump control signal can be delivered which causes the pump to deliver one or more quantities of a pH balancing fluid at once or over multiple delivery events. Similarly, upon determining natural yeast particulates above a threshold as identified from periodic images captures, such and other types of fluids might be similarly automatically delivered. Likewise via other settings, upon the ITD 3701’s detecting an onset of ovulation, fluid containing concentrations of spermatozoa could be dispensed every fifteen minutes while a patient sleeps at night. Such detection could involve an analysis of imager data while the ITD 3701 is being worn, and the fluid delivery triggering could occur only when such event is detected and associated timing is met. Confirmation of timing such as during nighttime sleep is accomplished via one or more of clock circuitry and orientation and/or motion sensors disposed within the ITD).

[0276] Basically, output of any one or more sensors (including imagers) can be analyzed within an ITD or outside thereof (on supporting computing systems) to determine whether thresholds have been exceeded or a condition or event has occurred. Such analyses may yield pump control signals automatically or via confirmation by the patient or supporting medical staff. Moreover, such sensor data analysis may be completely performed by: (i) the ITD’s and/or supporting system’s software and hardware; (ii) the patient or supporting medical staff; or (iii) a both of the above working together.

[0277] In addition, decisions regarding light therapy can be made via the same setup procedures and using the same infrastructures. In fact, light therapy and fluid delivery procedures can be intertwined into an overall therapy approach. Light therapy signaling to the one or more light therapy sources of the plurality of light source emitters 3717 can also be generated directly via direct interaction with a supporting user interface by the patient, doctor, or other assistants located locally or remotely, and in a manner similar to that of the pump control signaling. Alternatively, as with the pump control signaling, the light therapy signaling can be automatically produced according to preprogrammed settings. Such settings might define parameters for and invoke one or more of: (i) scheduled one time delivery; (ii) periodic repeating deliveries per schedule; (iii) series of unrelated deliveries per schedule; (iv) continuous delivery; (v) power intensity per delivery; and (vi) type or types of light being delivered.

[0278] As with fluid delivery, events or conditions detected (via various types of on board sensors) can (alone or with patient or medical staff assistance, initiation or confirmation) trigger one or more of the aforementioned preprogrammed settings. For example, based on coloration changes (via image data analysis) and pH level variations automatically and without requirement of confirmation, a first preprogrammed cleansing wash process triggers, followed immediately thereafter by both a continuous red light therapy and a short duration UV therapy process, wherein both light therapy processes are defined via preprogrammed settings. Many other types of triggering events with automatic and/or manual causation and intermixed sequential and/or parallel fluid and light therapy regimes are contemplated. For example, some fluids may be delivered for causing responses that are emphasized or fully activate when exposed to light, and thus the resulting performance requires a controlled overall procedure manageable by the ITD, patient or medical staff, and/or supporting systems.

[0279] FIG. 38 is a perspective diagram illustrating a fluid delivery embodiment for an intravaginal treatment device (ITD) with a fluid nozzle and an imager and light source assembly, both disposed within a cervical cap, that selectively deliver fluids and light therapies, respectively, and with a squeeze ball and tube for controlling manual fluid injection via the nozzle. Therein, an ITD 3801 has a cervical cap 3811 covering an imager assembly 3809 and fluid nozzles 3817 at
a head end (or anterior end of the ITD 3801), and has a squeeze ball 3803 at the tail end (or posterior end of the ITD 3801).

[0280] A silicone rubber tube 3805 may be detached from a housing stem 3803 of the ITD 3801 for convenience when the fluid system is not being used or during the process of cleaning and filling the squeeze ball 3803 with fluids. Although a squeeze ball 3803 is illustrated, other shapes and manual injections configurations such as a syringe may replace the squeeze ball 3803 temporarily or permanently. That is, a variety of types of injection mechanisms, some purely mechanical and some electro-mechanical can replace (for all or some types of fluid deliveries) the squeeze ball 3803 and the tube 3805, if needed. A fluid nozzle assembly 3819 has the fluid nozzles 3817 disposed thereon. The fluid nozzle assembly 3819 provides a fluid pathway to the fluid nozzles 3817 and there through to a target area with a vaginal channel such as a cervical area. In other words, when the squeeze ball 3803 is squeezed, fluid will be forced from the interior of the squeeze ball 3803 and, in sequence, through the tube 3805, an internal pathway 3821 within the housing stem 3807, the assembly 3819, and, finally, through the nozzles 3817.

[0281] The cervical cap 3811 is sized to cover (and perhaps even contain portions of) a cervix. With illuminators for the imager, light sources for therapy, and nozzles for fluid delivery being disposed within the cervical cap 3811, a more controlled treatment environment within the cervical region can be maintained. More specifically, along with the fluid nozzle assembly 3819, the imager assembly 3809 can be disposed within the cervical cap 3811. As illustrated in detail with reference to various other figures herein, the imager assembly contains a imager, lensing and a housing with illuminating white light supporting imager data capture (images and/or video data) as well as various therapeutic light sources. Although integrated into the housing as illustrated, all or some of such light sources may be disposed at other locations within the ITD 3801. As can be seen, the fluid nozzles 3817 are designed for delivery of fluids to at least partially encompass the imager’s field of view. In other words, fluids injected should contact at least part the target area being (or to be) imaged. Additionally, an extra nozzle can be added that targets the head end of the imager assembly so that cleaning thereof can be carried out without having to remove the ITD 3801 once it has been inserted and in operation.

[0282] The squeeze ball 3803 can also be used to deliver fluid during the insertion or the removal process so as to coat the entire vaginal channel. Likewise, when only partially inserted, fluid delivery can be invoked to, for example, target a specific artifact at a particular location perhaps midway into the vaginal channel that is not cervix related. The size and angle of the cervical cap 3811 can be changed by merely selecting and installing an alternate one of a plurality of differing sized and oriented counterpart cervical caps (not shown). The cervical cap can be made of any bio-compatible material such as soft, medical-grade silicone rubber. It may also comprise a reflective inner surface 3815 to assist in the illumination and light therapy process.

[0283] FIG. 39 is a perspective diagram illustrating another embodiment of an intravaginal treatment device (ITD) having a built-in fluid reservoir, pump, a fluid nozzle and dual imager and light source assemblies, and built in accordance with various aspects of the present invention, to capture imager data and deliver fluid and light source therapy. Therein, an ITD 3901 has a fluid reservoir and pumping system 3905 disposed with a housing stem 3919. Because a cap 3903 fully encloses an optics assembly 3917, fluid nozzles 3909 are disposed on the outside surface of the cap 3903 and aimed in a typical direction where a cervix may be found, which differs greatly from female to female.

[0284] As can be appreciated, the target of the nozzles 3909 and a mostly radial imager assembly 3913 have at least substantial overlap. Thus, the nozzles 3909 are provided to mostly service the area of the interest to the mostly radial imager assembly 3913 and not that of a mostly (if not fully) axial imager assembly 3911. An additional nozzle set servicing the imager assembly 3911 could be added at a different location on the cap 3903 with service from the fluid reservoir and pumping system 3905 or an independent counterpart thereof, if so desired.

