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(71) Applicant(s)
Illumigyn Ltd.

(72) Inventor(s)
Greenstein, Lior;Davara, Gilad A.;Ganon, Gad;Aviv, David

(74) Agent / Attorney
FPA Patent Attorneys Pty Ltd, Level 43 101 Collins Street, Melbourne, VIC, 3000, AU

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(71) Applicant: **ILLUMIGYN LTD.** [IL/IL]; Communication Center, 90850 Neve Ilan (IL).

(72) Inventors: **GREENSTEIN, Lior**; 42/4 HaZohar Street, 62914 Tel Aviv (IL). **DAVARA, Gilad A.**; 1/1 HaCarmel Street, 76305 Rehovot (IL). **GANON, Gad**; Yad Hana, 42840 Yad Hana (IL). **AVIV, David**; 2/5 HaAliya HaRishona Street, 38221 Hadera (IL).

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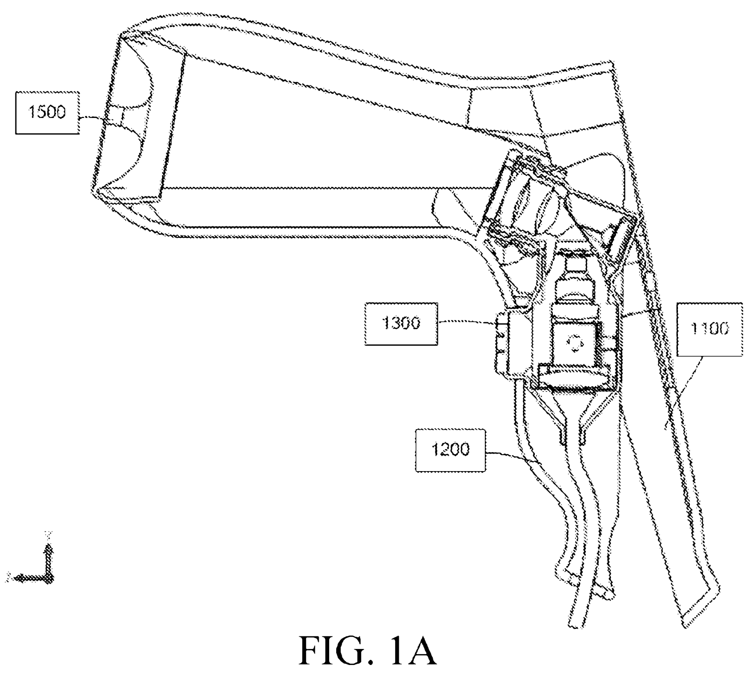

FIG. 1A

(57) **Abstract**: A system for direct imaging and diagnosing of abnormal cells in a target tissue includes an image acquisition system comprising a plurality of independently movable optical elements. The image acquisition system is arranged to capture at least one of a single image or multiple images or video of cells within the target tissue using at least one of bright field or dark field source divided into independently operated segments to obtain a plurality of data sets. An image analysis and control unit in communication with the image acquisition system analyzes the data sets and applies algorithms to the data sets for diagnosing abnormal cells.

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OPTICAL SPECULUM

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. provisional application Serial No. 61/879,263 filed September 18, 2013, the disclosure of which is hereby incorporated in its entirety by reference herein.

TECHNICAL FIELD

[0002] Embodiments relate in general to an optical system, such as for use as a speculum in colposcopy, gynecology examination hysteroscopy, and detecting and/or removing abnormal cells. In particular, embodiments relate to an optical speculum comprising an improved image acquisition system in which the various optical elements can be moved independently of one another.

BACKGROUND

[0003] Uterine cervical cancer is the second most common cancer in women worldwide, with nearly 500,000 new cases and over 270,000 deaths annually. Colposcopy is a medical diagnostic method that is used to detect cervical intraepithelial neoplasia (CIN) and cancer, together with a cytological screen (Papanicolaou smear; i.e., Pap smear). Colposcopy is a medical diagnostic procedure for viewing the cervix and the tissues of the vagina and vulva, and is a common gynecology procedure following an abnormal Pap smear. A colposcope is a low powered binocular microscope with a light source, magnifying lens, and imaging sensor for viewing and inspection of internal cavities, and may include video.

[0004] Colposcopy is the leading diagnostic method that is used to detect Cervical Intraepithelial Neoplasia (CIN) and cancer, together with cytological screen (Papanicolaou smear--Pap Smear). The purpose of a colposcopic examination is to identify and rank the severity of lesions, so that biopsies representing the highest-grade abnormality can be taken, if necessary. A green filter or green light source such as an LED may be used to accentuate vasculature. During the examination, a 3-5% acetic acid solution is applied to the cervix, causing abnormal and metaplastic epithelia to turn white. Cervical cancer precursor lesions and invasive cancer exhibit certain distinctly abnormal morphologic features that can be identified by colposcopy examination.

[0005] Cervical cancer precursor lesions and invasive cancer exhibit certain distinctly abnormal morphologic features that can be identified by colposcopic examination. The purpose of this examination is to identify and rank the severity of lesions, so that biopsies representing the highest grade abnormality can be taken, if necessary. During the examination, a 3-5% acetic acid solution is applied to the cervix, causing abnormal and metaplastic epithelia to turn white. A green filter or green light source such as an LED may be used to accentuate vasculature.

[0006] Today, the standard procedure for a gynecological exam invoices the use of a standard speculum with which the physician does a visual examination of the interior vaginal cavity, without any control of optimal illumination or proper optical magnification, thus creating the possibility of missing the detection of abnormal cells.

SUMMARY

[0007] In one embodiment, a system for direct imaging diagnosing and removing abnormal cells in a target tissue is provided, comprising: a disposable optical speculum having a track; an image acquisition system removably attached to the speculum and comprising a plurality of optical elements arranged to capture at least one of a single image or multiple images or video of cells within the target tissue using at least one of bright field or dark field source divided into independently operated segments to obtain a plurality of data sets, said optical elements slidably mounted to the track and in mechanical connection with a sliding mechanism that provides independent motion to each of said optical elements, the image acquisition system including a lens aperture adjacent the optical elements and a cogwheel to control a diameter of the lens aperture to provide both variable working distance and variable magnification; and an image analysis and control unit in communication with the image acquisition system, the image analysis and control unit analyzing the data sets and applying algorithms to the data sets for diagnosing abnormal cells. In some embodiments, the sliding mechanism comprises at least one motor.

[0008] The image acquisition system may integrate Bright field illumination, Dark Field illumination, UV light, IR light, RGB light, white light and any combination thereof.

[0009] The image acquisition system may include three separate and independent illuminations: WhiteMonochromatic/IR, UV Bright Field (BF) Illumination, and

White/Monochromatic Dark Field (DF) illumination for diffusive illumination and divided into segments for independent operation, UV LED located behind a dichroic mirror for fluorescence, and Bright Field (BF) multi spectral illumination.

[0010] The image analysis may be integrated and performed within said image acquisition system, located externally to said image acquisition system and any combination thereof.

[0011] The system may be assembled on and mechanically secured to a laparoscope and hysteroscope. In some embodiments, the system further comprises a locking mechanism between the laparoscope and the image acquisition system to assure image acquisition without distortions. In some embodiments, said laparoscope integrates a light collimation element guide for dark field illumination with an optical window.

[0012] The image acquisition system may include one or more high resolution imaging sensors; one of which is adapted to capture one or more images in definitive spectrum; and, the second one is adapted to capture one or more images for visualizing for the physician's live view.

[0013] The images may be transmitted to separate channels of said image analysis and control unit and presented separately on a screen.

[0014] The image acquisition system may further comprise a laser ablation module with a 2-D tilted mirror system to enable accurate ablation of abnormal cells, wherein said laser ablation module uses said data sets to eliminate the diagnosed abnormal cells, and the image acquisition system is designed to stop ablation when it is detected that abnormal cells no longer exist in the image. In some embodiments, the laser ablation module comprises a pulsed laser beam selected from the group consisting of infrared laser beam, green laser beam, and ultraviolet laser beam, said laser beam guided via a high power fiber to said target tissue using an imaging lens for focusing said pulse beam with sufficient pulse energy and pulse peak power to remove abnormal cells.

[0015] In an embodiment, the system comprises an optical disposable speculum.

[0016] The optical disposable speculum may comprise an optical window provided with a layer of elastic material disposed so as to prevent stray light from entering said image acquisition system.

[0017] The optical disposable speculum may be a single-use speculum.

[0018] The optical disposable speculum may comprise suction means for extracting fluids.

[0019] The optical disposable speculum may comprise means for preventing the collapse of the cervix wall.

[0020] The optical disposable speculum may comprise means for providing continuous or pulsed air pressure to prevent vapor and/or gas and liquids during the procedure that may occlude the image acquisition system.

[0021] In one embodiment, the image acquisition system may further comprise a zoom lens that can be implemented by using a miniature piezo or electric motor.

[0022] The image acquisition system may further comprise at least one of automatic, semi-automatic and manual illumination LEDs and a laser diode (LD) adjustment.

[0023] The image acquisition system may comprise a sensor imaging system selected from the group consisting of single sensor imaging systems and dual sensor imaging systems, said sensor imaging system comprising at least one element selected from the group consisting of color CMOS, monochrome CMOS, color CCD, and monochrome CCD and an illumination system based on one of LEDs or laser diode (LD). In some embodiments, said illumination system comprises a light source selected from the group consisting of (a) a source for making fluorescence or autofluorescence measurements selected from the group consisting of a UV LED source and a multi-spectral source, (b) an infrared source, and (c) any combination of the above.

[0024] In some embodiments, the illumination system comprises a source of white/monochromatic LEDs positioned near a lens aperture in order to optimize the delivery of light into the target tissue with minimum angle of incidence to optimize the reflection from the tissue using a second part of an objective lens. In some embodiments, said illumination system comprises a light source having one of an external strobe or camera electronic shutter to control the camera exposure time and prevent any saturation in the imaging system.

[0025] The image acquisition system may achieve depth perception in an acquired image by using at least one of a large depth of field, a continues zoom feature to receive a sequence of different images of the same X, Y position at different focal planes, and dark field illumination applied at different illumination angles using a source of external illumination system.

[0026] In one embodiment, the image acquisition system comprises a camera apparatus for obtaining fluorescence images, said camera apparatus comprising a camera, a lens attached to said camera, and a dichroic mirror that transmits UV and reflects visible and IR light.

[0027] In another embodiment, the image acquisition system comprises a camera apparatus for obtaining fluorescence images, said camera apparatus comprising a camera, a lens attached to said camera, a UV source in the Bright Field (BF); and, a long pass filter at wavelength of about 400 nm.

[0028] The system may further comprise a detector for detecting stray light generated by improper assembly of the optical disposable speculum to the image acquisition system.

[0029] The detector may be a separate unit or one of said sensors.

[0030] The system may be utilized in hysteroscopy procedures.

[0031] In one embodiment, a system for direct imaging, diagnosing and (optionally) removing abnormal cells in a target tissue is provided, comprising a disposable speculum; an image acquisition system comprising a plurality of optical elements arranged to capture at least one of a single image or multiple images or video of cells within the target tissue using at least one of bright field or dark field source divided into independently operated segments to obtain a plurality of data sets, said optical elements slidably mounted to a track and in mechanical connection with a sliding mechanism that provides independent motion to each of said optical elements, said image acquisition system assembled on and mechanically secured to an interior surface of said disposable speculum; and an image analysis and control unit in communication with the image acquisition system, the image analysis and control unit analyzing the data sets and applying algorithms to the data sets for diagnosing abnormal cells.

[0032] In some embodiments, the speculum comprises at least one selected from a group consisting of means for preventing the collapse of the cervix wall, suction means for extracting fluids, means for providing a continuous or pulsed flow of gas for removal of any liquids that may occlude the image acquisition system and any combination thereof.

[0033] In some embodiments, the image acquisition system has three separate and independent illuminations: White/Monochromatic/UV/RGB, IR Bright Field (BF) Illumination, and White/Monochromatic/RGB Dark Field (DF) illumination for diffusive illumination and divided into segments for independent operation, UV LED for Fluorescence located behind a dichroic mirror, and Bright Field (BF) multi spectral illumination.

[0034] In some embodiments, the image acquisition system includes one or more high resolution imaging sensors which capture different wavelength images of a whole field of the target tissue, wherein the images are transmitted to separate channels of said image analysis and control unit and presented separately on a screen.

[0035] In some embodiments, the image acquisition system further comprises a laser ablation module with a 2-D tilted mirror system to enable accurate ablation of abnormal cells, wherein said laser ablation module uses said data sets to eliminate the diagnosed abnormal cells, and the image acquisition system is designed to stop ablation when it is detected that abnormal cells no longer exist in the image.

[0036] In some embodiments, the laser ablation module comprises a pulsed laser beam selected from the group consisting of infrared laser beam, green laser beam, and ultraviolet laser beam, said laser beam guided via a high power fiber to said target tissue using an imaging lens for focusing said pulse beam with sufficient pulse energy and pulse peak power to remove abnormal cells.

[0037] In some embodiments, the image acquisition system further comprises a zoom lens that can be implemented by using a miniature piezo or electric motor.

[0038] In some embodiments, the image acquisition system further comprises at least one of automatic, semi-automatic and manual illumination LEDs and a laser diode adjustment.

[0039] In some embodiments, the image analysis and control unit is integrated within said image acquisition system.

[0040] In some embodiments, the system is utilized in hysteroscopy procedures.

[0041] In some embodiments, the said sliding mechanism comprises at least one motor. In some embodiments, the disposable optical speculum covers an optical head and yet enables a free working channel for taking a manual biopsy. In some embodiments, the system comprises a single-use disposable speculum and a multiple-use image acquisition system. In some embodiments, the system comprises a locking mechanism between the optical disposable speculum and the image acquisition system to assure image acquisition without distortions. In some embodiments, the optical disposable speculum integrates a light collimation element guide for dark field illumination with an optical window. In some embodiments, the optical disposable speculum comprises a unique RFID tag to identify said optical disposable speculum.

[0042] In an embodiment, a system for direct imaging and diagnosing of abnormal cells in a target tissue is provided, comprising a laparoscope; an image acquisition system comprising a plurality of optical elements arranged to capture at least one of a single image or multiple images or video of cells within the target tissue using at least one of bright field or dark field source divided into independently operated segments to obtain a plurality of data sets, said optical elements slidably mounted to a track and in mechanical connection with a sliding mechanism that provides independent motion to each of said optical elements, said image acquisition system assembled on and mechanically secured to said laparoscope; and an image analysis and control unit in communication with the image acquisition system, the image analysis and control unit analyzing the data sets and applying algorithms to the data sets for diagnosing abnormal cells.

[0043] In some embodiments, said sliding mechanism comprises at least one motor. In some embodiments, the laparoscope comprises a locking mechanism between the laparoscope and the image acquisition system to assure image acquisition without distortions. In some embodiments, said laparoscope integrates a light collimation element guide for dark field illumination with an optical window.

[0044] In an embodiment, a method for direct imaging, diagnosing and removing abnormal cells in a target tissue is provided, comprising steps of: (a) obtaining (i) an image acquisition system comprising a plurality of optical elements arranged to capture at least one of a single image or multiple images or video of cells within the target tissue using at least one of bright field or dark field source divided into independently operated segments to obtain a plurality of data sets, said optical elements slidably mounted to a track and in mechanical connection with a sliding mechanism that provides independent motion to each of said optical elements; (ii) an image analysis and control unit; (b) communicating said image analysis and control unit with said image acquisition system; and, (c) analyzing the data sets and applying algorithms to the data sets for diagnosing abnormal cells.

[0045] The method as defined above may be utilized in hysteroscopy procedures.

[0046] In the method as defined above, said sliding mechanism may comprise at least one motor.

[0047] In the method as defined above, the image acquisition system may have three separate and independent illuminations: White/Monochromatic/IR, UV Bright Field (BF) Illumination, and White/Monochromatic Dark Field (DF) illumination for diffusive illumination and may be divided into segments for independent operation, UV LED located behind a dichroic mirror for Fluorescence, and Bright Field (BF) multi spectral illumination.

[0048] In the method as defined above, the image acquisition system may include one or more high resolution imaging sensors which capture different wavelength images of a whole field of the target tissue, wherein the images are transmitted to separate channels of said image analysis and control unit and presented separately on a screen.

[0049] In the method as defined above, the image acquisition system may further comprise a laser ablation module with a 2-D tilted mirror system to enable accurate ablation of abnormal cells, wherein said laser ablation module uses said data sets to eliminate the diagnosed abnormal cells, and the image acquisition system is designed to stop ablation when it is detected that abnormal cells no longer exist in the image.

[0050] In the method as defined above, the laser ablation module may comprise a pulsed laser beam selected from the group consisting of infrared laser beam, green laser beam, and ultraviolet laser beam, said laser beam guided via a high power fiber to said target tissue using an imaging lens for focusing said pulse beam with sufficient pulse energy and pulse peak power to remove abnormal cells.

