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(54) Title: PATIENT INTERFACE FOR OPHTHALMOLOGIC DIAGNOSTIC AND INTERVENTIONAL PROCEDURES

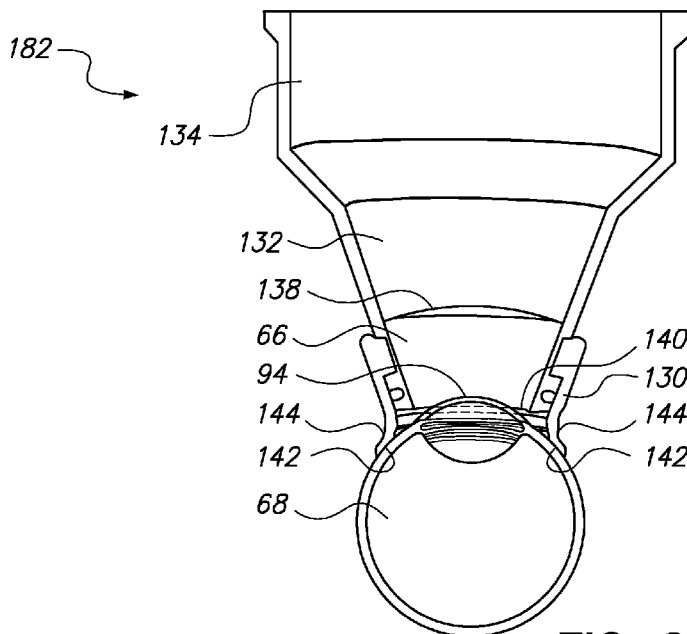


FIG. 3C

(57) Abstract: Configurations are described for conducting ophthalmic procedures to address cataract-related clinical challenges. In one embodiment, a one-piece patient contact interface may be utilized to couple a diagnostic and/or interventional system to a cornea of a patient; in another embodiment, a two-part configuration may be utilized; in another embodiment, a liquid interface two-part embodiment may be utilized.

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PATIENT INTERFACE FOR OPHTHALMOLOGIC DIAGNOSTIC AND
INTERVENTIONAL PROCEDURES

FIELD OF THE INVENTION

5 The invention relates to ophthalmic surgical procedures
and systems.

BACKGROUND

Cataract extraction is one of the most commonly performed
surgical procedures in the world with approximately 4 million
10 cases performed annually in the United States and 15 million
cases worldwide. This market is composed of various segments
including intraocular lenses for implantation, viscoelastic
polymers to facilitate surgical maneuvers, disposable
instrumentation including ultrasonic phacoemulsification tips,
15 tubing, and various knives and forceps. Modern cataract
surgery is typically performed using a technique termed
"phacoemulsification" in which an ultrasonic tip with an
associated water stream for cooling purposes is used to sculpt
the relatively hard nucleus of the lens after creation of an
20 opening in the anterior lens capsule termed "anterior
capsulotomy" or more recently "capsulorhexis". Following these
steps as well as removal of residual softer lens cortex by
aspiration methods without fragmentation, a synthetic foldable
intraocular lens, or "IOL", may be inserted into the eye
25 through a small incision.

One of the earliest and most critical steps in the
procedure is the creation, or performance, of capsulorhexis.
This step evolved from an earlier technique termed "can-opener
capsulotomy" in which a sharp needle was used to perforate the
30 anterior lens capsule in a circular fashion followed by the
removal of a circular fragment of lens capsule typically in
the range of 5-8 mm in diameter. This facilitated the next
step of nuclear sculpting by phacoemulsification. Due to a

variety of complications associated with variations of the can-opener technique, attempts were made by leading experts in the field to develop a better technique for removal of the anterior lens capsule preceding the emulsification step. The
5 concept of the capsulorhexis is to provide a smooth continuous circular opening through which not only the phacoemulsification of the nucleus can be performed safely and easily, but also for easy insertion of the intraocular lens. It provides both a clear central access for insertion, a
10 permanent aperture for transmission of the image to the retina by the patient, and also a support of the IOL inside the remaining capsule that would limit the potential for dislocation.

More modern techniques, such as those employing lasers to
15 assist with the creation of precision capsulorhexis geometries as well as other desired incisions, such as tissue structure relaxing incisions of various types, are disclosed, for example, in U.S. Publication Nos. 2006-0195076, 2010-0191226, 2008-0281413, 2009-0012507, 2010-0137850, 2008-028303, and
20 U.S. Patent Application Serial Nos. 61/289,837, 61/293,357, 61/297,624, and 61/302,437. Each of these technologies generally requires a patient interface - a structure to join the patient's eye and the laser and associated imaging systems, and to optimize the interaction between the
25 diagnostic and imaging technologies and the pertinent patient tissue structures. There is a need for further optimization of the patient interface options to advance the standard of care of the cataract patient.

30 BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 illustrates one embodiment of a diagnostic/interventional ophthalmic system.

Figures 2A-2C illustrate aspects of patient interface configurations featuring a focusing lens engaged adjacent a cornea of a patient.

5 Figures 3A-3C illustrate aspects of one-piece patient interface embodiments.

Figures 4A-4E illustrate aspects of two-piece patient interface embodiments.

10

Figures 5A-5C illustrate aspects of liquid interface two-piece patient interface embodiments.

Figures 6A-6D illustrate aspects of techniques for
15 utilizing configurations such as those described in reference to Figures 1-5C.

SUMMARY

20 One embodiment is directed to a system for intercoupling an ophthalmologic interventional system to an eye of a patient, comprising: a. a hollow reservoir housing defining an interior volume and having proximal and distal ends, wherein the distal end comprises a eye interface surface
25 configured to be removably and sealably coupled to the eye of the patient, and wherein the proximal end is configured to be mechanically interfaced with the interventional system in a manner that allows for open access to the interior volume for transporting liquids or gases in or out of the interior
30 volume; b. an optical element fixedly coupled to the hollow reservoir housing and occupying a portion of the interior volume; and c. a liquid layer formed within the interior volume of the reservoir housing and positioned, via one or

more loads that include gravitational loads, between the optical element and the eye. The hollow reservoir housing may comprise two parts that may be removably coupled to each other. The two parts may be removably coupled to each other using a configuration selected from the group consisting of:
5 a vacuum coupling interface, an interference fit interface, an electromagnetic coupling interface, a manually-actuated mechanical interface, and an electromechanically-actuated mechanical interface. The optical element may comprise a lens
10 having proximal and distal surfaces. The distal surface of the lens may be a convex surface. The eye interface surface may comprise a compliant circumferential seal member. The seal member may comprise two circumferential layers with a vacuum space interposed between the two layers. The system
15 may further comprise a vacuum loading device configured to apply a vacuum load into the vacuum space. At least one of the circumferential layers may have a tapered cross section. At least one of the circumferential layers may comprise a shape that is at least partially spherical. The liquid layer
20 may comprise about 2 cubic centimeters in volume.

The liquid layer may comprise a material selected from: water, saline, oil, viscoelastic gel, and perfluorocarbon liquid. The vacuum loading device may be configured to apply a vacuum load of between about 200mm of mercury and about
25 600mm of mercury. The hollow reservoir housing may comprise a proximal part and a distal part, wherein the optical element is fixedly coupled to the distal part. The hollow reservoir housing may comprise a proximal part and a distal part, and the optical element may be fixedly coupled to the proximal
30 part. The liquid layer may be in immediate contact with the optical element.

DETAILED DESCRIPTION

As described briefly above, one embodiment of a cataract diagnostic and interventional system may be implemented by a system that projects or scans an optical beam into a patient's eye (68), such as system (2) shown in Figure 1 which includes an ultrafast ("UF") light source 4 (e.g. a femtosecond laser). Using this system, a beam may be scanned in a patient's eye in three dimensions: X, Y, Z. In this embodiment, the UF wavelength can vary between 1010 nm to 1100 nm and the pulse width can vary from 100 fs to 10000 fs. The pulse repetition frequency can also vary from 10 kHz to 250 kHz. Safety limits with regard to unintended damage to non-targeted tissue bound the upper limit with regard to repetition rate and pulse energy; while threshold energy, time to complete the procedure and stability bound the lower limit for pulse energy and repetition rate. The peak power of the focused spot in the eye (68) and specifically within the crystalline lens (69) and anterior capsule of the eye is sufficient to produce optical breakdown and initiate a plasma-mediated ablation process. Near-infrared wavelengths are preferred because linear optical absorption and scattering in biological tissue is reduced across that spectral range. As an example, laser (4) may be a repetitively pulsed 1035 nm device that produces 500 fs pulses at a repetition rate of 100 kHz and an individual pulse energy in the ten microjoule range.

The laser (4) is controlled by control electronics (300), via an input and output device (302), to create optical beam (6). Control electronics (300) may be a computer, microcontroller, etc. In this example, the entire system is controlled by the controller (300), and data moved through input/output device IO (302). A graphical user interface GUI 304 may be used to set system operating parameters, process

user input (UI) (306) on the GUI (304), and display gathered information such as images of ocular structures.

The generated UF light beam (6) proceeds towards the patient eye (68) passing through half-wave plate, (8), and
5 linear polarizer, (10). The polarization state of the beam can be adjusted so that the desired amount of light passes through half-wave plate (8) and linear polarizer (10), which together act as a variable attenuator for the UF beam (6).

Additionally, the orientation of linear polarizer (10)

10 determines the incident polarization state incident upon beamcombiner (34), thereby optimizing beamcombiner throughput.

The UF beam proceeds through a shutter (12), aperture (14), and a pickoff device (16). The system controlled shutter (12) ensures on/off control of the laser for procedural and
15 safety reasons. The aperture sets an outer useful diameter for the laser beam and the pickoff monitors the output of the useful beam. The pickoff device (16) includes of a partially reflecting mirror (20) and a detector (18). Pulse energy, average power, or a combination may be measured using detector
20 (18). The information can be used for feedback to the half-wave plate (8) for attenuation and to verify whether the shutter (12) is open or closed. In addition, the shutter (12) may have position sensors to provide a redundant state detection.

25 The beam passes through a beam conditioning stage (22), in which beam parameters such as beam diameter, divergence, circularity, and astigmatism can be modified. In this illustrative example, the beam conditioning stage (22) includes a 2 element beam expanding telescope comprised of
30 spherical optics (24) and (26) in order to achieve the intended beam size and collimation. Although not illustrated here, an anamorphic or other optical system can be used to achieve the desired beam parameters. The factors used to

determine these beam parameters include the output beam parameters of the laser, the overall magnification of the system, and the desired numerical aperture (NA) at the treatment location. In addition, the optical system (22) can be used to image aperture (14) to a desired location (e.g. the center location between the 2-axis scanning device 50 described below). In this way, the amount of light that makes it through the aperture (14) is assured to make it through the scanning system. Pickoff device (16) is then a reliable measure of the usable light.

After exiting conditioning stage (22), beam (6) reflects off of fold mirrors (28, 30, & 32). These mirrors can be adjustable for alignment purposes. The beam (6) is then incident upon beam combiner (34). Beamcombiner (34) reflects the UF beam (6) (and transmits both the OCT 114 and aim 202 beams described below). For efficient beamcombiner operation, the angle of incidence is preferably kept below 45 degrees and the polarization where possible of the beams is fixed. For the UF beam (6), the orientation of linear polarizer (10) provides fixed polarization.

Following the beam combiner (34), the beam (6) continues onto the z-adjust or Z scan device (40). In this illustrative example the z-adjust includes a Galilean telescope with two lens groups (42 and 44) (each lens group includes one or more lenses). Lens group (42) moves along the z-axis about the collimation position of the telescope. In this way, the focus position of the spot in the patient's eye (68) moves along the z-axis as indicated. In general there is a fixed linear relationship between the motion of lens (42) and the motion of the focus. In this case, the z-adjust telescope has an approximate 2.times.beam expansion ratio and a 1:1 relationship of the movement of lens (42) to the movement of the focus. Alternatively, lens group (44) could be moved along

the z-axis to actuate the z-adjust, and scan. The z-adjust is the z-scan device for treatment in the eye (68). It can be controlled automatically and dynamically by the system and selected to be independent or to interplay with the X-Y scan device described next. Mirrors (36 and 38) can be used for aligning the optical axis with the axis of z-adjust device (40). After passing through the z-adjust device (40), the beam (6) is directed to the x-y scan device by mirrors (46 & 48). Mirrors (46 & 48) can be adjustable for alignment purposes. X-Y scanning is achieved by the scanning device (50) preferably using two mirrors (52 & 54) under the control of control electronics (300), which rotate in orthogonal directions using motors, galvanometers, or any other well known optic moving device. Mirrors (52 & 54) are located near the telecentric position of the objective lens (58) and focussing lens (66) combination described below. Tilting these mirrors (52/54) causes them to deflect beam (6), causing lateral displacements in the plane of UF focus located in the patient's eye (68). Objective lens (58) may be a complex multi-element lens element, as shown, and represented by lenses (60, 62, and 64). The complexity of the lens (58) will be dictated by the scan field size, the focused spot size, the available working distance on both the proximal and distal sides of objective 58, as well as the amount of aberration control. An f-theta lens 58 of focal length 60 mm generating a spot size of 10 .mu.m, over a field of 10 mm, with an input beam size of 15 mm diameter is an example. Alternatively, X-Y scanning by scanner (50) may be achieved by using one or more moveable optical elements (e.g. lenses, gratings) which also may be controlled by control electronics (300), via input and output device (302).