[0285] As in other embodiments, the size and shape of the cap 3903 can be changed by merely replacing the cap 3903 with another and reattaching the fluid nozzles to a fluid carrying pipe 3907. Although the fluid reservoir and pumping system 3905 as illustrated only contains a single fluid reservoir, multiple reservoir chambers can be added and serviced by one or more pumps for delivering a corresponding multiple types of fluids. The ITD 3901 may comprise a wearable ITD (with a relatively short version of the housing stem 3919) or have a hand maneuverable length (i.e., with a relatively long version of the housing stem 3919) that can be grasped even when the ITD 3901 is fully inserted. Triggering of light and fluid therapy approaches are identical to that discussed in relation to the ITD of FIG. 38. For example, the fluid injection process may be triggered after automatically detecting a condition that is confirmed remotely by a doctor at a certain hour of the day during the generation of video and with before and after images. A preprogrammed process associated with the above triggering might be terminated mid sequence upon determining that enough fluid has reached the target. That is, process initiation might not only be started (triggered) by conditions or events detected (by sensor data analysis by the ITD, associated support systems and/or staff) but may be stopped due to identification of the lack of such condition or event or yet another condition or event entirely. Moreover, with a real time video feed from the imager 3913 (for example) along with twisting, torquing and adjusting insertion depth of the ITD 3901, a patient or medical staff can direct the delivery of fluid to more accurately and effectively hit a target. The aforementioned applies equally to directing the light therapy emitters within the imager assemblies 3911, 3913 as well.

[0286] As mentioned before, fluids that may be delivered include almost any hopefully non-toxic and beneficial solutions such as: (i) drug suspensions; (ii) pH balancing and other cleaners; (iii) anti-coagulants; (iii) birth control (including “morning after”) suspensions; (iv) anti-bacterial, anti-viral or anti-fungal solutions; (v) preparatory solutions to assist any ITD sensor (optical or otherwise) such as those including acids, dyes, markers, conductive materials, etc.; and (vi) preparatory or enhancing solutions to assist the light therapy process such as with solutions containing selective binding agents having light activated responses.

[0287] In addition, although only light sensing imager arrays (sensors) that are contained within the imager assemblies 3911, 3913 are illustrated, the ITD 3901 can be fitted with a wide variety of additional sensors. Such other sensors can benefit from various types of fluids as mentioned above. In addition, they can be fully responsive to reflections from
the light therapy sources directly. For example, if an ultraviolet (UV) light emitter might be used to provide a particular therapy via (i) direct tissue interaction (ii) activation resulting from a delivered fluid, or (iii) direct interaction with viral, bacterial or fungal constructs. In addition, reflections of such UV lighting may also be detected by a sensor (such as an imager array) that is tuned to sense UV frequencies, and which produces imager data (images and video) that can be translated into the visible range for viewing by patients and medical staff in real time or reviewed post fact. [0288] FIG. 40 is a perspective diagram of an embodiment of an optics assembly having a stem, mounting structures and two mounted imager and light source assemblies that may be used in some embodiments of an intravaginal treatment device (ITD) in accordance with the present invention to deliver light therapy and capture imager data. In particular, an optics assembly 4001 contains a radial imager assembly 4007 (containing a mostly-radial oriented imager 4006) and the axial imager assembly 4015 (containing a mostly-axial oriented imager—not shown). The imager assemblies 4007 and 4015 are attached to a mounting structure 4003 of optics assembly 4041. The optics assembly 4041 can be moved in an axial direction 4039 and a rotational direction 4037. [0289] To increase focal distance in a mostly radial direction, the radial imager assembly 4007 is mounted slightly off center and upon a flexible portion 4005 of the mounting structure 4003. The imager assembly 4007, in addition to the imager 4006, has a lensing system 4027, a plurality of light therapy sources capable of emitting light at any specified one or more frequencies, i.e., via an IR light source 4023, UV light source 4025, monochromatic blue light source 4019, and monochromatic red light source 4021. The light therapy sources 4019, 4021, 4023 and 4025 are switched off or on at various power levels or duty cycles pursuant to local or remote control. In addition to continuous emission and fixed power levels, active and continuously power level variations (or other modulation techniques) over time may be employed to provide better therapeutic results. [0290] The axial imager assembly 4015 is mounted slightly off center of the cylindrical base 4003 to allow mounting space for the radial imager assembly 4007. The axial imager assembly 4015 is attached to a flexible vertical portion 4017 of the mounting structure 4003. The axial imager assembly 4015 also has lensing 4013 (supporting the underlying imager) and a plurality of light therapy sources mounted thereon, including: an IR light source 4011; UV light source 4013; blue light source 4033; and red light source 4029. Power, power level and duty cycle control as with the light therapy sources of the imager assembly 4007, can be fully controlled by internal processing circuitry, devices outside of the ITD, or by a combination of both. [0291] Light source illuminators supporting image data capture by the imagers within the assembly 4007 and 4015 are not shown but may also be incorporated into the imager assemblies 4007 and 4015 or into either another location within the optical assembly 4001 or at some other location within an ITD that includes such optical assembly 4001. Light source illuminators and their corresponding imagers may be selected or tuned to operate in any electromagnetic wave frequency including in the white light range. The radial imager assembly 4007 can be moved in the direction indicated by the arrow 4035 by perhaps ±20° to fit a particular female’s anatomy. Similar adjustments may be made to the axial imager assembly 4015. The complete optics assembly 4041 can be axially moved along the direction of a stem of an ITD, or rotated for better alignment as illustrated by arrow 4037. [0292] FIG. 41 is a schematic block diagram illustrating exemplary components and circuitry that may be found in whole or in part within the many embodiments of an intravaginal treatment device (ITD) of the ITDs set forth herein and built in accordance with and to illustrate various aspects of the present invention. In particular, circuitry 4101 includes an interface and control circuitry 4107 which arbitrates and prioritizes data acquisition and transmission to and from various ITD components and supporting devices and systems outside of the ITD. [0293] For example, the interface and control circuitry 4107 directs the capture of imager data via control signals delivered to imager devices 4103 and retrieves resultant captured imager data therefrom. The circuitry 4107 may store such image data locally within a memory 4109 and/or route to devices outside of the IDT via wired and/or wireless communication interfaces 4119 and 4121. The circuitry 4107 is responsive to incoming commands and controls via the communication interfaces 4119 and 4121 as well. Such commands and control are translated by circuitry 4107 into sequences of digital control signals delivered to various underlying components to carry out the specified functionality, e.g., activation selected ones of the imager devices 4103 and providing illumination therefor, activating fluid pump 4123, delivering stored information via the wireless communication interface 4121, etc. [0294] Other activities of the circuitry 4107 include activation, retrieval, storage and forwarding of other sensor data from a microphone 4115 and supplemental sensors such as orientation and motion indicators, fluid level indicators (fluid reservoir), pH sensors, thermometers, sonograms, EKGs, and a variety of other bio-sensors, for example. Sensor data retrieved may also be processed or preprocessed by the circuitry 4107 in preparation for display or analysis. If so, even further, automatic analysis could lead to conclusions all possibly performed by the circuitry 4107 or by an external support device. The circuitry 4107 also manages directly (or indirectly via remote control) the application of light and fluid therapies. [0295] Each of the imager devices 4103 responds to control signals to capture and forward imager data. The imager assembly 4103 may contain one or more of a monochromatic light sensitive imager 4131, a UV light source sensitive imager 4133, an IR light sensitive imager 4135, MRI (magnetic resonance imaging) imager 4137 and other source sensitive imagers 4151, such as sonogram imaging elements (not shown) or a select frequency of light that reveals venous growth to provides an early indication of potential cancerous cell activity. [0296] The light therapy block 4105 indicates a various selection of light sources that may be employed to treat a wide spectrum of conditions within a female reproductive organ. The UV source 4139 may be used for example to kill bacteria which respond to a specific frequency or frequencies in the UV spectrum. A red light source 4141 may be used to illuminate lesions, abrasions and cuts, by inducing tissue healing. A blue light source 4143 may be used against bacteria or virus infected tissues. The other light sources 4145 pertain to any therapy that involves light energy such as X-rays, laser, IR light, etc.
The internal light sources 4149 are the sources of light of specific frequencies and frequency ranges housed within an ITD of the present invention. An external light source 4147 are those light sources located outside of the ITD that produce light conveyed via fiber optics into the optics assembly of the ITD for imaging (illumination) and light treatment. As mentioned, the supplemental sensors 4113 are any of a variety of sensors that may be included in a particular ITD, e.g., bio-sensors, thermal sensors, pressure sensors, glucose sensors, IR sensors, position sensor, velocity sensors, gene chips, etc. The microphone 4115 is an audio range sensor that can be used to capture fetal or female heart rate(s), movement, etc.