[0051] In the method as defined above, said system may comprise an optical disposable speculum; further wherein said optical disposable speculum comprises an optical window provided with a layer of elastic material disposed so as to prevent stray light from entering said image acquisition system.

[0052] In the method as defined above, said speculum may comprise at least one selected from a group consisting of means for preventing the collapse of the cervix wall, suction means for extracting fluids, means for providing a continuous or pulsed flow of gas for removal of any liquids that may occlude the image acquisition system and any combination thereof.

[0053] In the method as defined above, said image acquisition system may further comprise a zoom lens that can be implemented by using a miniature piezo or electric motor.

[0054] In the method as defined above, the image acquisition system may further comprise at least one of automatic, semi-automatic and manual illumination LEDs and a laser diode adjustment.

[0055] In the method as defined above, said image acquisition system may comprise a sensor imaging system selected from the group consisting of single sensor imaging systems and dual sensor imaging systems, said sensor imaging system comprising at least one element selected from the group consisting of color CMOS, monochrome CMOS, color CCD, and monochrome CCD; and, an illumination system based on one or more of LEDs or laser diode.

[0056] In the method as defined above, said illumination system may comprise: bright field illumination; dark field external source illumination; and, a light source selected from the group consisting of (a) a source for making fluorescence or autofluorescence measurements selected from the group consisting of a UV LED source and a multi-spectral source, (b) an infrared source, and (c) any combination of the above.

[0057] In the method as defined above, the illumination system may comprise a source of white/monochromatic/IR and UV fluorescence LEDs positioned near a lens aperture in order to optimize the delivery of light into the target tissue with minimum angle of incidence to optimize the reflection from the tissue using a second part of an objective lens.

[0058] In the method as defined above, the image acquisition system may achieve depth perception in an acquired image by using at least one of a large depth of field, a contiguous zoom feature to receive a sequence of different images of the same X, Y position at different focal planes, and dark field illumination applied at different illumination angles using a source of external illumination system.

[0059] In the method as defined above, said image acquisition system may comprise a camera apparatus for obtaining fluorescence images, said camera apparatus comprising: a camera; a lens attached to said camera; and, a dichroic mirror that transmits UV and reflects visible and IR light.

[0060] In the method as defined above, said image acquisition system may comprise a camera apparatus for obtaining fluorescence images, said camera apparatus comprising: a camera; a lens attached to said camera; a UV source in the Bright Field (BF); and, a long pass filter at wavelength of about 400 nm.

[0061] In the method as defined above, said image acquisition system may comprise a light source having one of an external strobe or camera electronic shutter to control the camera exposure time and prevent any saturation in the imaging system.

[0062] In the method as defined above, a detector may be provided for detecting stray light generated by improper assembly of the optical disposable speculum to the image acquisition system.

[0063] In the method as defined above, said image analysis and control unit may be integrated within said image acquisition system.

BRIEF DESCRIPTION OF THE DRAWINGS

[0064] The invention will now be described with reference to the drawings, wherein:

[0065] FIG. 1 presents assembly (FIG. 1A) and exploded (FIG. 1B) views of the system herein disclosed, including an exemplary area inspected by the system;

[0066] FIG. 2 presents views of the design of one embodiment of the cover window in the lower part of the disposable optical speculum; FIG. 2A shows a cross sectional view of the design of one embodiment of the cover window in the lower part of the disposable optical speculum; and, FIG. 2B provides a close-up view of the front window lens shown in FIG. 2A.

[0067] FIG. 3 presents a schematic illustration of one embodiment of the image acquisition system;

[0068] FIG. 4 presents a cross-sectional view of the image acquisition system of FIG. 3;

[0069] FIG. 5 presents a partial ray-tracing diagram illustrating the bright field and dark field illumination provided by one embodiment of the system;

[0070] FIG. 6A and FIG. 6B show optical designs and chief rays for two embodiments of an optical layout comprising at least one imaging sensor; FIG. 6A presents an illustration of the optical design and chief rays for one embodiment of a system comprising a single imaging sensor; FIG. 6B presents an illustration of the optical design and chief rays for one embodiment of a system comprising a system comprising dual imaging sensor;

[0071] FIG. 7 shows exterior views of one embodiment of the camera housing (FIGS. 7A and 7B) and how the camera housing is integrated into the disposable speculum (FIGS. 7C and 7D);

[0072] FIG. 8 shows one embodiment of a sliding mechanism designed to allow independent movement of the optical components comprising one and or two imaging sensors for high dynamic imaging capabilities; FIG. 8A shows an isometric view of one embodiment of an optical train that comprises a sliding mechanism and two imaging sensors design; FIG. 8B shows a cross-sectional view of the embodiment illustrated in FIG. 8A; FIG. 8C shows an isometric view of one embodiment of an optical train that comprises a sliding mechanism and one imaging sensors design; FIG. 8D shows a cross-sectional view of the embodiment illustrated in FIG. 8C; FIG. 8E presents a front view of the distal end of end of the optical system in an embodiment in which it is used for bright field measurements and fluorescence measurements; and, FIG. 8F presents a front view of the distal end of end of the optical system and the dark field illumination in the field of view (1601) of the embodiment illustrated in FIG. 8E;

[0073] FIG. 9 presents the schematic structure of the system herein disclosed;

[0074] FIG. 10 illustrates the software initialization of the system herein disclosed;

[0075] FIG. 11 illustrates an image capture algorithm process flow;

[0076] FIG. 12 illustrates the process of image analysis, display of suspicious areas by contours and the sensing algorithm;

[0077] FIG. 13 illustrates one embodiment of an image analysis and control unit;

[0078] FIG. 14 illustrates a speculum embodiment with fluid and gas (vapor) evacuation capabilities; and

[0079] FIG.15 illustrates a speculum embodiment including a membrane for preventing collapse of cervix walls.

DETAILED DESCRIPTION

[0080] In the following description, various aspects of the invention will be described. For the purposes of explanation, specific details are set forth in order to provide a thorough understanding of the invention. It will be apparent to one skilled in the art that there are other embodiments of the invention that differ in details without affecting the essential nature thereof. Therefore the invention is not limited by that which is illustrated in the figure and described in the specification, but only as indicated in the accompanying claims, with the proper scope determined only by the broadest interpretation of said claims.

[0081] The term "SpeculuView" system refers hereinafter to an apparatus comprising a disposable optical speculum and an image acquisition system comprising a treatment module and an image analysis and control unit. Thus, according to one embodiment, the term "SpeculuView" is a gynoscope.

[0082] The term "Gynoscopy" system refers hereinafter to a cervix imaging procedure.

[0083] The term "hysteroscopy" refers hereinafter to the inspection of the uterine cavity by endoscopy with access through the cervix. It allows for the diagnosis of intrauterine pathology and serves as a method for surgical intervention (operative hysteroscopy).

Low cost and high-resolution colposcopy could have a direct impact on improving women's health care, reducing examination costs and avoidance of embarrassment. A low-cost hand-held image acquisition device would also assist the gynecologist in every day procedures and or the expert colposcopist, and improve screening cost-effectiveness in developing countries. Thus, a low-cost system comprising a speculum and an optical system appropriate for high-resolution colposcopy remains a long-felt but as yet unmet need.

[0084] The system described herein may be used for imaging in gynecology daily procedure exams, surgical procedures, colposcopy laparoscopy or hysteroscopy. In some embodiments, it comprises a treatment module for ablation of abnormal cells (e.g. cancerous cells) in the examined area (e.g. the uterine cervix).

[0085] One of the aims of the SpeculuView system is to provide an apparatus that enables the user to perform detailed, high-resolution observation of objects located within a relatively wide area (e.g. the uterine cervical cavity) and accurate ablation of abnormal cells (e.g. cancerous cells in the uterine cervix).

[0086] One of the advantages of the SpeculuView system is the Optional BF (Bright Field) with PBS (polarized beam splitter) or BS (Beam Splitter) with one (optional variable) polarizer near the illumination source and one polarizer near the sensor, instead of direct BF near the aperture or simple BS (Beam Splitter) allow cross polarization option for edge enhancement technique.

[0087] It should be emphasized that the system and method can also be utilized in hysteroscopy procedures. In such procedures the image acquisition system can be utilized to perform direct imaging, diagnosing and treatment within the uterus.

[0088] In the SpeculuView system, a disposable optical speculum is assembled on the image acquisition system on each examination. The disposable speculum creates a clean environment for the image acquisition system, preventing it from being contaminated and preventing cross-contamination of the patient, physician (e.g., the gynecologist), assisting nurse or any combination. Reference is now made to FIG. 1A, which shows an assembly cross section view of one embodiment of the SpeculuView system, including the inspection area, and including an example of a possible inspected area, the uterine cervix. Shown in the figure are a cross sectional view 1100 of the upper part of the disposable optical speculum; a cross sectional view 1200 of the lower part of the disposable optical speculum; a cross sectional view 1300 of the image acquisition system; and a cross sectional view 1500 of the uterine cervix, as a non-limiting example of an area examined by the system. Reference is now made to FIG. 1B, which shows an exploded view of one embodiment of the disposable optical speculum, showing upper part 1100 and lower part 1200. The design of the system herein disclosed enables a shortened time between examinations compared with designs known in the art.

[0089] Reference is now made to FIG. 2A, which shows a cross sectional view 1210 of the design of one embodiment of the cover window in the lower part of the disposable optical speculum. The figure illustrates the front window lens area 1211; breakable snap attachments for the image acquisition system 1212; and a cut release 1213 for the operating buttons. In the embodiment of the system illustrated in FIG. 2B, the image acquisition system is attached to the speculum via breakable snaps 1212 that break after the optical imaging system is detached from the speculum. The use of an embodiment comprising these breakable snaps ensures that a new disposable speculum will be used for each use of the system, since it will not be possible to insert the image acquisition system into a speculum that has already been used once.

[0090] Reference is now made to FIG. 2B, which provides a close-up view 1211 of the front window lens shown in FIG. 2A. The view shown in FIG. 2B includes a linear cylindrical collimating lens 1222 for a dark field LED source in the image acquisition system; an elastic layer

1221 for blocking stray light entering the image acquisition system (e.g. from dark field illumination or bright field illumination); and dark field illumination LED source 1311. In some embodiments, in order to prevent stray light from entering the image acquisition system (described in detail below), the window of the optical speculum is provided with a layer of elastic material 1221 that creates a fine-tuned coupling between the optical speculum and the image acquisition system. The layer of elastic material compensates for slight manufacturing or assembly mismatches between the other optical components.

[0091] The image acquisition system comprises bright field and dark field illumination and uses a LED source. Any LED or laser diode that can produce narrow band spectrum can be used for hyper spectral imaging may be used. As non-limiting examples, a UV LED source may be used (e.g. for fluorescence and/or autofluorescence measurements). As a second non-limiting example, a laser diode may be used.

[0092] A LED with output in the visible (single wavelength or white) or IR may be used as well. The IR source is used in embodiments in which in depth detection is desired. Reference is now made to FIGS. 3 and 4, which present schematic illustrations of one embodiment of the image acquisition system. FIG. 3 presents an external view, showing the body 1302 of the image acquisition system, camera head operating buttons 1303, and the dark field illumination LED source 1311. An internal view of this embodiment is shown in FIG. 4, which shows the dark field illumination LED source 1311; LEDs 1312; bright field illumination LED source 1313; imaging sensor area 1315; dichroic mirror 1708; and two groups of optical components that together comprise the objective lens system of the image acquisition system, front lens group 1340 and rear lens group 1320.

[0093] In some embodiments, group 1320 (see FIG. 4) is connected to the imaging sensor and a beam splitter and/or dichroic mirror, and includes the aperture stop where the bright field illumination components are nearly located. In some embodiments, group 1340 (see FIG. 4) includes a group of optical elements along with the disposable optical window 1211 (see FIG. 2A).

[0094] In some embodiments, particularly those in which fluorescence or autofluorescence measurements are made, dichroic mirror 1708 (see FIG. 4) is located between groups 1320 and

1340. The bright field light source is located near the dichroic mirror. In some embodiments, the multi-spectral, white, or UV light source is located on the other side of the dichroic mirror along the objective axis of group 1340.

[0095] In one embodiment, the illumination system comprises a UV LED light source for fluorescence image analysis in addition to bright and dark field white light sources. It is well-known in the art that cancerous cells are highly emphasized by this kind of illumination. In these embodiments, the optical design comprises a dichroic mirror that transmits light of the UV LED with $\lambda < 400$ nm and reflects light of the other light sources with $\lambda > 440$ nm.

[0096] Reference is now made to FIG. 5, which presents a ray-tracing diagram of the illumination provided by one embodiment the image acquisition system. Superimposed on a cross-sectional view of the system (an optical speculum assembled around an image acquisition system) are lines illustrating the dark field (1601) and bright field (1602) illumination rays.

[0097] Embodiments of the system may comprise one of two image acquisition designs: a single imaging sensor system comprising a color CMOS or CCD and an illumination system based on LEDs or laser diodes (LDs), or a dual imaging sensor system comprising two different CMOS or CCDs, (in some embodiments, one color and one monochrome), and an illumination system based on LEDs or LDs.

[0098] Reference is now made to FIG. 6A and FIG. 6B, which schematically illustrate two embodiments of optical designs for use in an optical head of an image acquisition system for viewing internal cavities (e.g., uterine cervix). Non-limiting examples of uses of the image acquisition system include video laparoscopy, which is enabled by the use of a special optical adapter assembled on the image acquisition system, and detection of abnormal cells in a laparoscopy procedure.

[0099] Reference is now made to FIG. 6A, which presents an illustration of the optical design and chief rays for one embodiment of a system comprising a single imaging sensor. Shown in the illustration are the area being examined (1701); optical elements comprising window 1704, first meniscus element 1705, bi-concave element 1706, first bi-convex element 1707, dichroic mirror 1708, aperture 1709, plano-convex element 1710, second meniscus element 1711, second bi-convex element 1712, beamsplitter 1713, (bi-convex) focusing element 1714, and imaging sensor 1315; and the chief (1702) and marginal (1703) return rays.

[0100] Reference is now made to FIG. 6B, which presents an illustration of the optical design and chief rays for one embodiment of a system comprising a system comprising dual imaging sensor. Shown in the illustration are the area being examined (1701); optical elements comprising window 1704, first meniscus element 1705, bi-concave element 1706, first bi-convex element 1707, dichroic mirror 1708, aperture 1709, plano-convex element 1710, second meniscus element 1711, second bi-convex element 1712, beamsplitter 1713, (bi-convex) first focusing element 1714a, first imaging sensor 1315a, (bi-convex) second focusing element 1714b, and second imaging sensor 1315b; and the chief (1702) and marginal (1703) return rays.

[0101] Reference is now made to FIGS. 7A-7D, which present schematic illustrations of one embodiment of a camera housing and its integration into the disposable speculum. FIG. 7A shows a rear view of the camera housing, illustrating the position of camera operating buttons 1303, and FIG. 7B shows a front view of the camera housing, illustrating front lens 1340. FIGS. 7C and 7D are rear and front views, respectively, of one embodiment of a speculum into which a camera housing has been integrated.

[0102] In some embodiments, the optical design comprises at least one motor perpendicular to the optical system axis moving at least one optical component in two or more stages.

[0103] Some embodiments of the system herein disclosed in which it comprises a sliding mechanism are illustrated in FIG. 8 (see 8A-8F). In contrast to embodiments such as those shown in FIGS. 6A and 6B, which have a fixed working distance and magnification, the embodiments shown in FIG. 8 (see 8A-8F), provide for both variable working distance and variable magnification.

[0104] Reference is now made to FIG. 8A, which shows an isometric view of one embodiment of an optical train that comprises a sliding mechanism. In the embodiment shown in the figure, the optical train is housed inside of a disposable speculum. In the embodiment illustrated, three movable lens groups (some of which comprise a single lens) are mounted in mounts 3020, 3030, 3040 and 3050. The mounts are slidably mounted to track 3000 which is attached to the speculum. The track allows linear motion of the optic elements while keeping them aligned.

Cogwheel 3031 is used to control the diameter of the aperture. In the embodiment shown, each of lens mounts 3020 and 3030 is slidably mounted to track 3000. In some embodiments of the system, each lens group can be moved independently of each of the others. In some embodiments of the system, the motion of the lens groups is actuated manually via mechanical connections running from the lens mounts to a point external to the housing (speculum, laparoscope, etc.) In other embodiments of the system, the motion of the lens groups is actuated by the motor or motors mentioned above, each of which is in mechanical connection with the lens mount or mounts that it controls.

[0105] Reference is now made to FIG. 8B, which shows a cross-sectional view of the embodiment illustrated in FIG. 7a. Shown in FIG. 8B are the area being examined (1801); optical elements comprising Disposable Meniscus window 1804, Protected window 1805, first bi Concave element 1806, Dichroic mirror 1807, Bright field Beam Splitter 1808, bi-convex element 1809, Plano-convex element 1810, aperture 1811, second bi-concave element 1812, Meniscus element 1813, Meniscus element 1815, Bi-Convex 1816, beam splitter 1817, first imaging sensor 1315a, and second imaging sensor 1315b.