The aiming and treatment scan patterns can be automatically generated by the scanner (50) under the control

of controller (300). Such patterns may be comprised of a single spot of light, multiple spots of light, a continuous pattern of light, multiple continuous patterns of light, and/or any combination of these. In addition, the aiming pattern (using aim beam 202 described below) need not be identical to the treatment pattern (using light beam 6), but preferably at least defines its boundaries in order to assure that the treatment light is delivered only within the desired target area for patient safety. This may be done, for example, by having the aiming pattern provide an outline of the intended treatment pattern. This way the spatial extent of the treatment pattern may be made known to the user, if not the exact locations of the individual spots themselves, and the scanning thus optimized for speed, efficiency and accuracy. The aiming pattern may also be made to be perceived as blinking in order to further enhance its visibility to the user.

An optional focussing lens (66), which also may be loosely termed a "contact lens", which can be any suitable ophthalmic lens, can be used to help further focus the optical beam (6) into the patient's eye (68) while helping to stabilize eye position. The positioning and character of optical beam 6 and/or the scan pattern the beam 6 forms on the eye (68) may be further controlled by use of an input device such as a joystick, or any other appropriate user input device (e.g. GUI 304) to position the patient and/or the optical system.

The UF laser (4) and controller (300) can be set to target the surfaces of the targeted structures in the eye (68) and ensure that the beam (6) will be focused where appropriate and not unintentionally damage non-targeted tissue. Imaging modalities and techniques described herein, such as for example, Optical Coherence Tomography (OCT), Purkinje imaging,

Scheimpflug imaging, confocal or nonlinear optical microscopy, fluorescence imaging, or ultrasound may be used to determine the location and measure the thickness of the lens and lens capsule to provide greater precision to the laser focusing methods, including 2D and 3D patterning. Laser focusing may also be accomplished using one or more methods including direct observation of an aiming beam, Optical Coherence Tomography ("OCT"), Purkinje imaging, Scheimpflug imaging, confocal or nonlinear optical microscopy, fluorescence imaging, ultrasound, or other known ophthalmic or medical imaging modalities and/or combinations thereof. In the embodiment of Figure 1, an OCT device (100) is described. An OCT scan of the eye will provide information about the axial location of the anterior and posterior lens capsule, the boundaries of the cataract nucleus, as well as the depth of the anterior chamber. This information is then be loaded into the control electronics (300), and used to program and control the subsequent laser-assisted surgical procedure. The information may also be used to determine a wide variety of parameters related to the procedure such as, for example, the upper and lower axial limits of the focal planes used for cutting the lens capsule and segmentation of the lens cortex and nucleus, and the thickness of the lens capsule among others.

The OCT device (100) in Figure 1 includes a broadband or a swept light source (102) that is split by a fiber coupler (104) into a reference arm (106) and a sample arm (110). The reference arm (106) includes a module (108) containing a reference reflection along with suitable dispersion and path length compensation. The sample arm (110) of the OCT device (100) has an output connector (112) that serves as an interface to the rest of the UF laser system. The return signals from both the reference and sample arms (106, 110) are

then directed by coupler (104) to a detection device (128), which employs either time domain, frequency or single point detection techniques. In Figure 1, a frequency domain technique is used with an OCT wavelength of 920 nm and bandwidth of 100 nm. Exiting connector (112), the OCT beam (114) is collimated using lens (116). The size of the collimated beam (114) is determined by the focal length of lens (116). The size of the beam (114) is dictated by the desired NA at the focus in the eye and the magnification of the beam train leading to the eye (68). Generally, OCT beam (114) does not require as high an NA as the UF beam (6) in the focal plane and therefore the OCT beam (114) is smaller in diameter than the UF beam (6) at the beamcombiner (34) location. Following collimating lens (116) is aperture (118) which further modifies the resultant NA of the OCT beam (114) at the eye. The diameter of aperture (118) is chosen to optimize OCT light incident on the target tissue and the strength of the return signal. Polarization control element (120), which may be active or dynamic, is used to compensate for polarization state changes which may be induced by individual differences in corneal birefringence, for example. Mirrors (122 & 124) are then used to direct the OCT beam 114 towards beamcombiners (126 & 34). Mirrors (122 & 124) may be adjustable for alignment purposes and in particular for overlaying of OCT beam (114) to UF beam (6) subsequent to beamcombiner (34). Similarly, beamcombiner (126) is used to combine the OCT beam (114) with the aim beam (202) described below. Once combined with the UF beam (6) subsequent to beamcombiner (34), OCT beam (114) follows the same path as UF beam (6) through the rest of the system. In this way, OCT beam (114) is indicative of the location of UF beam (6). OCT beam (114) passes through the z-scan 40 and x-y scan (50) devices then the objective lens (58), focussing lens (66) and on into

the eye (68). Reflections and scatter off of structures within the eye provide return beams that retrace back through the optical system, into connector (112), through coupler (104), and to OCT detector (128). These return back reflections provide the OCT signals that are in turn interpreted by the system as to the location in X, Y, Z of UF beam (6) focal location.

OCT device (100) works on the principle of measuring differences in optical path length between its reference and sample arms. Therefore, passing the OCT through z-adjust does not extend the z-range of OCT system (100) because the optical path length does not change as a function of movement of 42. OCT system (100) has an inherent z-range that is related to the detection scheme, and in the case of frequency domain detection it is specifically related to the spectrometer and the optical bandwidth of the light source. In the case of OCT system (100) used in Figure 1, the z-range is approximately 3-5 mm in an aqueous environment. Passing the OCT beam (114) in the sample arm through the z-scan of z-adjust (40) allows for optimization of the OCT signal strength. This is accomplished by focusing the OCT beam (114) onto the targeted structure while accommodating the extended optical path length by commensurately increasing the path within the reference arm (106) of OCT system (100).

Because of the fundamental differences in the OCT measurement with respect to the UF focus device due to influences such as immersion index, refraction, and aberration, both chromatic and monochromatic, care must be taken in analyzing the OCT signal with respect to the UF beam focal location. A calibration or registration procedure as a function of X, Y Z should be conducted in order to match the OCT signal information to the UF focus location and also to the relate to absolute dimensional quantities.

Observation of an aim beam may also be used to assist the user to directing the UF laser focus. Additionally, an aim beam visible to the unaided eye in lieu of the infrared OCT and UF beams can be helpful with alignment provided the aim beam accurately represents the infrared beam parameters. An aim subsystem (200) is employed in the configuration shown in Figure 1. The aim beam (202) is generated by an aim beam light source (201), such as a helium-neon laser operating at a wavelength of 633 nm. Alternatively a laser diode in the 630-650 nm range could be used. The advantage of using the helium neon 633 nm beam is its long coherence length, which would enable the use of the aim path as a laser unequal path interferometer (LUPI) to measure the optical quality of the beam train, for example. Once the aim beam light source generates aim beam (202), the aim beam (202) is collimated using lens (204). The size of the collimated beam is determined by the focal length of lens (204). The size of the aim beam (202) is dictated by the desired NA at the focus in the eye and the magnification of the beam train leading to the eye (68). Generally, aim beam (202) should have close to the same NA as UF beam (6) in the focal plane and therefore aim beam (202) is of similar diameter to the UF beam at the beamcombiner (34) location. Because the aim beam is meant to stand-in for the UF beam (6) during system alignment to the target tissue of the eye, much of the aim path mimics the UF path as described previously. The aim beam (202) proceeds through a half-wave plate (206) and linear polarizer (208). The polarization state of the aim beam (202) can be adjusted so that the desired amount of light passes through polarizer (208). Elements 206 & 208 therefore act as a variable attenuator for the aim beam (202). Additionally, the orientation of polarizer (208) determines the incident polarization state incident upon beamcombiners (126 and 34),

thereby fixing the polarization state and allowing for optimization of the beamcombiners' throughput. Of course, if a semiconductor laser is used as aim beam light source (200), the drive current can be varied to adjust the optical power.

5 The aim beam (202) proceeds through a shutter (210) and aperture (212). The system controlled shutter (210) provides on/off control of the aim beam (202). The aperture (212) sets an outer useful diameter for the aim beam (202) and can be adjusted appropriately. A calibration procedure measuring the

10 output of the aim beam (202) at the eye can be used to set the attenuation of aim beam (202) via control of polarizer (206). The aim beam (202) next passes through a beam conditioning device (214). Beam parameters such as beam diameter,

15 divergence, circularity, and astigmatism can be modified using one or more well known beaming conditioning optical elements. In the case of an aim beam (202) emerging from an optical fiber, the beam conditioning device (214) can simply include a beam expanding telescope with two optical elements (216 and

20 218) in order to achieve the intended beam size and collimation. The final factors used to determine the aim beam parameters such as degree of collimation are dictated by what is necessary to match the UF beam (6) and aim beam (202) at the location of the eye (68). Chromatic differences can be taken into account by appropriate adjustments of beam

25 conditioning device (214). In addition, the optical system (214) is used to image aperture (212) to a desired location such as a conjugate location of aperture (14). The aim beam (202) next reflects off of fold mirrors (222 & 220), which are preferably adjustable for alignment registration to UF beam

30 (6) subsequent to beam combiner (34). The aim beam (202) is then incident upon beam combiner (126) where the aim beam (202) is combined with OCT beam (114). Beamcombiner (126) reflects the aim beam (202) and transmits the OCT beam (114),

which allows for efficient operation of the beamcombining functions at both wavelength ranges. Alternatively, the transmit and reflect functions of beamcombiner (126) can be reversed and the configuration inverted. Subsequent to
5 beamcombiner (126), aim beam (202) along with OCT beam (114) is combined with UF beam (6) by beamcombiner (34).

A device for imaging the target tissue on or within the eye (68) is shown schematically in Figure 1 as imaging system (71). Imaging system includes a camera (74) and an
10 illumination light source (86) for creating an image of the target tissue. The imaging system (71) gathers images which may be used by the system controller (300) for providing pattern centering about or within a predefined structure. The illumination light source (86) for the viewing is generally
15 broadband and incoherent. For example, light source (86) can include multiple LEDs as shown. The wavelength of the viewing light source (86) is preferably in the range of 700 nm to 750 nm, but can be anything which is accommodated by the beamcombiner (56), which combines the viewing light with the
20 beam path for UF beam (6) and aim beam (202) (beamcombiner 56 reflects the viewing wavelengths while transmitting the OCT and UF wavelengths). The beamcombiner (56) may partially transmit the aim wavelength so that the aim beam (202) can be visible to the viewing camera (74). Optional polarization
25 element (84) in front of light source (86) can be a linear polarizer, a quarter wave plate, a half-wave plate or any combination, and is used to optimize signal. A false color image as generated by the near infrared wavelength is acceptable. The illumination light from light source (86) is
30 directed down towards the eye using the same objective lens (58) and focussing lens (66) as the UF and aim beam (6, 202). The light reflected and scattered off of various structures in the eye (68) are collected by the same lenses (58 & 66) and

directed back towards beamcombiner (56). There, the return light is directed back into the viewing path via beam combiner and mirror (82), and on to camera (74). Camera (74) can be, for example but not limited to, any silicon based detector array of the appropriately sized format. Video lens (76) forms an image onto the camera's detector array while optical elements (80 & 78) provide polarization control and wavelength filtering respectively. Aperture or iris (81) provides control of imaging NA and therefore depth of focus and depth of field.

5 A small aperture provides the advantage of large depth of field which aids in the patient docking procedure. Alternatively, the illumination and camera paths can be switched. Furthermore, aim light source (200) can be made to emit in the infrared which would not directly visible, but

15 could be captured and displayed using imaging system (71). Coarse adjust registration is usually needed so that when the focussing lens (66) comes into contact with the cornea, the targeted structures are in the capture range of the X, Y scan of the system. Therefore a docking procedure is preferred,

20 which preferably takes in account patient motion as the system approaches the contact condition (i.e. contact between the patient's eye (68) and the focussing lens (66)). The viewing system (71) is configured so that the depth of focus is large enough such that the patient's eye (68) and other salient

25 features may be seen before the focussing lens (66) makes contact with eye (68). Preferably, a motion control system (70) is integrated into the overall control system (2), and may move the patient, the system (2) or elements thereof, or both, to achieve accurate and reliable contact between the

30 focussing, or "contact", lens (66), the housing thereof, and/or the eye (68). Furthermore, as described below, vacuum suction subsystem and flange may be incorporated into the system and used to stabilize the interfacing between the

focusing lens (66), pertinent housing thereof, and the eye (68). In one embodiment the physical alignment of the eye (68) relative to other portions of the system (2) via the focussing lens (66) may be accomplished while monitoring the output of the imaging system (71), and performed manually or automatically by analyzing the images produced by imaging system (71) electronically by means of control electronics (300) via IO (302). Force and/or pressure sensor feedback may also be used to discern contact, as well as to initiate the vacuum subsystem.