The user interface 4117 may be fairly simplistic and comprise only a power button and relying on external support devices for more complex input and display interaction. Alternatively, an ITD can be configured with a more complex input device and display supporting vastly superior interaction, and perhaps without the need for a supporting external device to operate and even display internally generated data or conclusions. For example, a user can inject fluids using injection syringe or squeeze ball (discussed in FIG. 5) or automatically direct such functionality via internal pumps and reservoirs via the user interface(s) 4117. Such user could be the patient, doctor, medical assistants, etc.

The wired communication interface 4119, if present, may utilize proprietary and industry standard communication protocols compatible with external support devices, e.g., USB, firewire, ethernet, etc. Similarly, if present, the wireless communication interface 4121 may also offer proprietary and industry standard communication, such as Bluetooth, Zig-bee, or Wi-Fi. A fluid pump 4123 associated with a fluid reservoir 4125 may contain any number of fluids as described in detail relating to the preceding figures. The power regulator unit 4111 manages power delivery to ITD components and circuitry. Depending on the construct, power can be delivered wirelessly, via wire, replaceable or rechargeable batteries 4129, etc. Power charging and regulation circuitry 4127 manages the delivery to ensure stable and sufficient power is distributed and, if employed, the rechargeable batteries 4129 receive adequate recharging.

FIG. 42 is a perspective and cross-sectional diagram illustrating an inserted ITD having a radial illumination mechanism to support delivery of light therapy along the length of the vaginal channel. As illustrated, within a reproductive system 4201, a therapy light 4213 built within a stem portion of an ITD 4209 to deliver light therapy to areas along the length of the vaginal channel. Similarly therapy lighting is also placed as described heretofor in an optics assembly 4215 of the ITD 4209. Both sources of therapy lighting are controlled by underlying circuitry within the ITD 4209, and may also be controlled via control signals originating outside thereof from external support devices.

Outside of the reproductive system domain, it is known that light of specific frequencies, frequency ranges, and under certain modifications and duty cycles, can at least assist in curing infections, e.g., the use of blue light for treating acne vulgaris, and UV lighting to destroy bacteria or deliver therapy for psoriasis and eczema. Also known outside of the reproductive system domain is the use of therapy lighting to promote healing, e.g., red light for healing skin roughness, cuts, etc. It is also known that the X-rays destroy both cancer and surrounding. High intensity laser light can be similarly useful.

If configured with appropriate therapy delivery and monitoring infrastructure, the ITD 4209 can not only follow a predefined therapy delivery procedure, but can also adjust the procedure based on sensor data (e.g., imager data) feedback so as to maximize the therapeutically effects while focusing in on the desired areas to be treated and to optimize the during and intensity of overexposure. Such feedback may be gathered during the therapy session and at some time after a session in a series of therapy sessions, to support such optimization. For example, overexposure might not be revealed until some time after exposure to the light therapy during a therapy session. In other cases, it might be revealed by sensor data during a session. Mid-session indications can then be used to adjust the intensity or duration of therapy given at a current session, while post session indications can be used to similarly adjust a subsequent therapy session. Either way, such indications may yield a decision to terminate all further therapy. And of course, this applies to any type of therapy delivered by the ITD 4209, including but not limited to the various light therapies illustrated, fluid therapies (used separately or in conjunction with the light therapies), and other types of therapies delivered by other bio-chemical, electrical or electro-mechanical sources installed within the ITD 4209.

For example, an X-ray source emitter can be controlled to target a particular optically discernible area on a cervix. During exposure, either X-ray reflections can be targeted or heat signatures from an infrared imager can be captured to produce real time images and feedback as to where and how effective treatments are proceeding. Intensity can be adjusted then to account for cancerous growth depths across the various locations of the surface region under treatment. With precise guidance of the X-ray or laser emitter (perhaps via on-off and intensity control via raster scanning arrangement similar to that of FIG. 20) such as an X-ray beam or laser beam, an optical image can be used to confuse exposure of the emission to a specific target within the optical field of view. For targeting confirmation and efficacy, reflections to corresponding imagers or heat signature images from infrared imagers can be used. The surface area of three-dimensional targets (artifacts) target can also require more or less overall intensity (via emission intensity or duration of exposure) at each point therein to correspond to the varying thickness of the underlying artifact. For example, the target areas with greater depth and treatment, and with lesser treatment at edges.

The therapy light 4213 may be a single or a plurality of incandescent or fluorescent lamp with or without appropriate filters (e.g., a “black light”) or any other lighting mechanism that provides a more radial light emission along the axis of the stem portion of the ITD 4209 as shown. As with the therapy lighting associated with the optics assembly 4215, the therapy light 4213 may produce light of one or more frequencies and/or one or more frequency ranges, and in a continuous or modulated approach for a specific therapeutic goal. Emissions from the therapy light 4213 impact organisms, viruses, fungus, fluids and tissues of or upon the vaginal walls 4205. For example, if the light therapy is directed to reduce an overabundant natural flora growth, such light tuned to such flora will be adversely effected and either illuminate or reduce the need for anti-fungal and anti-bacterial cremes.