[0106] It should be emphasized that FIGS. 8A-8B present an illustration of the optical design and for one embodiment of a system comprising a system comprising a dual imaging sensor: a beam splitter and a lens. .

[0107] FIGS. 8A and 8B further comprise two stationary groups represented by numerical references 3010 and 3050.

[0108] Numerical reference 3050 represents the dual imaging sensor (1315a and 1315b), Bi-Convex 1816, beam splitter 1817; and numerical reference 3010 comprises a disposable Meniscus window 1804, Protected window 1805, bi Concave element 1806, Dichroic mirror 1807, Bright field Beam Splitter 1808.

[0109] Reference is now made to FIGS. 8C-8D, which present an illustration of the optical design for one embodiment of a system comprising a single imaging sensor.

[0110] Shown in FIGS. 8C-8D are the area being examined 1801; optical elements comprising Disposable Meniscus window 1804, Protected window 1805, first bi Concave element 1806, Dichroic mirror 1807, Bright field Beam Splitter 1808, bi-convex element 1809, Plano-convex element 1810, aperture 1811, second bi-concave element 1812, Meniscus element 1813, Meniscus element 1815, Bi-Convex 1816, beamsplitter 1817 and imaging sensor 1315.

[0111] It should be pointed out that FIG. 8D, which shows a cross-sectional view of the embodiment illustrated in FIG. 8C.

[0112] As in the embodiment illustrated in FIGS. 8A-8B, in the embodiment illustrated in FIGS. 8C-8D, three movable lens groups (some of which comprise a single lens) are mounted in mounts 3020, 3030, and 3040. The mounts are slidably mounted to track 3000 which is attached to the speculum. The track allows linear motion of the optic elements while keeping them aligned. Cogwheel 3031 is used to control the diameter of the aperture. In the embodiment shown, each of lens mounts 3020 and 3030 is slidably mounted to track 3000. In some embodiments of the system, each lens group can be moved independently of each of the others. In some embodiments of the system, the motion of the lens groups is actuated manually via mechanical connections running from the lens mounts to a point external to the housing (speculum, laparoscope, etc.) In other embodiments of the system, the motion of the lens groups is actuated by the motor or motors mentioned above, each of which is in mechanical connection with the lens mount or mounts that it controls.

[0113] Reference is now made to FIG. 8E, which presents a front view of the distal end of end of the optical system in an embodiment in which it is used for fluorescence measurements. Shown are LEDs 1820, dichroic mirror 1807, beamsplitter 1808, and rays illustrating bright field (1603) and fluorescence (1602) radiation.

[0114] Reference is now made to FIG. 8F, which presents a front view of the distal end of end of the optical system and the dark field illumination in the field of view. Shown are bright field LEDs 1820, dark field LEDs 1822, dichroic mirror 1807, beamsplitter 1808, and rays illustrating dark field (1601) radiation in the field of view.

[0115] In some embodiments, the image acquisition system acquires multi-spectral or video images. In some embodiments, the image acquisition system comprises an integrated laser ablation module for treatment of abnormal cells (e.g., cancerous cells in the uterine cervix).

[0116] Reference is made again to FIG. 8E, which presents a front view of the distal end of the optical system in an embodiment in which the system is used for bright field illumination and fluorescence measurements. Shown are bright field LEDs 1820 and 1821 for fluorescence, dichroic mirror 1807, beamsplitter 1808, and rays illustrating bright field (1603) and fluorescence (1602) radiation. Reference is now made to FIG. 8F, which presents a front view of the distal end of end of the optical system and the dark field illumination in the field of view. Also shown are bright field LEDs 1820 and 1821 for fluorescence, dark field LEDs 1822, dichroic mirror 1808, beamsplitter 1808, and rays illustrating dark field (1601) radiation in the field of view, bright field (1603), and fluorescence (1602) radiation.

[0117] In some embodiments, the image acquisition system acquires multi-spectral or video images. In some embodiments, the image acquisition system comprises an integrated laser ablation module for treatment of abnormal cells (e.g., cancerous cells in the uterine cervix).

[0118] In some embodiments, the optical design comprises at least one motor perpendicular to the optical system axis moving at least one optical component in two or more stages.

[0119] Some embodiments of the system herein disclosed in which it comprises a sliding mechanism are illustrated in FIGS. 8A-8F. In contrast to embodiments such as those shown in FIGS. 6A and 6B, which have a fixed magnification, the embodiments shown in FIGS. 8A-8F, provide for both variable working distance and variable magnification.

[0120] Reference is now made to FIG. 8A, which shows an isometric view of one embodiment of an optical train that comprises a sliding mechanism. In the embodiment shown in the figure, the optical train is housed inside of a disposable speculum. In the embodiment illustrated, four lens groups (some of which comprise a single lens) are mounted in mounts 3010, 3020, 3030, 3040 and 3050. The mounts are slidably mounted to track 3000 which is attached to the speculum. The track allows linear motion of the optic elements while keeping them aligned. Cogwheel 3031 is used to control the diameter of the aperture. In the embodiment shown, each of lens mounts 3020, 3030 and 3040 is slidably mounted to track 3000. In some embodiments of the system, each lens group can be moved independently of each of the others. In some embodiments of the system, the motion of the lens groups is actuated manually via mechanical connections running from the lens mounts to a point external to the housing (speculum, laparoscope, etc.) In other embodiments of the system, the motion of the lens groups is actuated by the motor or motors mentioned above, each of which is in mechanical connection with the lens mount or mounts that it controls.

[0121] There may be two possible options for focusing:

[0122] Option 1: A fixed lens mechanical design that requires an optimal location positioning procedure. It is the physician who guides the disposable optical speculum with the camera head installed in front of the examined area (e.g., uterine cervix) and activates a fine tuning positioning process. In the optimal location positioning procedure, the image analysis and control unit continuously grabs images and produces focus results, which recommend to the physician to make final positioning corrections (see FIGS. 1A-1B).

[0123] Option 2: When using a non-fixed lens mechanical design, an automatic focus mechanism sets an optimal location of the lens. It is the physician who guides the disposable optical speculum with the camera head installed in front of the examined area (e.g., uterine cervix) and activates a fine tuning focus positioning process. In the optimal location positioning procedure, the image analysis and control unit continuously grabs images and produces the best focus results (see FIGS. 8A-8F).

[0124] In order to reach depth perception, there are three main features in this system.

[0125] 1) The system has the option for a large depth of field.

[0126] 2) Using the contiguous zoom feature, the system can receive a sequence of different images of the same (X,Y) position at different focal planes. In this method, good perception of the inspected object depth can be attained.

[0127] 3) The system applies dark field and bright field illumination which illuminate in different angles or by using an external illumination source element in the case of using the system with a laparoscope adapter. As a non-limiting example, the system may be designed to divide and control the illumination source (e.g., two sections). By use of one section of the source in the first image and a second section of the source in the second image the system may provide depth perception of the inspected object.

[0128] High resolution over the whole field is assured in order to insure detection of all cancerous cells in one image.

[0129] Using these three methods the system can identify, for example, the thickness and surface topology of a tumor cell.

[0130] Reference is now made to FIG. 9, which shows a schematic structure of the SpeculuView system: Disposable optical speculum, Image Acquisition System modules, Image Analysis and Control Unit modules.

[0131] Reference is now made to FIG. 10, which illustrates the software initialization flow (1900) in one embodiment of the system herein disclosed. The software initialization module involves activation of the illumination source in the working limits within the dynamic range of the system, and recognition of stray light that indicates that the disposable optical speculum is not properly mounted.

[0132] In the embodiment shown in FIG. 10, the initialization routine for the image acquisition system illustrated in FIG. 10 begins with a self-calibration procedure (1910): the required amplification of the input signal needed to provide the best image for analysis is determined, and other steps of calibration of the image acquisition such as correction of the white balance to prevent acquisition of images with unrealistic color or gray levels are performed. A step (1920) of improper assembly detection is then performed. In this step, the image analysis and control unit verifies that the disposable optical speculum has been assembled and secured correctly. A manual interactive focusing procedure (1930) is them performed as needed.

[0133] Reference is now made to FIG. 11, which illustrates image capture algorithm process flow 2000. A light source type (e.g. UV and/or white light) for image acquisition is selected (2010); the light mode (continuous or flash) is chosen for optimal detection (2020); the optimal illumination amplification (i.e. the illumination amplification that yields the optimal image acquisition) is selected (2030); the optimal illumination time is determined (2040); and an image is acquired and analyzed (2050) to determine whether any changes are needed for optimal image acquisition. If it is determined that changes are needed for optimal image acquisition, the image capture algorithm is reinitiated.

[0134] Reference is now made to FIG. 12, which illustrates the process of image analysis, display of suspicious areas by contours and the scoring algorithm.

[0135] Reference is now made to FIG. 13, which illustrates an image acquisition system that is connected to the image analysis and control unit in some embodiments. The image analysis and control unit is a software package which may be implemented on special design hardware or a standard PC with custom hardware. The control and analysis system is provided in box 2110, and contains an optical read-write drive 2120 (non-limiting examples of suitable drives include DVD-RW and Blu-Ray-RW drives). Power to the control and analysis system is controlled by on/off operating button 2130. The camera head is connected to the analysis and control unit via a peripheral data connection 2140; the data connection may be of any suitable type known in the art such as USB. Also shown in the figure are image acquisition cable connector 2150 and the visual display 2160; in some embodiments, the visual display comprises an LCD touch screen.

[0136] Reference is now made to FIG. 14, which illustrate the optical disposable speculum with a suction system for fluid and gas (and/or vapor) during a gynecology procedure. The suction system may be located inside the lower speculum blade 1200 and may include a wide are for fluid suction 4013 and/or holes for gas (vapor) suction 4102. The suction system also collects the fluids at the distal end 4104 of the speculum (near the optical lens), and can provide continuous or pulsed air pressure to keep the lens clean from fluid using a hole 4105 which creates positive pressure on the optical disposable lens to remove residues of fluid. The suction system may be connected to a suction pump at the end of the tube 4101 with a flexible tube.

[0137] Reference is now made to FIG. 15 which illustrates a speculum with a thin membrane which is connected to both sides of the speculum lower and upper blades 4202, 4203. When the gynecologist opens the speculum, the membrane is stretched and creates two walls that prevent the cervix walls from collapsing.

[0138] The image analysis and control unit automatically adjusts the intensity of each illumination mode independently (i.e., white (bright field and or dark field illumination), multi-spectral illumination (e.g. UV and or IR)).

[0139] Data acquired from the examined area (e.g., uterine cervix) by the image acquisition system is analyzed by the image analysis and control unit which provides tissue diagnosis. In case there are abnormal cells, the image analysis and control unit identifies the suspicious regions which should be treated (e.g., by using a cell ablation system).

[0140] The disposable optical speculum may be coupled with a unique RFID (Radio Frequency Identification) tag. By assigning to each speculum a unique serial/lot number, the image analysis and control unit will assure the use of a brand new disposable optical speculum for each patient and for each examination. The tag number associated with the disposable optical speculum will be specified in the patient's examination file.

[0141] The image analysis and control unit is able to analyze white and/or multi spectral images taken under the use of reflectance and auto-fluorescence reagents (i.e., contrast agents).

[0142] The image analysis and control unit is based on an open, modular, and feature-based architecture. Analysis methods are designed for use with one or more imaging sensors, white and/or multi spectral illumination types.

[0143] In some embodiments, the image analysis and control unit provides methods based on unique algorithms for accurate removal of abnormal cells (e.g., by identifying their margins). In some embodiments of the system, the image analysis and control unit comprises an algorithm to create a map of contours, namely the borders between healthy and abnormal cells. In some embodiments, the image analysis and control unit uses Picture Archiving and Control System (PACS) methods for image archiving and management.

[0144] Reflectance and/or fluorescence images are acquired from the abnormal cells. Optionally, the reflectance and/or fluorescence images may be acquired using a short pulse of light to illuminate the tissue being examined. Various reflectance and fluorescence images may be acquired under the same, or different, configurations of illumination.

[0145] Abnormal cells may be destroyed by ablation. The ablation procedure is operated either automatically, or by manual control of the set of adjustable mirrors to focus on candidate abnormal cells. Upon completion of destruction by ablation, additional reflectance or fluorescence images may be acquired to verify the completion of the procedure.

[0146] In typical embodiments, the laser ablation system comprises an imaging sensor, a flexible/solid optical fiber, a laser system, a set of mirrors near the laser head and near the beam splitter which is located near the tip of the fiber, and an optical system that locally images the tested area. In some embodiments, a long pass filter is located between the lens and the fibers in order to subtract the Violet/UV light from the image for fluorescence.

[0147] In some embodiments, the laser ablation system is located in the area of the imaging sensors 1315.

[0148] In typical embodiments that incorporate a laser ablation system, the laser ablation is performed by passing a pulsed laser beam through collimating optics, a set of mirrors, a fiber bundle, another mirror, a beam splitter and second focusing optics. There are two optional places to use a motorized adjustable set of mirrors. In the case where a straight solid fiber bundle is used, the laser beam location can be adjusted using the mirrors near the laser, otherwise the adjustable steering mirror may be positioned in front of the beam splitter near the edge of the fiber bundle and its tilted angles controlled remotely. This adjustable set of mirrors receives a set of angles/travels as an output from the image analysis report or a set of points from the physician manually to manipulate the orientation laser beam to selectively impinge on desired locations of malignant tissue to be destroyed.

[0149] Overcoming deficiencies of prior art colposcope systems, the system provides:

[0150] a disposable optical speculum with a working channel for the physician;

[0151] a small camera with multi spectral internal illumination systems:

[0152] bright field LEDs (through the lens) illumination;

[0153] dark field LEDs illumination with a specific illumination angle;

[0154] an internal UV illumination ("through the lens illumination") for abnormal cell detection by fluorescence or auto fluorescence;

[0155] an internal IR illumination ("through the lens illumination");

[0156] an opportunity to examine with sufficient resolution fine objects at a short distance with maximum patient protection; and,

[0157] optional *in situ*, real time laser ablation of abnormal cells (e.g., cancerous cells).

[0158] The disposable optical speculum may provide a working channel, and an adjustable locking mechanism for lower and upper speculum blades.

[0159] The working channel may be used for obtaining a Pap-Smear specimen, and passing working tools (e.g., biopsy tools).

[0160] Embodiments separately provide a disposable optical speculum which is a part of the whole optical design and is assembled on the image acquisition system, thus providing a safe cross contamination protection for the examined patient.

[0161] Embodiments provide a high resolution imaging system which comprises one or more imaging sensors, thus providing high dynamic range image. The importance of such information is that it can be used for computer calculation since such an image with high dynamic range is hard to display or print.

[0162] Embodiments separately may provide a system and methods including a detection algorithm for abnormal cell screening.

[0163] Embodiments may provide a special abnormal cell detection algorithm designed specifically for the uterine cervix.

[0164] The optical system may comprise a design of an optical zoom lens system along the optical axis, or a discrete zoom design (e.g., slider design).

[0165] The image acquisition system may include an electro optical element which functions as an integrated system for multi spectral imaging and treatment. The image acquisition system is locked to the disposable optical speculum with a releasable secured mechanical lock.

[0166] Embodiments provide a system and methods for high resolution imaging of the examined area (e.g., uterine cervix). The system provides image analysis for tissue abnormalities.

[0167] Embodiments may be used as an image analysis for tissue abnormalities such as cervical intraepithelial neoplasia (CIN) or invasive cancer.

[0168] The system control and analysis unit provides a real time image or live video that is acquired from the examined area (e.g. the uterine cervix). It provides tissue diagnosis and it may provide the ability to ablate, in an accurate manner, the abnormal cancerous cells. Images or live video and analysis results are displayed both to the physician and patient.

[0169] The imaging acquisition system acquires color and/or monochrome images. The acquired data of the examined area is analyzed by the image analysis and control unit. The image and analysis control unit outputs a graphical representation of suspicious regions and classification of the detected tissue.

[0170] The imaging acquisition system may acquire color and/or monochrome images from the uterine cervix.

[0171] There are two main image capture modes. Manual mode requires the physician to control the illumination parameters before the image is acquired and delivered for final analysis. Automatic mode does not require any intervention of the physician with respect to the illumination configuration. As described in detail above, the algorithm for setting the optimal image capture parameters continuously grabs images while changing the values of illumination type, mode, intensity and exposure time in order to produce an optimal image for analysis.

[0172] A numerical analysis for autofluorescence imaging for pathological tissue detects a cancerous area in a given image. The numerical analysis for auto fluorescence imaging includes a pathological tissue algorithm that uses the special characteristics of the reflected ultraviolet light source. The numerical analysis for autofluorescence imaging for pathological tissue detects and renders suspicious regions in a given image, and generates a pathological lesion scoring for the region.

