



(19) **United States**

(12) **Patent Application Publication**  
**Bennett et al.**

(10) **Pub. No.: US 2011/0188716 A1**

(43) **Pub. Date: Aug. 4, 2011**

(54) **INTRAVAGINAL DIMENSIONING SYSTEM**

(52) **U.S. Cl. .... 382/128; 600/301**

(76) **Inventors: James D. Bennett, Hroznetin (CZ);  
Andrew W. Ziarno, Thalheim (DE)**

(21) **Appl. No.: 12/890,830**

(57) **ABSTRACT**

(22) **Filed: Sep. 27, 2010**

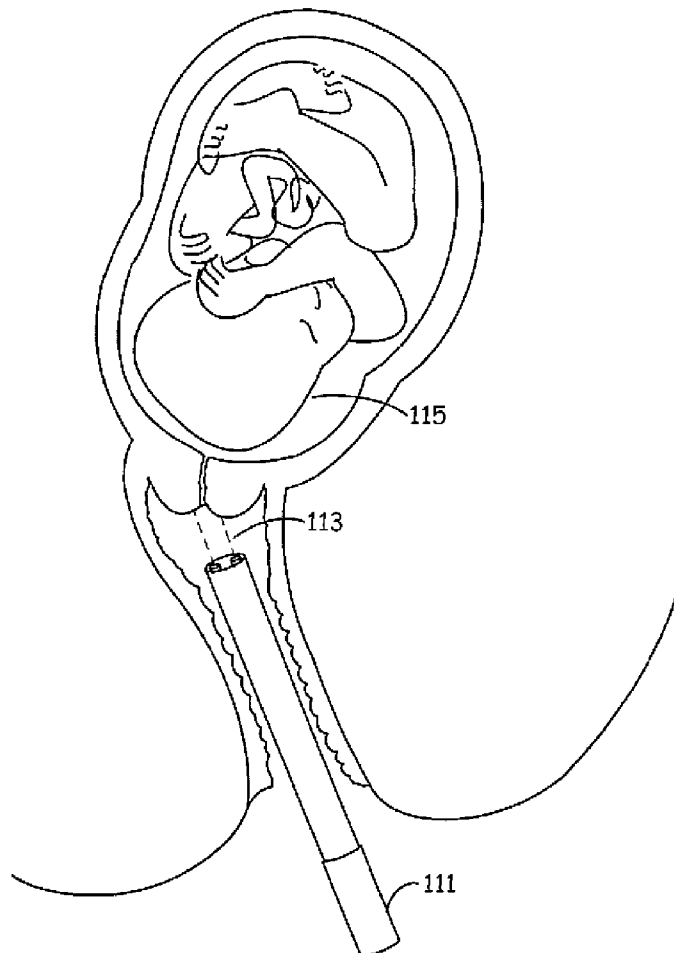
**Related U.S. Application Data**

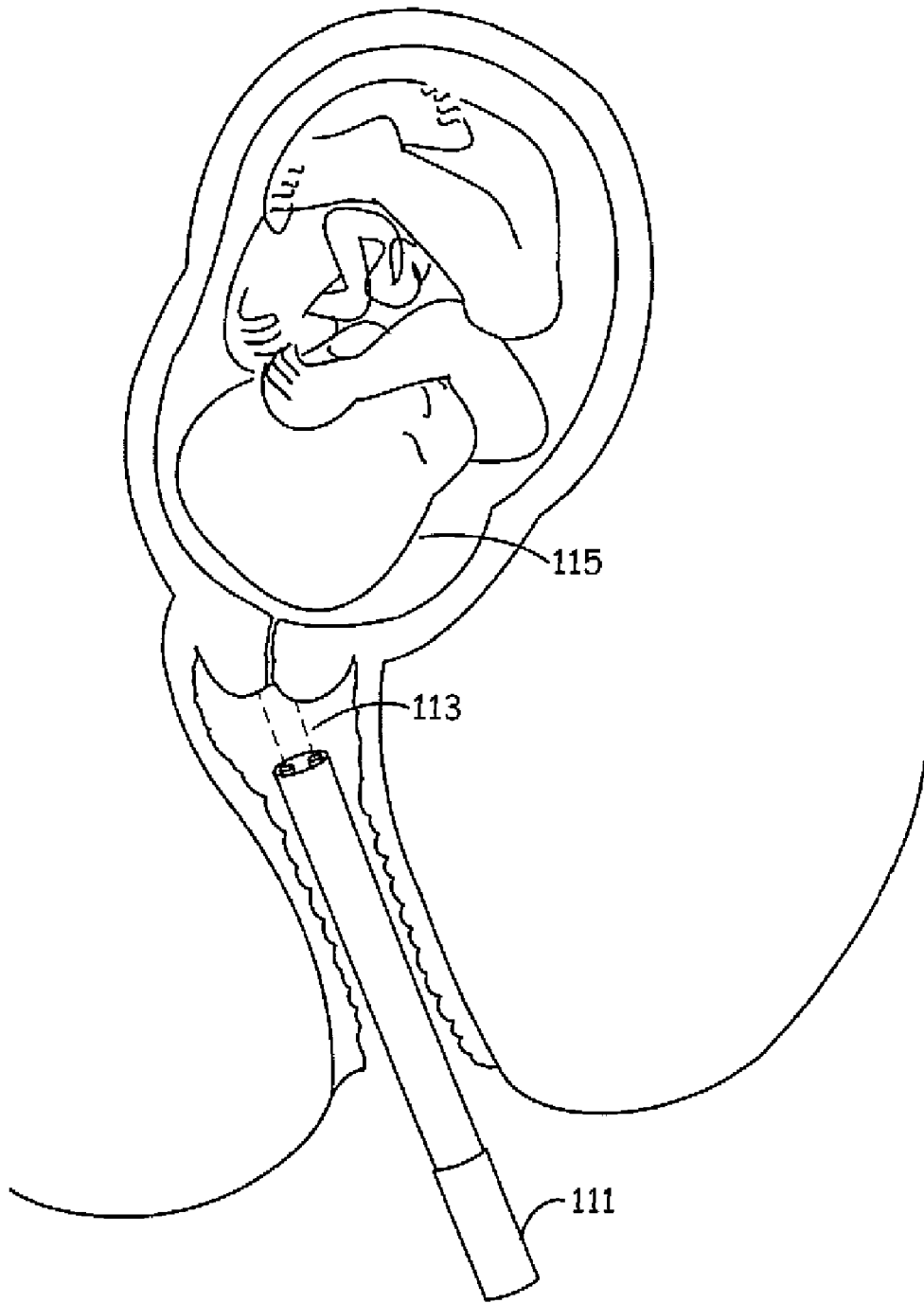
(60) Provisional application No. 61/246,375, filed on Sep. 28, 2009, provisional application No. 61/246,405, filed on Sep. 28, 2009, provisional application No. 61/246,396, filed on Sep. 28, 2009, provisional application No. 61/290,792, filed on Dec. 29, 2009, provisional application No. 61/263,416, filed on Nov. 23, 2009.

**Publication Classification**

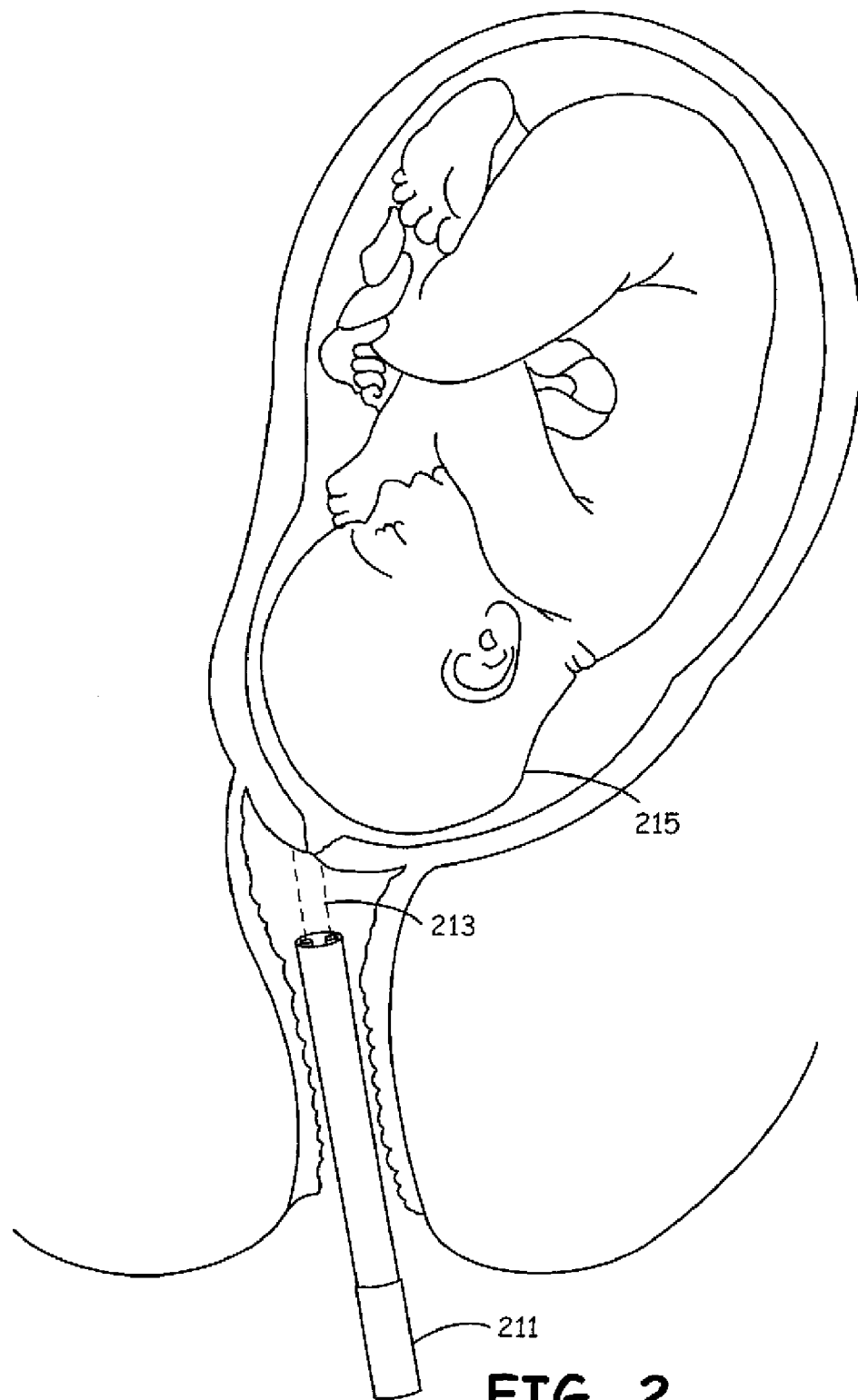
(51) **Int. Cl.**  
**G06K 9/00** (2006.01)  
**A61B 5/00** (2006.01)

An intravaginal monitoring device and its supporting network infrastructure; wherein the intravaginal monitoring device generates scaling and dimensioning, using infrared, ultraviolet or laser signals, in conjunction with a supporting software at the server and/or client sides. The scaling and dimensioning are performed using one or more of many possible algorithmic and hardware based techniques. Reproductive health care management web pages or system interfaces present scaling and dimensioning and emphasis changes over time. The generations scaling and dimensioning, including color and shade variation identifications, incorporate various schemes for a woman's cervix during routine checkup, cervix and aperture openings during pregnancy checkup, and cervix containing an artifact during checkup and treatments. The artifact may represent, for example, stages of ovulation, pregnancy, infections, sexually transmitted diseases and cancer.