Figure 2A depicts one embodiment of a focussing lens (66) configuration wherein the distal aspect (178) of the lens (66) is placed into direct contact with the cornea (94). The scanned beam (90) exiting the system (88) crosses the proximal surface (176) of the lens (66), passes through the lens (66), exits across the distal surface (178) of the lens (66), crosses the cornea (94), and eventually reaches the crystalline lens (69) to facilitate interventional steps such as capsulorhexis. A close-up view is illustrated in Figure 2B, to demonstrate the notion of undesirable corneal folds (96), which may be associated with excess applanation loads placed upon the cornea with contact lens (66) configurations having a relatively large radii of curvature relative to that of the cornea (in such cases, relatively large applanation loads may be applied to ensure surface contact between the lens 66 and the relatively convex shape of the cornea 94). We have found that corneal folds (96) can degrade the optical path to the interior of the eye, reducing the reliability of laser interaction with the tissue of the eye. Further, it is also generally desirable to minimize intraocular pressure during diagnostic and interventional procedures, and large applanation loads tend to increase intraocular pressure. As a result, in the embodiments depicted in Figures 3A-3C and 4A-

4E, comprise focusing lenses (66) with distal surface radii of curvature that are substantially close to that of the typical human cornea, thus substantially mitigating applanation and/or interfacing loads, as described in further detail below.

5 Referring to Figure 2C, one embodiment of a patient interface (182), which may be referred to as a "one-piece" interface, is shown interfaced with a movable portion (160) of a diagnostic and interventional system such as that described in reference to Figure 1, the patient interface (182)
10 comprising a corneal interface (130), a conical lower housing portion (132) which houses a focusing lens (66), and a cylindrical upper housing portion (134) with a proximal aspect configured to mechanically interface and couple with the movable portion (160) of the diagnostic and interventional
15 system. Figure 3A illustrates a similar configuration, with the patient interface (182) removably coupled to the movable portion (160) of a diagnostic and interventional system. Figure 3B shows a closer up orthogonal view of a patient interface (182) such as that depicted in Figures 2C and 3A.
20 The proximal aspect of the cylindrical upper housing portion (134) forms a geometric coupling interface (136) configured for removable coupling with the movable portion (160) of a diagnostic and interventional system. Figure 3C illustrates a cross sectional view of the embodiment of Figure 3B to show
25 the position of the focusing lens (66) within the conical lower housing portion (132) as well as the direct interfacing of the distal surface (140) of the lens (66) with the cornea (94), and the cross sectional features of the flexible (in one embodiment comprising a flexible material such as silicone)
30 cornea interface (130), including a cross-sectionally bi-lobed contact surface (142) that creates a vacuum channel (142) between the two lobes which may be utilized to removably couple the cornea interface (130) to the surface of the cornea

(94) with an applied vacuum condition such as between about 300 and 600 mm of mercury. In one embodiment, the distal surface (140) of the lens (66) has a radius of curvature equal to about 8.3mm, which is slightly larger than that of the average human cornea (94), to provide an engagement configuration wherein the distal surface (140) may be slowly engaged with the cornea at approximately the center of the distal surface (140), and then with increased engagement and very slight applanating loads, bubbles and fluids squeezed outward from the center of contact, ultimately resulting in a relatively clean interfacing for diagnostic and interventional purposes. The shape of the cornea in the depiction of Figure 3C is the unloaded (un-applanated) shape, to illustrate that there is an intentional mismatch between the distal surface (140) and the unloaded corneal (94) shape in the depicted embodiment (in an actual loaded scenario, the surfaces would directly meet, as described above).

Referring to Figures 4A-4E, another embodiment (may be referred to as a "two-piece" embodiment) is depicted, wherein a configuration such as that shown in Figures 2C-3C may be deconstructed or decoupled to provide for convenient hand-manipulated placement (i.e., through the use of a lightweight handle 150) of the bottom portion (148) before subsequent coupling with the top portion (152) and movable portion (160) of a diagnostic and interventional system. Together, the top and bottom portions (152, 148) may comprise a "hollow reservoir housing" which defines an interior volume and is configured to be interfaced to the eye as described herein. The top and bottom portions may be removably coupled to each other using a vacuum coupling interface, an interference fit (i.e., press fit) interface, an electromagnetic coupling interface (i.e., wherein a current is applied to enforce a junction, and the current may be turned off to release the

junction), a manually-actuated mechanical interface (i.e., wherein a latch or fitting may be manually actuated or moved to enforce a locking or unlocking of the interface), or an electromechanically-actuated mechanical interface (i.e.,

5 wherein a latch or fitting may be electromechanically actuated or moved, such as by a solenoid or other actuator, to enforce a locking or unlocking of the interface). Referring to Figure 4A, a patient's face (146) and eye (68) are shown with a bottom portion (148) coupled to the cornea and/or sclera of

10 eye (68) using vacuum loads applied using a vacuum port (154) to bring a flexible interface such as those shown in Figures 2C-3C into releasable engagement with the cornea and/or sclera. The lower portion shown in Figure 4A has relatively low mass and low moment of inertia, and may be manipulated

15 easily by hand into a desired position, after which vacuum may be applied through the port (154) to create the temporary engagement. Subsequently, the top portion (152) may be coupled to the bottom portion (148) with a mechanical interfacing (156) that may comprise a slight interference fit

20 (i.e., such as a snap fit), to form an assembled two-part patient interface (184) which may be coupled to a movable portion (160) of a diagnostic and interventional system, as described above. Figures 4C and 4D depict another interfacing embodiment wherein a spring clamp (158) may be utilized to

25 removably couple the bottom portion (148) and top portion (152). Figure 4D is a cross sectional view of the embodiment of Figure 4C. Figure 4E depicts another interfacing embodiment wherein a rotatable collet type coupling member (162) may be utilized to removably couple the bottom portion

30 (148) and top portion (152), by hand-manipulated rotation of the coupling member (162) relative to the bottom portion (148).

Figures 5A-5C depict another two-part patient interface (186) embodiment (this embodiment may be referred to as a liquid interface two-part embodiment), comprising an optical element such as a focusing lens element (92) similar to those described above (element 66) with the exception that the distal surface (178) of the focusing lens element (92) does not come into direct contact with the surface of the cornea (94) and/or sclera - rather, there is a liquid layer (172) interposed between the distal surface (178) of the focusing lens element (92) and the cornea (94) and/or sclera. The optical element (92) may have proximal and distal surfaces, and the distal surface may be a convex surface. In one embodiment, the distal surface of the optical element (92) is directly interfaced (i.e., submerged or directly exposed to) with the liquid layer, leaving the liquid layer as the unifying connection between the eye and the optical element (92). In one embodiment the liquid layer may comprise about 2 cubic centimeters of liquid. The liquid may comprise a material such as water, saline, oil (such as silicon oil), ophthalmic viscoelastic gel, or perfluorocarbon liquid. In the depicted two-part embodiment, the optical element (92) is fixedly coupled to the top, or proximal, portion (152) of the patient interface; in another embodiment, the optical element (92) may be fixedly coupled to the bottom, or distal, portion (148) of the patient interface. As shown in Figure 5A, a conical bottom portion (160) is coupled to a flexible interface (130) similar to those described above in reference to the one-part and two-part patient interface configurations. As with the aforementioned embodiments, the flexible interface (130) may comprise a compliant circumferential seal member which may comprise two or more circumferential layers with a vacuum space interposed therebetween to facilitate vacuum-enforced coupling of the seal member against the tissue of the

eye (using, for example, a vacuum load between about 200mm mercury and about 600mm mercury, which may be applied or generated using a vacuum device such as a regulated mechanical vacuum pump). At least one of the circumferential layers may have a cross sectional shape that is tapered (i.e., with the smaller portion of the taper more immediately adjacent the eye tissue), and at least one of the circumferential layers may comprise a shape that is at least partially spherical (i.e., akin to a slice of a spherical shape). A manual manipulation handle is coupled to the bottom portion (160) to allow for easy coupling of the relatively low mass and inertia bottom portion (160) to the cornea and/or sclera (for example, with coupling retention provided by vacuum through the vacuum port 154) before interfacial (168) engagement of the bottom portion to the top portion (166), which is configured to be removably coupled to a movable portion (160) of a diagnostic and interventional system such as that described in reference to Figure 1 (for example, using a mechanical coupling interface, vacuum, or other removable coupling means). As shown in Figures 5A-5C, the interfacial engagement (168) preferably is configured such that the liquid layer (172) is open to the external environment (i.e., to the atmospheric pressure configuration of the patient examination or operating room) such that additional fluid may be added by direct pour or syringe (i.e., through one of the depicted access features 165); similarly, liquid may be poured out of the un-encapsulated environment by changing the orientation of the patient and/or patient interface relative to gravity and pouring the liquid out (i.e., through one of the depicted access features 165). The access features (165) may comprise one or more vents, ports, windows, or the like which provide direct access between the volume defined for the liquid layer (172) and the nearby atmosphere. Such a configuration, which

may be deemed an "open configuration" (as opposed to a closed or encapsulated configuration wherein a volume of liquid may be at least temporarily encapsulated within a tank or other structure) wherein the liquid layer (172) has immediate access to the outside environment, is advantageous for several reasons: a) open allows immediate access to the fluid pooled in the patient interface as a liquid layer - which allows for easier filling, refilling, and draining; b) open allows for fluid to escape when coupling a two-part design; without such easy escape, unwanted interfacial pressures may be built up and/or accumulated; c) open allows for gas to more easily escape, and gas typically manifests itself in the liquid layer environment as bubbles, which suboptimally change the optical scenario (i.e., they distort the treatment beam fidelity, and may cause opacities or other unwanted optical distortions).

Figures 5B and 5C show two slightly different cross sectional views of the embodiment of Figure 5A. Referring to Figure 5B, a liquid layer (172) is shown interposed between the distal surface (178) of the focusing lens (92) and the cornea (94) and/or sclera, which are not in physical contact with each other. The liquid layer (172) acts as a light-transmissive medium. In the depicted embodiment, the liquid layer freely floats in the bottom portion 164 before interfacial (168) coupling of the bottom portion (164) and top portion (166) (i.e., the liquid layer 172 rests due to gravity in the bottom of the bottom portion 164 after the bottom portion 164 has been coupled to the cornea 94 and/or sclera using the bi-lobed lip portion 144, which may be fed vacuum through the vacuum channels 170 which are connected to the vacuum port 154 shown in Figure 5C). In one embodiment, the outer diameter of the bi-lobed flexible seals (144) is about 21mm, and the inner diameter is about 14.5mm, leaving about 14mm of clear aperture available for a broad range of interventional laser cutting,

including but not limited to corneal incisions such as limbal relaxation cuts, etc. One additional benefit of the liquid interface is that the optical characteristics of the lens element (92) may be optimized without as much regard to the anatomical fit of the proximal and distal face radii of curvature as with the direct-contact style lens elements (for example, element 66 above). Further, there is greater freedom of materials selection for the focusing lens (92). In one embodiment, the focusing lens (92) comprises an approximately 13mm thick piece of material commercially available under the tradename "BK-7" (RTM) from Schott North America, Inc. of Elmsford, NY, the lens (92) having an approximately 245mm convex proximal surface radius of curvature, and an approximately 68mm convex proximal surface radius of curvature. Additionally, the displacement of the lens (92) away from the cornea (94) and/or sclera better facilitates anterior corneal and/or scleral surface cutting via laser without lens particle contamination. OCT imaging, as available, for example, in the system described in reference to Figure 1, may be utilized to confirm the dimensions of the fluid gap between the cornea (94) and/or sclera and the focusing element (92). In one embodiment the liquid or fluid layer (172) comprises saline. In other embodiments, liquids may be specified with customized dispersive, refractive, bubble resisting, and other qualities.

In another embodiment, the two main temporarily or removably coupleable portions of the patient interface structure (148, 152) may be more permanently coupled (i.e., either before the procedure, or during manufacturing of the parts wherein they be fixedly coupled to each other or formed together as one construct), in the form of a "one-piece" liquid-facilitated patient interface, with features identical to those described above in reference to Figures 4A-

5C, but without the decouplable interface between such portions (148, 152).