[0173] As mentioned above, embodiments can also be utilized in hysteroscopy procedures. In such procedures the image acquisition system can be utilized to perform direct imaging, diagnosing and treatment within the uterus. In such embodiments, the system is assembled on and mechanically secured to a hysteroscope.

[0174] While exemplary embodiments are described above, it is not intended that these embodiments describe all possible forms of the invention. Rather, the words used in the specification are words of description rather than limitation, and it is understood that various changes may be made without departing from the spirit and scope of the invention. Additionally, the features of various implementing embodiments may be combined to form further embodiments of the invention.

[0175] Reference to any prior art in the specification is not an acknowledgment or suggestion that this prior art forms part of the common general knowledge in any jurisdiction or that this prior art could reasonably be expected to be understood, regarded as relevant, and/or combined with other pieces of prior art by a skilled person in the art.

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WHAT IS CLAIMED IS:

1. A system for direct imaging, diagnosing and removing abnormal cells in a target tissue, comprising:

a disposable optical speculum having a track;

an image acquisition system removably attached to the speculum and comprising a plurality of optical elements arranged to capture at least one of a single image or multiple images or video of cells within the target tissue using at least one of a bright field or dark field source divided into independently operated segments to obtain a plurality of data sets, said optical elements slidably mounted to the track and in mechanical connection with a sliding mechanism that provides independent motion to each of said optical elements, the image acquisition system including a lens aperture adjacent the optical elements and a cogwheel to control a diameter of the lens aperture to provide both variable working distance and variable magnification; and

an image analysis and control unit in communication with the image acquisition system, the image analysis and control unit analyzing the data sets and applying algorithms to the data sets for diagnosing abnormal cells.

2. The system according to claim 1, wherein said sliding mechanism comprises at least one motor.

3. The system according to claim 1 or claim 2, wherein the image acquisition system has three separate and independent illuminations: White/Monochromatic/IR, UV Bright Field (BF) Illumination, and White/Monochromatic Dark Field (DF) illumination for diffusive illumination and divided into segments for independent operation, UV LED located behind a dichroic mirror for Fluorescence, and Bright Field (BF) multi spectral illumination.

4. The system according to any one of the preceding claims, wherein the image acquisition system includes one or more high resolution imaging sensors which capture different wavelength images of a whole field of the target tissue, wherein the images are transmitted to separate channels of said image analysis and control unit and presented separately on a screen.

5. The system according to any one of the preceding claims, wherein the image acquisition system further comprises a laser ablation module with a 2-D tilted mirror system to enable accurate ablation of abnormal cells, wherein said laser ablation module uses said data sets

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to eliminate the diagnosed abnormal cells, and the image acquisition system is designed to stop ablation when it is detected that abnormal cells no longer exist in the image.

6. The system according to claim 5, wherein the laser ablation module comprises a pulsed laser beam selected from the group consisting of an infrared laser beam, a green laser beam, and an ultraviolet laser beam, said laser beam guided via a high power fiber to said target tissue using an imaging lens for focusing said pulse beam with sufficient pulse energy and pulse peak power to remove abnormal cells.

7. The system according to any one of the preceding claims wherein said optical disposable speculum comprises an optical window provided with a layer of elastic material disposed so as to prevent stray light from entering said image acquisition system.

8. The system according to any one of the preceding claims, wherein said speculum comprises a suction system for removal of any liquids that may occlude the image acquisition system.

9. The system according to claim 8, wherein the suction system provides air pressure to remove fluid from occluding the image acquisition system.

10. The system according to any one of the preceding claims, wherein said speculum includes upper and lower blades with a membrane connected therebetween for preventing collapse of cervix walls.

11. The system according to any one of the preceding claims, wherein said image acquisition system further comprises a zoom lens that can be implemented by using a miniature piezo or electric motor.

12. The system according to any one of the preceding claims, wherein the image acquisition system further comprises at least one of automatic, semi-automatic and manual illumination LEDs and a laser diode adjustment.

13. The system according to claim 1, wherein said image acquisition system comprises: a sensor imaging system selected from the group consisting of single sensor imaging systems and dual sensor imaging systems, said sensor imaging system comprising at least one element selected from the group consisting of color CMOS, monochrome CMOS, color CCD, and monochrome CCD; and,

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an illumination system based on one or more of LEDs or laser diode.

14. The system according to claim 13, wherein said illumination system comprises:

bright field illumination;

dark field external source illumination; and,

a light source selected from the group consisting of (a) a source for making fluorescence or autofluorescence measurements selected from the group consisting of a UV LED source and a multi-spectral source, (b) an infrared source, and (c) any combination of the above.

15. The system according to claim 13 or claim 14, wherein the illumination system comprises a source of white/monochromatic/TR and UV LEDs positioned near a lens aperture in order to optimize the delivery of light into the target tissue with minimum angle of incidence to optimize the reflection from the tissue using a second part of an objective lens.

16. The system according to any one of the preceding claims, wherein the image acquisition system achieves depth perception in an acquired image by using at least one of a large depth of field, a contiguous zoom feature to receive a sequence of different images of the same X,Y position at different focal planes, and dark field illumination applied at different illumination angles using a source of external illumination system.

17. The system according to claim 1, wherein said image acquisition system comprises a camera apparatus for obtaining fluorescence images, said camera apparatus comprising:

a camera;

a lens attached to said camera; and,

a dichroic mirror that transmits UV and reflects visible and IR light.

18. The system according to claim 1, wherein said image acquisition system comprises a camera apparatus for obtaining fluorescence images, said camera apparatus comprising:

a camera;

a lens attached to said camera;

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a UV source in the Bright Field (BF); and,

a long pass filter at wavelength of about 400 nm.

19. The system according to claim 17, wherein said image acquisition system comprises a light source having one of an external strobe or camera electronic shutter to control the camera exposure time and prevent any saturation in the imaging system.

20. The system according to any one of the preceding claims, further comprising a detector for detecting stray light generated by improper assembly of the optical disposable speculum to the image acquisition system.

21. The system according to any one of the preceding claims, wherein said image analysis and control unit is integrated within said image acquisition system.

22. The system according to any one of the preceding claims, utilized in hysteroscopy procedures.

23. The system according to any one of the preceding claims, wherein the disposable optical speculum covers an optical head and yet enables a free working channel for taking a manual biopsy.

24. The system according to any one of the preceding claims, wherein the disposable optical speculum is single use and the multiple-use image acquisition system is multiple use.

25. The system according to any one of the preceding claims, further comprising a locking mechanism between the disposable optical speculum and the image acquisition system to assure image acquisition without distortions.

26. The system according to any one of the preceding claims, wherein said disposable optical speculum integrates a light collimation element guide for dark field illumination with an optical window.

27. The system according to any one of the preceding claims, wherein said disposable optical speculum comprises a unique RFID tag to identify said optical disposable speculum.

28. The system according to any one of the preceding claims, wherein said image acquisition system assembled on and mechanically secured to a laparoscope.