**FIG. 1**



**FIG. 2**

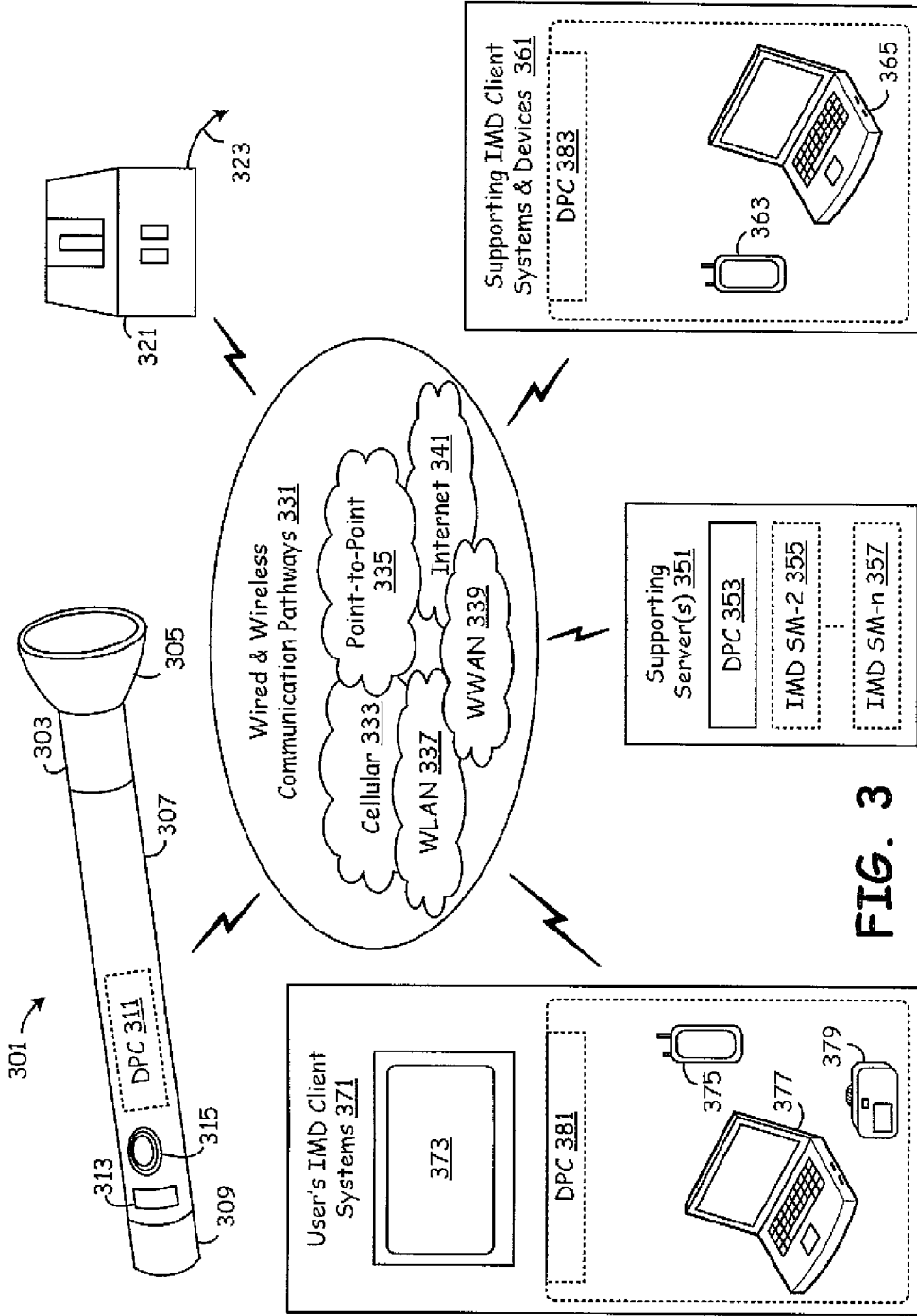


FIG. 3

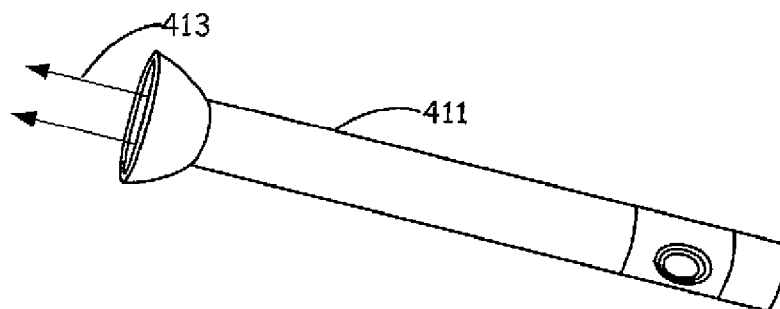


FIG. 4a

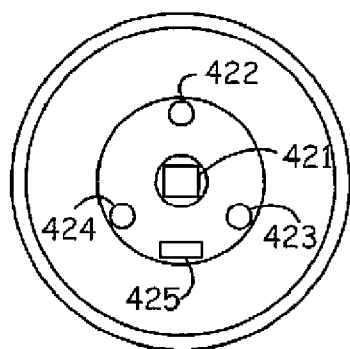


FIG. 4b

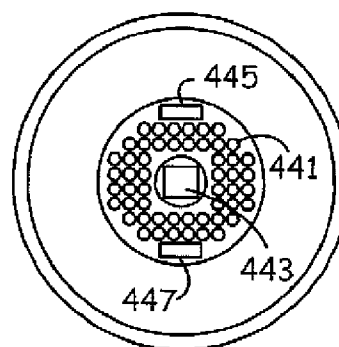


FIG. 4d

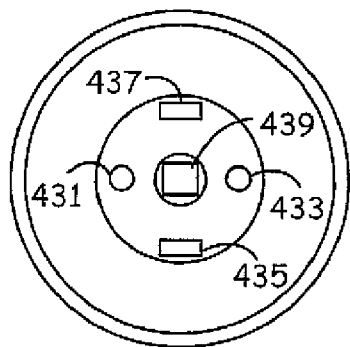


FIG. 4c

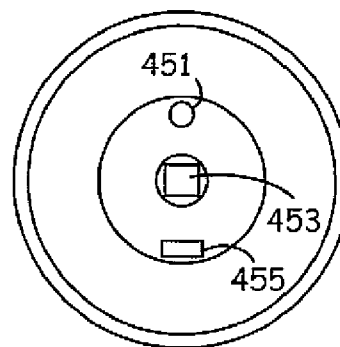


FIG. 4e

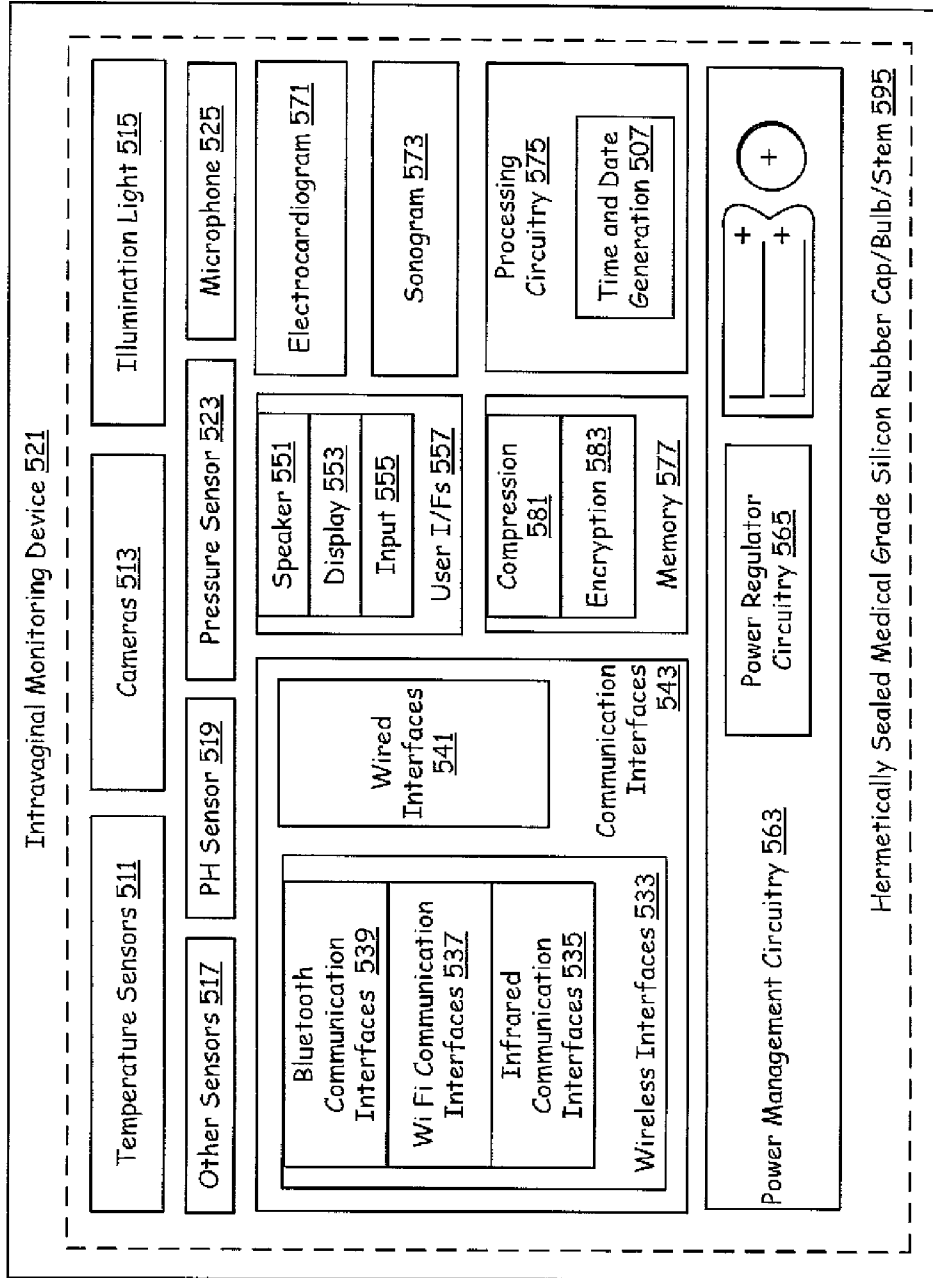
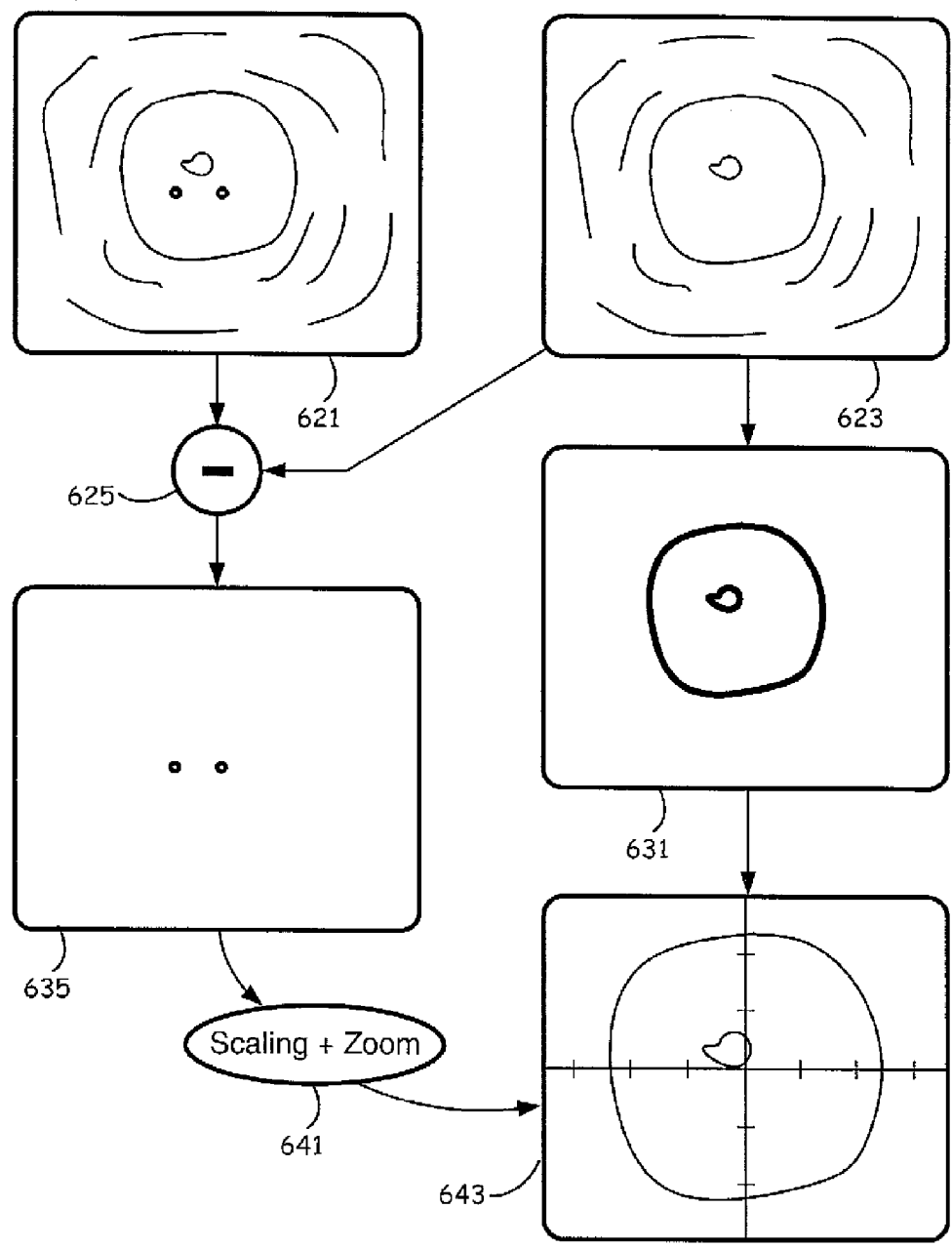


FIG. 5



**FIG. 6**

Cervix Average Diameter: 4.75cm

Cervical Opening Average Diameter: 0.7mm

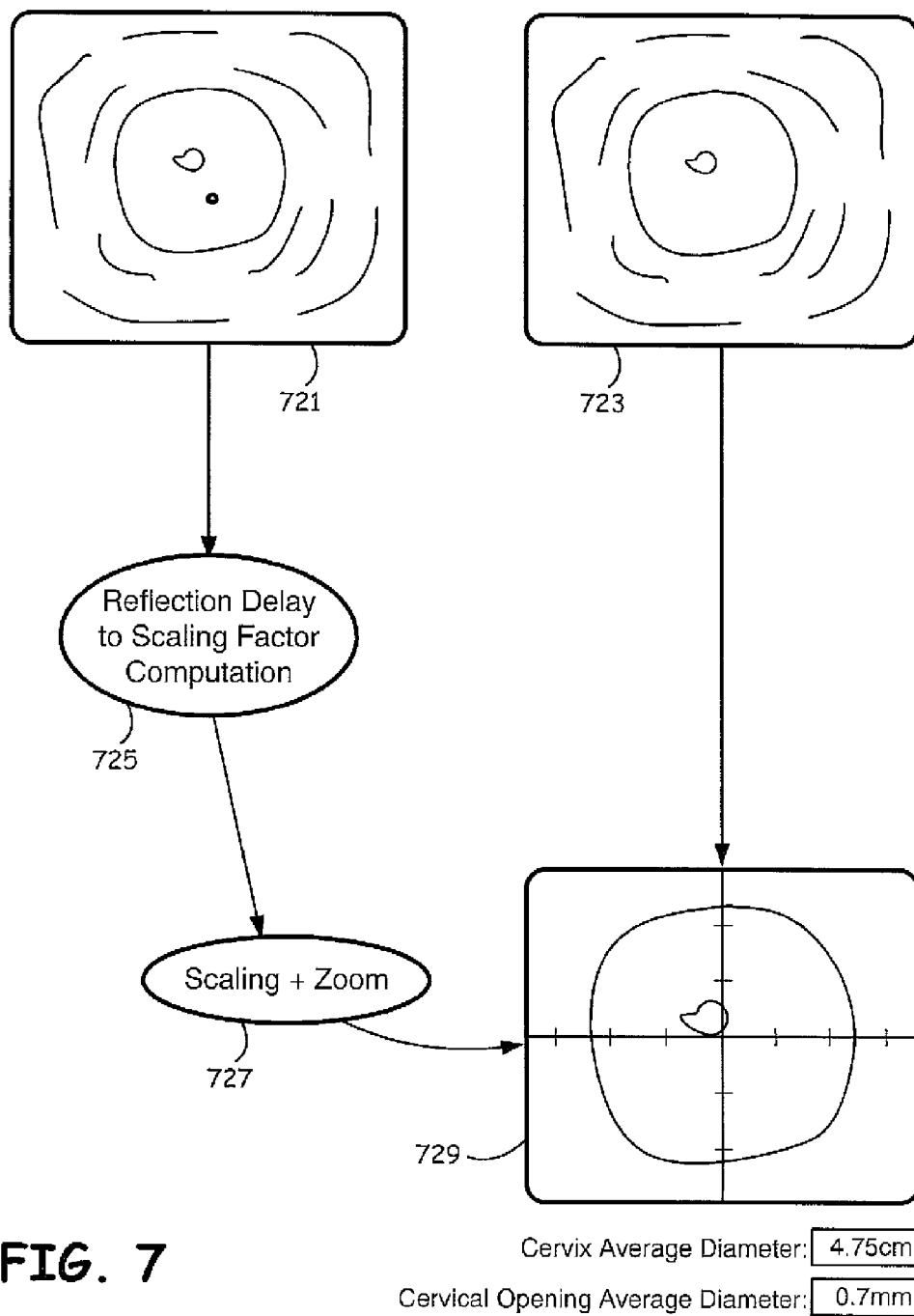
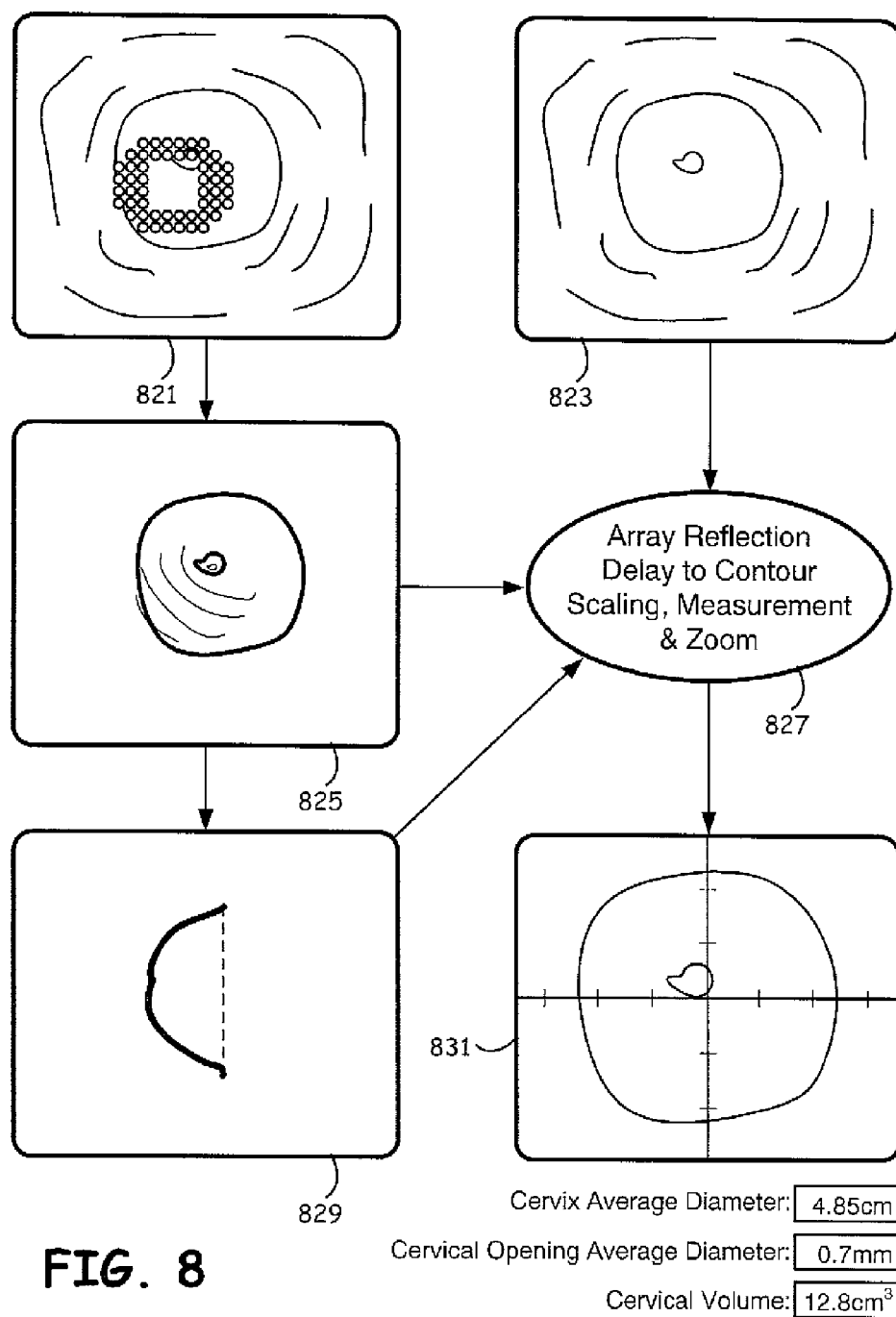