Referring to Figures 6A-6D, various implementation embodiments utilizing configurations such as those described above are illustrated. Referring to Figure 6A, subsequent to preoperative diagnostics and patient preparation steps (320), a patient may be positioned in a substantially horizontal position for patient interface docking (322) (i.e., due to the desire to not fight gravity when using a one or two part embodiment; further, in a liquid interface two part embodiment, it is obviously desirable to not have the liquid spill out of the bottom portion). With the patient interface coupled to a movable portion of the system (324) (i.e., by a mechanical interface coupling, vacuum coupling, etc), the movable portion may be utilized to move the patient interface into a desirable interfacing position relative to the patient's cornea and/or sclera (326), where the patient interface may be removably coupled to the cornea and/or sclera (for example, using vacuum, or mechanical load or pressure to create a liquid-tight seal which may also serve to stabilize the eye) (328). With the docking completed, the procedure may be conducted along with intraoperative imaging (330). After completing the procedure, the patient interface may be decoupled (i.e., by releasing the vacuum) from the cornea and/or sclera (332).

Referring to Figure 6B, another embodiment is depicted wherein the first two and last two steps are the same as in the embodiment of Figure 5A, and the intermediate steps comprise providing a two-piece patient interface configuration that is removably couplable to the eye, to itself (i.e., the two pieces), and proximally to the system (334), removably coupling the bottom portion to the cornea and/or sclera (336), moving the system into a position whereby the top portion,

when coupled to the bottom portion, may be easily coupled to the system (338), and coupling the top portion to the system (340).

Referring to Figure 6C, an embodiment is depicted that is similar to that of Figure 6B, with the addition of an
5 intermediary step 342 (i.e., to accommodate a liquid interface two-part patient interface configuration) of adding liquid (i.e., by pouring it in, injecting it in with a syringe, etc) to the bottom portion after the bottom portion is coupled to
10 the cornea and/or sclera. Figure 6D illustrates an embodiment similar to that of Figure 6C, with the exception that the liquid layer may be added (342) before the bottom portion is fully coupled to the cornea and/or sclera (336). Such a configuration may lead to some leakage of fluid between the
15 bottom portion and the cornea and/or sclera and subsequently into the vacuum system.

Various exemplary embodiments of the invention are described herein. Reference is made to these examples in a non-limiting sense. They are provided to illustrate more
20 broadly applicable embodiments of the invention.

Any of the devices described for carrying out the subject diagnostic or interventional procedures may be provided in packaged combination for use in executing such interventions. These supply "kits" may further include instructions for use
25 and be packaged in sterile trays or containers as commonly employed for such purposes.

The invention includes methods that may be performed using the subject devices. The methods may comprise the act of providing such a suitable device. Such provision may be
30 performed by the end user. In other words, the "providing" act merely requires the end user obtain, access, approach, position, set-up, activate, power-up or otherwise act to provide the requisite device in the subject method. Methods

recited herein may be carried out in any order of the recited events which is logically possible, as well as in the recited order of events.

Exemplary embodiments of the invention, together with
5 details regarding material selection and manufacture have been set forth above. As for other details of the invention, these may be appreciated in connection with the above-referenced patents and publications. For example, one or more lubricious coatings (e.g., hydrophilic polymers such as
10 polyvinylpyrrolidone-based compositions, fluoropolymers such as tetrafluoroethylene, hydrophilic gel or silicones) may be used in connection with various portions of the devices, such as relatively large interfacial surfaces of movably coupled parts, if desired, for example, to facilitate low friction
15 manipulation or advancement of such objects relative to other portions of the instrumentation or nearby tissue structures. The same may hold true with respect to method-based embodiments of the invention in terms of additional acts as commonly or logically employed.

20 In addition, though the invention has been described in reference to several examples optionally incorporating various features, the invention is not to be limited to that which is described or indicated as contemplated with respect to each variation of the invention. Various changes may be made to the
25 invention described and equivalents (whether recited herein or not included for the sake of some brevity) may be substituted. In addition, where a range of values is provided, it is understood that every intervening value, between the upper and lower limit of that range and any other stated or intervening
30 value in that stated range, is encompassed within the invention.

Also, it is contemplated that any optional feature of the inventive variations described may be set forth and claimed

independently, or in combination with any one or more of the features described herein. Reference to a singular item, includes the possibility that there are plural of the same items present. More specifically, as used herein and in claims associated hereto, the singular forms "a," "an," "said," and "the" include plural referents unless the specifically stated otherwise. In other words, use of the articles allow for "at least one" of the subject item in the description above as well as claims associated with this disclosure. It is further noted that such claims may be drafted to exclude any optional element. As such, this statement is intended to serve as antecedent basis for use of such exclusive terminology as "solely," "only" and the like in connection with the recitation of claim elements, or use of a "negative" limitation.

Without the use of such exclusive terminology, the term "comprising" in claims associated with this disclosure shall allow for the inclusion of any additional element--irrespective of whether a given number of elements are enumerated in such claims, or the addition of a feature could be regarded as transforming the nature of an element set forth in such claims. Except as specifically defined herein, all technical and scientific terms used herein are to be given as broad a commonly understood meaning as possible while maintaining claim validity.

CLAIMS

1. A system for intercoupling an ophthalmologic
5 interventional system to an eye of a patient, comprising:
- a. a hollow reservoir housing defining an interior volume
and having proximal and distal ends, wherein the distal end
comprises a eye interface surface configured to be removably
and sealably coupled to the eye of the patient, and wherein
10 the proximal end is configured to be mechanically interfaced
with the interventional system in a manner that allows for
open access to the interior volume for transporting liquids or
gases in or out of the interior volume;
- b. an optical element fixedly coupled to the hollow
15 reservoir housing and occupying a portion of the interior
volume; and
- c. a liquid layer formed within the interior volume of the
reservoir housing and positioned, via one or more loads that
include gravitational loads, between the optical element and
20 the eye.
2. The system of claim 1, wherein the hollow reservoir
housing comprises two parts that may be removably coupled to
each other.
- 25
3. The system of claim 2, wherein the two parts are
removably coupled to each other using a configuration selected
from the group consisting of: a vacuum coupling interface,
an interference fit interface, an electromagnetic coupling

interface, a manually-actuated mechanical interface, and an electromechanically-actuated mechanical interface.

4. The system of claim 1, wherein the optical element
5 comprises a lens having proximal and distal surfaces.
5. The system of claim 4, wherein the distal surface of the lens is a convex surface.
- 10 6. The system of claim 1, wherein the eye interface surface comprises a compliant circumferential seal member.
7. The system of claim 6, wherein the seal member comprises two circumferential layers with a vacuum space interposed
15 between the two layers.
8. The system of claim 7, further comprising a vacuum loading device configured to apply a vacuum load into the vacuum space.
- 20
9. The system of claim 7, wherein at least one of the circumferential layers has a tapered cross section.
10. The system of claim 6, wherein at least one of the
25 circumferential layers comprises a shape that is at least partially spherical.

11. The system of claim 1, wherein the liquid layer comprises about 2 cubic centimeters in volume.

12. The system of claim 1, wherein the liquid layer comprises
5 a material selected from: water, saline, oil, viscoelastic gel, and perfluorocarbon liquid.

13. The system of claim 8, wherein the vacuum loading device
10 is configured to apply a vacuum load of between about 200mm of mercury and about 600mm of mercury.

14. The system of claim 2, wherein the hollow reservoir housing comprises a proximal part and a distal part, and wherein the optical element is fixedly coupled to the distal
15 part.

15. The system of claim 2, wherein the hollow reservoir housing comprises a proximal part and a distal part, and wherein the optical element is fixedly coupled to the proximal
20 part.