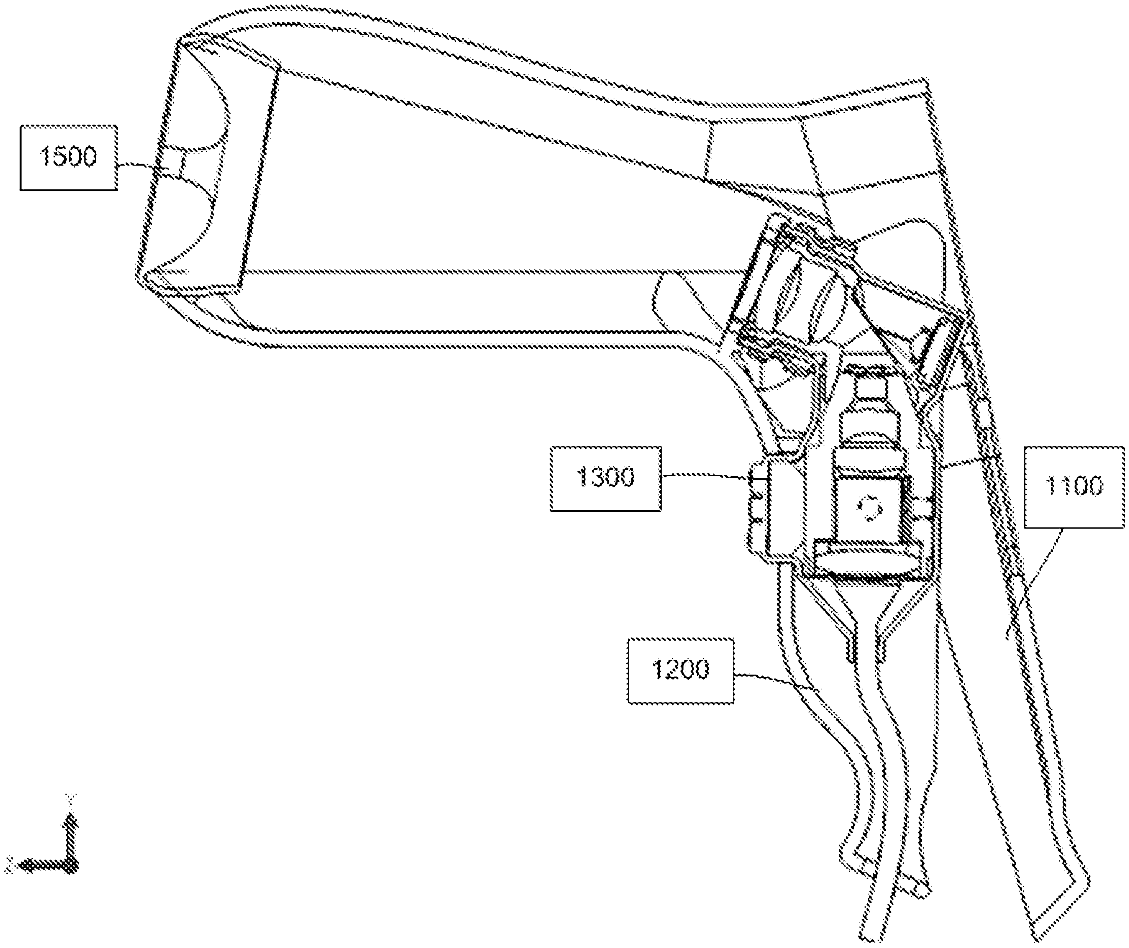


FIG. 1A

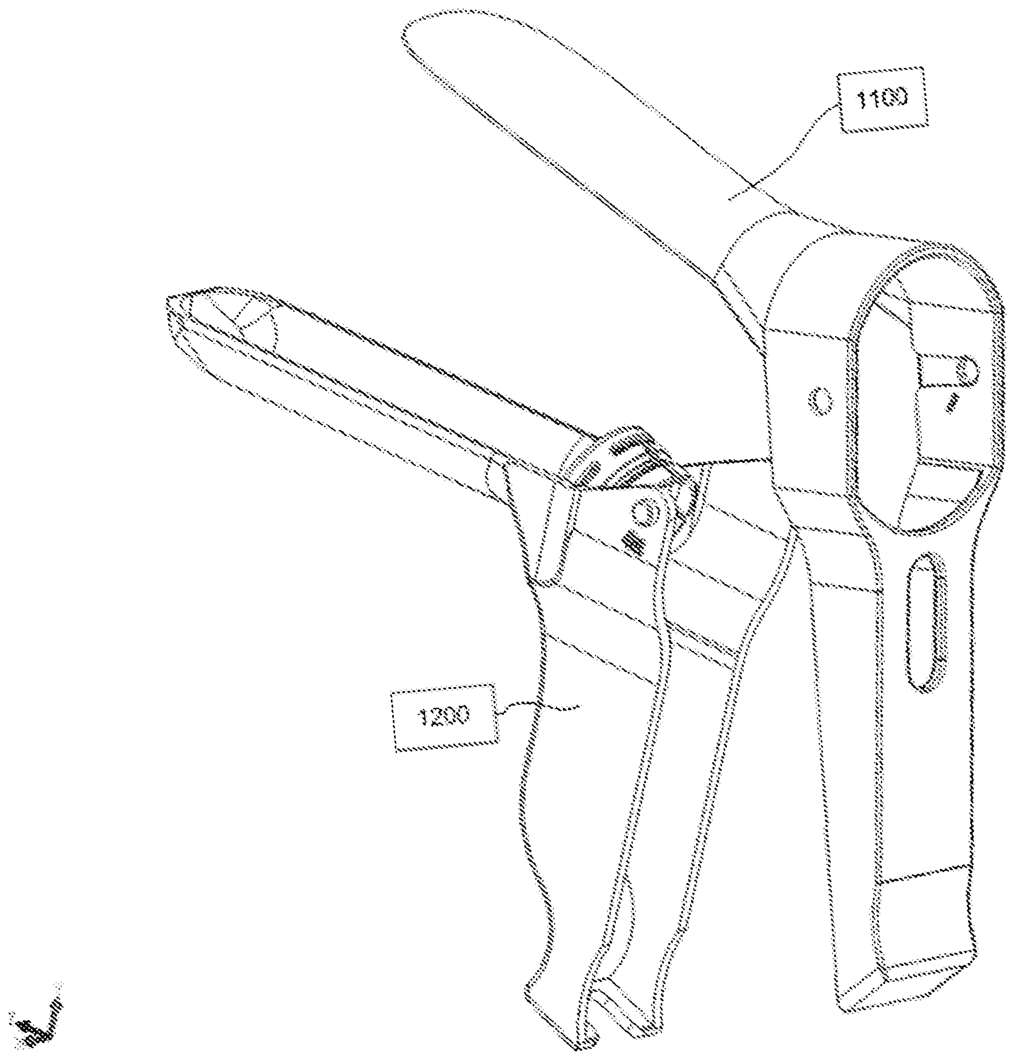


FIG. 1B

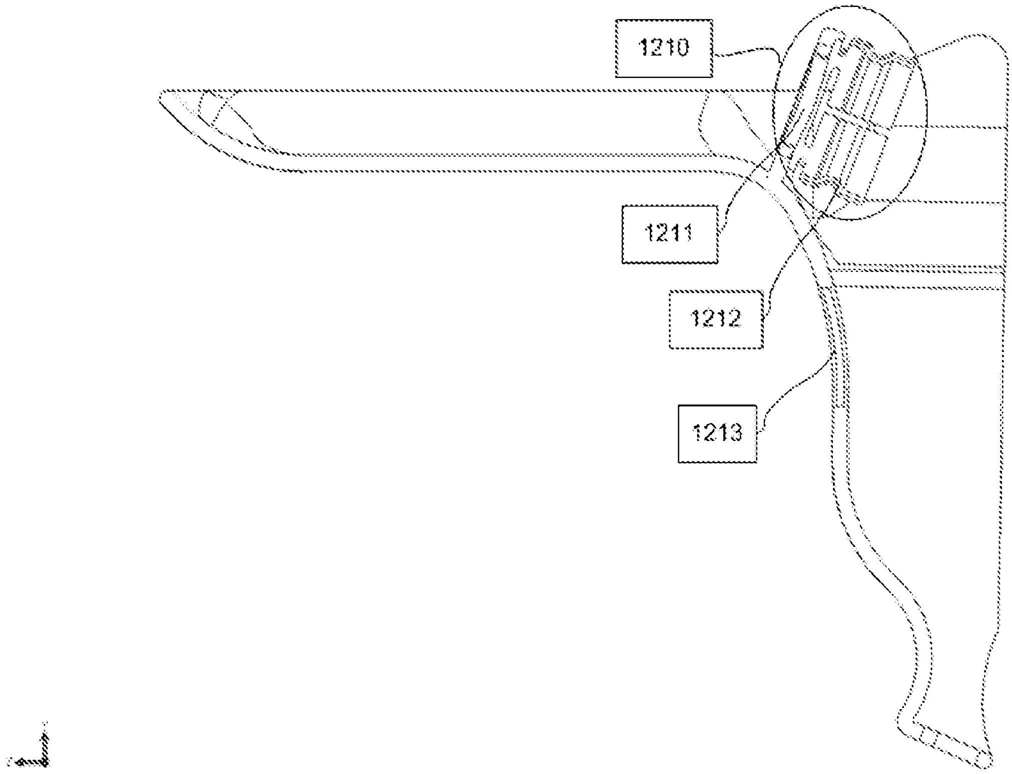


FIG. 2A

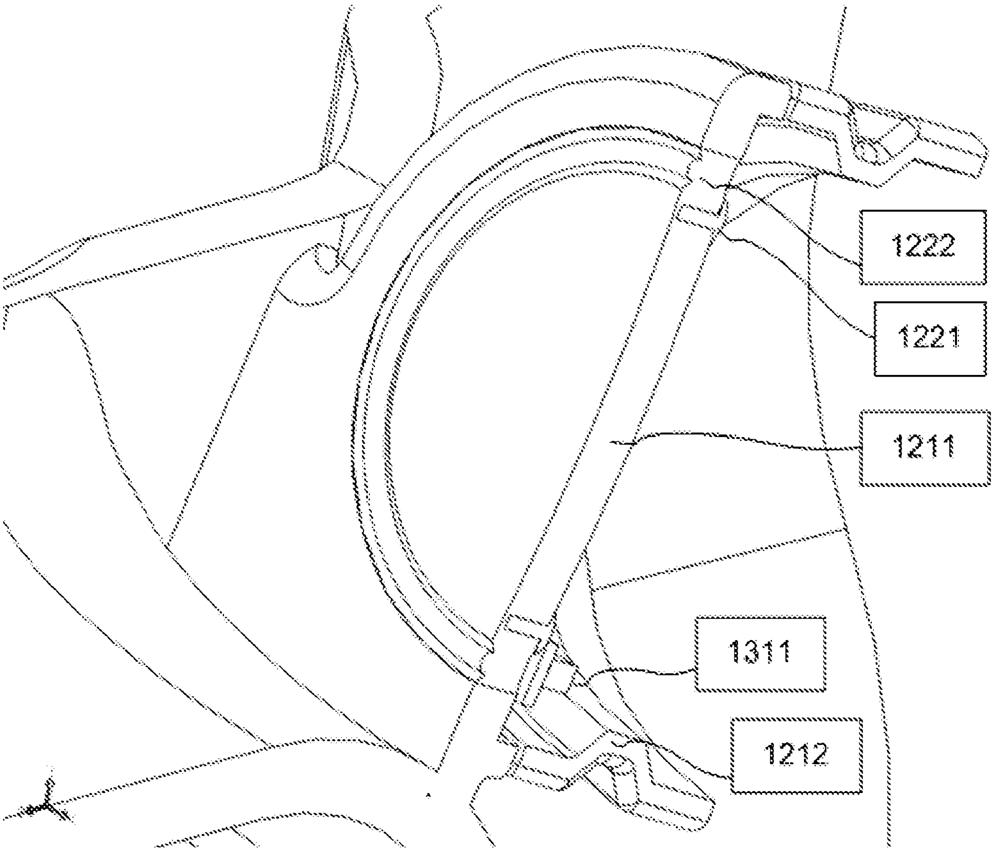


FIG. 2B

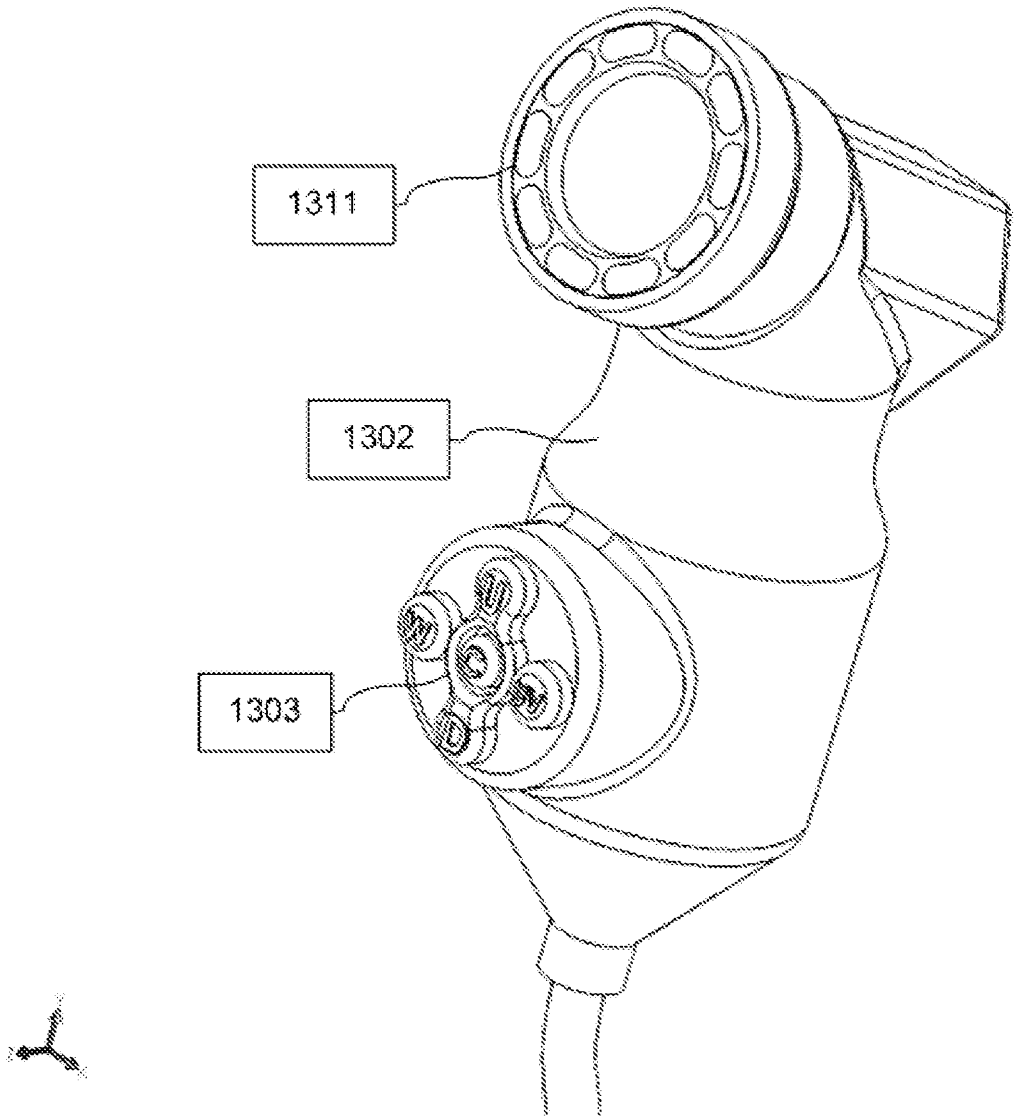


FIG. 3

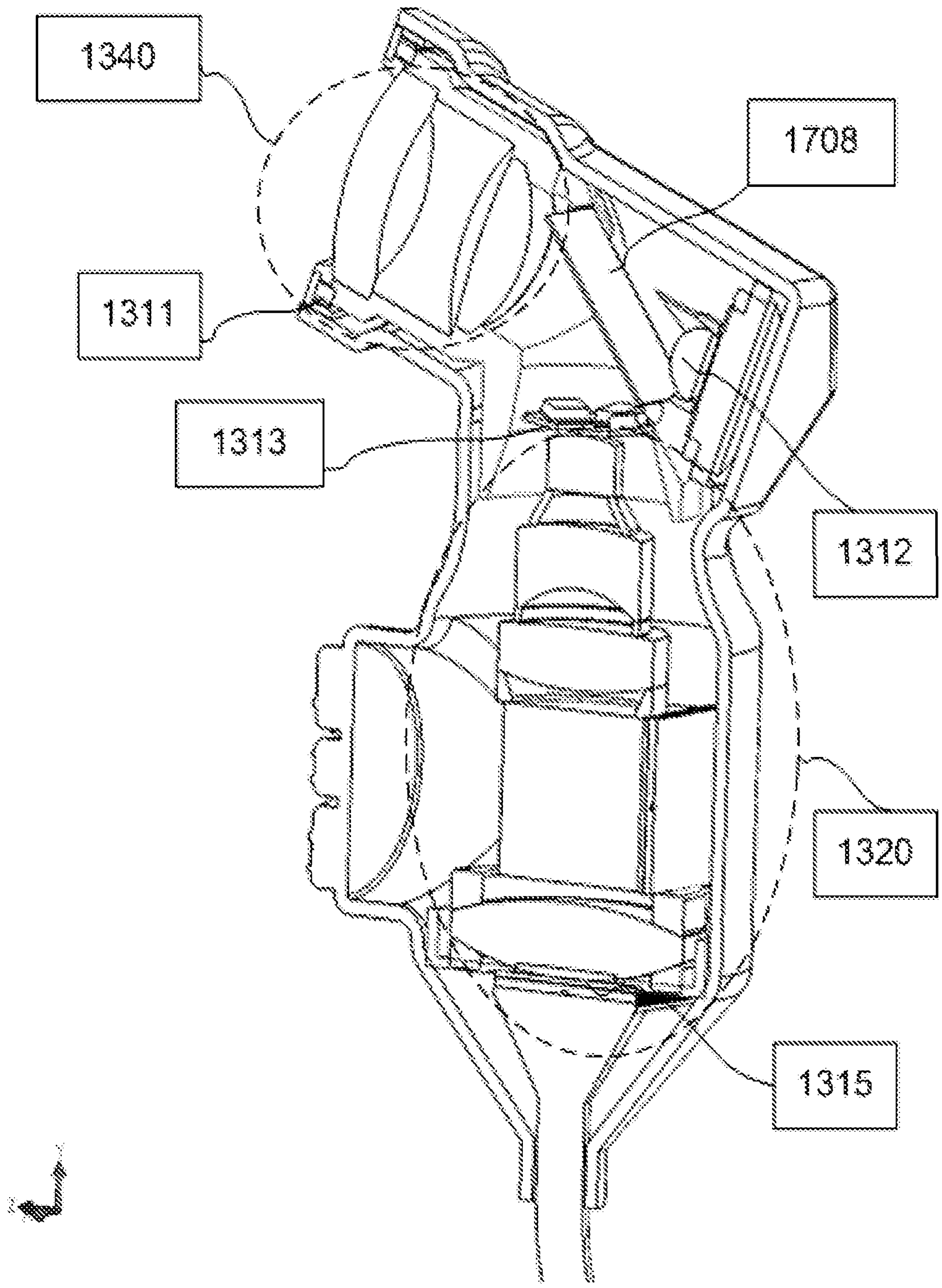


FIG. 4

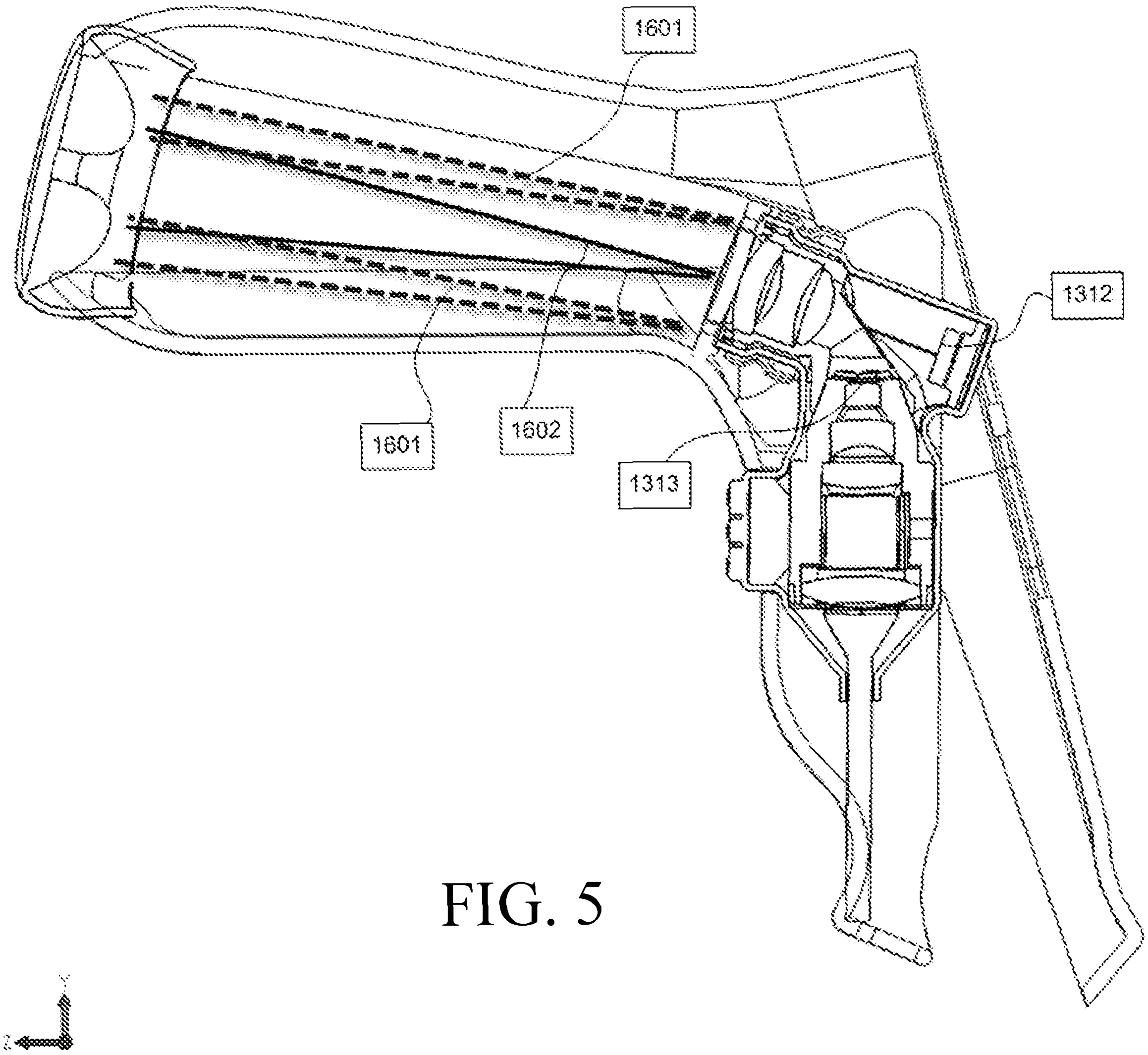


FIG. 5

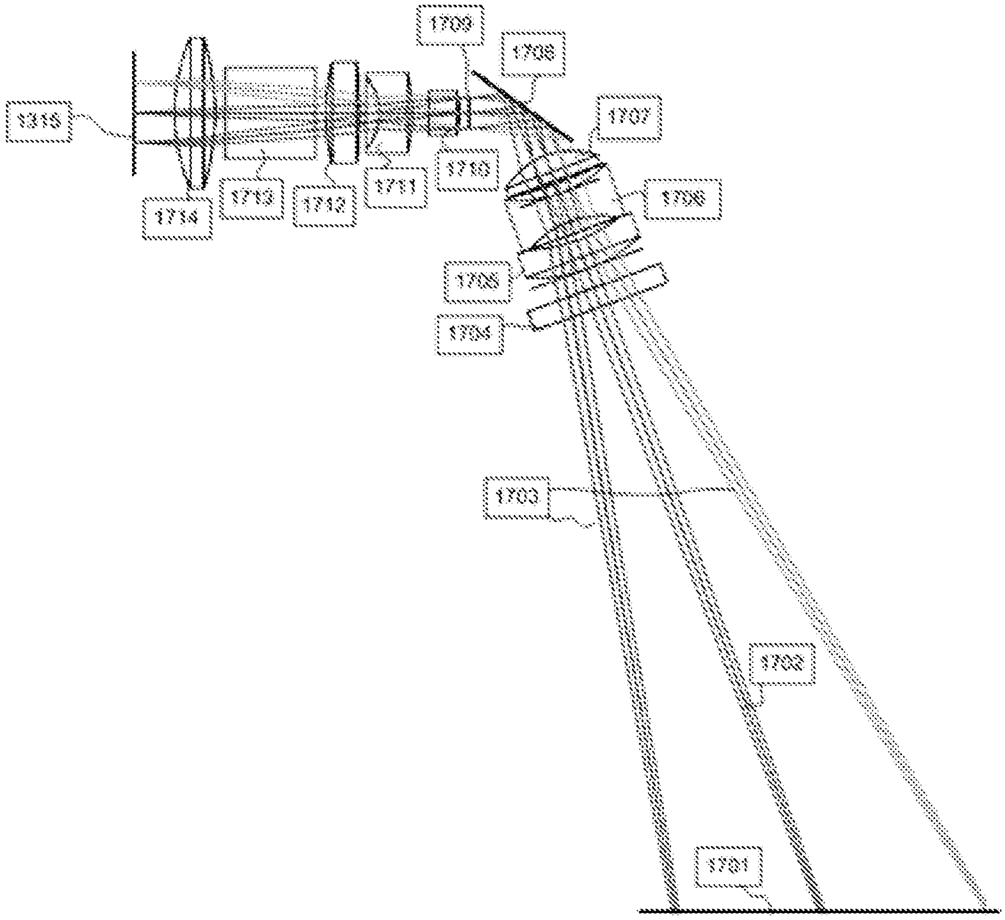
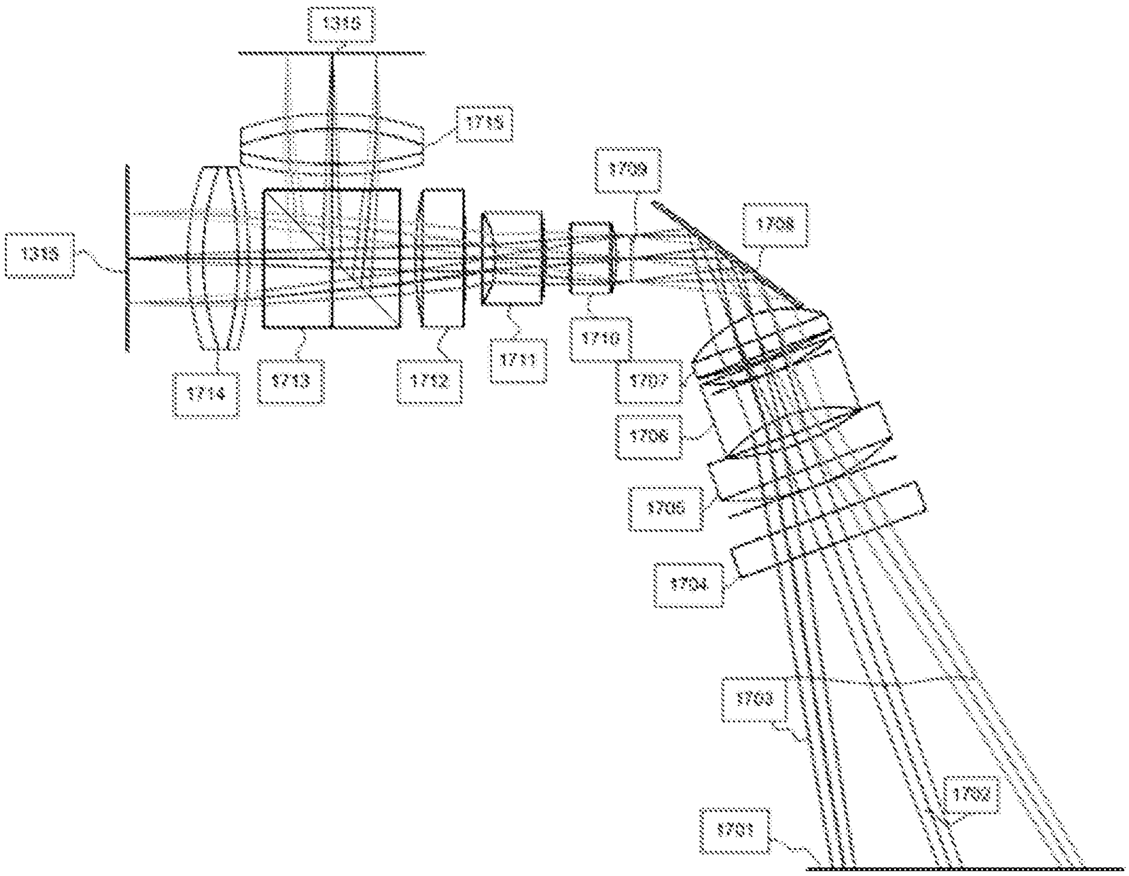