FIG. 7





**FIG. 8**

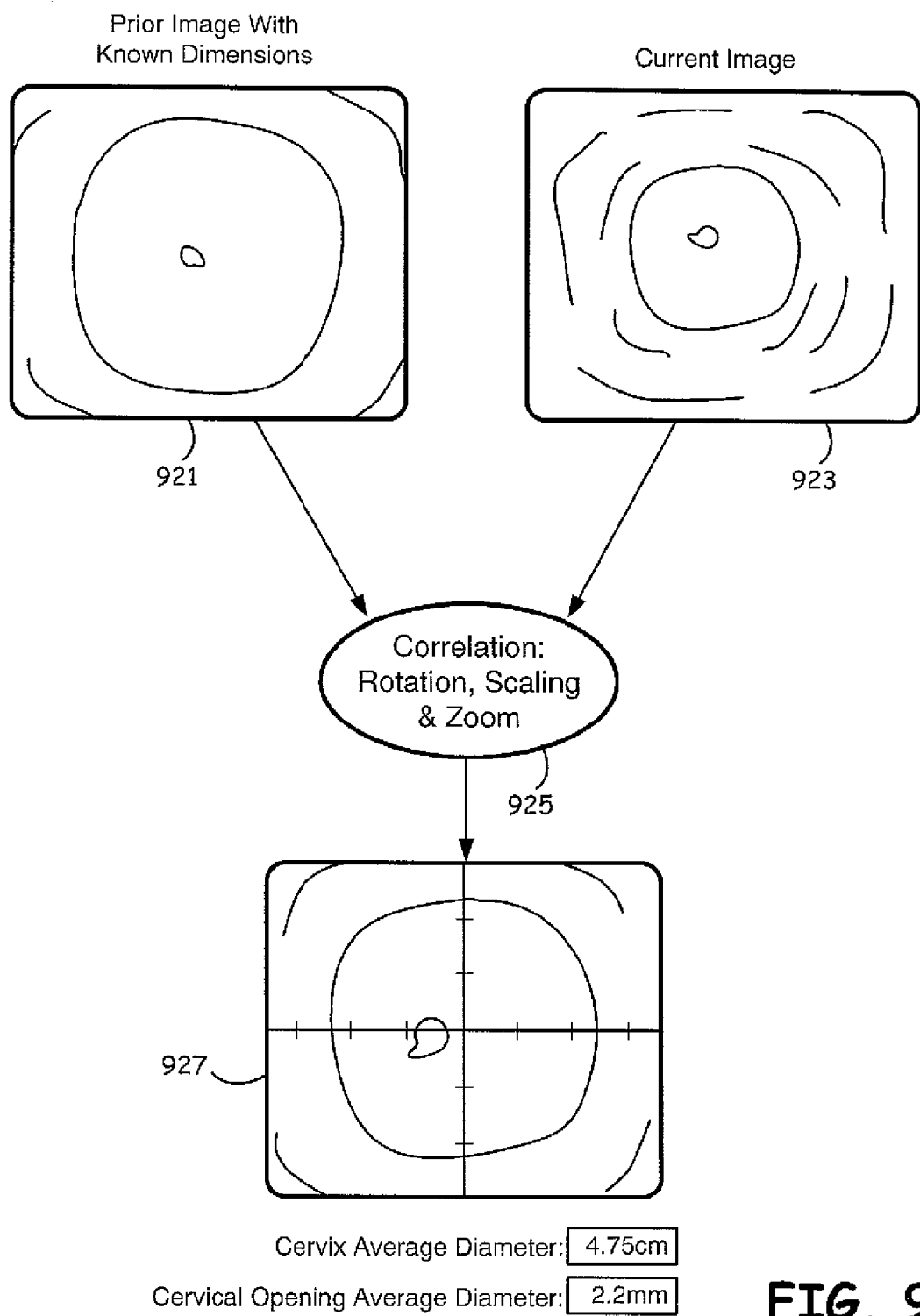


FIG. 9

Reproductive Health Management 1011

Data View Records Queries Mail Forum Research Accounts IMD Setup Support Shopping

Window: Begin 1/1/09 11:15AM End 4/1/09 12:09AM Position 2/5/09 1:22PM

Measurement	Value
Cervix Diameter (Avg)	3.4 cm
Cervix Base Area	8.2 cm sq.
Cervix Perimeter	10.7 cm
Cervix Circular Deviation	9.6 %
Cervix Volume	5.1 cm cbd.
Cervix Height	1.1 cm
Dilation Diameter (Avg)	3.9 mm
Dilation Opening Area	8.7 mm sq.
Dilation Perimeter	12.2 mm
Dilation Circular Deviation	28.5 %
Artifact Perimeter	2.7 cm
Artifact Area	19.6 mm sq.

IMD Status: Tethered (or Wireless or Disconnected) 1013 Online Status: Connected (or Local) 1015

FIG. 10

Reproductive Health Management 1111

Data View Records Queries Mail Forum Research Accounts IMD Setup Support Shopping

Window: Begin 1/1/09 1:15AM End 4/1/09 12:09AM Position 2/5/09 1:22PM

Cervix Colorization

Current  Avg

Inner Ring:  Middle Ring:  Outer Ring:  Entirety:

Inner OS Colorization

Current  Avg

Entirety:

Notes

Inner OS colorization indicates minimal blood discharge on day 23 of ovulation cycle

IMD Status: Tethered (or Wireless or Disconnected) 1113 Online Status: Connected (or Local) 1115

FIG. 11

Reproductive Health Management 1211

Data View Records Queries Mail Forum Research Accounts IMD Setup Support Shopping

Window: Begin 1/1/09 11:15AM End 4/1/09 12:09AM Position 2/5/09 1:22PM

Cervix	
Diameter (Avg):	3.2 cm
Height:	3.4cm
Width:	2.9 cm
Base Area:	8.2 cm sq.
Perimeter:	10.7 cm
Circular Deviation:	10.9 %
Volume:	5.1 cm cbd.
Depth:	6.2 mm

Dilation	
Diameter (Avg):	9.1 mm
Height:	9.9 mm
Width:	8.2 mm
Opening Area:	65.0 mm sq.
Perimeter:	31.1 mm
Circular Deviation:	12.4 %

IMD Status: Tethered (or Wireless or Disconnected) 1213 Online Status: Connected (or Local) 1215

FIG. 12

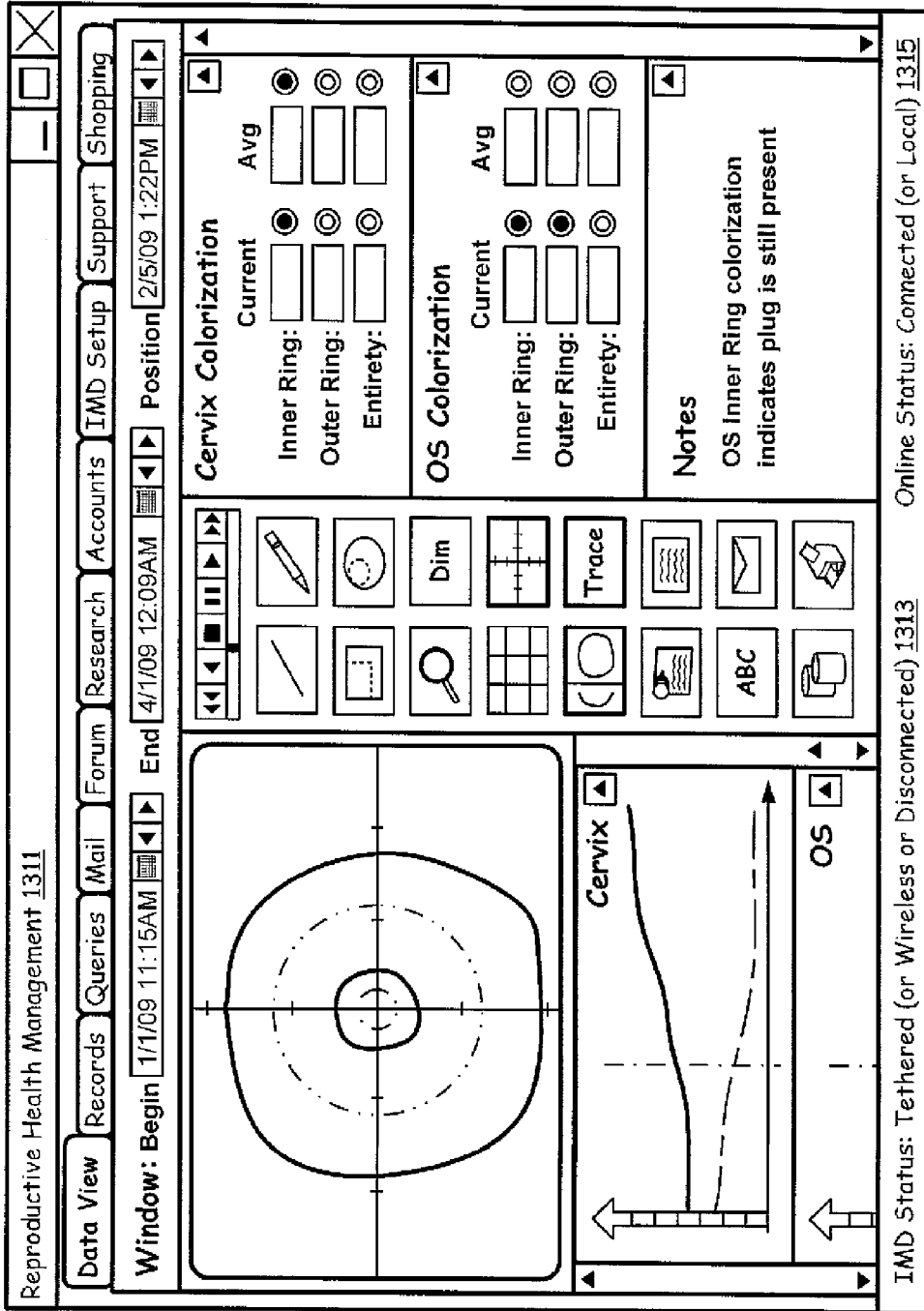


FIG. 13

Reproductive Health Management 1411

Data View Records Queries Mail Forum Research Accounts IMD Setup Support Shopping

Window: Begin 1/1/09 11:15AM End 4/1/09 12:09AM Position 2/5/09 1:22PM

Artifact

Diameter: 1.55 cm  
Base Area: 1.3 cm sq.  
Perimeter: 6.7 cm  
Circular Deviation: 59.6 %  
Volume: 91.2mm cbd  
Depth (Avg): 0.7 mm  
Growth Rate: (6.5)% / day  
Color Entirety:  
Color Inner Ring:  
Color Outer Ring:

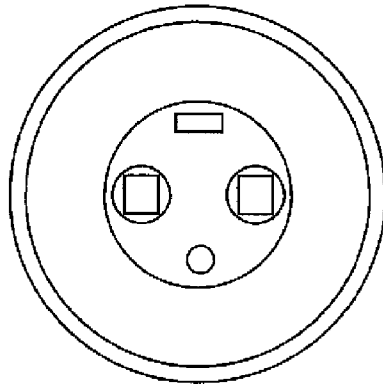
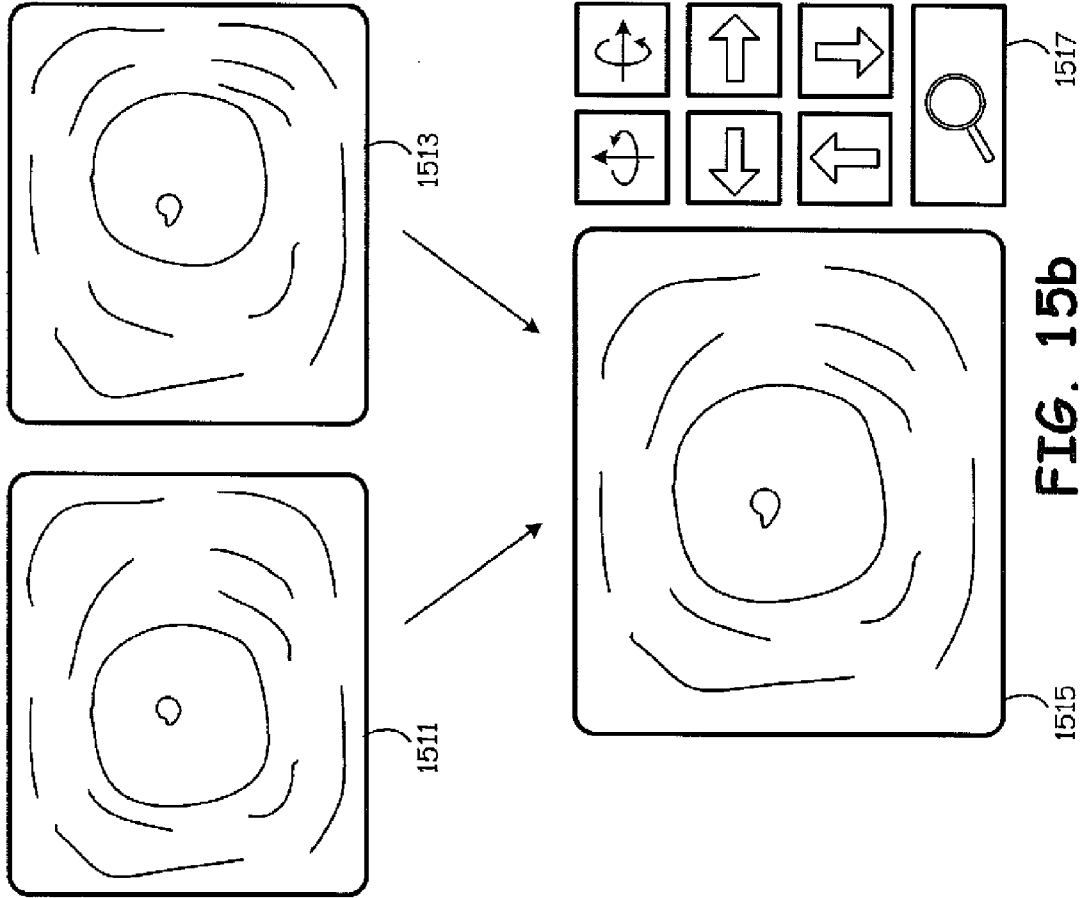
Notes  
Day 9 -- Decrease in overall artifact size and inner and outer ring colorization indicates treatment efficacy

Scale: grid = 5mm

Cervix  
Dilation

IMD Status: Tethered (or Wireless or Disconnected) 1413 Online Status: Connected (or Local) 1415

FIG. 14





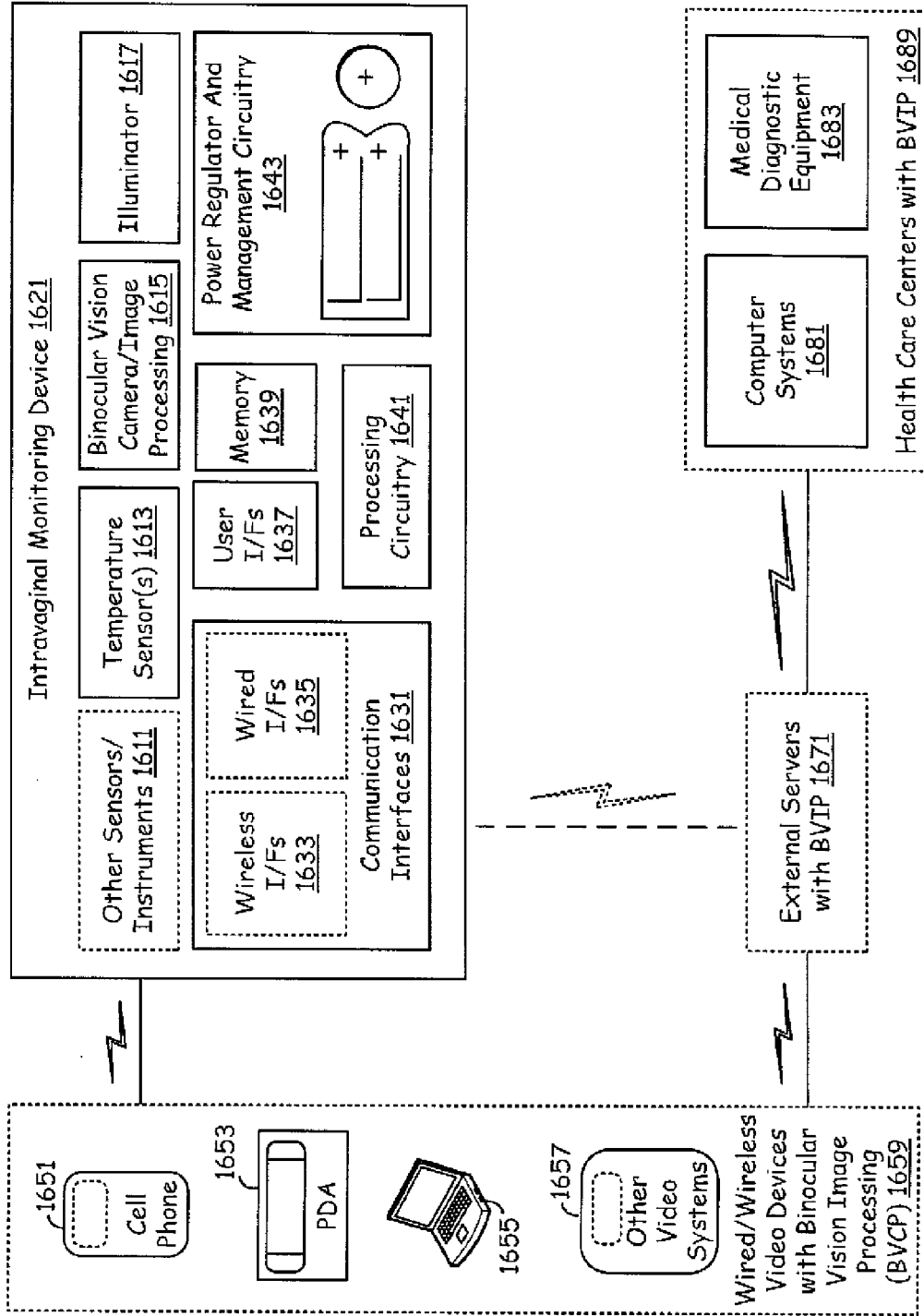
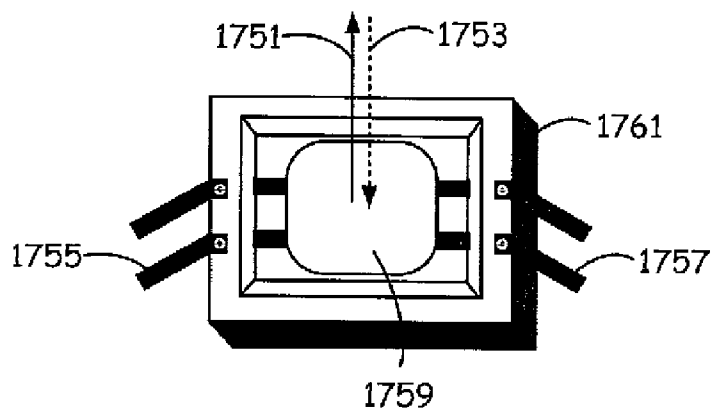
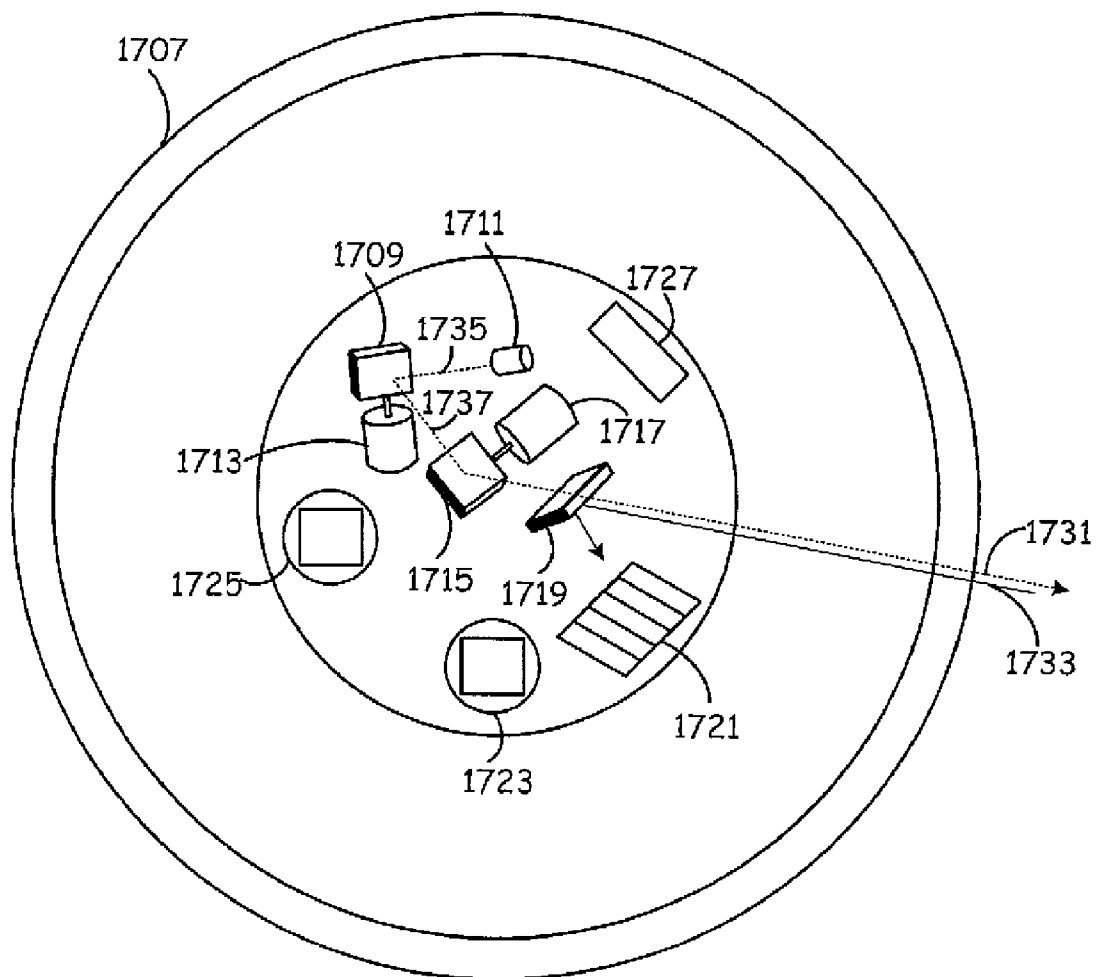