Similarly, the ITD 4209 of present invention is also used for healing and enhancing the elasticity of the vaginal channel walls 4205, for example, using red light emissions. Moreover, if the optics assembly 4215 and end portion of the
ITD 4209 are appropriately sized, the ITD 4209 can be inserted into further intravaginal areas such as through a cervical channel 4223 and beyond into the uterus, and to provide similar therapies for healing and to address therein viral, fungal and bacterial intruders, for example. The guiding of the ITD 4209 inside the vaginal channel and cervical region and monitoring thereof is assisted by local or remote “control and monitoring system”, which have video display or screen showing the head end of ITD 4209. The optics assembly 4215 with axial imager assembly 4217 and radial imager assembly 4219 is used to capture video image (frames) of intravaginal channel/intracervical region walls.

[0306] Other aspects of the present invention can be found in additional functionality relating to all of the above embodiments such as that set forth as follows.

[0307] In a first embodiment, an application runs on a mobile phone that displays the data collected from an intravaginal monitoring device. The mobile phone may be an Apple™ brand phone, a Samsung™ brand phone, a Google™ brand phone, a Motorola™ brand phone, a Blackberry™ brand phone, and a Nokia™ brand phone, and so forth. The mobile phone may also be a smart phone.

[0308] The mobile phone may also consist of a graphic reflecting an event or condition associated with a female’s reproductive health. The graphic may be associated or related to: (1) an event or condition associated with a family’s fertility, female’s reproductive health; (2) female’s strength of her vaginal muscles; (3) female’s pregnancy, detection of an infection; (4) detection of a sexually transmitted disease condition or event; (5) detection of a precancerous cervical condition; (6) detection of a human papilloma virus detection; (7) detection related of a cervical injuries; and/or (8) detection of an abortion.

[0309] The aforementioned mobile phone may also include a mode of operation that consists of an automated rhythm method providing electronic information to a female regarding her fertility cycle, and in which data from the intravaginal device is used as an input into the mode of operation. The mode of operation may include displaying data related to a determination of a pregnancy. The mobile phone’s display may also have modes of operations that depict: (1) a photo of a doctor; (2) a photo of a female; (3) parameters related to prenatal monitoring; (4) parameters related to a female; (5) parameters related to a fetus and a female; (6) a labor prediction display; (7) a premature birth parameter display; (8) a false labor display; (9) a true labor indicator; and (10) illustrating contraction timing.

[0310] Additional measurements, display and illustrations done by the aforementioned mobile phone may include: (1) a cervical dilatation measurement; (2) illustrating fluid flow; (3) illustrating position of a cervix (position of the cervix is selected from the group consisting of a central position, an anterior position, and a posterior position, for example); (4) an advertising (selected from the group consisting of a diaper advertisement, a baby food advertisement, a baby furniture advertisement, a baby clothing advertisement, an advertisement related to a product for a newborn, an advertisement related to a product for a mother, an advertisement related to a product for a father, an advertisement related to a nutritional supplement for a newborn, an advertisement related to medical services, an advertisement related to insurance coverage, and an advertisement related to services related to a premature baby); (5) indicating the condition of the tons of a female (the firmness or softness of muscles surrounding a female’s womb); (6) a time line related to the release of waters pre-birth; (7) parameters related to a fetus in a womb (related to the position of body parts of a being in a womb of a female); (8) a condition of a female’s cervix; (9) a post birth healing monitoring mode of operation; (10) a menopause onset detection mode of operation; and (11) graphics for an in-vitro fertilization mode of operation.

[0311] A process for providing in vitro fertilization using the intravaginal monitoring device and a mobile phone consists of: (1) displaying on a mobile phone a calendar or chart indicating peak fertility days to a female, and providing said female an in vitro fertilization therapy, in combination and monitoring fertility drug performance. The therapy itself consists of a drug therapy (such as a fertility medication that is injected, a fertility medication that is taken orally, a fertility medication that is taken by nasal spray, and a fertility injection, for example). The mobile phone mode of operations for coordinating administration of a fertility therapy with a female’s menstrual cycle, the mobile phone having a mode of operation from receiving data from an intravaginal monitoring device. The mobile phone itself may consist of a photo of a sex partner, a photo of a doctor, a photo of family member’s, and a photo or graphic depicting a cervix or measurement associated the said cervix. The aforementioned mobile phone mode of operation also presents the information on the display of the screen so that a user can determine infertile days.

[0312] In one embodiment, a system for getting pregnant, consisting of a mobile phone having a fertility calendar, and an intravaginal device for monitoring fertility events, is considered; such that the device communicates with the mobile phone. In conjunction with the system, a method for getting pregnant and a kit for getting pregnant are considered here, consisting of a mobile phone and intravaginal device system to determine peak fertility days, and taking a fertility drug therapy. The aforementioned method and kit may include: (1) having multi-organic sex; (2) drug therapy is selected from the group consisting of a progesterone therapy, a gonadotropin therapy (for example, the gonadotropin therapy is a recumbent gonadotropin therapy), alone or in combination with other fertility drugs; (3) the drug therapy is selected from the group consisting of a GnRH Agonist therapy, a Lupron Depot® therapy, and a drug therapy administrated on different calendar schedules depending on the female; (4) the drug therapy is selected from the group consisting of a gonadotropin-releasing Hormone antagonist therapy, a drug therapy preventing the release of LH and or FSH, a clomiphene citrate therapy, a Clomid® therapy, a drug therapy to stimulate ovulation, a Clomid® therapy, a Serophene® therapy, and a Milophene® therapy, and a human Menopausal Gonadotropin (hMG) therapy.

[0313] The mobile phone may include a sonogram image of a being in a womb of a female in data storage of the mobile phone, and a mode of operation for presenting data associated with a pregnancy. The mobile phone may consist of a communication link with an intravaginal monitoring device.

[0314] A system for tracking events during a pregnancy and birthing process are also considered in one of the embodiments, consisting of a mobile phone (having an application to receive data from an intravaginal monitoring device, an external electronic monitor sized and dimensioned to be worn on a pregnant female’s stomach, the monitor consisting of a communication link to said mobile phone). The mobile phone also has a graphic user interface consisting: (1) a graphic depicting cervical opening size; (2) a mode of operation for automatic
birthing alerts to an expectant father; (3) a mode of operation for displaying the expected weight of the being in the womb, the weight being calculated based upon a weight determination (such as a predetermined statistical weight data file, and a weight determined by sonogram dimensions of the being in the womb); (4) an expectant parent information about an expected birth of a child (such as location information regarding an expectant mother, location information regarding a birthing center, location information regarding a medical professional responsible for a birth, location information regarding an expectant father, location information regarding an emergency treatment center, location information regarding an institution having facilities to manage a high risk birth, location information for the fastest route to a location for giving birth, location information regarding family or friends of an expectant mother, and location information of a medical clinic).

The mode of operations of the mobile phones may include: (1) a display for prediction of the time of active labor; (2) a display that distinguishes between active labor and passive labor, and provides an indicator (such as an audible indicator, a preprogrammed voice indicator, a visual indicator, and audio visual indicator, and a vibrational indicator) of same to a user; (3) storing a plurality of data communicated from an intravaginal monitoring device to the mobile phone; (4) storing a plurality of data communicated from an intravaginal monitoring device to the mobile phone; so forth.