1709
1708
1315
1707
1710
1706
1713
1712
1711
1714
1705
1704
1703
1702
1701

FIG. 6A


1316
1715
1315
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1713
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1710
1707
1706
1705
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1702
1701

FIG. 6B

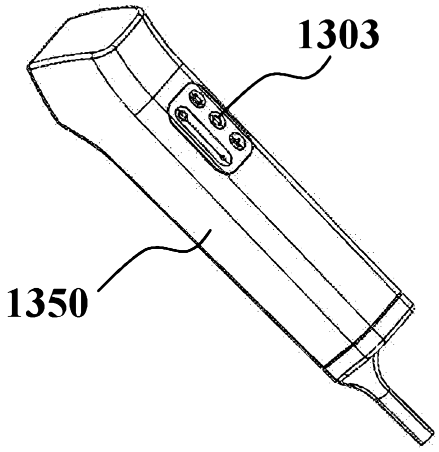


FIG. 7A

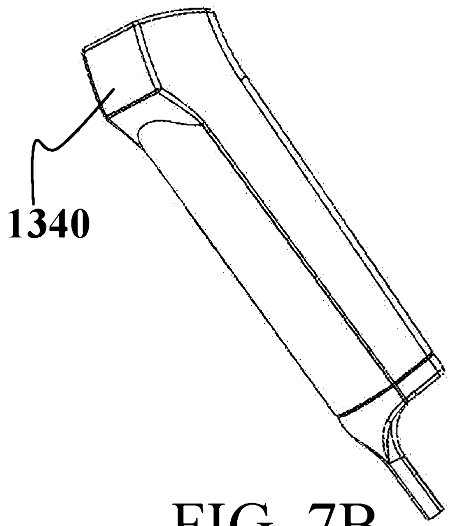


FIG. 7B

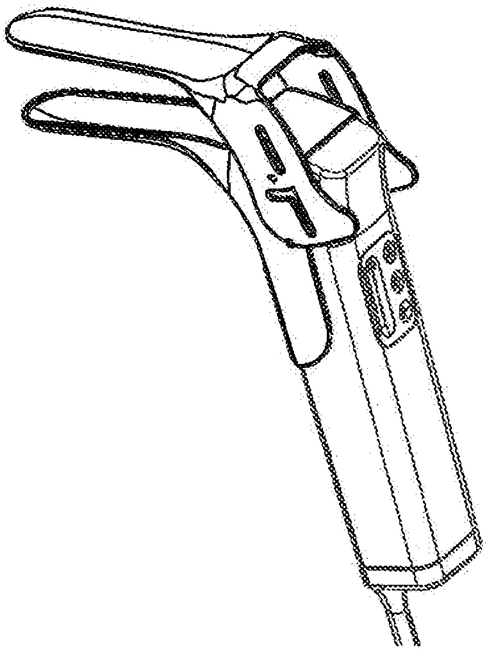


FIG. 7C

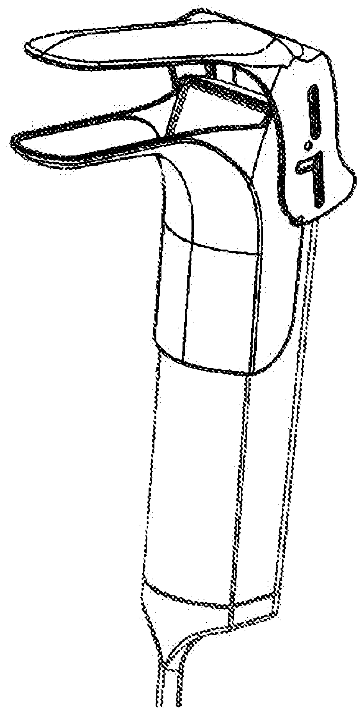


FIG. 7D

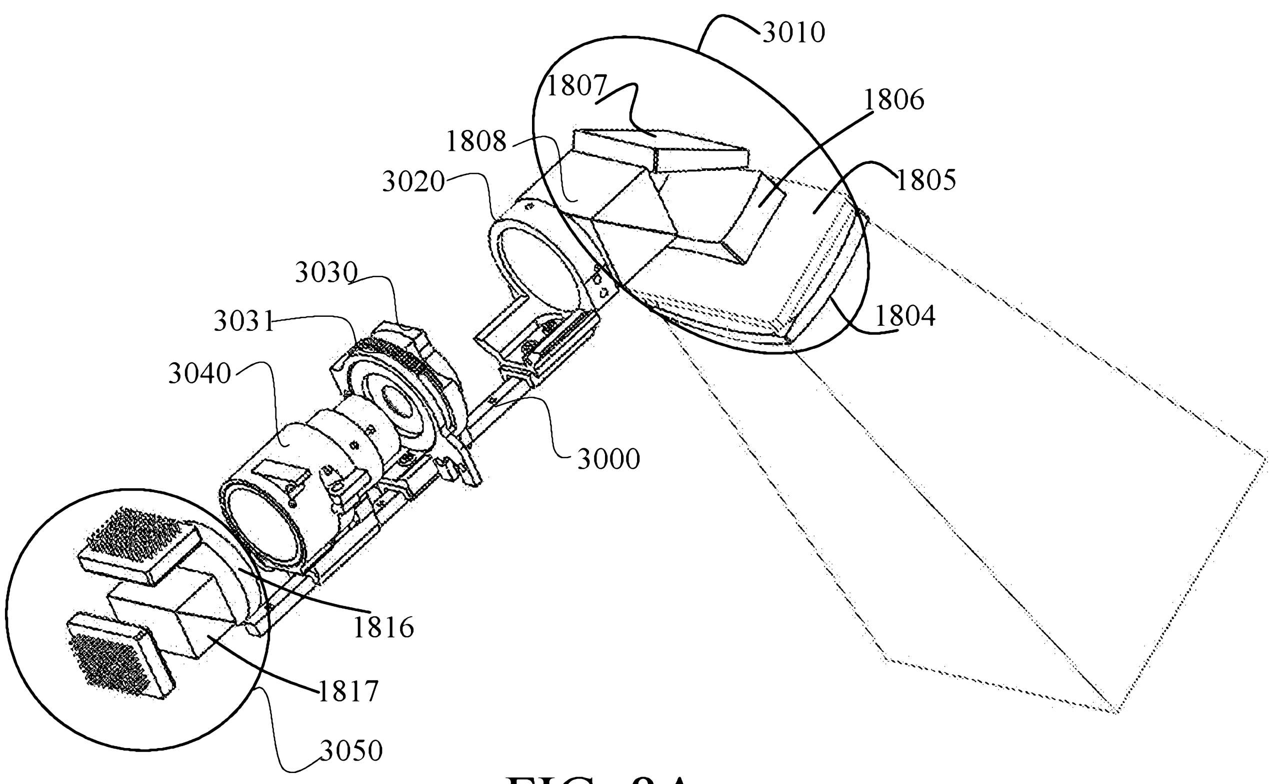

3010
1807
1806
1808
1805
3020
3030
1804
3031
3040
3000
1816
1817
3050

FIG. 8A

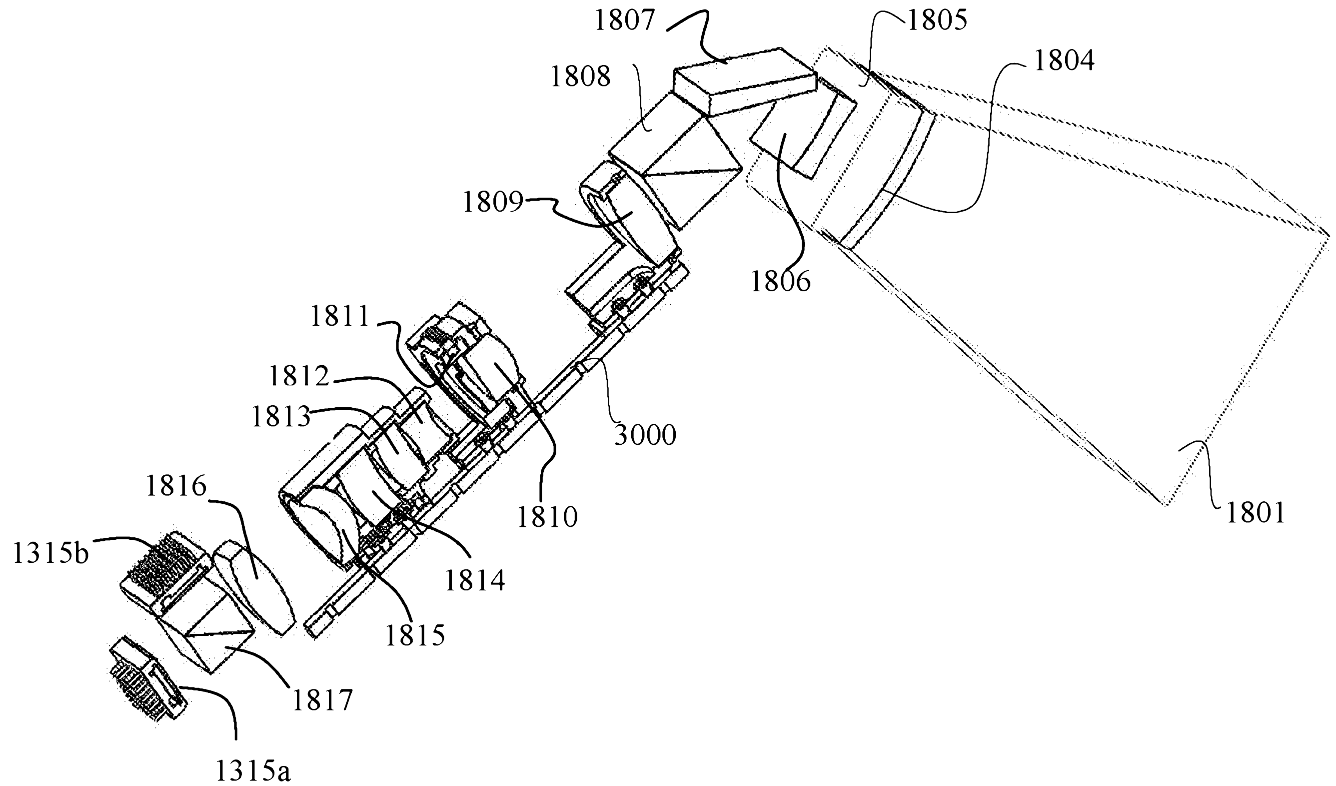

1807
1805
1804
1808
1809
1806
1811
1812
3000
1813
1810
1816
1801
1315b
1814
1815
1817
1315a

FIG. 8B

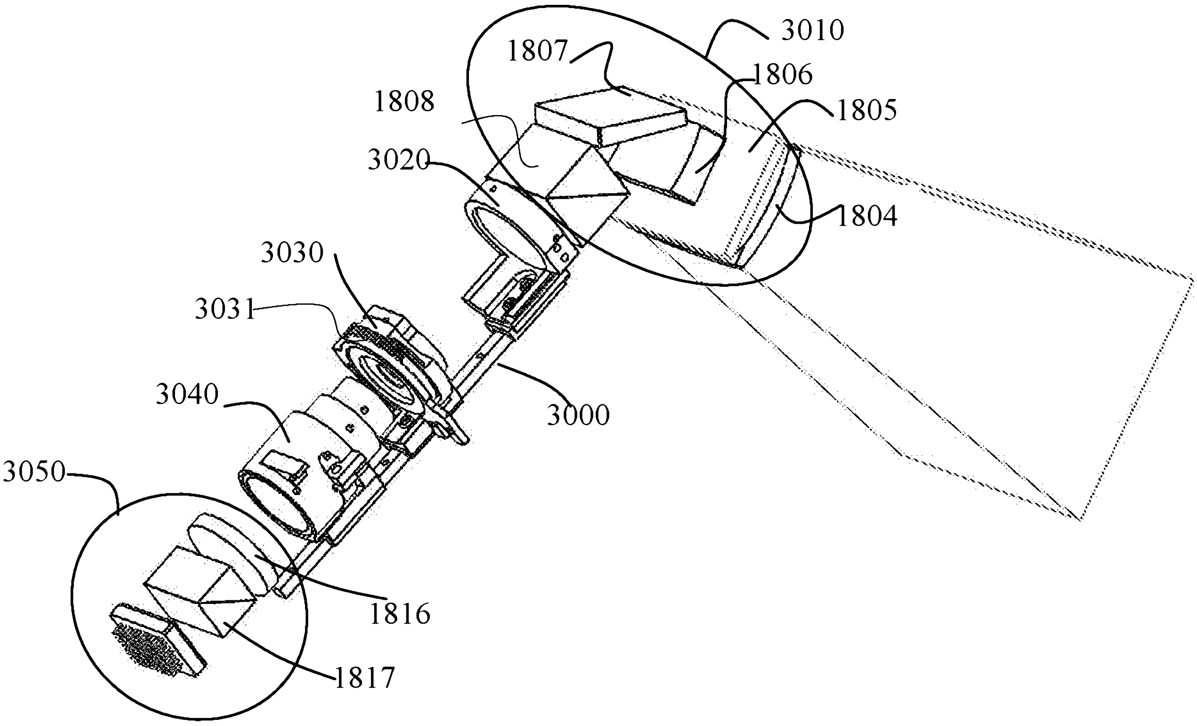
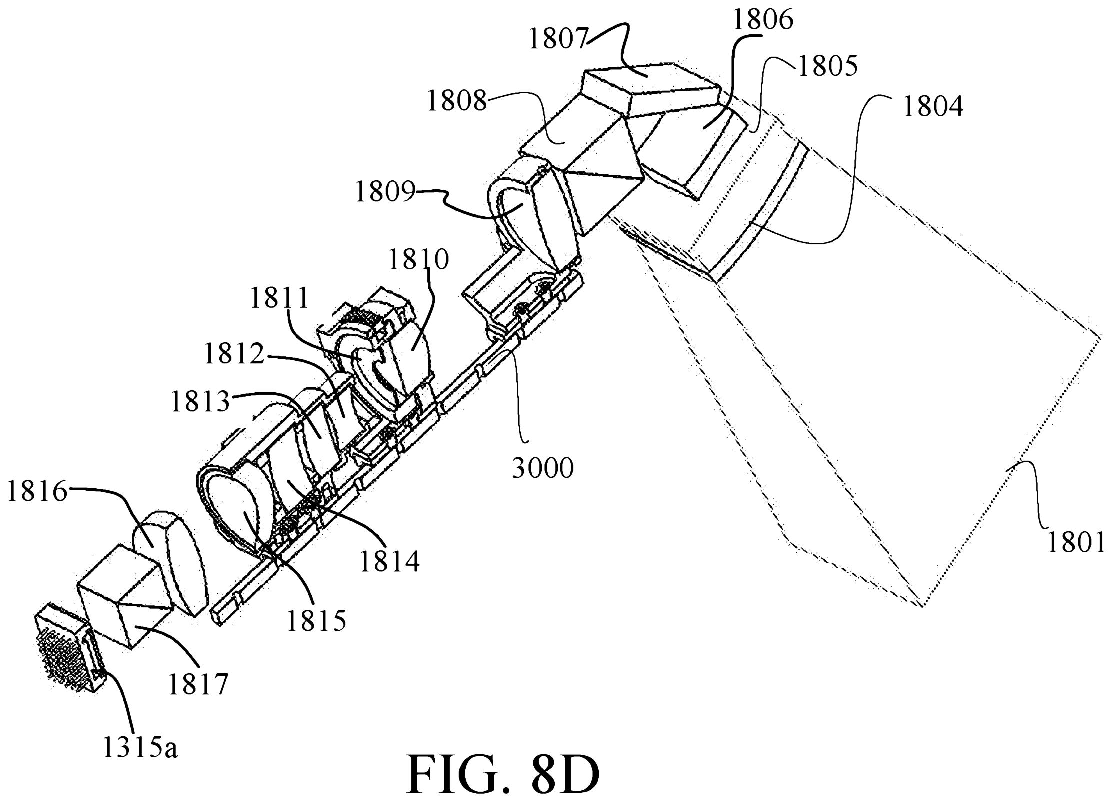