FIG. 16



**FIG. 17a**



**FIG. 17b**

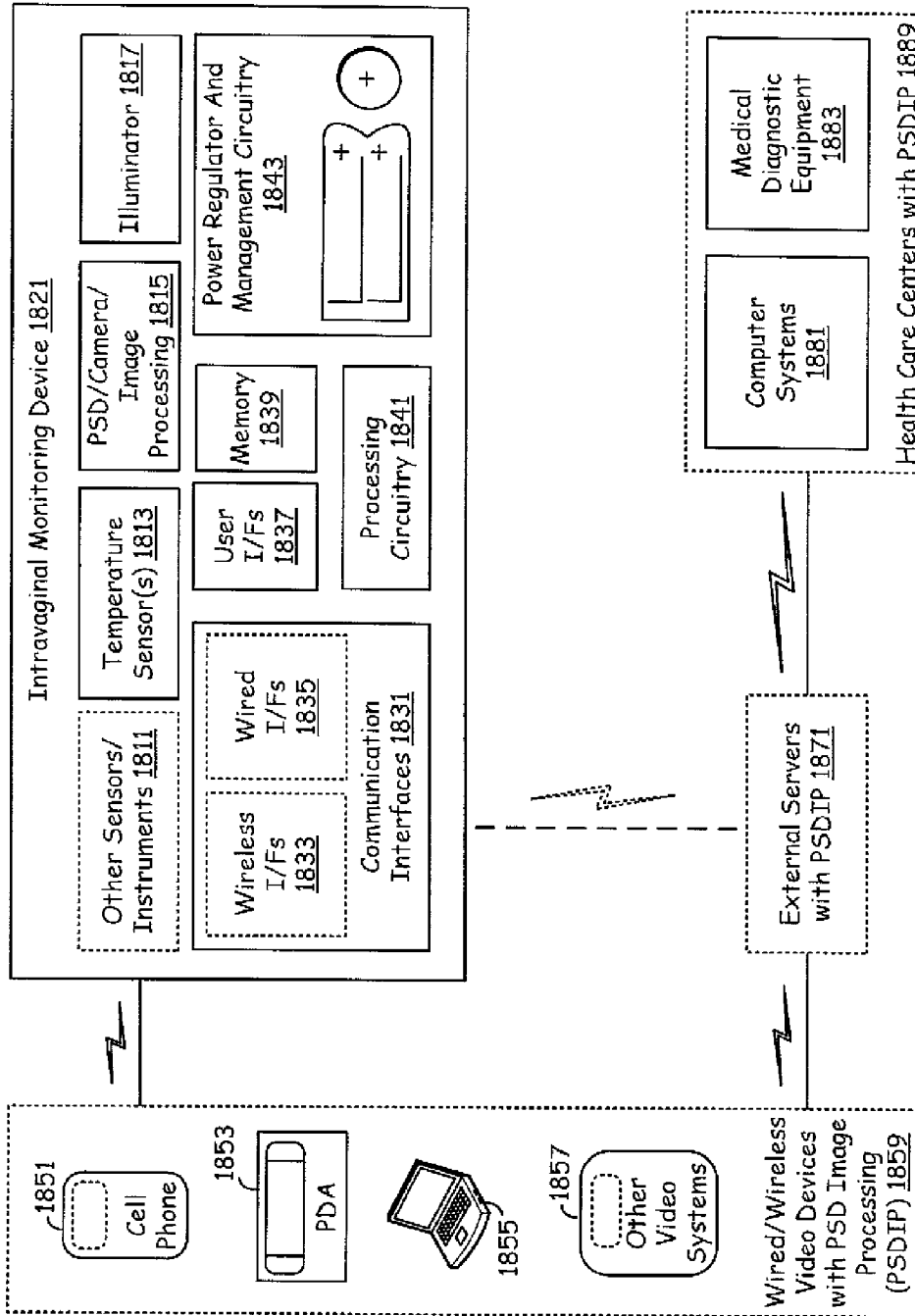


FIG. 18

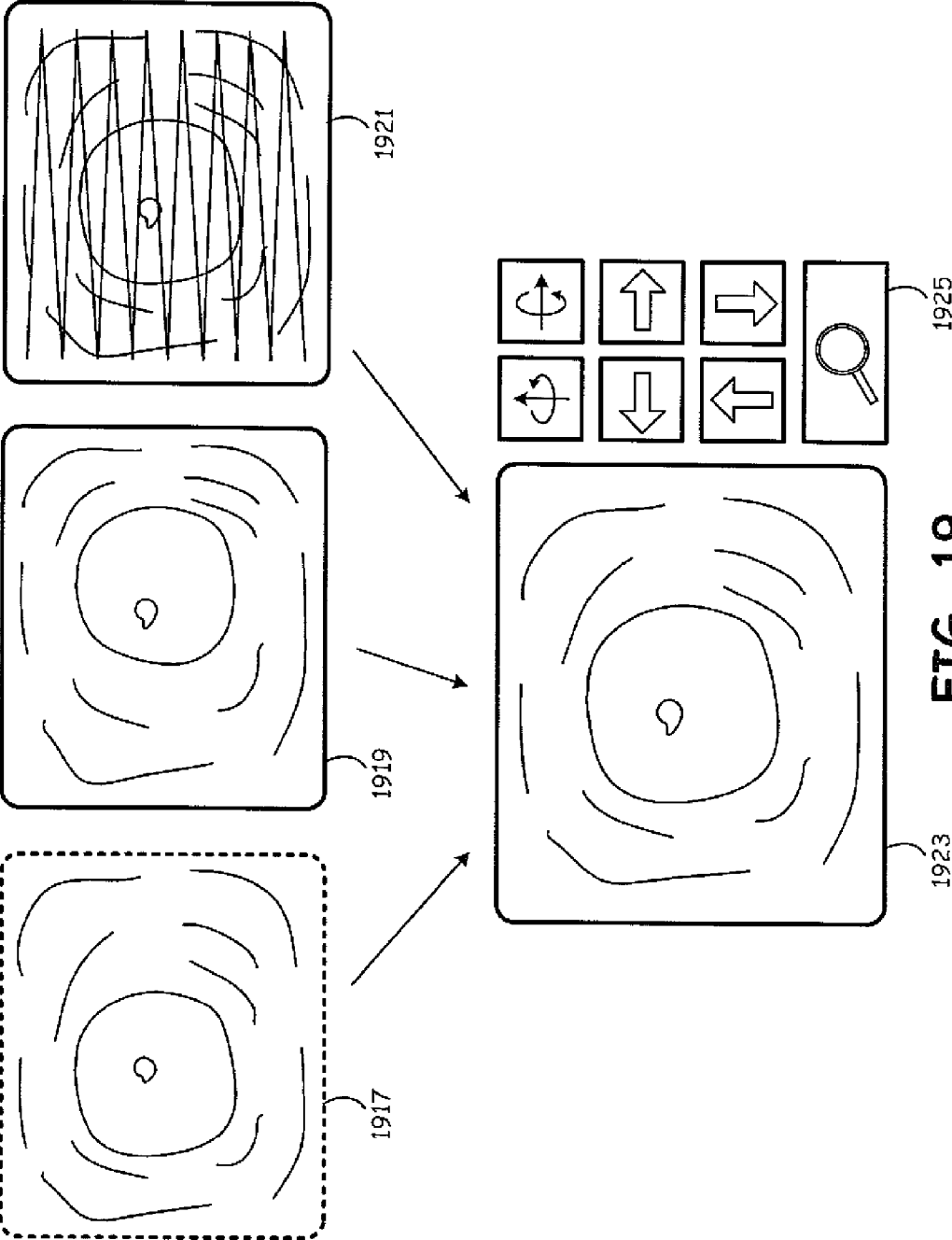


FIG. 19

## INTRAVAGINAL DIMENSIONING SYSTEM

### 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 Ziarno et al.;

[0003] b) U.S. Provisional Application Ser. No. 61/246,405 filed Sep. 28, 2009, entitled "Network Supporting Intravaginal Monitoring Device, Method and Post Harvesting Processing of Intravaginally Processed Data" by Ziarno et al.;

[0004] c) U.S. Provisional Application Ser. No. 61/246,396 filed Nov. 23, 2009, entitled "Network Supporting Intravaginal Monitoring Device" by Ziarno 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 Ziarno et al.; and

[0006] e) U.S. Provisional Application Ser. No. 61/263,416 filed Nov. 23, 2009, entitled "Intravaginal Monitoring Architecture" by Ziarno et al.

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

[0008] a) U.S. patent application Ser. No. \_\_\_\_\_ filed on even date herewith by Ziarno 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;

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;

[0011] 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;

[0012] 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

[0013] 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

[0014] 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

[0015] 1. Technical Field

[0016] The invention generally relates to medical devices, and more particular to medical devices used in obstetrics and gynecology.

[0017] 2. Related Art

[0018] Reproductive health care being one of the important aspects of a woman's health care, it becomes imperative that constant monitoring is an essential part of it. The monitoring should span ideally from teenage to all the way toward old age (even when there are no apparent reproductive health care problems, for the woman concerned).

[0019] As mentioned above, the reproductive health care involves a wide area of the women's wellbeing and it is of critical importance to be able to monitor this aspect of a women's lifestyle. Healthy lifestyle of the woman typically covers reproductive health that begins at teen years all the way to old age. However, shortage of health care professionals makes it difficult to constantly monitor intravaginal conditions that include conditions that can be monitored via vaginal fluid discharges, cervical colors and color changes, ovulation related conditions, menopause related conditions, and sexually transmitted diseases related conditions and child birth related conditions. Addition to all these conditions, treatments also necessitate constant monitoring.

[0020] However, the health care professionals cannot monitor the above mentioned diagnostic aspects, at present, without the presence of the woman in the health care clinics. This consumes a vast amount of resources on the woman's part as well as time and resources spent by the health care professionals. This is especially true in the country (rural) side and developing parts of the world, where both health care services are hard to access from the point of view of the woman and hard for the health care professional to reach the woman and provide timely assistances.

[0021] In addition to the health care professionals being able to provide timely assistances and services, as a part of the woman's lifestyle, the women often wish to discuss these issues with friends and/or other people. The fact that others are also suffering from similar reproductive health related problems allows them to lend a helping hand to each other (at least by providing comforting thoughts).

[0022] These and other limitations and deficiencies associated with the related art may be 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 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 diagram illustrating placement of an embodiment of an intravaginal monitoring device (IMD) that is built in accordance with various aspects of the present invention, and wherein scaled two and three dimensional images are captured for use in predicting gynecological events or conditions which in the present illustration might relate to cervical dimensions indicative of a current state of pregnancy.

[0025] FIG. 2 is a diagram illustrating a characteristic cervical changes in latter stage pregnancy which can be auto-

matically or visually identified using image capture and associated scaling information gathered by an embodiment of an intravaginal monitoring device (IMD) which is built in accordance placement of the intravaginal monitoring device.

[0026] FIG. 3 is a schematic block diagram illustrating an embodiment of a monitoring architecture of the present invention, wherein an IMD captures imager data and collects measurement information (using for example infrared, ultraviolet, or visual spectrum emissions and sensing) for exchange with supporting client devices, server devices and associated software.

[0027] FIG. 4a-e are perspective diagrams illustrating various scaling and dimensioning schemes and components found at the anterior end of various IMD embodiments and illustrating various aspects of the present invention.

[0028] FIG. 5 is a schematic block diagram illustrating circuitry that might be used in an IMD built in accordance with the present invention such as the IMD of FIG. 3.

[0029] FIG. 6 is a conceptual flow diagram illustrating one embodiment of a scaling and dimensioning technique employing a pair of marker beams that can be used with an IMD such as those illustrated in FIG. 3, FIG. 4a, or FIG. 4c.

[0030] FIG. 7 is a conceptual flow diagram illustrating another embodiment of a scaling and dimensioning technique employing a single marker beam that can be used with an IMD such as that of FIG. 3 or FIG. 4e.

[0031] FIG. 8 is a conceptual flow diagram illustrating a further embodiment of a scaling and dimensioning technique employing a marker array that can be used with an IMD such as that of FIG. 3 or FIG. 4d.

[0032] FIG. 9 is a conceptual flow diagram illustrating a scaling and dimensioning scheme employing comparisons between current images and prior manually-scaled images that can be used with an IMD such as that of FIG. 3.

[0033] FIG. 10 is a screen diagram illustrating a snapshot image of one embodiment of a reproductive health care management system (i.e., web page or dedicated software application) for use with various types of IMDs having various types of imaging, scaling and dimensioning infrastructures, and wherein information regarding a patient's cervix can be reviewed and managed.

[0034] FIG. 11 is a screen diagram illustrating various other features of the reproductive health care management system of FIG. 10, wherein colorization tracking and analysis techniques are applied.

[0035] FIG. 12 is a screen diagram illustrating various other features of the reproductive health care management system of FIG. 10, with focus on tracking of dilation of a cervical channel and associated analysis and review.

[0036] FIG. 13 is a screen diagram illustrating various other features of the reproductive health care management system of FIG. 10, wherein colorization analysis is used during the course of pregnancy.

[0037] FIG. 14 is a screen diagram illustrating various other features of the reproductive health care management system of FIG. 10, focusing on a gynecological artifact analysis.

[0038] FIGS. 15a-b are schematic diagrams illustrating a binocular vision system for generating three dimensional image display, measurement and scaling for a further embodiment of an IMD built in accordance with the present invention.

[0039] FIG. 16 is a schematic diagram illustrating a monitoring architecture including an IMD with binocular vision

three dimensional processing components, and a variety of external supporting devices accessible via a communication network.

[0040] FIG. 17b is a perspective schematic diagram that illustrates the use of a PSD with either an integrated or external emitter to identify contours and dimensions of an intravaginal target (e.g., a cervix or artifact) via a scanning arrangement.

[0041] FIG. 18 is a schematic diagram of a monitoring architecture much like that of FIG. 16, yet supporting the IMD of FIG. 17b.

[0042] FIG. 19 is a diagram illustrating one approach to generate contour information from scanning information collected by the IMD of FIG. 17b

#### DETAILED DESCRIPTION OF THE DRAWINGS

[0043] FIG. 1 is a diagram illustrating placement of an embodiment of an intravaginal monitoring device (IMD) that is built in accordance with various aspects of the present invention, and wherein scaled two and three dimensional images are captured for use in predicting gynecological events or conditions which in the present illustration might relate to cervical dimensions indicative of a current state of pregnancy. In particular, an intravaginal monitoring device (an IMD 111) is inserted so as to be able to capture images of a cervix within a vaginal channel that fall within a field of view of an on-board imager (not shown). When in such inserted position, one or more of a variety of techniques can be employed to generate scaling information that can be used to determine image scaling and cervical dimensions.

[0044] One such technique is illustrated. Specifically, the IMD 111 is fitted with one or more laser diodes operating for example in the infrared range. The one or more laser beams are bounced off the surface of the cervix, and the IMD 111 with independent sensor(s) or using its imager array, collects reflection information from the beams. From the reflection information, distances, scaling and contour information may be produced. Other operating ranges beyond infrared could also be used, such as using infrared, red, or ultraviolet emissions. Furthermore, other scaling and measurement techniques, many of which are set forth in the various embodiments herein, could be additionally or alternatively employed.

[0045] Not only can various aspects of the cervix can be imaged and measured, but any other gynecological artifact, event or condition can be monitored and studied. Regarding the cervix, characteristics such as color, height, diameter, dilation, fluid presence, etc., provide significant information which without an IMD are relegated to periodic doctors' office visits.

[0046] With the IMD 111, once the images, scaling and measurement information of the cervix are gathered, they can be routed via networks to enable the health care professionals (gynecologists, obstetricians, or veterinarians in case of animals, for instance) timely monitoring access and ability to identify and track cervical changes.

[0047] The scale, dimensions and colors are obtained by one of plurality of methods, in accordance with the present invention, upon which the images are overlaid for accurate measurements and color identifications. An image screen, for instance, allows the user or health care professional to obtain images of the cervix or cervical dilation, cervix immediately after coitus, during early stages and later stages of pregnancy, artifacts and upon clicking on a dimension (Dim, in FIGS. 9

through 14) button overlays the image upon a scale. The screen also provides accurate numerical measurements on a separate column, of a selected area, which allows the health care professional to figure out the size of the cervix or cervical dilation, cervix immediately after coitus, during early stages and later stages of pregnancy, artifacts.

**[0048]** Similarly, a colorization screen allows the images of the cervix or cervical dilation, cervix immediately after coitus, during early stages and later stages of pregnancy, artifacts and upon clicking on a button, overlays the image upon a color scaling and dimensioning. The screen also provides accurate numerical color measurements on a separate column, of a selected area, which allows the health care professional to identify the size of the cervix or cervical dilation, cervix immediately after coitus, during early stages and later stages of pregnancy, artifacts.

**[0049]** These dimensions are important, for instance, for the health care professional to identify the reproductive health of the user, though the observations of the sizes and colors of the cervix or cervical dilation, cervix immediately after coitus, during early stages and later stages of pregnancy, artifacts (such as a rash, differently colored patch of a skin, cancerous growth).

**[0050]** In another approach to the scaling and measurement, the intravaginal monitoring device 111 utilizes lights from two infrared, ultraviolet or laser diodes 113 (depicted in the FIG. 4c) that generate two points within an image. Immediately after that (say, in less than few milliseconds), the intravaginal monitoring device 111 also takes another image of the very same area. Then, the image without two infrared, ultraviolet or laser points is subtracted from the one that has two points to generate scaling and dimensioning. This scaling can then independently be applied or zoomed on any area of the image.

**[0051]** Similarly, the intravaginal monitoring device 111 may utilize lights from one infrared, ultraviolet or laser diode 113 (depicted in the FIG. 4e) to measure reflection delay and hence computes scaling factor. In a third embodiment of the scaling and dimensioning schemes, the intravaginal monitoring device 111 utilizes lights from three infrared, ultraviolet or laser diodes 113 (depicted in the FIG. 4b).

**[0052]** Instead or to support another scaling or measurement process, the intravaginal monitoring device 111 may utilize lights from an array of infrared, ultraviolet or laser diodes 113 (depicted in the FIG. 4d) to measure reflection delay to contour scaling, measurement and zooming. The intravaginal monitoring device 111 may also utilize correlation with a first image to compute rotation, scaling and zooming.