16. The system of claim 1, wherein the liquid layer is in immediate contact with the optical element.

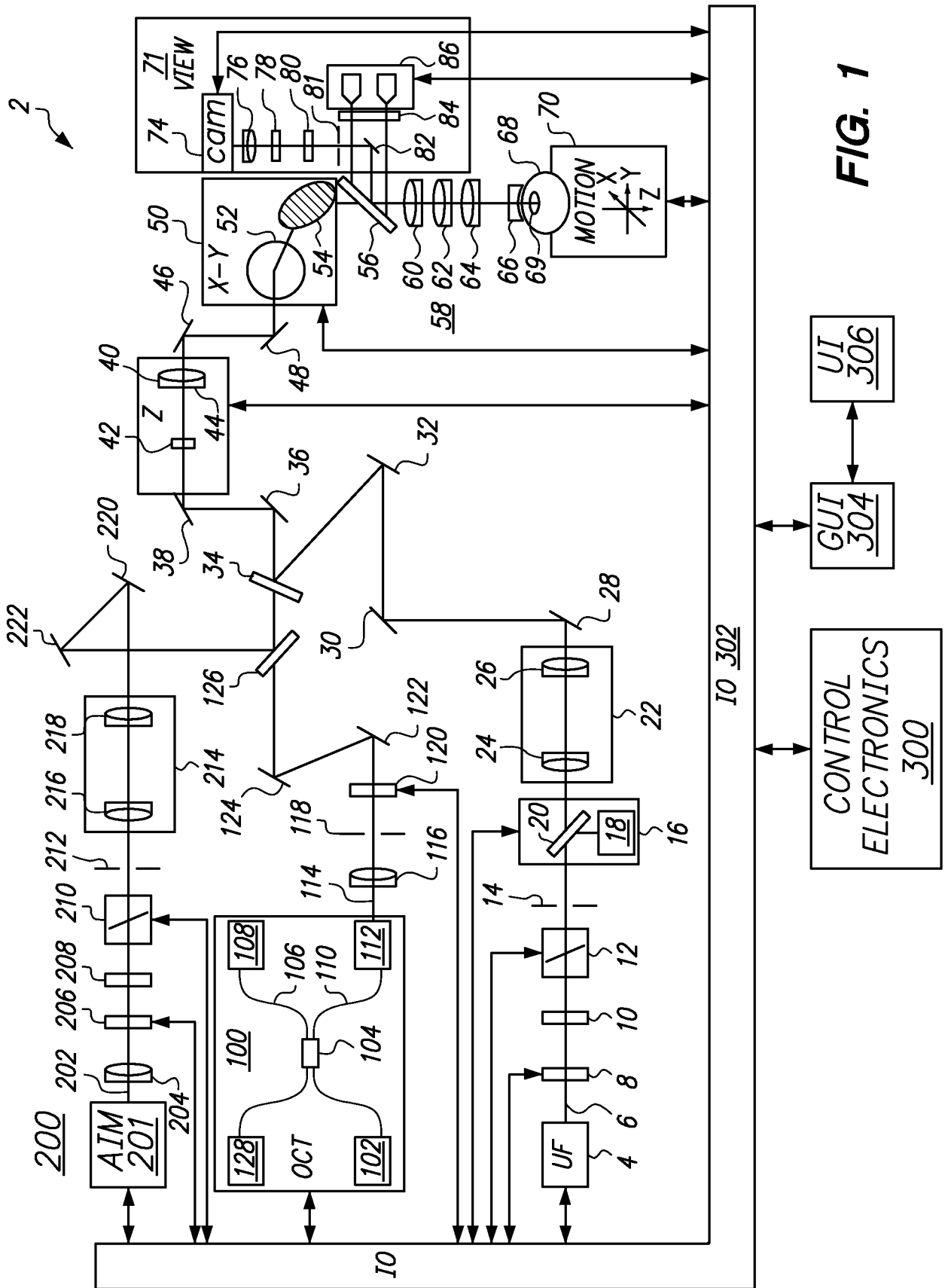


FIG. 1

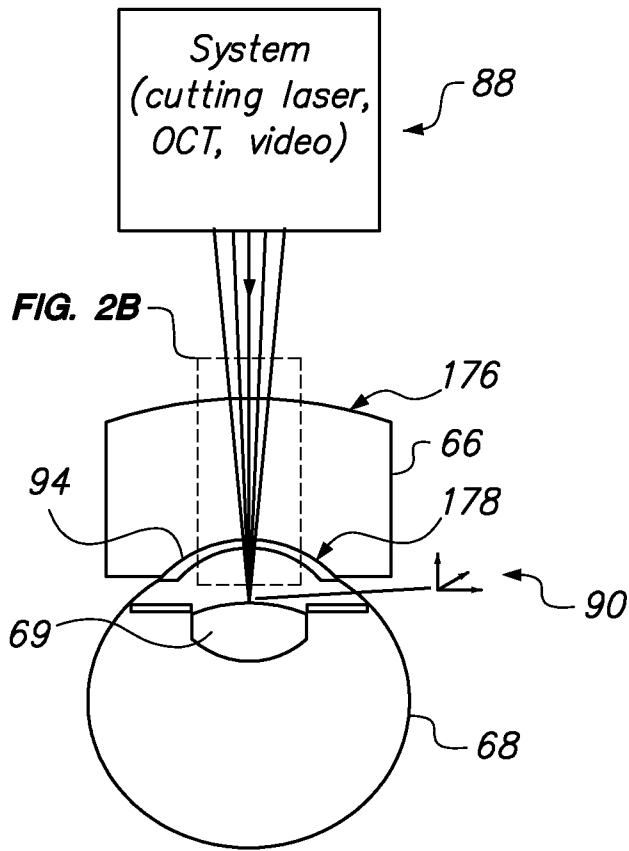


FIG. 2A

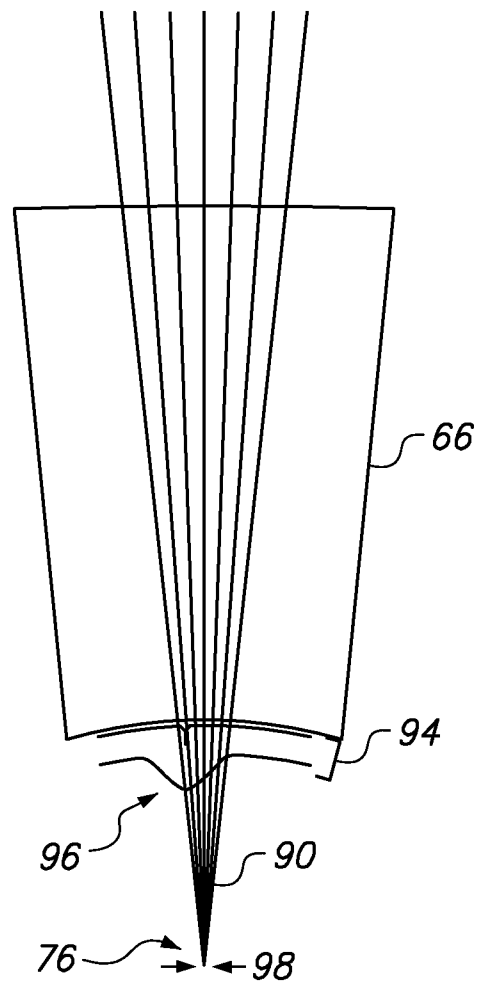


FIG. 2B

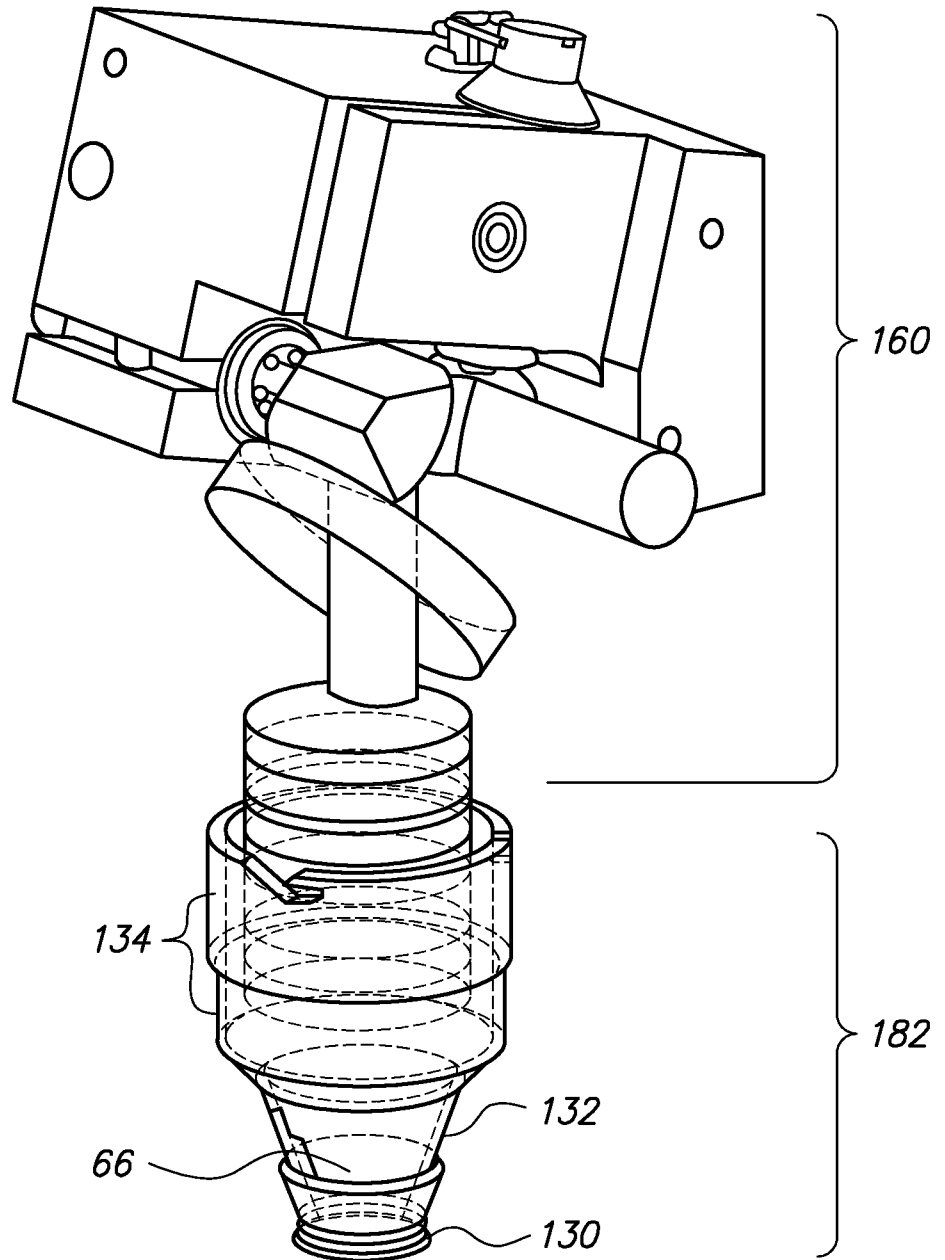


FIG. 2C

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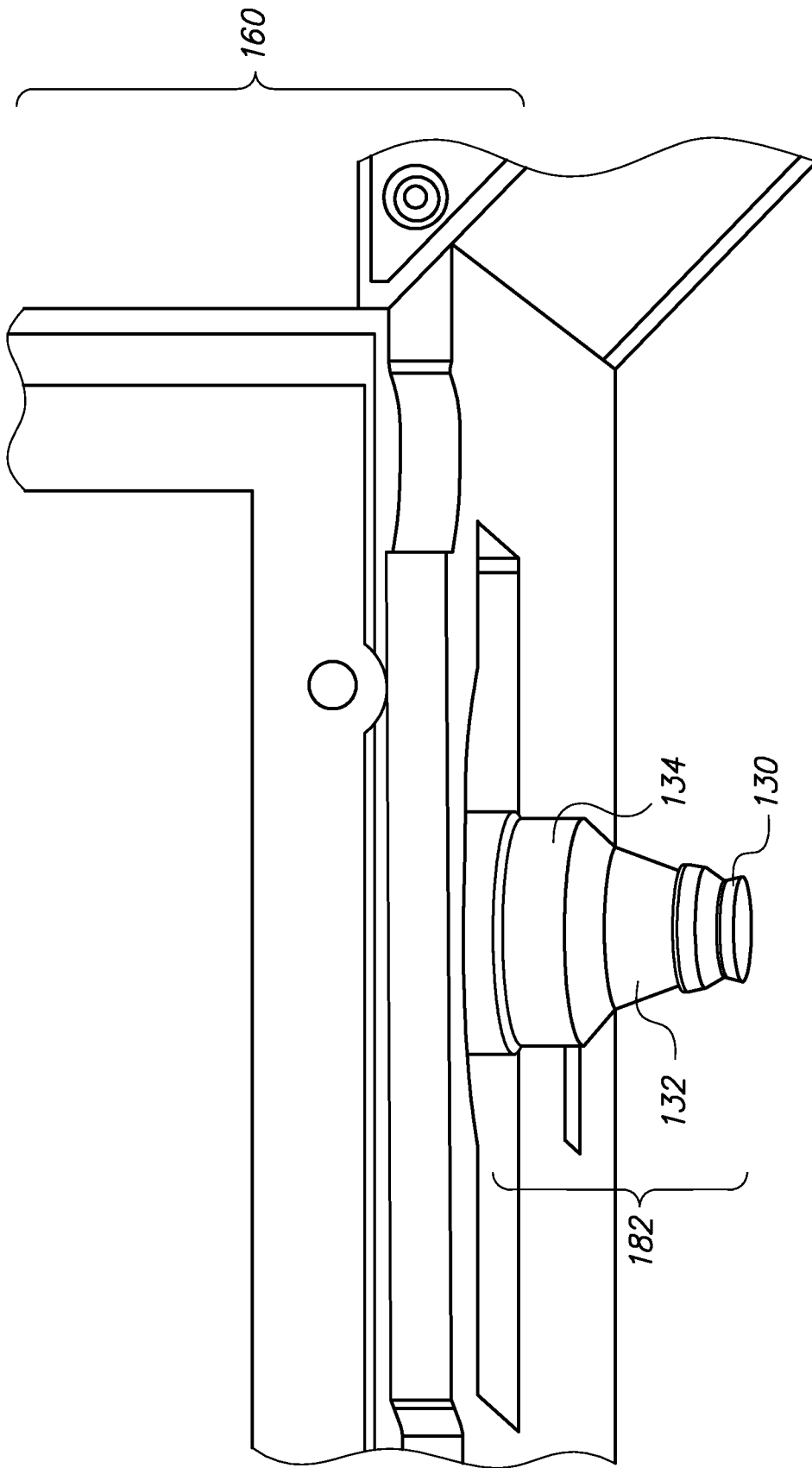