The mobile phone's applications (for processing data received from an intravaginal monitoring device) may include: (1) a mode of operation for obtaining wired data from the intravaginal monitoring device; (2) a mode of operation for obtaining data wirelessly from the intravaginal monitoring device; (3) a mode of operation for transmitting said data from the mobile phone to a remote device wireless communicating to the remote device (such as a server communicatively linked to the Internet, a server communicatively linked to an intranet, an electronic device forming part of a wide area network, an electronic device forming part of a metropolitan area network, an electronic device forming part of a local area network). The mobile phone's applications may also consist of a mode of operation for communicating data received from an intravaginal monitoring device, and optionally an external monitoring device having sensors thereon for monitoring physiological parameters of an expectant mother or being in a womb.

Instead of the mobile phone, an independent electronic, wireless device and network having the features, functionality and modes of operation of the disclosures herein are also considered. Similarly, an electronic, wired device and network having the features, functionality and modes of operation of the disclosures herein are also considered. Mobile phones consisting of: (1) applications for receiving and post processing data received from a wireless intravaginal device sensing physiological parameters related to the health of a female; (2) applications for receiving and post processing data received from a wireless intravaginal device sensing physiological parameters related to a being in a womb; (3) smart phone functionality and a post processing mode of operation for receiving and processing data from an intravaginal monitoring device; and so forth are also considered.

Similarly, an external data communication device (for example, incorporated into an item of apparel) consisting of a mode of operation for processing data harvested by an intravaginal monitoring device, in which said processing comprising providing displays regarding parameters related to a female's reproductive health is also considered. A network consisting of a mobile phone (for example, a smart phone with an operating system), and an intravaginal monitoring device communicatively linked to the smartphone is also considered. The smartphone supports email, the emails related to: (1) the female reproductive health data; (2) female and medical professional communications.

A mobile phone, further consisting of a mobile communications device, communicatively linked to the aforementioned smart phone, the mobile communications device may include another smartphone, a smartphone with an application to provide a medical professional with data about a patient, a smartphone with an application to provide an expectant father with information about a pregnant female, a smartphone with an application to provide an expectant mother with information about a child within her womb, and a smartphone with an application to provide insurance or national health care insurance information to a provider of medical services, is considered in one another embodiment.

The smartphone network consisting of an intravaginal monitoring device and the smartphone is considered in one embodiment. The smartphone consists of an application that includes a personal organizer, advertising data, a female user interface (including a miniature QWERTY keyboard, a touch screen, a D-pad, a built-in camera, a contact management, an accelerometer, built-in navigation hardware and software, the ability to read document data, media software for playing music, browsing photos and viewing video clips, Internet browsers). An intravaginal monitoring device sized and dimensioned to provide data from with a vagina, comprising an accelerometer is also considered. A network consists of an intravaginal monitoring device and a mobile communications device communicatively linked to the intravaginal monitoring device, the monitoring device consisting of an accelerometer, or optionally the mobile communication device consisting of an accelerometer.

A network consisting of an intravaginal monitoring device and mobile communications device, and a secure communication link between the monitoring device and the mobile communications device is also considered, in one of the embodiments. Further, the aforementioned network may further consist of a secure communication link between the mobile communications device and a device communicatively linked to the Internet. A network consisting of an intravaginal monitoring device and a mobile communications device, and a data archive comprising image data from a plurality of females of internal female organs is also considered in one of the embodiments.

In another embodiment, a network comprising an intravaginal monitoring device sized and dimensioned to fit inside a vagina and a web site on the Internet accessible by a female to view data harvested by said intravaginal monitoring device is considered. The network may further consist of a smartphone (such as a BlackBerry™ brand phone) that includes an application for processing data harvested by said intravaginal monitoring device. In the aforementioned network, the smartphone may also consist of a contact list (that includes data of an obstetrics or gynecology medical professional). The contact list data may also include data of a sex partner of a female, data of a family member of a female, data of a birthing center, data of a clinic, data of a clinic to treat a female infertility problem, data of treatment center for a
sexually transmitted disease, data of a medical professional, data of a medical professional treatment group, and data of a medical diagnostic center.

[0323] A network, consisting of an intravaginal monitoring device with a built in memory for storing physiological data, and a mobile communication device with a built in memory (the monitoring device having a mode of operation for sending data from the memory of the monitoring device to the memory of the mobile communication device) is considered in one of the embodiments. A network consisting of a plurality of Nokia™ smart phones, each the smart phone communicatively linked with an individual intravaginal monitoring device is also considered.

[0324] A network consisting of a plurality of smart phones each of the smart phones consisting of a smart phone camera for taking pictures, the smart phone camera having a focal length suitable for taking pictures at least 3 meters to infinity, and a plurality of intravaginal monitoring devices communicatively linked to an individual smart phone, each of the intravaginal monitoring devices capable of harvesting a digital image with a camera having a focal capable capturing an image from 0.1 cm to 10 cm from the camera is also considered, in one of the embodiments. The aforementioned camera may be a digital CMOS camera, for example; consisting of an array. The smart phone itself may consist of hardware and software permitting WiFi and or WiMax data communication. An intravaginal monitoring device consisting of hardware and software permitting wireless web browsing is also considered. A network consisting of an intravaginal monitoring device and a smart phone communicating therewith, said smart phone capable of wireless web browsing is also considered.

[0325] A network consisting of an intravaginal monitoring device, a mobile communications device, the mobile communications device, and optionally the intravaginal monitoring device consisting of an operating system is also considered. The aforementioned operating system may include Windows CE Pocket PC OS, and a Palm OS.

[0326] A network consisting of an intravaginal monitoring device, the device communicatively linked to a mobile communications device, the mobile communications device consisting of an open source platform is also considered. A network consisting of a device sized and dimensioned to fit into a vagina, and be wearable, and a mobile communications device consisting of an Android™ operating system is also considered. A network consisting of a device sized and dimensioned to fit into a vagina, and be wearable, and a mobile communications device consisting of an HTC smart phone is also considered. A network consisting of a device sized and dimensioned to fit into a vagina, and be wearable, and a mobile communications device consisting of a software suite is also considered. The software suite may consist of Google™ applications such as a map application, calendar application, a Gmail™ application, a Google Chrome Lite full HTML web browser, and a third party application. The software suite may consist of a paid for application downloadable from an Apple™ applications node located on the Internet. The software suite may also be a smart phone application delivered directly to the mobile communications device, such as an iPhone™ and an iPod™, and in which said software suite is delivered to said mobile communications device directly over a cellular network, a wifi network, or a WiMax network, alone or in combination. The software suite may include a Symbian operating system, an iPhone operating system, a RIM operating system, a BlackBerry operating system, a Windows Mobile operating system, a Linux operating system, a Palm Web operating system, an Android operating system, an Android and or Web operating system built on top of Linux, and an iPhone operating system derived from an BSD operating system and or a NeXTSTEP operating systems, alone or in combination.