3010
1807
1806
1808
1805
3020
1804
3030
3031
3040
3000
3050
1816
1817

FIG. 8C


1807
1806
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1808
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1810
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1812
1813
3000
1816
1814
1801
1815
1817
1315a

FIG. 8D

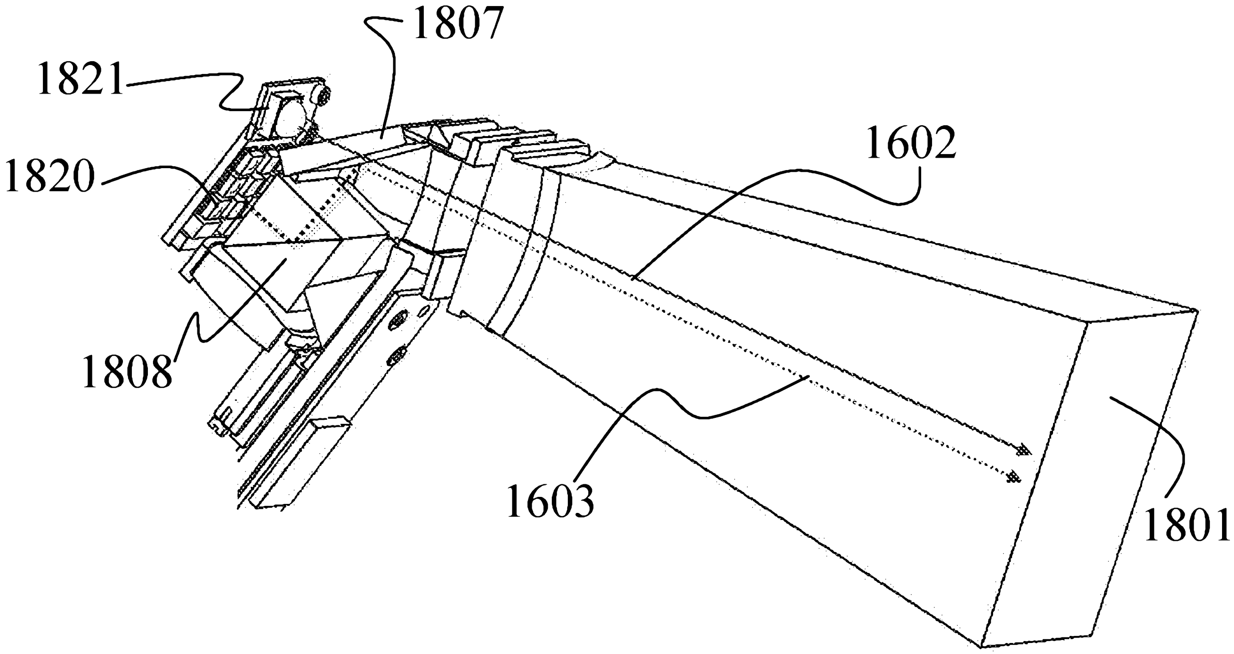
1807
1821
1602
1820
1808
1603
1801

FIG. 8E

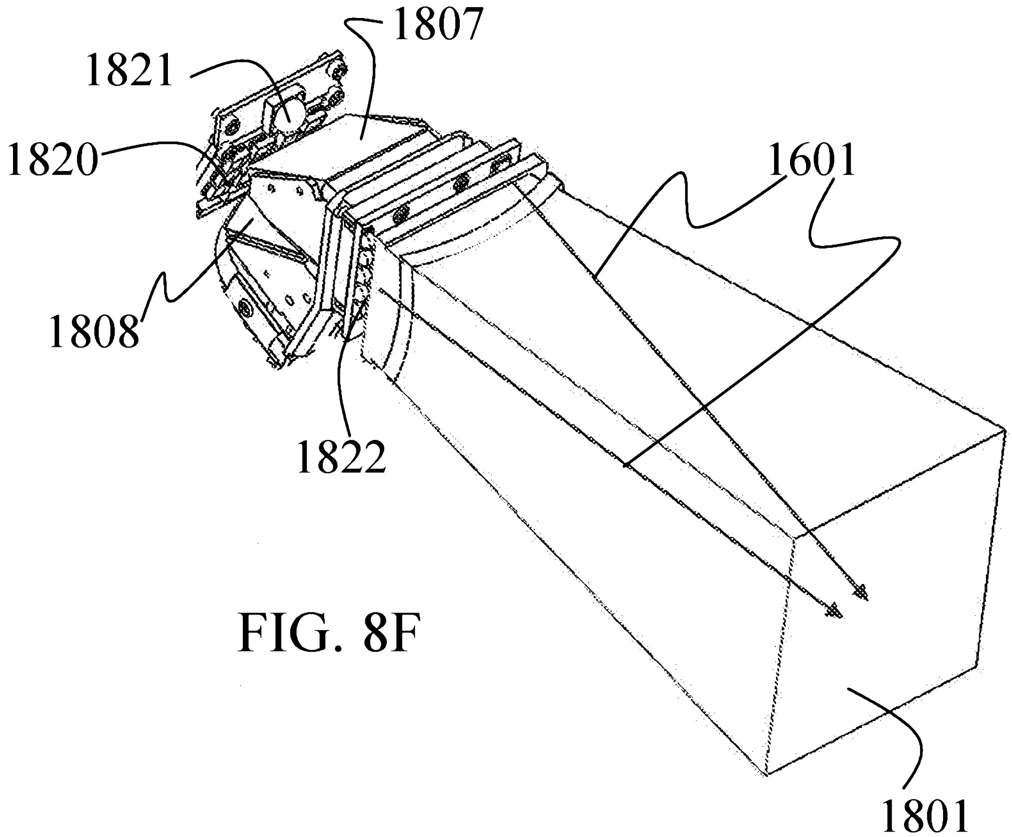
1807
1821
1820
1601
1808
1822
1801

FIG. 8F

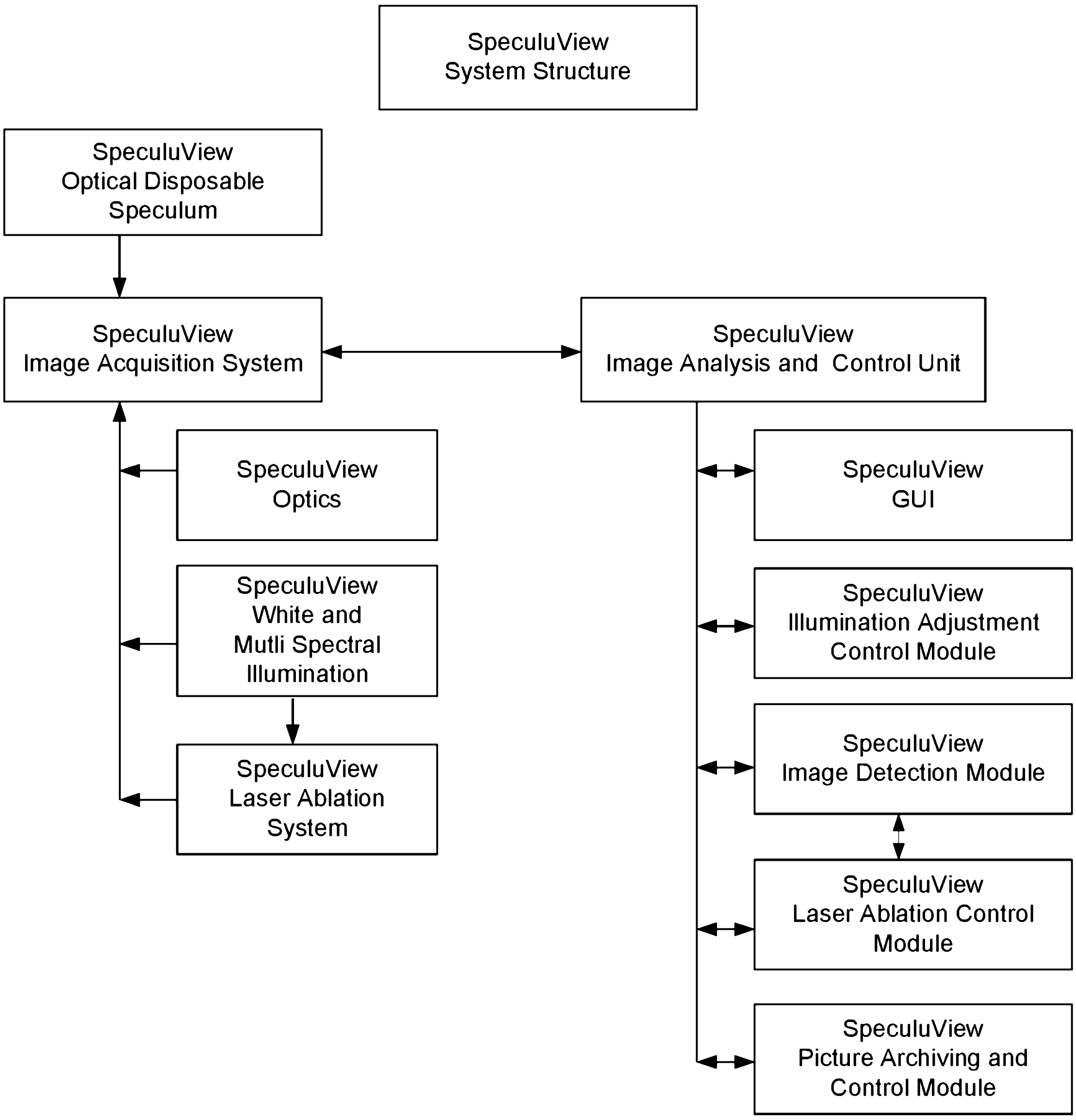
SpeculuView
System Structure
SpeculuView
Optical Disposable
Speculum
SpeculuView
Image Acquisition System
SpeculuView
Image Analysis and Control Unit
SpeculuView
Optics
SpeculuView
White and
Mutli Spectral
Illumination
SpeculuView
Laser Ablation
System
SpeculuView
GUI
SpeculuView
Illumination Adjustment
Control Module
SpeculuView
Image Detection Module
SpeculuView
Laser Ablation Control
Module
SpeculuView
Picture Archiving and
Control Module

FIG. 9

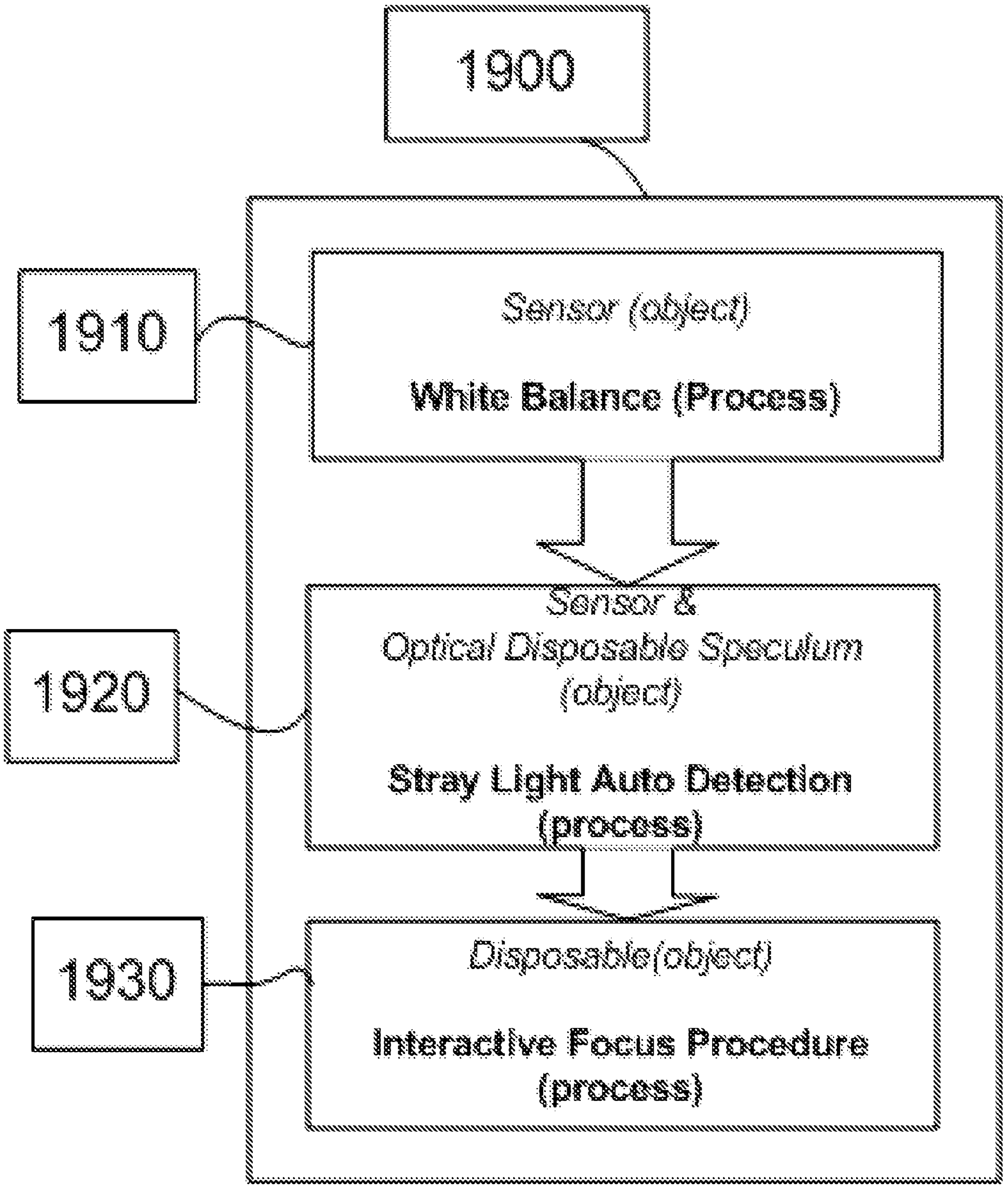
1900
1910
Sensor (object)
White Balance (Process)
1920
Sensor &
Optical Disposable Speculum
(object)
Stray Light Auto Detection
(process)
1930
Disposable(object)
Interactive Focus Procedure
(process)