FIG. 3A

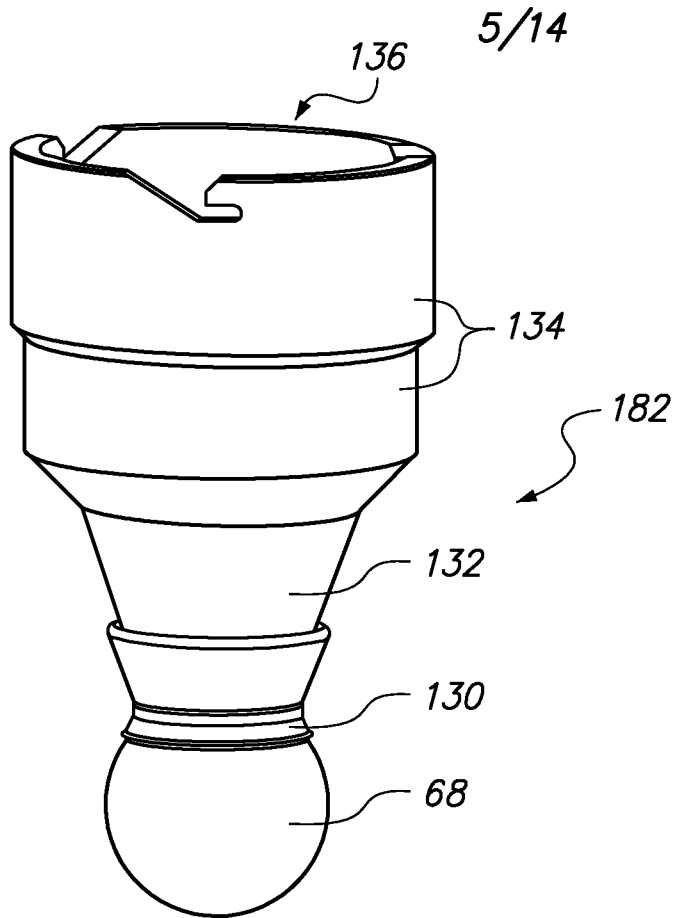


FIG. 3B

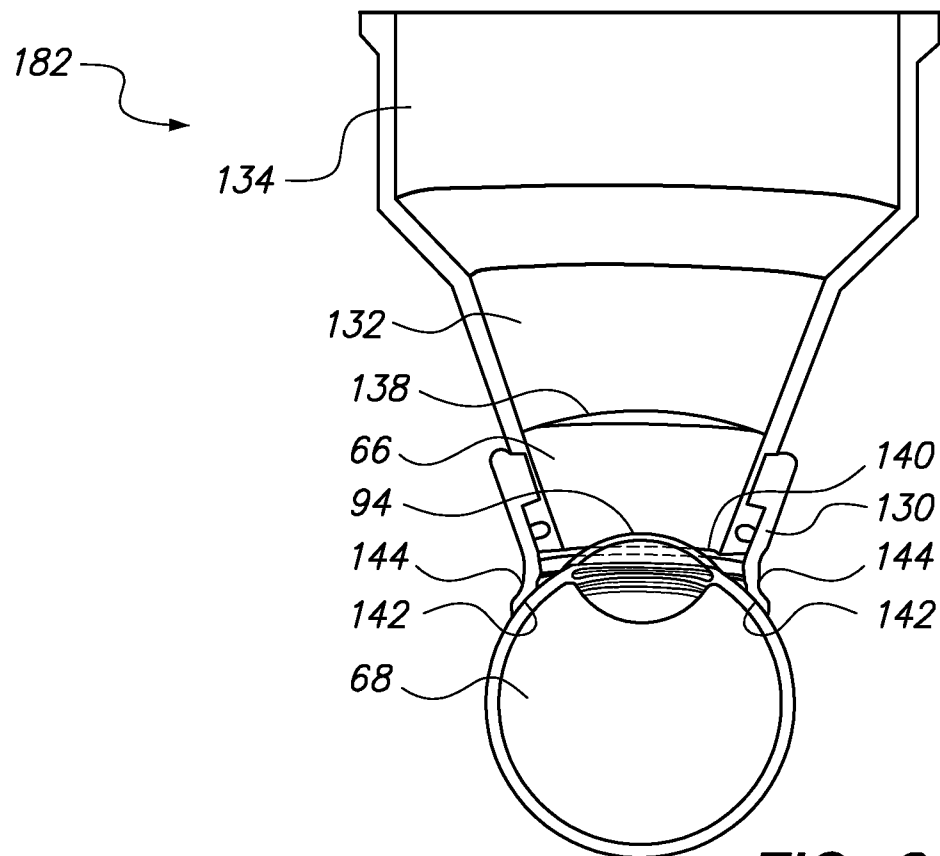


FIG. 3C

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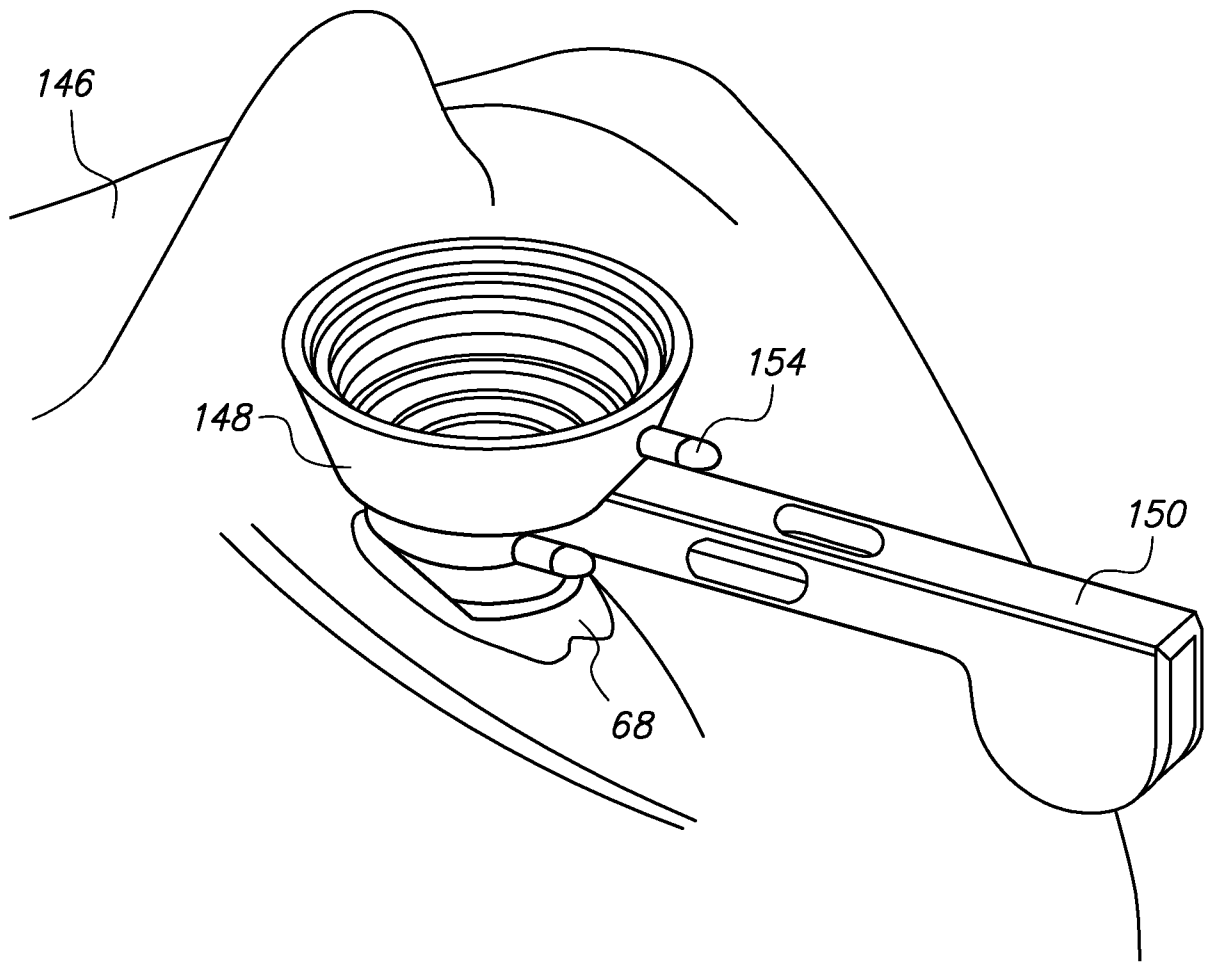


FIG. 4A

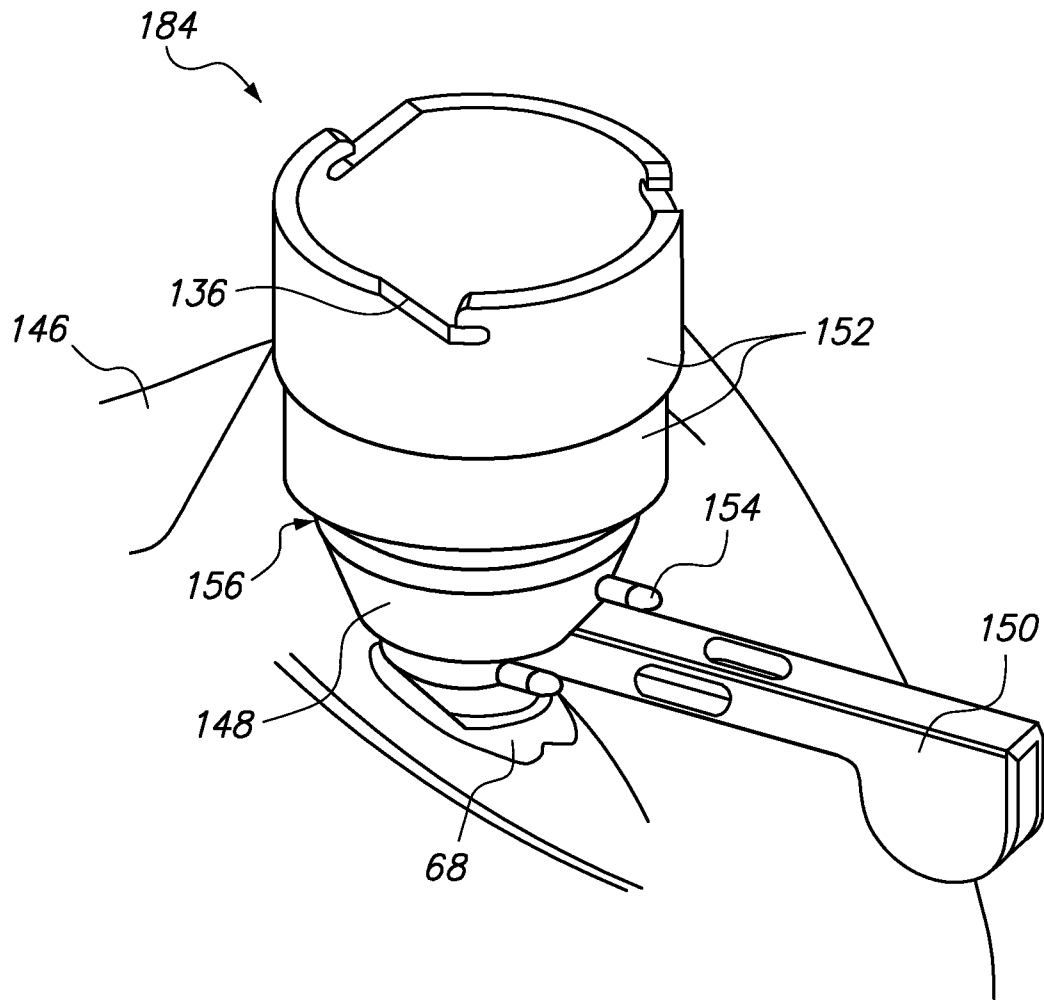


FIG. 4B

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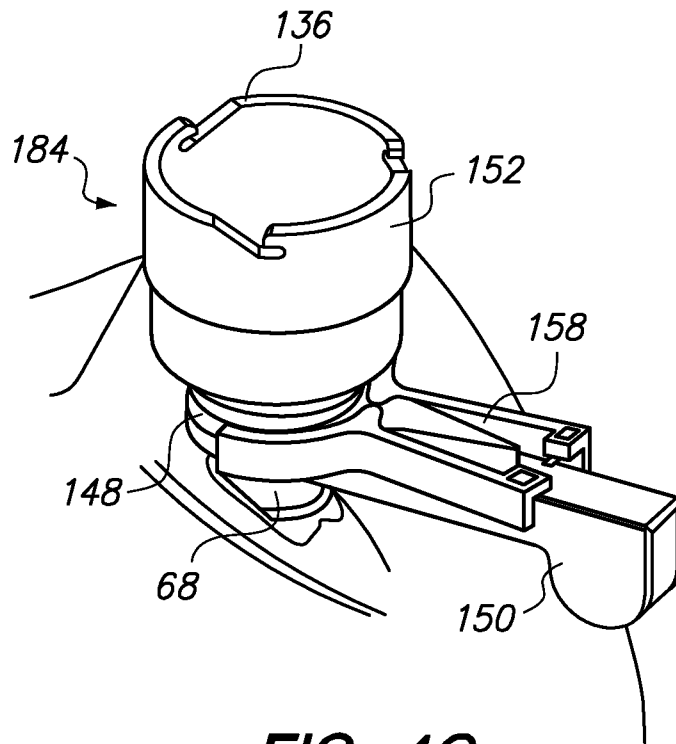