[0328] A communications network consisting of a node consisting of a self powered, intravaginal monitoring device, and a GPS receiver located remotely from said intravaginal monitoring device, the device and the GPS receiver consisting of a mode of operation for communicating with one another, is also considered in one of the embodiments. The GPS receiver may consist of a mode of operation for providing the geographical location of the intravaginal monitoring device. The communications network may further consist of a node on the network for communication of data of the geographical location to a location processing node on the network. The geographical location data is may include a location of an expectant mother, a location of an expectant father, a location of a medical professional, a location of a clinic to treat a female health condition and or event, a location of a hospital, a location of a nearest health care provider, a location of a midwife, and a location of a in vitro fertility center.

[0329] A self powered device, consisting of an intravaginal monitor for monitoring conditions of a female and/or being within a womb of the female, and a GPS receiver, is also considered in one of the embodiments. The GPS receiver calculates its position by precisely timing the signals sent by the GPS satellites above the Earth. The GPS receiver consists of a triangulation algorithm and the position of the device and the GPS receiver is displayed on a moving map display. The moving map display further consists of a direction and speed data; and the GPS receiver and the device further consist of an antenna. The antenna or optionally multiple antennas, is tuned to the frequencies transmitted by more than one satellite. The communications network or intravaginal monitoring device of any of the disclosures herein, in which the aforementioned receiver is tuned to multiple channels, is also considered. The communications network or intravaginal monitoring device of any of the disclosures herein, in which said receiver relays position data to a receiving node on a communications network is also considered.

[0330] The communications network or intravaginal monitoring device of any of the claims herein, further consisting of a navigation mode of operation. The navigation mode of operation may include a navigation mode to direct a pregnant female to a birthing center, a navigation mode of operation to guide a female to female health condition or event crisis management center, a navigation mode of operation to guide an expectant father to an expectant mother, a navigation mode of operation to guide an expectant mother to a medical professional, a navigation mode of operation to guide a female to a clinic, a navigation mode of operation to guide a plurality of people who have been involved in the conception process to a single location for a birth, a navigation mode of operation to guide a medical professional to a female, a navigation mode of operation to guide a first responder to a female in need of
medical attention related to a female condition or medical event, and a navigation mode of operation.

A mobile communications device for two way communications via a cellular or Internet network, consisting of a display having an alert generated from data harvested from an intravaginal monitoring device, whereby the intravaginal monitoring device is communicatively linked to the mobile communications device is also considered in one of the embodiments. A mobile communications device for two way communications via a cellular or Internet network, consisting of a display having graphic or text generated from data harvested from an intravaginal monitoring device, the data consisting of heart rate data is also considered in one of the embodiments. The heart rate data may include an expectant mother’s heart rate, and a being the womb’s heart rate. The aforementioned mobile communications device further consists of an identification data consisting of a name of a female, data of a week of pregnancy, data on the number of pregnancies of a female, data of the last menstruation of a female, data of a medical professional, data representative of a sonogram of a being within a womb.

A mobile communications device for two way communications via a cellular or Internet network, consisting of a display having data representative of a cervix is also considered in one of the embodiments. A mobile communications device for two way communications via a cellular or Internet network, consisting of a display showing cervical dilatation is also considered in one of the embodiments. A mobile communications device for two way communications via a cellular or Internet network, consisting of a display having a numerical indication of cervical dilatation is also considered in one of the embodiments. A mobile communications device for two way communications via a cellular or Internet network, consisting of a display showing a date and time, and cervical dilatation at said data and time is also considered in one of the embodiments. A mobile communications device for two way communications via a cellular or Internet network, consisting of a display showing cervical dilatation over time is also considered in one of the embodiments. A mobile communications device for two way communications via a cellular or Internet network, consisting of a display having showing data harvested from an intravaginal monitoring device is also considered in one of the embodiments. A mobile communications device for two way communications via a cellular or Internet network, consisting of a display having data harvested from an intravaginal monitoring device, whereby the intravaginal monitoring device is communicatively linked to said mobile communications device is also considered in one of the embodiments. A mobile communications device for two way communications via a cellular or Internet network, consisting of a graphic user interface for an expectant father illustrating data on an expectant mother, and optionally data on a child in said expectant mother’s womb is also considered in one of the embodiments.

A kit for a mobile communications device for two way communications via a cellular or Internet network, consisting of the mobile communications device, and an intravaginal monitoring device (consisting of an electronic portion) is also considered in one of the embodiments. The kit may include: (1) a plurality of interchangeable heads (containing the electronic portions), sized and dimensioned to provide a field of view with a vagina; (2) a plurality of disposable transparent sleeves, sized and dimensioned to fit over said intravaginal monitoring device; (3) a carrying case; such that it: (i) is sized and dimensioned to fit into a female’s handbag; (ii) is shaped so as to provide removability of the mobile communications device and the intravaginal monitoring device; (iii) includes a plurality of pouches and a zipper; and (iv) consists of two halves, and in which said two halves snap shut and snap open; (4) the intravaginal monitoring device consisting of a plurality of sensors for monitoring physiological conditions or events.

A network consisting of: an intravaginal monitoring device for visualizing conditions or events within a vagina, the device consisting of a camera, and having a wireless data transmission mode of functionality, and a remote device, the remote device located outside of a female’s body is also considered in one of the embodiments. In one embodiment, a method is used by a server in a communication network, e.g., communication network. The communication network has a plurality of sensor devices and a support computer. Within such a network, it is appreciated that the management of a group of pregnant females in a birthing center, and outside of a birthing center pregnant females is facilitated using the method, and the communication pathways provided for by the method. For example, Hospital A’s birthing center admits pregnant female patient’s B-Z. Patient’s B-Z are utilizing the device and methods of the invention prior to admission so that clinically relevant data on each patient is provided while each of the pregnant females B-Z, are at home, work, at the birthing center, or any location remote from the birthing center.

These patient’s mobile phones are provided instructions so as to properly time their admission depending on how advanced their labor cycle is, and otherwise proceed under Doctor’s orders. The appropriate nurse midwife or physician is provided with a visual working environment through their work stations with real time or substantially real time information of which patient will next go into active labor (vs. being in passive labor), and delivery. The medical professional’s time and hospital beds and other resources, including monitors, are then brought to where they are needed, just in time. If simultaneous pregnant females go into active labor, then additional resources can be organized in advance and obtained in a timely manner without stretching existing resources, e.g., doctors and nurses, to thin or creating a life threatening situation for the pregnant females or their unborn babies because of lack of qualified staff or specialists.

Within the birthing center, the visual working environment displays, for example, include information related to the sensed data, in whole or in part, on pregnant females B-F. Clinically, pregnant female B is in passive labor, has a window with her image data, relevant medical information data, location data, image of her cervix data (including all relevant clinical parameters), contraction information data, breaking of the waters status data, information sensed related to her fetus data, etc. in the same window (or other screen). Clinically, pregnant female C is in active labor. A window with Female C’s image data, room number data, cervical diameter (greater than 6 cm) data, effacement information data, temperature data, next of kin contact information data, and fetal information data appear in the visual work environment. The nurse midwife’s work station or smart phone issues an alert regarding pregnant female patient C. The alert notifies Nurse Mid Wife Z’s, and she focuses resources on pregnant female C, as she is about to deliver.