**[0053]** FIG. 2 is a diagram illustrating a characteristic cervical changes in latter stage pregnancy which can be automatically or visually identified using image capture and associated scaling information gathered by an embodiment of an intravaginal monitoring device (IMD) which is built in accordance placement of the intravaginal monitoring device. When placed so as to face the outer surface of the cervix 213, the intravaginal monitoring device 211 generates scaling and measurement information, using any or multiples of the plurality of approaches set forth in this application.

**[0054]** The intravaginal monitoring device 211 can also be used to monitor later stages of pregnancy, when the routine speculum or finger based observations become more dangerous and more difficult, respectively. These observations are necessary to judge cervical or fetal health conditions or to

estimate the birthing date or time. Some of the conditions associated with a pregnancy include sexually transmitted diseases (such as Chlamydia), yeast infections, indications of potential premature delivery, incorrect baby orientation with the uterus, development issues, umbilical cord obstructions, etc., need to be timely identified even during periods between typical doctors' office visits. Using the IMD 211 of the present invention, much of these and other conditions or indications thereof can be identified, evaluated and tracked even when the patient is remote from a doctor's office.

**[0055]** Sometimes, in such situations, on site monitoring (and admissions to the hospitals) can be avoided if continuous monitoring using the IMD 211 is employed. During the last stages of pregnancy, even with normal and healthy fetus and the woman, continuous monitoring is advisable.

**[0056]** When these are the cases, the intravaginal monitoring device 211 comes in handy and placement of a thin the intravaginal monitoring device 211 along with scaling, dimensioning and color measurement features makes it easy for a health care professional (gynecologist or obstetrician, for instance) to judge the health conditionings (during these later stages of pregnancy).

**[0057]** The scale, dimensions and colors in these cases as well are obtained by one of plurality of methods (described with reference to the FIG. 1), upon which the (fetus or cervix) images are overlaid for accurate measurements and color identifications. An image screen, for instance, allows the user or health care professional to obtain images of the cervix or cervical dilation, during later stages of pregnancy, upon clicking on a dimension (Dim, in FIGS. 9 through 14) button overlays the image on a scale. The screen also provides accurate numerical measurements on a separate column, of a selected area, which allows the health care professional to figure out the size of the cervix or cervical dilation during the later stages of pregnancy.

**[0058]** Similarly, a colorization screen allows the images of the cervix or cervical dilation, during later stages of pregnancy overlays the image upon a color scaling and dimensioning. The screen also provides accurate numerical color measurements on a separate column, of a selected area, which allows the health care professional to identify the size of the cervix or cervical dilation during later stages of pregnancy.

**[0059]** FIG. 3 is a schematic block diagram illustrating an embodiment of a monitoring architecture of the present invention, wherein an IMD 301 captures imager data and collects measurement information (using for example infrared, ultraviolet, or visual spectrum emissions and sensing) for exchange with supporting client devices, server devices and associated software. "Measurement information" as used herein refers to information that can be used for one or more of image scaling or generation of dimensions for either two or three dimensional shapes (e.g., lengths, height, circumferences, diameters, volumes, areas, and perimeter lengths).

**[0060]** After generating imager data and measurement information, the intravaginal monitoring device 301 can apply the measurement information to the imager data or forward one or both via wired and/or wireless communication pathways 331 to supporting software at the server and client sides. Client side, a user's IMD client systems 371 can be found. Accessible via the pathways 331, supporting server(s) 351 can be found. Perhaps at a doctor's office, supporting IMD client or server systems & devices, i.e., external support systems 361, can be found.

**[0061]** The depiction also shows flow of data between the intravaginal monitoring device **301** and supporting network infrastructure **371**, **351**, **361** via communication pathways **333**, **335**, **337**, **339** and/or **341**, that includes flow of scaling, dimensioning and colorization information (that starts at the intravaginal monitoring device **301**, via dimension processing and control—DPC—module **311**). Essentially, this flow of data is meant to view the image along with dimension, scaling and colorization collected within the memory (may be a built-in memory or memory stick) of the intravaginal monitoring device **301** and then deliver them, for inspection, suggestions, recommendations, discussions and/or treatment, to the user, health care professionals, user forums or for secure storage.

**[0062]** For instance, the images may allow the woman, users of the forums, health care professionals, to inspect, suggest, recommend, discuss and/or treat one of more of conditions related to (along with dimension, scaling and colorization data): (a) Routine reproductive health; (b) Menstrual cycles; (c) Menopause; (d) Sexually transmitted diseases; and (e) Pregnancy checkups (may also include pre and/or post coitus periods). All of these checkups otherwise would necessitate the presence of the female person in question at the health care professional's office, consuming valuable time and adding to needless health care costs. In all these, to come to appropriate conclusions, scaling, dimensioning and colorizations of the images are very essential. Using the intravaginal monitoring device **301** and some preliminary knowledge of reproductive health and well being, the woman may herself observe the cervix (and the vaginal discharges thereon) and be able to take many scaled and colorized images (and hence be able to judge health conditions, possibly, in conjunction with health care professionals).

**[0063]** To begin with, the intravaginal monitoring device **301** can communicate with the supporting infrastructures such as user's IMD (Intravaginal Monitoring Device) dimension processing and control module **381**, supporting server(s) dimension processing and control module **353** and/or supporting IMD (Intravaginal Monitoring Device) dimension processing and control module **383** in many different ways: (a) A memory stick intravaginal monitoring device **301** and USB port within the client module (inside the personal computer **377**) assist in viewing the data contents on the personal computer **377** (along with scaling, dimensioning and colorization information) and deliver directly to the supporting server(s) **351** and viewed through web pages. To enable this, the intravaginal monitoring device **301** contains a unique network ID; (b) The intravaginal monitoring device **301** may be plugged directly to a television **373** or personal computer **377** display using dimension processing and control module **381** and display driver; (c) The intravaginal monitoring device **301** may be plugged it into a personal computer **377** (and the personal computer **377** considers it as a memory device and copies all of the files and data (along with scaling, dimensioning and colorization data) from the intravaginal monitoring device **301**, the personal computer **377** uses memory device interface **385** to do this); (d) The browser goes on to query mode and the website or server **351** connects to the intravaginal monitoring device **301** and pulls out information (along with scaling, dimensioning and colorization data); and so forth.

**[0064]** These supporting local personal computing devices **371** may include cell phones **375**, personal computers **377** and video recorder **379**, or simply an access point, for

instance (each containing dimension processing and control module **381**). The intravaginal monitoring device **301**, while inserted in place (inside the vaginal channel) or after usage and removal, allows an authenticated supporting personal computing device **371** to send control signals (as well as firmware and other logistical program codes) and receive images/video clips/sensor/scaling and dimensioning/colorization data and so forth from the intravaginal monitoring device **301**.

**[0065]** To make all of the above mentioned functionality and flow of data (scaling, dimensioning and colorization data as well) possible, the intravaginal monitoring device **301** contains a head or cap **305**, stem **303**, **307** (that contains many of the electronic components including a display **313**, some of the sensors and batteries), bottom cap **309** (that allows insertion and removal of batteries and exposes mini USB port for wired communications) and an on/off switch **315**. The on/off switch **315** also allows independent selections of modes, wireless on/off, wired on/off, scaling, dimensioning and colorization on/off (by keeping on clicking **315** until the mode is selected).

**[0066]** FIG. **4a-e** are perspective diagrams illustrating various scaling and dimensioning schemes and components found at the anterior end of various IMD embodiments and illustrating various aspects of the present invention. The IMD **411** (FIG. **4a**) is representative of one possible form factor for an IMD with the optics configurations of FIGS. **4b-e**.

**[0067]** In FIG. **4a**, the IMD **411** may contain one, two, three or a plurality of infrared, ultraviolet or laser light sources (diodes, for instance) that emit light **413** and in some embodiments leave a visible mark on the images while in others, receive modulated reflected signals. These data are then used perhaps along with captured image data for scaling, dimensioning, contouring, colorizations, etc.

**[0068]** FIG. **4b** is a perspective view illustrating one optics arrangement found in an embodiment of the IMD **411** (FIG. **4a**) built in accordance with various aspects of the present invention. Therein, three emitters **422**, **423**, **424**, are used along with imager **421** and a flash illuminator **425** to capture image data and measurement information. Although separate detectors from the emitters **422**, **423**, **424** could be used, as illustrated, emitted reflections as well as the image data are captured by the imager **421**.

**[0069]** FIG. **4c** depicts yet another embodiment (one of the many possible configurations that generate scaling, dimensioning, contouring and/or colorization data) of an IMD such as that of FIG. **4a**. Therein, two photodetector pairs **431**, **433**, e.g., each a paired emitter and detector, are used to both deliver and captures reflections from a target area. From the captured reflections, measurement information may be extracted.

**[0070]** FIG. **4d** provides another perspective view of another optics arrangement found in a further embodiment of the IMD **411** (FIG. **4a**) employing a fixed array of emitters **441** which interact, via reflections off of the target area being imaged, with an imager **443**. From these reflections, the imager **443** captures data used to produce measurement information. The imager **433** also utilizes a pair of illuminators **445**, **447** to capture image data. Such image data capture and emitter reflection data can be simultaneously or sequentially captured, depending on the configuration.

**[0071]** FIG. **4e** depicts a second embodiment another optics arrangement found in a further embodiment of the IMD **411** (FIG. **4a**) wherein a photodetector pair **451** is used to both



deliver and captures reflections from a target area, while an imager 453 captures image data with illumination assistance from an illuminator 455. Such captures as before can occur simultaneously or sequentially.

[0072] Regarding all of FIGS. 4*b-e*, there are many ways of producing measurement information from the underlying four configurations. Many of these ways are described in more detail with reference to subsequent figures such as FIGS. 5-8.

[0073] FIG. 5 is a schematic block diagram illustrating circuitry that might be used in an IMD built in accordance with the present invention such as the IMD of FIG. 3. The components within the hermetically sealed rubber cap/bulb/stem include cameras 513, illumination light 515 and temperature sensors 511, PH sensor 519, pressure sensors 523, microphone 525, electrocardiogram sensing 571, sonogram sensing 573, and other sensors 517. These are typical diagnostic components many or all of which can be included in the IMD 521.

[0074] Similarly, user interfaces 557 include input 555, display 553 and speaker 551 units. These interfaces provide the user some control over the functionalities of the intravaginal monitoring device 521. Moreover, the components within the hermetically sealed rubber cap/bulb/stem also include processing circuitry 575 (that includes a time and date generation block 507 for time and date stamping) and memory 577, communication interfaces 543 (that include wired 541 and wireless 533 interfaces), and power management circuitry 563 (that includes power regulator circuitry 565 and batteries of various types).

[0075] The memory 577, in some embodiments, may include some preprocessing modules, such as compression 581 and encryption 583, to save storage space and to secure the data stored, respectively. The wireless interfaces 533 may include one or more of Bluetooth® communication interfaces 539, WiFi communication interfaces 537, and infrared communication interfaces 535.

[0076] Note that the infrastructural support for the intravaginal monitoring device 521 is described with reference to the FIG. 16 (excepting that of the binocular cameras, the infrastructural support in the FIG. 16 provides support for the schemes of FIG. 4*b* through FIG. 4*e*) or FIG. 18.

[0077] FIG. 6 is a conceptual flow diagram illustrating one embodiment of a scaling and dimensioning technique employing a pair of marker beams that can be used with an IMD such as those illustrated in FIG. 3, FIG. 4*a*, or FIG. 4*c*. Therein, first image data 621 contains two marker dots (from an emitter) located at precisely known separation distances. For example, parallel emitters spaced one centimeter apart within an optical assembly (see, e.g., FIG. 4*c*) will produce when calibrated a one centimeter spacing on a target from an imagers point of view. That is, two dimensional image data containing the markers and the space there between constitute measurement information which can be used to scale the underlying and related image data.

[0078] A second of the images 623 (“second image data”) may be taken without the emitters being active (e.g., captured perhaps few millisecond before or after capturing the image 621). The difference between image data of images 621, 623, that is image data 635, permits easily identification of the markers. Using recognition techniques including edge detection algorithms, the perimeter of a cervix and cervical channel entrance can be identified as shown in image data 631. Then, based on scaling, framing and zoom information (determined

from the markers and the cervical perimeter location within the image data 623), a reticle can be produced and applied to an appropriately zoomed and framed image data 623, i.e., resulting image data 643. Additionally, using a similar approach, actual cervical characteristics such as average diameters, lengths, heights, and other types of measurement information can be produced.

[0079] FIG. 7 is a conceptual flow diagram illustrating another embodiment of a scaling and dimensioning technique employing a single marker beam that can be used with an IMD such as that of FIG. 3 or FIG. 4*e*. Therein, a single infrared, ultraviolet or laser light emitter may be used to deliver modulated infrared, ultraviolet or other electromagnetic emissions and with reflection measurements and signal processing enabling a determination of distance (e.g., via measuring round trip emission propagation times). This allows, via a process depicted, to generate scaling, dimensioning, contouring, colorizations and other measurement information.

[0080] Specifically, image 721 depicts a marker beam (“dot”) that impacts and reflects from a cervical surface. From the reflection, a distance measurement is generated which is in turn applied to image data 723 for scaling purposes. As before, with scaling and perhaps zooming and framing techniques, image data 729 can be constructed along with a scaled reticle overlay. Also as before and based on the distance and scaling (“measurement information”) along with edge detection algorithms, cervical lengths, dimensions, areas and volumes can be calculated.

[0081] FIG. 8 is a conceptual flow diagram illustrating a further embodiment of a scaling and dimensioning technique employing a marker array that can be used with an IMD such as that of FIG. 3 or FIG. 4*d*. With this approach, an array of infrared, ultraviolet or other laser light sources (as depicted in the FIG. 4*d*) are used to emit light over a wider area of the cervix to support more accurate contour creation as well as all other more accurate measurement information. Although each of the emitters in the array may have a corresponding detector, a single imager can be used for both the imager data capture and the reflection data.

[0082] Processing of such configurations could take many forms. As shown, for example, at first an image 823 containing only the cervix area can be captured. Then, shortly thereafter (to avoid correlation mis-matches) all, some or element by element, each element of an emitter array (see FIG. 4*d*) emits a modulated signal which is captured after surface reflection via a sensor (such as an independent photodetector or the imager itself). Through signal processing, contour data can be extracted. Also, by simultaneously turning all or some elements of the emitter array on at the same time, an image can be captured, image 821, which can supplement scaling based on known distances between elements.

[0083] Using recognition and edge detection, image 825 can be created. By combining all measurement information and processing, real and supplemental (simulated) contours can be created to produce either three dimensional image data, or multiple 2D views such as image 829 (a side contour-view) and image 831 (a view fully normal to the cervical plane). Of course, other measurement information can be extracted such as average diameters, volumes, etc.