FIG. 4C

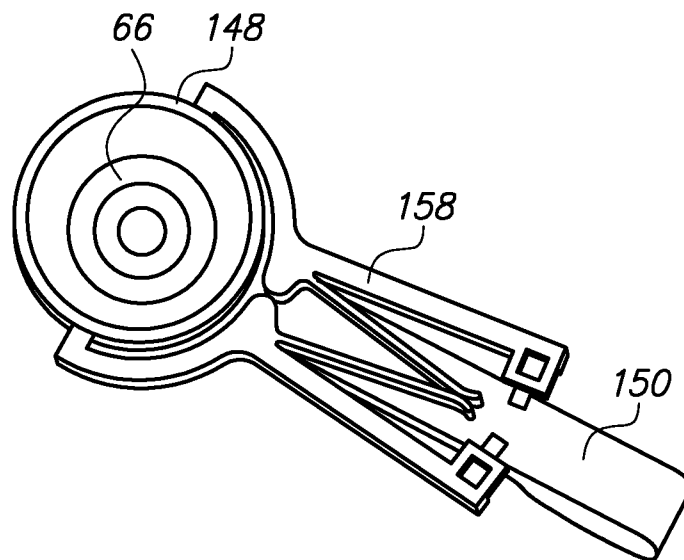
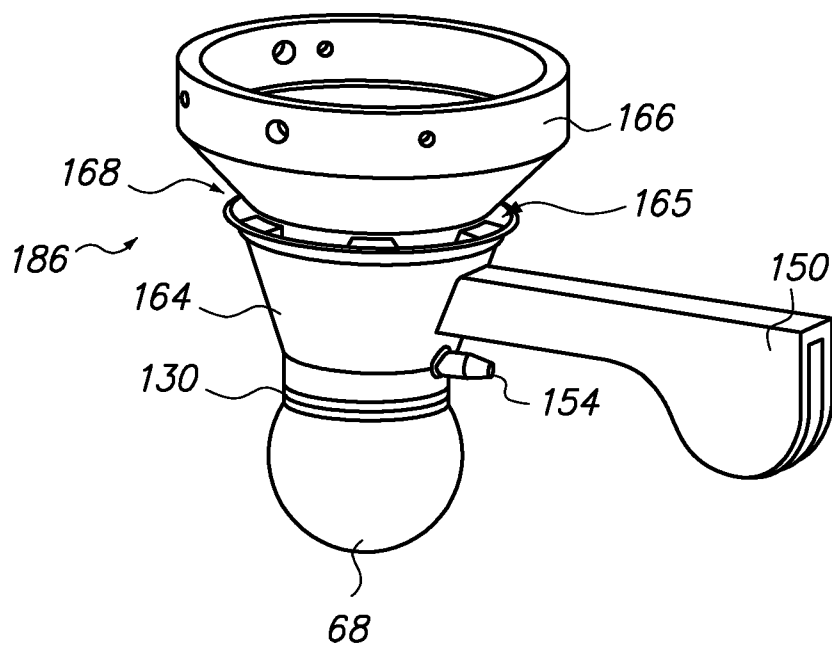
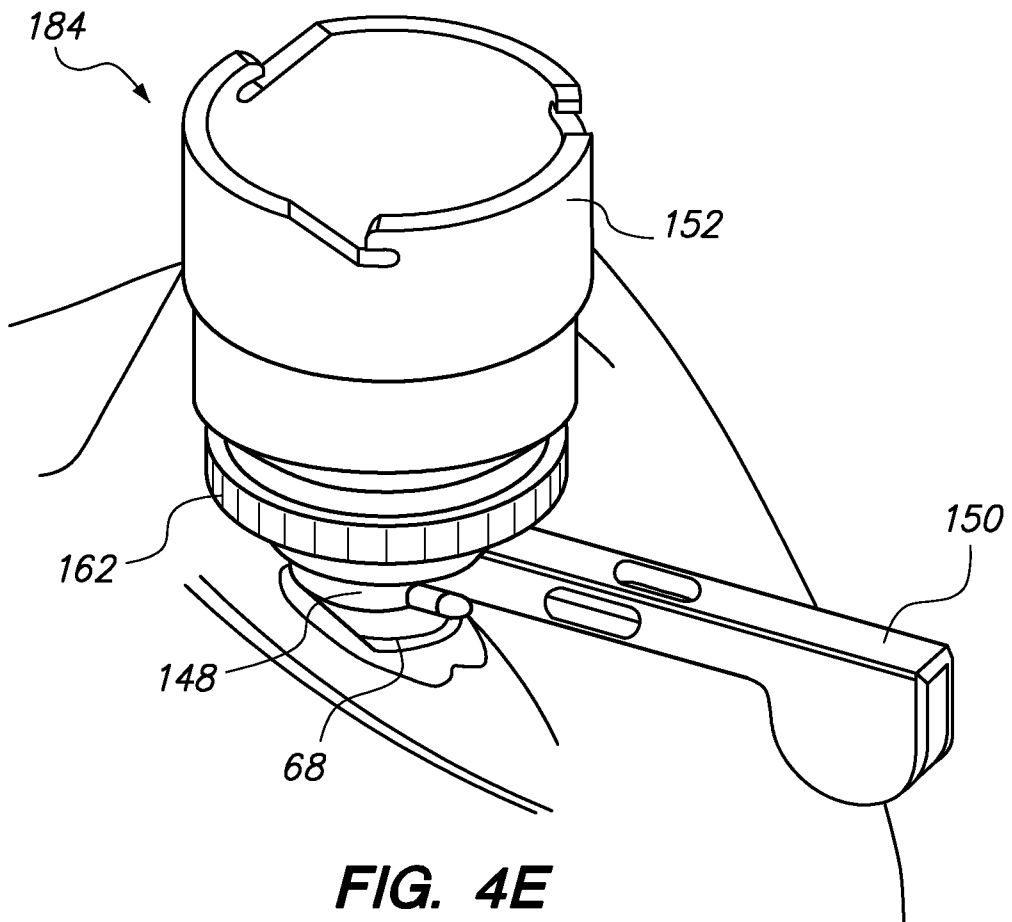


FIG. 4D

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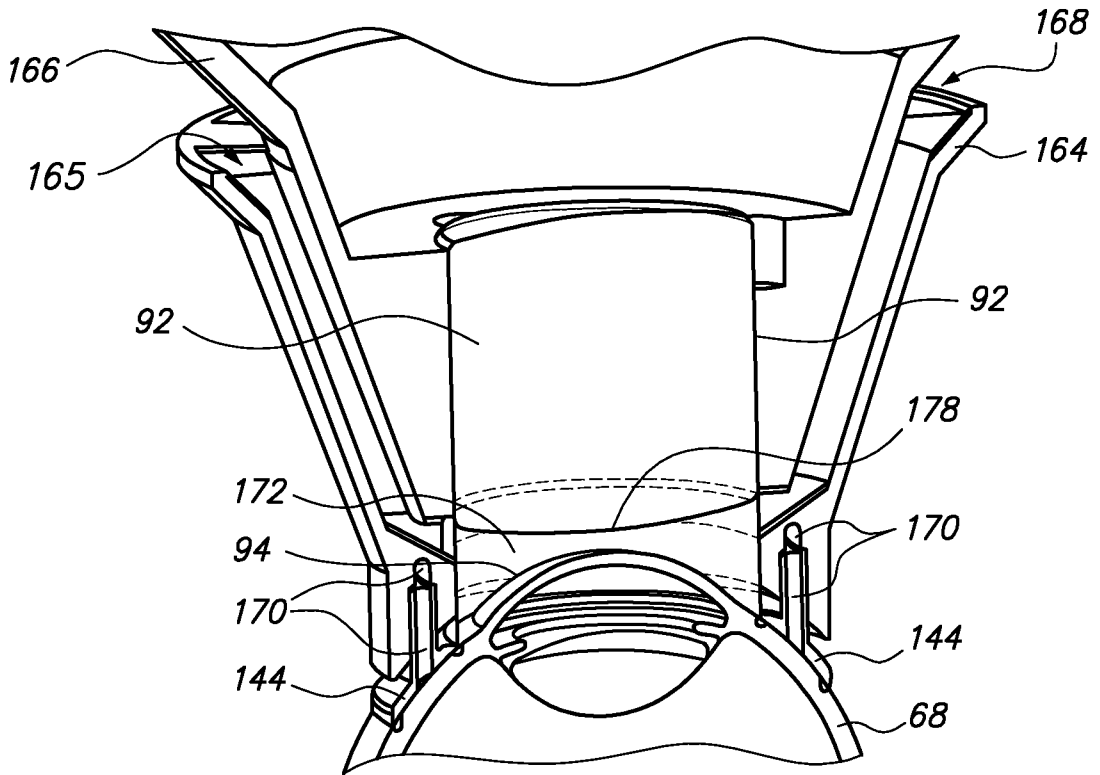