FIG. 10

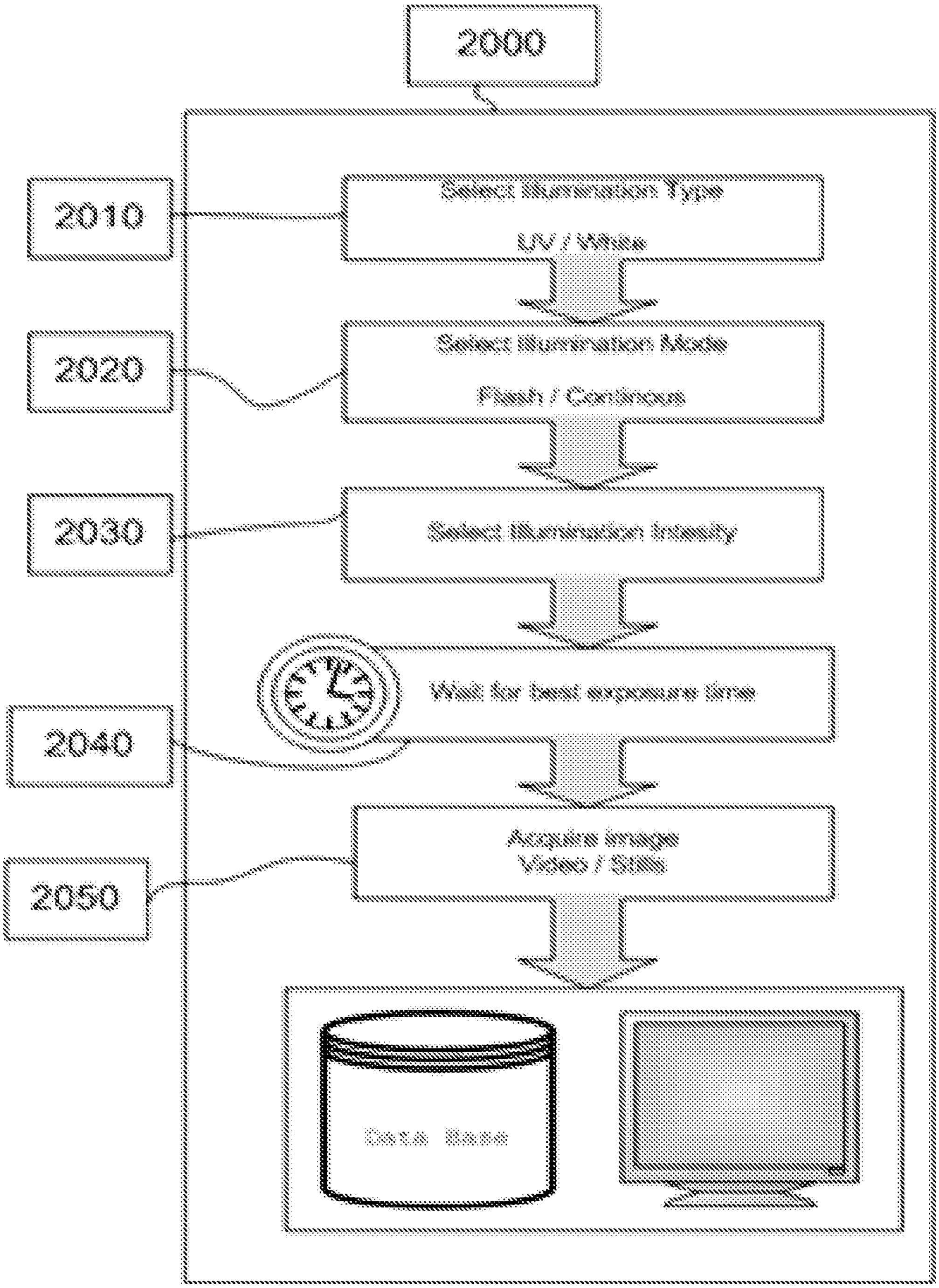
2000
2010
Select Illumination Type
UV / White
2020
Select Illumination Mode
Flash / Continous
2030
Select Illumination Intesity
Wait for best exposure time
2040
Acquire image
Video / Stills
2050
Data Base

FIG. 11

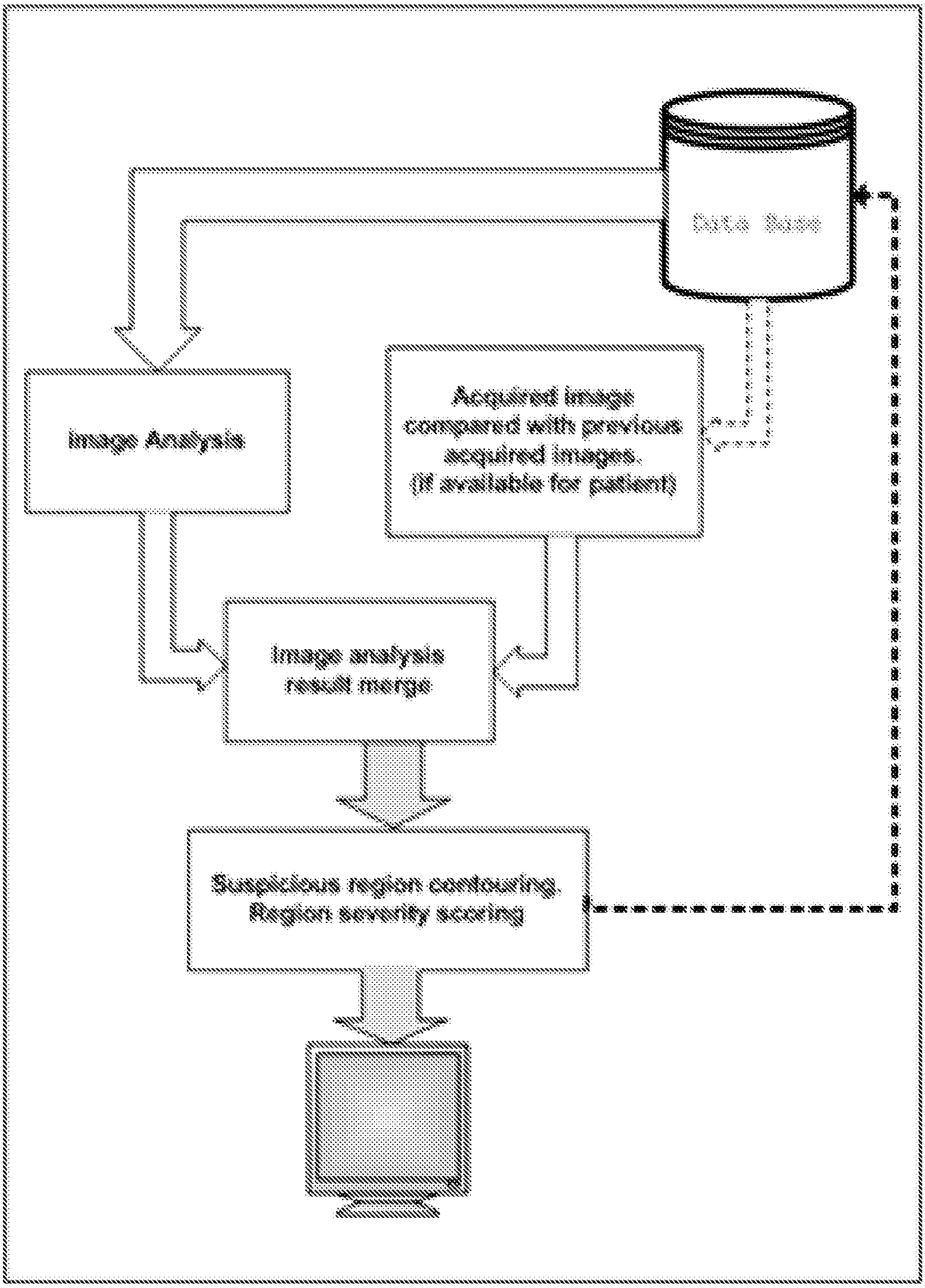
Data Base
Image Analysis
Acquired image compared with previous acquired images. (If available for patient)
Image analysis result merge
Suspicious region contouring. Region severity scoring

FIG. 12

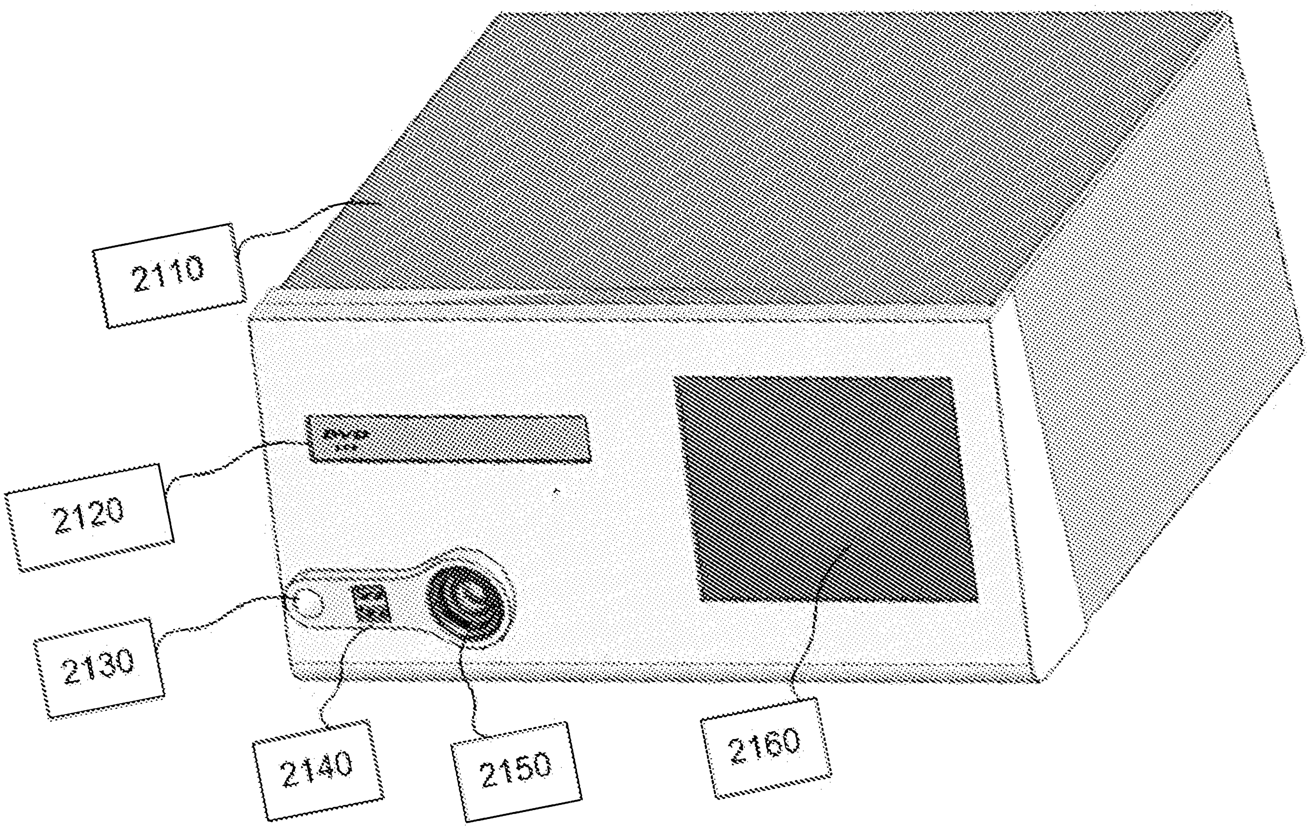

FIG. 13

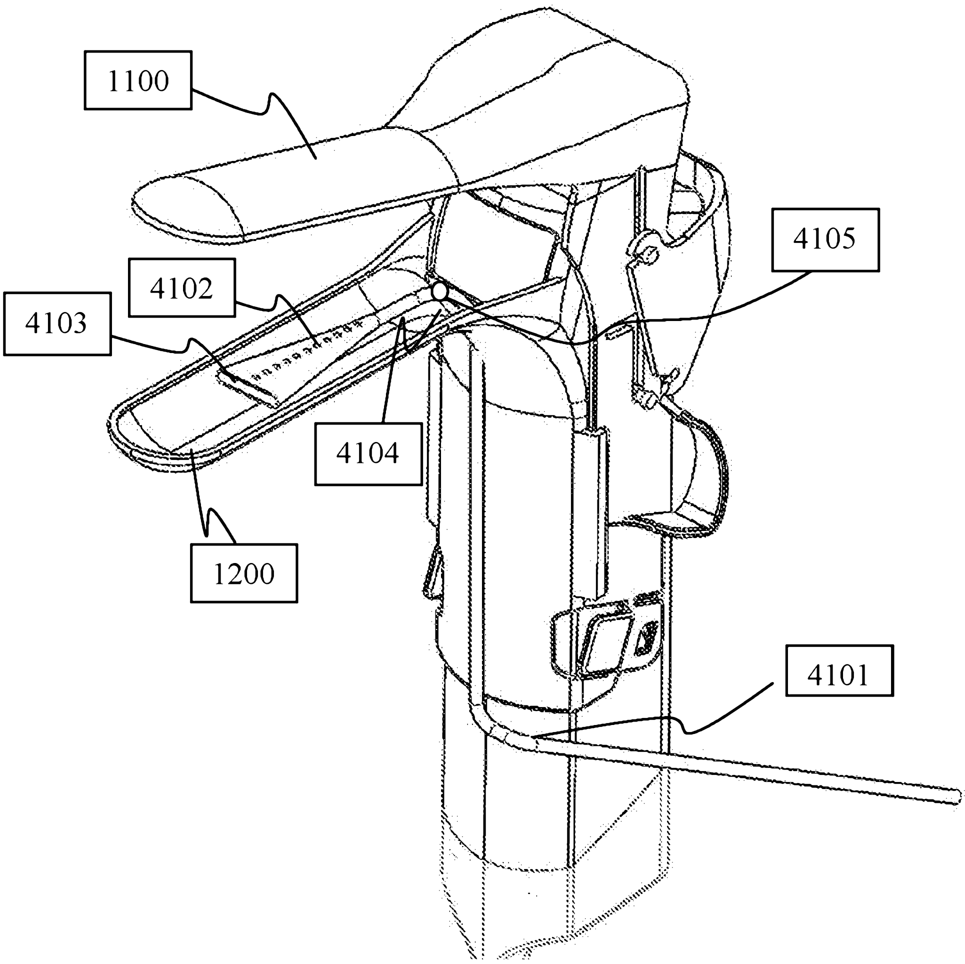

FIG. 14

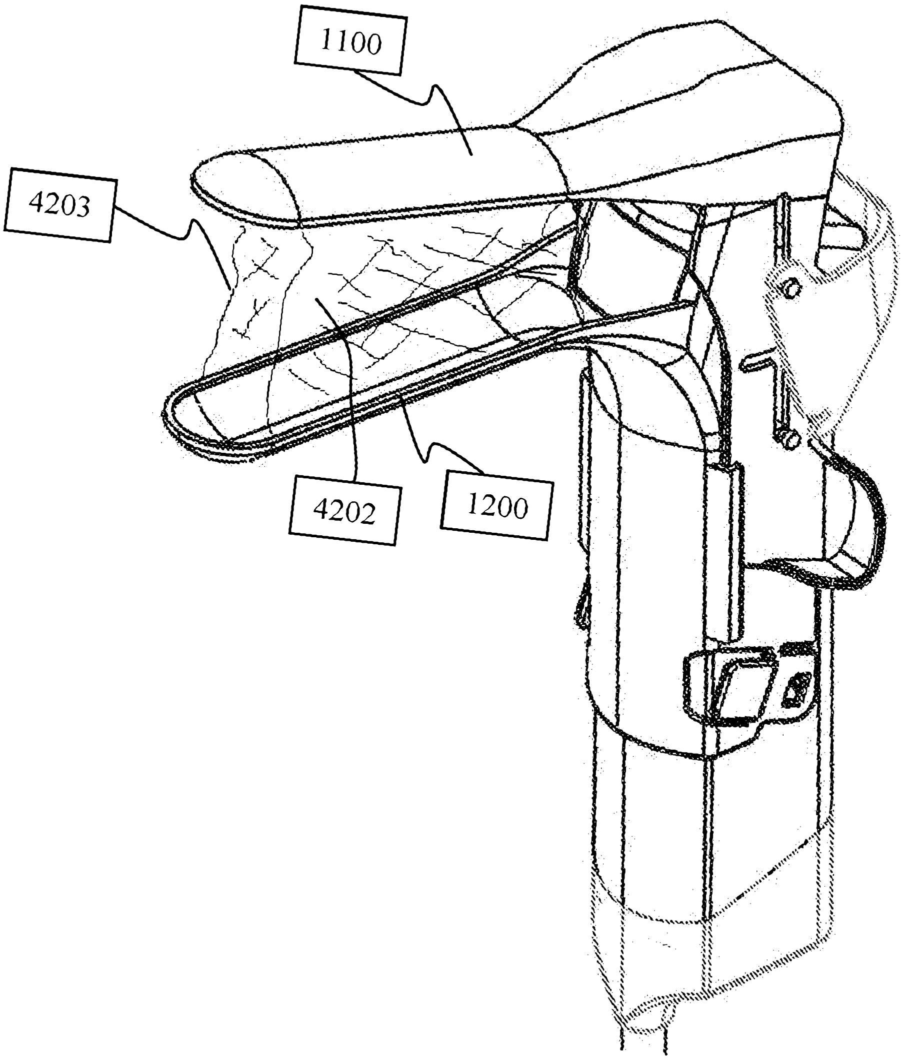

FIG. 15