By way of further example, pregnant female D is 26 weeks pregnant, is at risk for a premature birth event, and is being monitored remotely by nurse midwife Z utilizing
device 105. Nurse midwife Z notices several disturbing trends concerning pregnant female D on a window reflecting data relating to pregnant female C. Graphs and other visual interfaces of cervical depth data taken over the last three hours indicates that pregnant female D’s cervix has been thinning, that her cervical OS has gone from 0.5 cm to 2.5 cm, and that other clinically relevant parameters indicate that she is at high risk of a premature birthing event imminently. Nurse midwife Z is presented with an alert in her visual working environment.

As a result of the alert, the method causes Nurse midwife Z’s phone to ring with a pre-recorded voice message alert. The pre-recorded message alert results in an automated call to pregnant female D on her mobile phone and sends an sms to her and to her Doctor, Doctor E, and instructs pregnant female D that the system has sent an alert to dispatch an ambulance to pregnant female D’s location for her so that she can be admitted to the birthing center immediately.

Pregnant female D’s location data was provided to the ambulance operator via his mobile phone on his visual working environment display using the GPS functionality of pregnant female D’s mobile phone and/or the intravaginal monitoring device and system. An alert was provided to pregnant female D’s husband support device over the communication network when he was at work, providing a pre-recorded message requesting that he call his wife regarding the pregnancy. This happens, and the husband and wife immediately discuss the status of the pregnancy.

D’s husband tracks his wife’s physical location in the ambulance using GPS functionality on his phone (via a specific application) in his visual working environment which is communicatively linked to the server and the intravaginal monitoring device and/or wife’s cell phone’s GPS functionality, and follows the ambulance to the hospital to be there for his wife. The ambulance brings pregnant female D to the birthing center within 15 minutes of Nurse Midwife Z’s alert and call.

At the birthing center, Doctor D determines, that since pregnant female D arrived to the birthing center in a quickly, and before her condition deteriorated further, she is a candidate for a therapy. He performs the therapy, which involves placement of a cervical prosthesis, bed rest, and other therapies. The therapy is successful and pregnant female D gives birth to a healthy newborn son at 38 weeks of gestation. The combination of the method of diagnosis utilizing the communication network of the present invention, and therapy results in a successful outcome. In one embodiment, a method of decreasing insurer or governmental health system costs is provided. The method includes providing an intravaginal monitoring device capable of identifying an event during a pregnancy; determining whether or not a pregnant female is having a pre-mature birthing event; and, treating the pregnant female to decrease the gestation time of a being within the womb of the pregnant female.

By way of further example, pregnant female E is 37 weeks pregnant during her first pregnancy, and being home monitored with an intravaginal monitoring device 105. Clinically, pregnant female E feels periodic contractions. She feverishly calls her husband and has her husband leave his job as a school bus driver, and drives home immediately believing she is going into labor. She calls the birthing center from her mobile phone by pressing a preprogrammed number in her mobile phone application, and requests to speak with her Doctor, Doctor E, now. Doctor E is not at the birthing center since he has taken a long overdue vacation with his wife in Hawaii.

At home, pregnant female E and her husband are panicking since they are scared and unsure what to do since this is their first baby. Pregnant female E actsuates the intravaginal monitoring device 105 and inserts it into her vaginal canal. Device 105 harvests sensor data and communicates it via the communication network to a support device. The support device analyzes the sensor data to determine if one or more clinically relevant threshold parameters are met. If yes, an appropriate alert is generated, and communicated and routed over the communication network to nodes on the network.

The method also generates a patient profile, e.g., using one or more applications. Nurse Mid Wife Z reviews pregnant female E’s profile on her visual working environment in real time and while in real time the network shares the profile with Doctor E who views it on his iPad on the golf course in Hawaii. The visual working environment display generated using applications running on one or more nodes in the network indicates that pregnant female E is having periodic contractions, that she does not evidence cervical effacement, and that her cervical OS graph does not show any change over time and is at 0.5 cm, and that fetal parameters are all normal. No alerts are activated for network distribution since the sensed data, and or combination thereof, has not reached relevant thresholds. A conclusion is made by the application software that no hospital admission alert is necessary, and that it is likely that pregnant female E is only having Braxton-Hicks contractions and that no hospital admission is required, and communicates, and properly addresses this information for routing to Nurse Mid Wife Z and Doctor E respective support devices. Nurse Mid Wife Z consults with Doctor E, and Doctor E, and optionally humanly confirms that pregnant female E is having Braxton-Hicks contractions, that she is not in active labor, and that no hospital admission is required. Doctor E, presses a button on his wirelessly connected iPad accessing an application related to the intravaginal monitoring device specific to patient E, and or data files related to patient E created from data harvested by the monitoring device, performs a confirmatory human review of the data, and then calls patient E, and instructs pregnant patient E that she should stay at home, and not proceed to the hospital for admission at this time, as she is not in active labor. Pregnant female E follows Doctor E’s orders, and takes some bed rest and the Braxton-Hicks contractions pass.

Two weeks later, pregnant patient E has another set of periodic contractions which are being remotely monitored by the intravaginal device 105 with its sensors. The sensor data is communicated and properly routed via the communication pathways described herein. The sensor data indicates that pregnant female E is entering normal labor, and an alert is issued via the communication pathway to the Mid Wife’s and Doctor’s supporting devices. At this time Nurse Midwife Z, notices the alert and reviews pregnant patient E’s profile remotely and confirms that the sensed profile parameters indicate that pregnant patient E is going into normal labor as the alert indicated, and instructs her to come to the birthing center for admission. Pregnant patient E’s husband is alerted that is the “real deal” via an alert communicated to his supporting device via the communication network and communication pathway, and that the baby will arrive in the range of
2 to 6 hours based upon trend analysis of the sensed data. He rushes home from work, drives his wife to the hospital, where she is admitted, goes into normal labor and delivery, and delivers a healthy baby girl. Doctor E was alerted via an alert presented on his smart phone of the impending delivery in advance so he was able to hop out of the shower, review patient E's pregnancy profile data communicated to his support device via the communication pathway and communication network, and delivered the healthy baby girl. It is appreciated that the device and methods of the previous invention reduce stressful, wasteful, unnecessary hospital admissions when they are not needed, and provide for timely hospital admissions when they are most needed, saving lives and reducing the incidence of premature birth (with the huge emotional and financial drain associated therewith) when coupled with efficacious, and timely therapies.

Throughout the present application, various embodiments are used to illustrate some of various aspects of the present invention. It should be clear to one of ordinary skill in the art that yet other embodiments constructed based on elements extracted from several or more of the embodiments specifically described herein are contemplated.