FIG. 5B

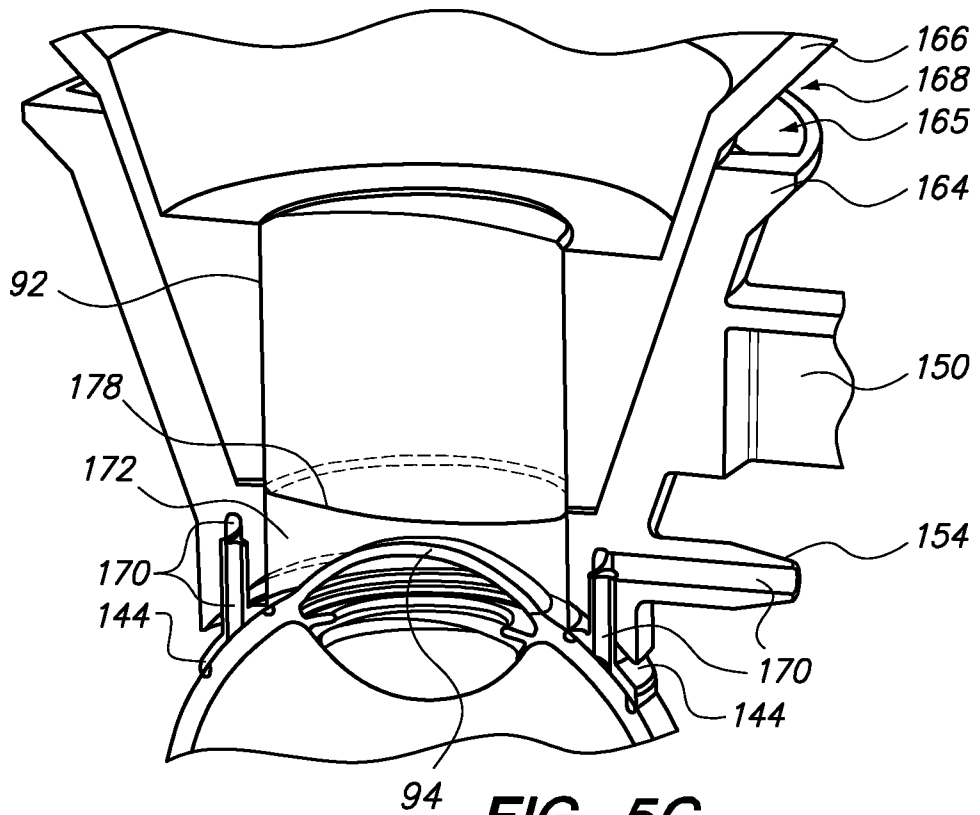


FIG. 5C

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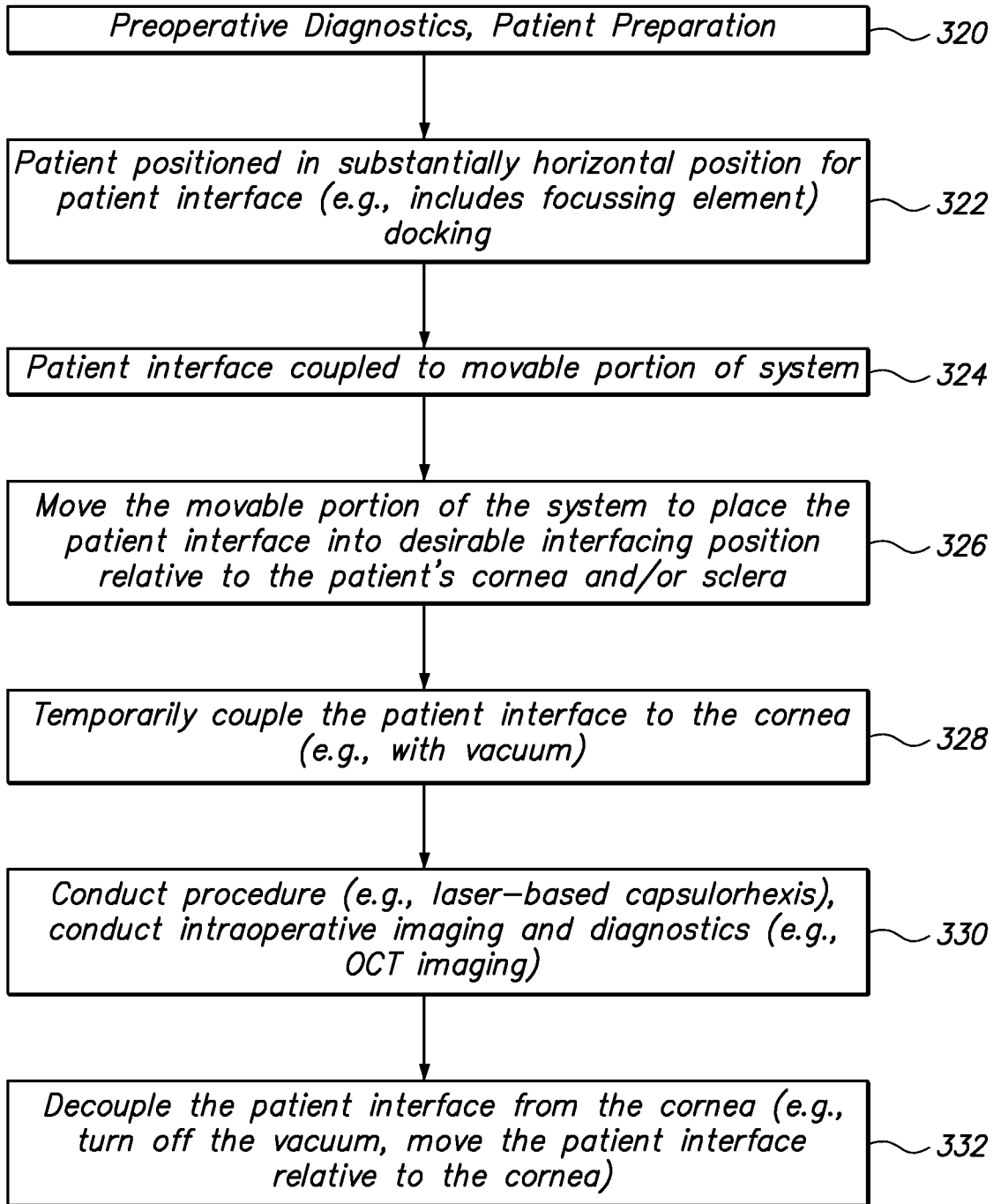
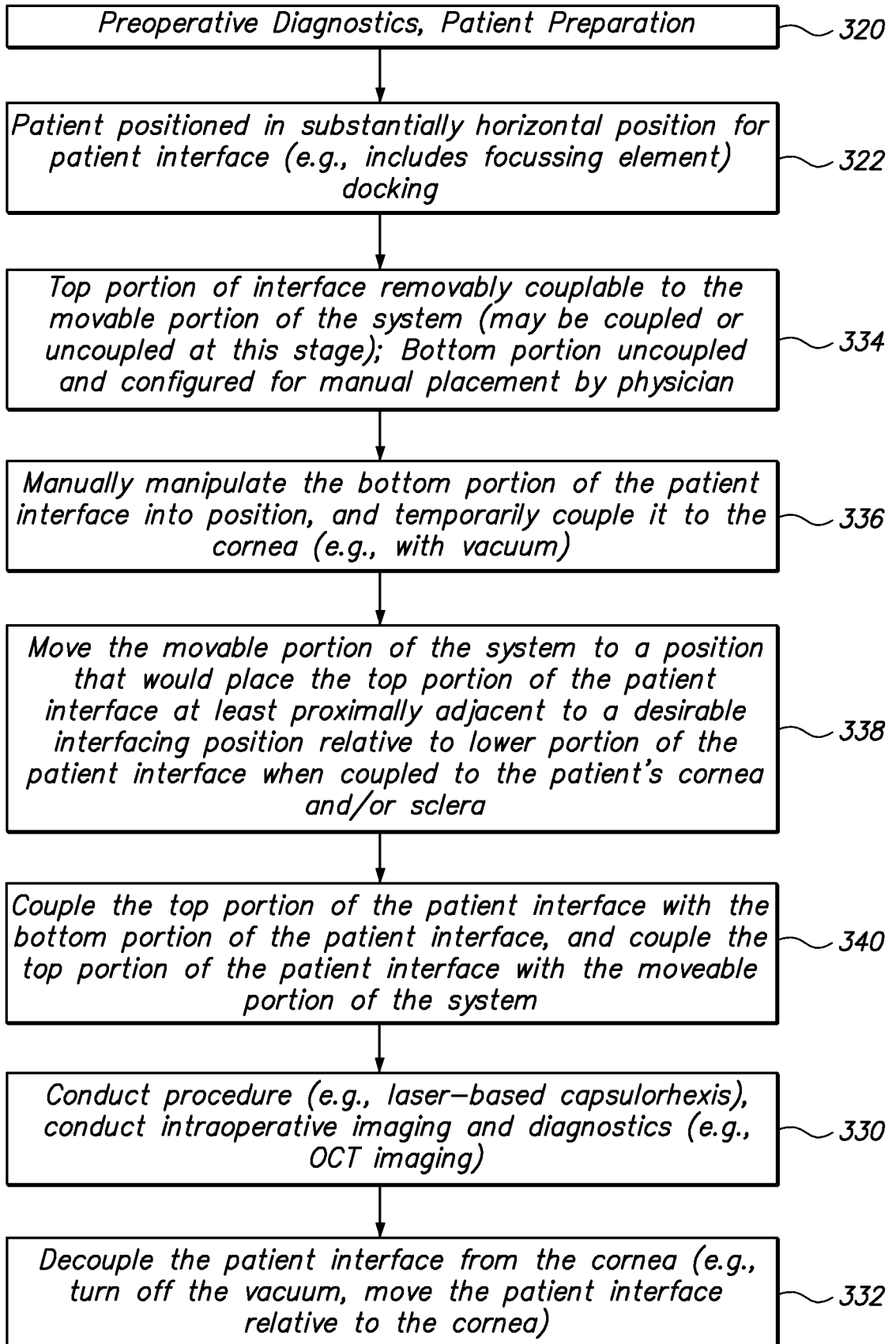
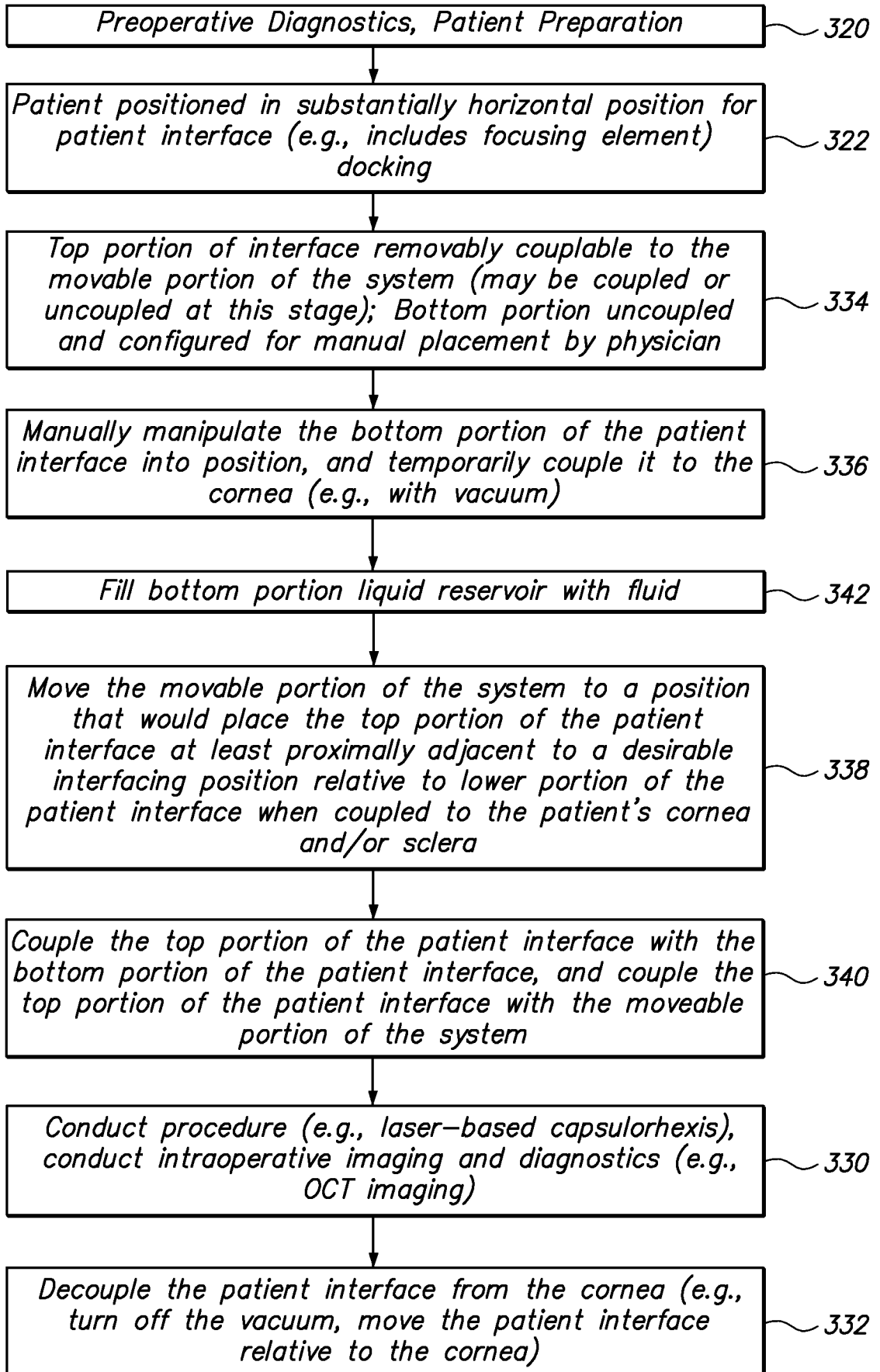


FIG. 6A

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**FIG. 6B**

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**FIG. 6C**

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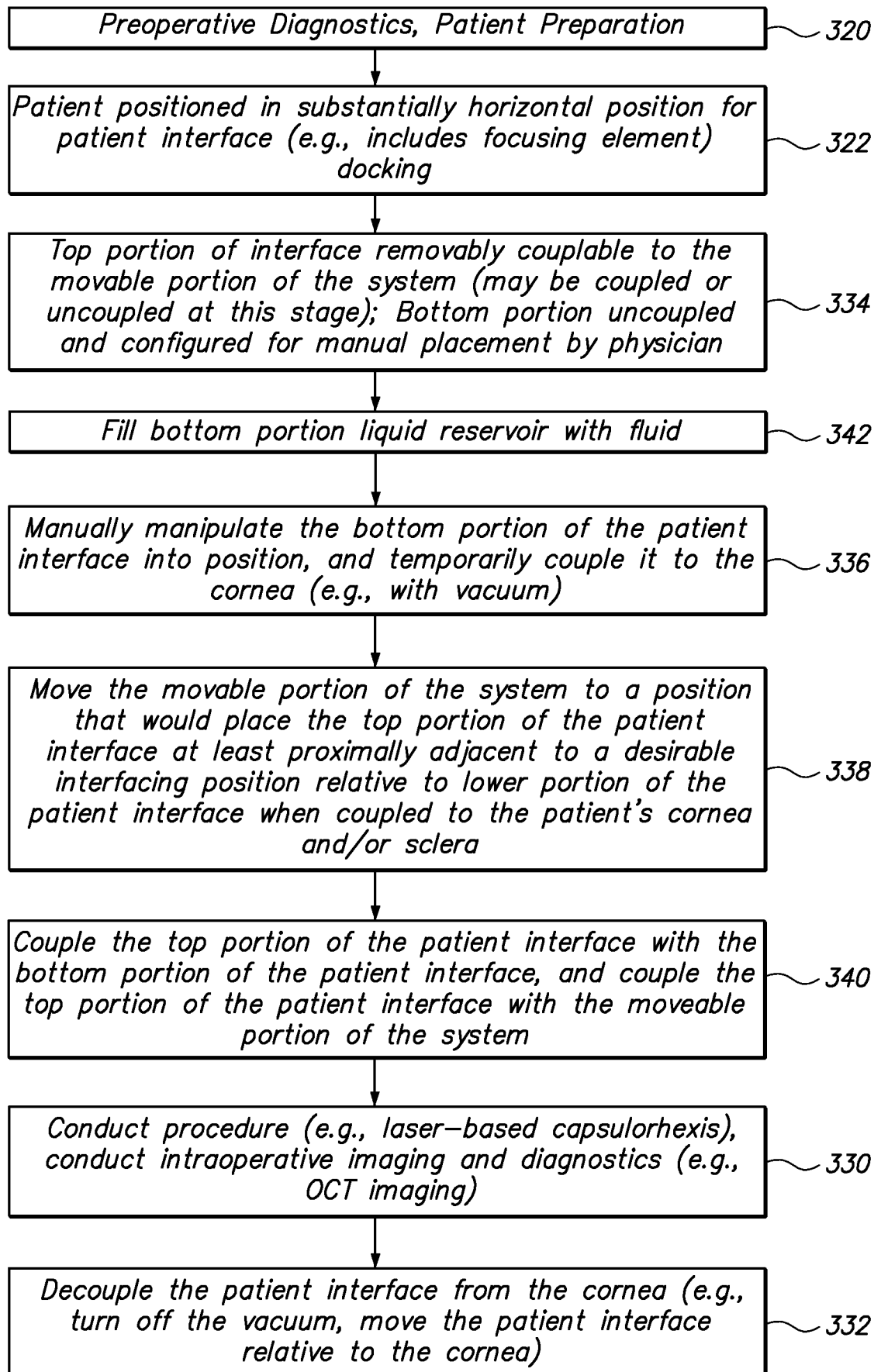


FIG. 6D

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2011/050448

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F9/009
ADD.
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED
Minimum documentation searched (classification system followed by classification symbols)
A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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| X | DE 44 30 720 A1 (ZEISS CARL FA [DE]) 22 June 1995 (1995-06-22) figures 2a,2c,3 column 3, line 45 - line 60 column 4, line 20 - line 32 column 5, paragraph 63 - column 6, paragraph 45 column 7, line 13 - column 8, line 7 ----- -/-- | 1-3,11, 12,15,16 |

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents :

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- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

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| Date of the actual completion of the international search 1 December 2011 | Date of mailing of the international search report 09/12/2011 |
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| Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016 | Authorized officer Jansen, Birte |
|--|---|

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2011/050448

| C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT | | |
|--|--|------------------------|
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| X,P | ----- US 2011/022035 A1 (PORTER GERRIT N [US] ET AL) 27 January 2011 (2011-01-27) abstract figures 1,3,6 paragraphs [0024], [0027], [0032], [0035], [0037], [0039], [0043] claims 17,21 | 1-4, 6-13,15, 16 |
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

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