[0084] FIG. 9 is a conceptual flow diagram illustrating a scaling and dimensioning scheme employing comparisons between current images and prior manually-scaled images that can be used with an IMD such as that of FIG. 3. Specifi-

cally, a prior image **921** with known dimensions of the same woman is kept as a reference and a current image **923** is correlated with it to come up with dimensional values.

**[0085]** The correlation results in dimensions of the current image **923** that includes radius, circumference and then, these scaling dimensions **925** are used separately to scale, to arrive at the image **927**.

**[0086]** The current image **923** is then superimposed on the arrived scaling and dimensioning values to be able to observe the cervix or cervical dilation, cervix immediately after coitus, during early stages and later stages of pregnancy and artifacts.

**[0087]** The prior image with known dimensions (and other measurement information) may be obtained by another (perhaps more capable) intravaginal monitoring device, for instance, during a visit to the health professional (gynecologist or obstetrician, for instance). Such measurement information can also be collected manually during such a visit.

**[0088]** FIG. **10** is a screen diagram illustrating a snapshot image of one embodiment of a reproductive health care management system (i.e., web page or dedicated software application) for use with various types of IMDs having various types of imaging, scaling and dimensioning infrastructures, and wherein information regarding a patient's cervix can be reviewed and managed. All of FIGS. **10-14**, the screen display and underlying software, along with other embodiments thereof can be displayed on any computing device such as a smart phone, pda, tablet computer, or laptop computer and operate in real time communication with an IMD or at any time thereafter in a review mode. Such software may take the form of a dedicated application (such as a downloaded "app" from a cloud and even partially running in the cloud) or via a web site with served up windows or pages. It may also operate on devices local to the IMD currently in operation or remotely therefrom via point to point communication links or via network routing pathways.

**[0089]** In particular, in FIG. **10**, along with depictions of a woman's scaled and contoured cervix displays, many other derived measurement information can be identified, tracked and compared over such woman's history and with averages of other women in her age and racial group.

**[0090]** The illustration shows a data view screen of the reproductive health care management software containing many tabs such as data view, records, queries, mail, forum, research, accounts, IMD setup, support and shopping. The data view page also shows a time scale beginning and ending to scroll through (for the user or a health care professional) and the current position of the image. At the bottom left, a small window shows values graphically the selected (via radio buttons on the right) entities.

**[0091]** A tool box at the center allows the user or health care professional to manipulate the current image on the window that includes marking, selecting (square and circle), zooming, dimensioning values (Dim), scaling and dimensioning, three dimensional image displaying, tracing, notes among others.

**[0092]** An image display window shows image of the cervix during routine checkup with the third dimensional display on the left hand side. The scaling and dimensioning are obtained by one, two, three or a plurality of infrared, ultraviolet or laser light sources (diodes, for instance) that emit light and in some embodiments leave a visible mark on the images while in others, receive modulated reflected signals. The scaling can be changed (to get a proper view of some

specific area of the cervix, for instance) and when done so, it changes the size of the image on the screen.

**[0093]** On the right hand side of the screen, the actual values of various parameters of the display on the left are shown (note that the values shown inside the boxes are representative only and not the actual values). The actual values, among many others, include diameter (average), base area, perimeter, circular deviation (deviation from the actual circle), volume and height of the cervix. Moreover, the actual values also include dilation values such as diameter (average), opening area, perimeter and circular deviation as well as actual values of any artifacts such as perimeter and area. At the bottom of the screen shown are IMD status **1013** and online status of the IMD **1015**.

**[0094]** FIG. **11** is a screen diagram illustrating various other features of the reproductive health care management system of FIG. **10**. Colorization analysis is supported across common regions of the cervix which can be compared with prior image capture data or other averages data to evaluate changes over time or unusual variations, both of which being indicative of a gynecological event or condition, or onset thereof.

**[0095]** For instance, various reproductive health care conditions are associated with some specific colors of the cervix, dilation and especially that of the artifacts, if any. Therefore, for a user or health care professional, it is essential to know the actual colors, for example, of inner OS. This allows the user or health care professional to know the exact nature of the disease associated with the specific image.

**[0096]** On the right hand side of the screen, the actual values of various parameters (of colors) of the display are shown (note that the values shown inside the boxes are representative only and not the actual values). The actual values, among many others, include current and average values of inner and outer ring, middle ring and entirety. This allows the user or health care professional to identify, by ways of numerical values, the nature of the problem at hand. Similarly, values for the inner OS are also provided in another box. Additionally, a space is provided for notes, for the benefit (to be able to remember in the future, for instance) of the user or health care professional.

**[0097]** Colorization analysis not only identifies variations from one image to another captured at some other time, it also includes spectral analysis assist in the identification of artifacts or conditions underlying a particular image, and perhaps not even discernible via normal visual inspection. For example, when a cervical surface becomes inflamed (more red) or more grey, determinations relating to menopause onset, ovulation, conception, infection, etc., might be more likely or not. Colorization analysis techniques such as comparisons with prior captured images within the same woman, might better identify such colorization changes automatically rather than require a viewer to make such determination (although they can via the display window). In addition, fluids or a surface artifact may be present in minute sizes or quantities that are highly likely to point to some gynecological event or condition that can be characterized and sought via a single image or as a step related to multiple image comparisons. For example, traces of blood might be present, particles associated with an over abundance of yeast, chlamydia, etc., may have color signatures that can be separated from the color signatures of normal fluids, surface conditions, and surface characteristics. In effect, a color imager can be used as a visible light spectral analyser (via filters within each pixel of the color imager). Moreover, imagers spanning outside of the

optics range might also be used to enhance this colorization analysis. If so, the full spectrum although not all visible is still referred to herein as "colorization analysis."

**[0098]** The illustration also shows many tabs such as data view, records, queries, mail, forum, research, accounts, IMD setup, support and shopping. The data view page also shows a time scale beginning and ending to scroll through (for the user or a health care professional) and the current position of the image. At the bottom left, a small window shows graphically the values of selected (via radio buttons on the right) entities.

**[0099]** A tool box at the center allows the user or health care professional to manipulate the current image on the window that includes marking, selecting (square and circle), zooming, dimensioning values (Dim), scaling and dimensioning, three dimensional image displaying, tracing, notes among others. At the bottom of the screen shown are IMD status **1113** and online status of the IMD **1115**.

**[0100]** FIG. **12** is a screen diagram illustrating various other features of the reproductive health care management system of FIG. **10**, with focus on tracking of dilation of a cervical channel and associated analysis and review. Such interaction can be used for example to track ovulation cycling or pregnancy. For example, during pregnancy, cervical channel dilation is an important factor in forecasting premature, post-term and normal birthing onset.

**[0101]** Specifically, it is not always possible to judge health of a pregnant woman, especially in cases where premature delivery is necessary or due. Hence, during pregnancy, it is essential to monitor the cervical dilations regularly, to be able to come to conclusions regarding the reproductive health (that includes infections that especially occur during pregnancy), or to estimate the delivery period.

**[0102]** An image display window of FIG. **12** shows image of the cervix during pregnancy checkup with the third dimensional display of the cervix on the left hand side. The scaling and dimensioning are obtained by using infrared, ultraviolet or laser light sources (diodes, for instance) that emit light and in some embodiments leave a visible mark on the images while in others, receive modulated reflected signals. The scaling can be changed (to get a proper view of some specific area of the cervix or cervical dilations, for instance) and with it the size of the image on the screen also changes.

**[0103]** On the right hand side of the screen, the actual values of various parameters of the display on the left are shown (note that the values shown inside the boxes are representative only and not the actual values). The actual values, among many others, include diameter (average), height, width, base area, perimeter, circular deviation (deviation from the actual circle), volume and depth. Moreover, the actual values also include dilation values such as diameter (average), height, width, opening area, perimeter and circular deviation.

**[0104]** The illustration also shows a data view screen of the reproductive health care management software containing many tabs such as data view, records, queries, mail, forum, research, accounts, IMD setup, support and shopping. The data view page, in addition, shows a time scale beginning and ending to scroll through (for the user or a health care professional) and the current position of the image. At the bottom left, a small window shows values graphically the selected (via radio buttons on the right) entities.

**[0105]** A tool box at the center allows the user or health care professional to manipulate the current image on the window

that includes marking, selecting (square and circle), zooming, dimensioning values (Dim), scaling and dimensioning, three dimensional image displaying, tracing, notes among others. At the bottom of the screen shown are IMD status **1213** and online status of the IMD **1215**.

**[0106]** FIG. **13** is a screen diagram illustrating various other features of the reproductive health care management system of FIG. **10**, wherein colorization analysis is used during the course of pregnancy. As is the case with FIG. **11**, during pregnancy, it is essential for a health care professional to judge the reproductive health using colors of various parts of the cervix or cervical dilations. The screen **1311** provides such a view for the health care professional.

**[0107]** For instance, pregnancy is associated with many conditions, some are routine while others are malignant. Therefore, for the user or health care professional, it is essential to know the actual colors of OS, along with scaling and dimensioning. This allows the user or health care professional to know the exact nature of the developments related to the pregnancy (that is, associated with the specific image).

**[0108]** On the right hand side of the screen, the actual values of various parameters (of colors of the cervix) of the display are shown (note that the values shown inside the boxes are representative only and not the actual values). The actual values of the cervix colors, among many others, include current and average values of inner and outer ring, middle ring and entirety. This allows the user or health care professional to identify, by ways of numerical values, the nature of the problem at hand. Similar values of the OS colorizations are also provided in another box.

**[0109]** The illustration also shows many tabs such as data view, records, queries, mail, forum, research, accounts, IMD setup, support and shopping. The data view page also shows a time scale beginning and ending to scroll through (for the user or health care professional) and the current position of the image. At the bottom left, a small window shows values graphically the selected (via radio buttons on the right) entities.

**[0110]** A tool box at the center allows the user or health care professional to manipulate the current image on the window that includes marking, selecting (square and circle), zooming, dimensioning values (Dim), scaling and dimensioning, three dimensional image displaying, tracing, notes among others. At the bottom of the screen shown are IMD status **1313** and online status of the IMD **1315**.

**[0111]** FIG. **14** is a screen diagram illustrating various other features of the reproductive health care management system of FIG. **10**, focusing on a gynecological artifact review and analysis. The image window (of the data view page) depicted on the left hand side illustrates an artifact along with cervical dilations and a three dimensional image on the left side. This illustration allows a health care professional to arrive at precise conclusion as to the nature of the disease (which may be a cancerous growth or a sexually transmitted disease) and provide appropriate treatment. Also, it allows the health care professional to monitor periodically the progress of the disease toward cure or a pharmaceutical or other treatment's effectiveness. To do this, the health care professional needs scaling and dimensioning of the image (in specific, the artifact).

**[0112]** For instance, pregnancy is associated with many conditions, some are routine while others are malignant. Therefore, for the user or health care professional, it is essential to know the actual colors of various artifacts (one such

artifact is shown on the left hand side window, which may be routine or malignant), along with scaling and dimensioning. This allows the user or health care professional to know the exact nature of the developments or disease associated with the specific image.

[0113] Similarly, various reproductive health care conditions are associated with some specific colors of the cervix, dilation and especially that of the artifacts, if any. Therefore, for a user or health care professional, it is essential to know the actual colors by, for example, zooming in on a specific area that might contain an artifact (depicted is the artifact of the FIG. 10 or FIG. 11 zoomed to a 5 mm grid scale to form a 2× zoom). This allows the user or health care professional to know the exact nature of the disease associated with the specific image.

[0114] This scaling, dimensioning and colorizations (illustrated) are obtained by using infrared, ultraviolet or laser light sources (diodes, for instance) that emit light and in some embodiments leave a visible mark on the images while in others, receive modulated reflected signals. The scaling, dimensioning and colorizations can be changed (to get a proper view of some specific area of the artifacts, for instance, as illustrated) and with it the size of the image on the screen also changes.

[0115] On the right hand side of the screen, the actual values of various parameters of the display on the left are shown (note that the values shown inside the boxes are representative only and not the actual values). The actual values, among many others, include diameter, base area, perimeter, circular deviation, volume, depth (average), growth rate, color entirety, color inner ring, color outer ring, as related to the artifact.

[0116] The illustration also shows a data view screen of the reproductive health care management software containing many tabs such as data view, records, queries, mail, forum, research, accounts, IMD setup, support and shopping. The data view page, in addition, shows a time scale beginning and ending to scroll through (for the user or a health care professional) and the current position of the image. At the bottom left, a small window shows values graphically the selected (via radio buttons on the right) entities.

[0117] A tool box at the center allows the user or health care professional to manipulate the current image on the window that includes marking, selecting (square and circle), zooming, dimensioning values (Dim), scaling and dimensioning, three dimensional image displaying, tracing, notes among others. At the bottom of the screen shown are IMD status 1413 and online status of the IMD 1415.

[0118] FIGS. 15a-b are schematic diagrams illustrating a binocular vision system for generating three dimensional image display, measurement and scaling for a further embodiment of an IMD built in accordance with the present invention. FIG. 15a depicts two imager based cameras (along with a flash illuminator). A single photodetector pair is also shown for supplemental and possibly confirmatory distance data.

[0119] Referring to FIG. 15b, two images 1511, 1513 are captured by the two cameras of FIG. 15a which are spaced at a known distance apart and at known orientation angle differentials (if any). Conceptually, wherever there is high pixel correlation between two regions of the two photos, that area is likely further distant than those seemingly in motion are nearer.

[0120] When processed on a pixel by pixel basis with correlation and a variety of other known image processing tech-

niques, the two images 1511, 1513 can be used to produce a three dimensional image 1515. The image 1515 can be displayed on a screen supporting three dimensional viewing, or can be used to produce two dimensional “views” of the three dimensional image data as can be appreciated through rotation, panning and zoom functionality accessible via a toolbar 1517.

[0121] As previously mentioned, the use of the photodetector distance measurement (e.g., via modulation and delay measurement), or any other infrastructure disclosed herein with differing approaches to identifying measurement information, can be used to verify or calibrate the resultant three dimensional image data. Thereafter, relatively accurate measurements including those of distances along contours and volumes can be measured.

[0122] In specific, FIG. 15b shows the necessary processing of the binocular images (taken from two slightly different angles) to obtain a three dimensionally contoured image. The binocular vision image processing essentially involves two images 1511 and 1513 taken from slightly different angles and combined together. This combined image 1515, along with scaling and dimensioning provides an illusion of a three dimensional image. The scaling and dimensioning of the contours can be made to appear from different angles using a toolbar 1517.

[0123] FIG. 16 is a schematic diagram illustrating a monitoring architecture including an IMD with binocular vision three dimensional processing components, and a variety of external supporting devices accessible via a communication network. Therein, binocular vision and three dimensional processing components can be found within a hermetically sealed IMD 1621. The IMD 1621 operates within a monitoring architecture for exchange of information and control signaling, and to provide support. Also within the monitoring architecture, electronic video systems 1659, external servers 1671, and diagnostic equipment and computing systems in health care centers 1689 can be found. Communication can occur in a point to point, wired or wireless links or via network routing.