The terms “circuit” and “circuitry” as used herein are refer to an independent circuit or to a portion of a multifunctional circuit that performs multiple underlying functions. For example, depending on the embodiment, processing circuitry be be implemented as a single chip processor or as a plurality of processing chips. Likewise, a first circuit and a second circuit be be combined in one embodiment into a single circuit or, in another embodiment, operate independently perhaps in separate chips. The term “chip”, as used herein, refers to an integrated circuit. Circuits and circuitry are comprise general or specific purpose hardware, or are comprise such hardware and associated software such as firmware or object code.

As one of ordinary skill in the art will appreciate, the terms “operably coupled” and “communicatively coupled,” as are be used herein, include direct coupling and indirect coupling via another component, element, circuit, or module where, for indirect coupling, the intervening component, element, circuit, or module does not modify the information of a signal but are adjust its current level, voltage level, and/or power level. As one of ordinary skill in the art will also appreciate, an inferred coupling (i.e., where one element is coupled to another element by inference) includes direct and indirect coupling between two elements in the same manner as “operably coupled” and “communicatively coupled.”

The present invention has also been described above with the aid of method steps illustrating the performance of specified functions and relationships thereof. The boundaries and sequence of these functional building blocks and method steps have been arbitrarily defined herein for convenience of description. Alternate boundaries and sequences can be defined so long as the specified functions and relationships are appropriately performed. Any such alternate boundaries or sequences are thus within the scope and spirit of the claimed invention.

The present invention has been described above with the aid of functional building blocks illustrating the performance of certain significant functions. The boundaries of these functional building blocks have been arbitrarily defined for convenience of description. Alternate boundaries could be defined as long as the certain significant functions are appropriately performed. Similarly, flow diagram blocks are also have been arbitrarily defined herein to illustrate certain significant functionality. To the extent used, the flow diagram block boundaries and sequence could have been defined otherwise and still perform the certain significant functionality. Such alternate definitions of both functional building blocks and flow diagram blocks and sequences are thus within the scope and spirit of the claimed invention.

One of average skill in the art will also recognize that the functional building blocks, and other illustrative blocks, modules and components herein, can be implemented as illustrated or by discrete components, application specific integrated circuits, processors executing appropriate software and the like or any combination thereof. Moreover, although described in detail for purposes of clarity and understanding by way of the aforementioned embodiments, the present invention is not limited to such embodiments. It will be obvious to one of average skill in the art that various changes and modifications are be practiced within the spirit and scope of the invention, as limited only by the scope of the appended claims.

6. A method used by a self-powered device that can be communicatively coupled with a computing device, the device sized for at least partial insertion into a female reproductive system via a vaginal channel, the method comprising: capturing by a first sensor, when the device is at least partially inserted within the vaginal channel, first sensor data relating to the female reproductive system; capturing by a second sensor, when the device is at least partially inserted within the vaginal channel, second sensor data relating to a physical parameter of a fetus within said female’s womb; and wirelessly communicating the first sensor data and the second sensor data to the computing device.

7-11. (canceled)

12. A device that is sized for at least partial insertion into a female reproductive system via a vaginal channel, the device comprising: a housing; a first sensor disposed in the housing at a location that supports gathering of first sensor data from the female reproductive system; processing circuitry disposed in the housing that receives input; memory, disposed in the housing, that is coupled to the processing circuitry; the memory storing operating instructions to be carried out by the processing circuitry; the operating instructions defining at least two operating procedures, said operating procedures related to periodic pregnancy monitoring; and the processing circuitry selecting one of the at least two operating procedures based on the input.

13-20. (canceled)

21. A method associated with a female reproductive system, the method comprising: retrieving optical imager data related to a target area within the female reproductive system, the target area being accessible via a vaginal channel of the female reproductive system; performing an automated analysis of the optical imager data; and producing information based on the analysis, the information at least assisting in identifying a status for at least a portion of the female reproductive system.

22-26. (canceled)

27. A method used by a computing device that interacts with a monitoring device, the monitoring device having an optical imager that captures imager data from a female reproductive system via a vaginal channel, the method comprising: receiving a first portion of the imager data, the first portion of
the imager data having been captured by the optical imager during a first imaging session; storing the first portion of the imager data; receiving a second portion of the imager data, the second portion of the imager data having been captured by the optical imager during a second imaging session; retrieving the first portion of the imager data from storage; comparing the first portion of the imager data with the second portion of the imager data; and producing, based at least in part on the comparison, status information relating to at least a portion of the female reproductive system.

28. The method of claim 27, wherein the status information relates to a non-human animal estrus event.

32. A method used by a server in a communication network, the communication network also having a plurality of sensor devices and a support computer, each of the plurality of sensor devices capturing sensor data via a vaginal channel of a female reproductive system, the method comprising: establishing communication with the plurality of sensor devices; receiving the sensor data captured by at least one of the plurality of sensor devices via the vaginal channel of the female reproductive system; generating display data based on the sensor data received; and delivering the display data to the support computer.

34. The method of claim 33, wherein the server supports sales.

36-37. (canceled)

38. A method used by a server in a communication network to make a related data selection from a plurality of data, the communication network comprising a medical sensor device that captures sensor data via a vaginal channel of a female reproductive system, the method comprising: establishing communication with the medical sensor device; receiving the sensor data captured by the medical sensor device; and selecting the related data from the plurality of data, the selection being based at least in part on the sensor data received.

39. The method of claim 38, wherein the plurality of data comprises a plurality of advertisement data.

40. The method of claim 38, wherein the plurality of data comprises a plurality of data.

41-63. (canceled)

64. A method of decreasing insurer or governmental health system costs comprising: providing an intravaginal monitoring device capable of identifying an event during a pregnancy; determining whether or not a pregnant female is having a pre-mature birthing event; and treating said pregnant female to increase the gestation time of a being within the womb of said pregnant female.

65. A telemedicine system comprising: a wireless, battery powered, intravaginal monitoring device having at least two cervical sensors, the two cervical sensors selected from the group consisting of a cervical dilation sensor and a cervical effacement sensor; and, an external wireless, battery powered, electronic smart patch having at least two sensors, the two sensors selected from the group consisting of a maternal contraction sensor and a fetal heart rate sensor; and an external communication device communicatively and wireless linked to the intravaginal monitoring device and the electronic smart patch.

66-68. (canceled)

69. The telemedicine system of claim 65, further comprising a remote server, in which the external communication device is communicatively linked to the remote server, the remote server post processing data harvested by the cervical dilation sensor, cervical effacement sensor, maternal contraction sensor and fetal heart rate sensor to obtain post processed data, and the post processed data being communicated to a second communication device.

70. The telemedicine system of claim 69, in which the second communication device is a microprocessor controlled device comprising a graphical user interface, the graphical user interface presenting a graph, the graph selected from the group consisting of a cervical dilation graph, a cervical effacement graph, a fetal heart rate graph, and a maternal contraction rate graph.

71-72. (canceled)

73. A telemedicine system comprising a communication device, a server, and a plurality of wireless, self-powered intravaginal monitoring devices communicating data harvested from a plurality of females to said server, and said server communicating said data to said communication device.

74-75. (canceled)

76. The telemedicine system of claim 73 in which said females comprise females estrus.

77. (canceled)

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