[0124] Within the IMD 1621, electronic components located within a hermetically sealed housing can be found. Although illustrated within the bounds of the IMD 1621 some of the components and circuitry therein may be distributed to local supporting devices and even to distant devices through some communication pathway. The electronic components include binocular vision camera (along with binocular image processing) 1615, illuminator 1617, temperature sensors 1613, other sensors and/or instruments 1611 (that may for example include sonogram and/or electrocardiogram sensors and associated processing circuitry), communication interfaces 1631, user interfaces 1637, memory 1639, processing circuitry 1641 and power regulator and management circuitry 1643.

[0125] The communication interfaces 1631 include wireless 1633 (such as Bluetooth) and wired 1635 interfaces that allow the captured and temporarily stored images and sensor data in the memory 1639 to be transferred to external wired/wireless video devices 1659, such as cell phones 1651, personal digital assistant 1653, computers 1655 and other video systems 1657. The other video systems 1657 may include digital photo and video devices, car tech and GPS devices, cell phones and smart phones, computers and hardware (e.g., notebooks, etc.), gaming devices, home theater devices, MP3 and video players and televisions. The wired/wireless video

devices **1659** also have the binocular vision image processing modules that enable a viewer to observe a three dimensional image.

[0126] The captured and temporarily stored binocular images and sensor data from these wired and/or wireless devices **1659** may be observed by the woman or a health care professional or may later be transferred to external servers **1671** for further processing (that is, the binocular vision image processing modules enable a viewer to observe a three dimensional images). Finally the woman may utilize them whichever the way she deem fit, that includes sharing them (and requesting for more information via Internet regarding a particular condition) or transferring them to health care centers **1689**. Alternatively, the captured and temporarily stored images and sensor data in the memory **1639** may also be transferred (via, wireless or wired communication paths) directly from the intravaginal monitoring device **1621** to the external servers **1671**.

[0127] Ultimately, in the health care centers **1689**, they might end up in computers **1681** or medical diagnostic equipments **1683**, for further investigations by the health care professionals. The computers **1681** or medical diagnostic equipments **1683** may also have the binocular vision image processing modules that enable a health care professional to observe a three dimensional image.

[0128] Excepting for the binocular vision, the supporting infrastructure of the current diagram is also applicable to other embodiments of IMDs described here within, such as the IMDs referenced in relation to FIG. 4a-e.

[0129] FIGS. 17a-b are schematic diagrams illustrating another three dimensional scaling and dimensioning approach for an alternate embodiment of an IMD, using a position sensitive photodetectors (PSD) **1721**, **1761** which captures reflected laser diode emissions from a scanning arrangement. In FIG. 17a, the PSD **1761** (such as ones from Silicon Sensor®) converts the energy from an incident light spot into a continuous, position relative, electrical output signals. Such signal is relative to the total incident light pattern and indicates the “optical center” of the incident light. The PSD **1761** may be a single or a double axis device. In some embodiments, the PSD **1761** is configured as a package with a built in emitter than produces an emission (light) that reflects back to the position sensitive photodetector arrangement. In other embodiments, the PSD **1761** does not incorporate the emitter. The depiction of the PSD **1761** also shows four connector pins **1755**, **1757**.

[0130] FIG. 17b is a perspective schematic diagram that illustrates the use of a PSD with either an integrated or external emitter to identify contours and dimensions of an intravaginal target (e.g., a cervix or artifact) via a scanning arrangement. Therein, a laser diode **1711** may act as an emitter for a PSD **1721** by directing the emitted laser light toward a first mirror **1709** that scans the beam in an oscillatory back and forth motion as directed by a corresponding rocker drive motor **1713**. The motor **1713** does not spin 360 degrees but “rocks” back an forth within a fixed angular range such as 10-45 degrees. The scanning reflected beam **1737**, travels to another mirror **1715** that oscillates at a slower rate than the first, as directed by the second drive motor **1717**.

[0131] Together, the first and second mirrors **1709**, **1715** raster scan (in a somewhat “Z” shaped scanning pattern) the output of the laser diode **1711** over the target area (e.g., a cervix) by passing with minimal interference through a beam splitter **1719**. The reflected x-y scanning beam (reflected from

the cervix) **1733** is reflected by the beam splitter and directed to a Position Sensitive Detector (PSD) **1721** which is a one (but could be two) dimensional array of photodetectors. The output of the PSD **1721** produced from reflected light **1733** from the target and via a highly reflective portion of the beam splitter **1719** allows for the generation of signals indicative of both beam position along the axis and the distance to the target. Along with timing signals associated with the rocking motion of the mirror **1715**, second axis signals can be produced.

[0132] From the first and second axis signals, a full contour and sizing of the target can be produced. Images captured via for example one or both of the binocular pair of imagers **1723**, **1725** (with the assistance of illuminator **1727**) can be used along with the measurement data from the PSD and constructed from the timing signals associated with the mirror **1715** movement to create a very accurate three dimensional image data set for real time or post processed viewing, interaction and analysis.

[0133] FIG. 18 is a schematic diagram of a monitoring architecture much like that of FIG. 16, yet supporting the IMD of FIG. 17b. In particular, the diagram illustrates two or three dimensional processing components (using PSD) within the hermetically sealed intravaginal monitoring device **1821**. Therein, a position sensitive photodetector is used to determine an exact X-Y location plus a Z distance across the surface of an intravaginal imaging target such as a cervix. Devices external to the intravaginal monitoring device **1821**, includes electronic video systems **1859**, external servers **1871** and diagnostic equipments in health care centers **1889**.

[0134] The illustration depicts electronic components located within the hermetically sealed intravaginal monitoring device **1821** (a part of it may be located external to it). The electronic components include Position Sensitive Detector (PSD) and camera (along with PSD Image Processing—PS-DIP) **1815**, illuminator **1817**, temperature sensors **1813**, other sensors and/or instruments **1811** (that may include sonogram and electrocardiogram), communication interfaces **1831**, user interfaces **1837**, memory **1839**, processing circuitry **1841** and power regulator and management circuitry **1843**.

[0135] As mentioned above, the PSD is only used with scanning to determine an exact X-Y location on the cervix plus a Z distance, and, in turn, the PSDIP produces a wire-frame based upon the proportional current output of the PSD. This distance per X-Y location is then overlaid onto the normal image data to extract three-dimensional information.

[0136] The communication interfaces **1831** include wireless **1833** (such as Bluetooth®) and wired **1835** interfaces that allow the captured and temporarily stored images and sensor data in the memory **1839** to be transferred to external wired/wireless video devices **1859**, such as cell phones **1851**, personal digital assistant **1853**, computers **1855** and other video systems **1857**. The other video systems **1857** may include digital photo and video devices, car tech and GPS devices, cell phones and smart phones, computers and hardware (e.g., notebooks, etc.), gaming devices, home theater devices, MP3 and video players and televisions. The wired/wireless video devices **1859** also have the PSD image processing modules that enable a viewer to observe a three dimensional image.

[0137] The captured and temporarily stored images (via PSD) and sensor data from these wired and/or wireless devices **1859** may be observed by the woman or a health care professional or may later be transferred to external servers **1871** for further processing (that is, the PSD image process-

ing modules enable a viewer to observe a three dimensional images). Finally the woman may utilize them whichever the way she deem fit, that includes sharing them (and requesting for more information via Internet regarding a particular condition) or transferring them to health care centers **1889**. Alternatively, the captured and temporarily stored images and sensor data in the memory **1839** may also be transferred (via, wireless or wired communication paths) directly from the intravaginal monitoring device **1821** to the external servers **1871**.

**[0138]** Ultimately, in the health care centers **1889**, they might end up in computers **1881** or medical diagnostic equipments **1883**, for further investigations by the health care professionals. The computers **1881** or medical diagnostic equipments **1883** may also have the PSD image processing modules that enable a health care professional to observe a three dimensional image.

**[0139]** Except for the Position Sensitive Detector (PSD) camera (along with PSD image processing) **1815**, the supporting infrastructure of the current diagram is also applicable to the imaging devices of the FIG. **4a-e**.

**[0140]** FIG. **19** is a diagram illustrating the functionality of two or three dimensional scaling and dimensioning for an IMD such as that of FIG. **17b**, which uses position sensitive photodetectors (PSD) and an associated laser diode scanning arrangement. Specifically, a dual axis PSD or a single axis PSD with scan timing signals can identify distances and overall contour of an intravaginal target.

**[0141]** Scanning can be performed at any resolution desired and beyond that represented by the screen **1921**. For example, 25 scanning rows may be used so as to minimize the overall processing power required or at a much higher row count. Either way, the X, Y, Z information act as a frame onto which image data **1919** (and in binocular configurations, along with image **1917**) is mapped. Thus, a possibly much higher resolution image data can act as a "skin" on a "wire frame" from the scanning system.

**[0142]** More specifically, the scanning of the target, that is the X, Y, Z coordinates, create a wireframe onto which a 2D image captured by an imager can be mapped. In this monocular example, the mapping of the X-Y 2D image is done onto the scanner's 3D frame based on the rate of change in the Z plane.

**[0143]** For example, a flat object in a photo (a 2D image) that was arranged in parallel with the CCD plane can easily be mapped onto a wireframe, by using signal processing techniques. A so oriented, flat object that is one inch across, for example, would be mapped to a one inch area on a wireframe. However, if the object is placed at an angle to the CCD plane, the object might look to be one inch in the photo, but in reality be 3 inches long. So the pixels of the one inch length in the photo need to be mapped onto the 3 inches in the wireframe. In this case, a 2D image needs be "stretched" across the wireframe.

**[0144]** With two (binocular) or more image capture devices arranged at different angles, further detail (resolution) can be provided in regions experience more rapid z-axis changes for one imager than that of another, reducing the amount of stretching required. Similarly, adding further imagers will further decrease the required stretching and thus provide higher overall resolution 3D image data set.

**[0145]** The 3D wireframe thus obtained is absolute XYZ coordinate numbers for the entire contour of the corresponding one or more imager capture areas. From the 3D data set,

it is possible to produce varieties of measurement information, such as calculations of distances along straight lines as well as across tissue surface pathway between any two points. Edge detection algorithms may be used then onwards to identify the cervical base ring and the cervical OS (opening) or other artifact shapes and produce varieties of further measurement information related thereto.

**[0146]** The current depiction illustrates the above mentioned processing involved with the PSD wireframe capturing (either taken monocular **1917** or binocularly, that is, **1917** and **1919** taken from two slightly different but fixed angles) and mapping on to the image to obtain an image with two or three dimensional information attached to it, respectively. As mentioned above in detail, the two or three dimensional PSD wireframe capturing essentially involves scanning a target with a beam of light moving repeatedly from left to right and right to left, while moving from top to bottom.

**[0147]** The toolbar **1925** interacts with the 3D data set to allow a viewer to rotate, pan and zoom. This allows a patient or a health care professional to make a more accurate inspection of the intravaginal target.

**[0148]** Although human reproductive systems are described herein, all aspects set forth throughout the various embodiments of the present application are equally applicable to other female species.

**[0149]** The terms "circuit" and "circuitry" as used herein may refer to an independent circuit or to a portion of a multi-functional circuit that performs multiple underlying functions. For example, depending on the embodiment, processing circuitry may be implemented as a single chip processor or as a plurality of processing chips. Likewise, a first circuit and a second circuit may 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 may comprise general or specific purpose hardware, or may comprise such hardware and associated software such as firmware or object code.

**[0150]** As one of ordinary skill in the art will appreciate, the terms "operably coupled" and "communicatively coupled," as may 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 may adjust its current level, voltage level, and/or power level. As one of ordinary skill in the art will also appreciate, 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."

**[0151]** 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.

**[0152]** 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 may 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.

[0153] 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.

[0154] 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 may be practiced within the spirit and scope of the invention, as limited only by the scope of the appended claims.

We claim:

1. An monitoring device sized for at least partial insertion into a vaginal channel, the vaginal channel having a cervix disposed therein, and the monitoring device comprising:
  - a housing having an anterior portion and a posterior portion;
  - an imager, disposed within the anterior portion of the housing, that captures imager data;
  - at least one sensing component disposed within the anterior portion of the housing;
  - processing circuitry coupled to the imager and the at least one sensing component; and
  - the at least one sensing component together with the processing circuitry provides a first type of measurement information that can be applied to the imager data.
2. The monitoring device of claim 1, wherein the at least one sensing component comprises at least one photodetecting component that is independent of the imager.
3. The monitoring device of claim 2, further comprising an emitter that delivers emissions, via reflection off of the cervix, to the at least one sensing component.
4. The monitoring device of claim 1, further comprising communication circuitry through which the first type of measurement information is passed outside of the monitoring device.
5. The monitoring device of claim 1, wherein the at least one sensing component comprises a position sensitive detector.
6. The monitoring device of claim 3, wherein the imager data comprises color information to be used in a colorization analysis.
7. A monitoring system for viewing a target area within a vaginal channel, the monitoring system comprising:
  - a first device sized for at least partial insertion into the vaginal channel, the first device

- comprising an imager that captures imager data from the target area;
  - a second device, via instructions set forth in a software application, directs presentation of media that is based on the imager data captured by the imager of the first device;
  - a communication channel through which the imager data is delivered by the first device to the second device; and
  - the second device utilizes measurement information in the presentation of the media.
8. The monitoring system of claim 7, wherein the first device further comprising an emitter that produces a light beam that assists in generating the measurement information.
  9. The monitoring system of claim 7, wherein the imager of the first device assists in the generation of the measurement information.
  10. The monitoring system of claim 7, wherein the first device further comprising a position sensitive detector that assists in the generation of the measurement information.
  11. The monitoring system of claim 7, wherein the first device further comprising a second imager that captures second imager data from the target area.
  12. The monitoring system of claim 11, wherein the measurement information is generated from the imager data captured from the imager and the second imager captured by the second imager.
  13. The monitoring system of claim 12, wherein at least a portion of the generation of the measurement information occurs within the second device.
  14. The monitoring system of claim 7, wherein the imager data comprises color information to be used in a colorization analysis.
  15. The monitoring system of claim 7, wherein comparisons of the media at various points in time are made to identify changes.
  16. A method used to review conditions within a vaginal channel, the method comprising:
    - inserting an imager into the vaginal channel;
    - capturing imager data from a portion of the vaginal channel that include a target area;
    - retrieving measurement information relating to the target area;
    - using the measurement information with at least part of the imager data; and
    - displaying media representative of the at least part of the imager data.
  17. The method of claim 16, further comprising displaying a dimension relating to the displayed media generated based on the measurement information, and the at least part of the imager data comprises the target area.
  18. The method of claim 16, wherein the displayed media representation is based on a three dimensional data set.
  19. The method of claim 16, further comprising comparing a first part of the media with a second part of the media to identify changes over time.
  20. The method of claim 19, further comprising presenting at least indications of the changes over time that are identified.

\* \* \* \* \*