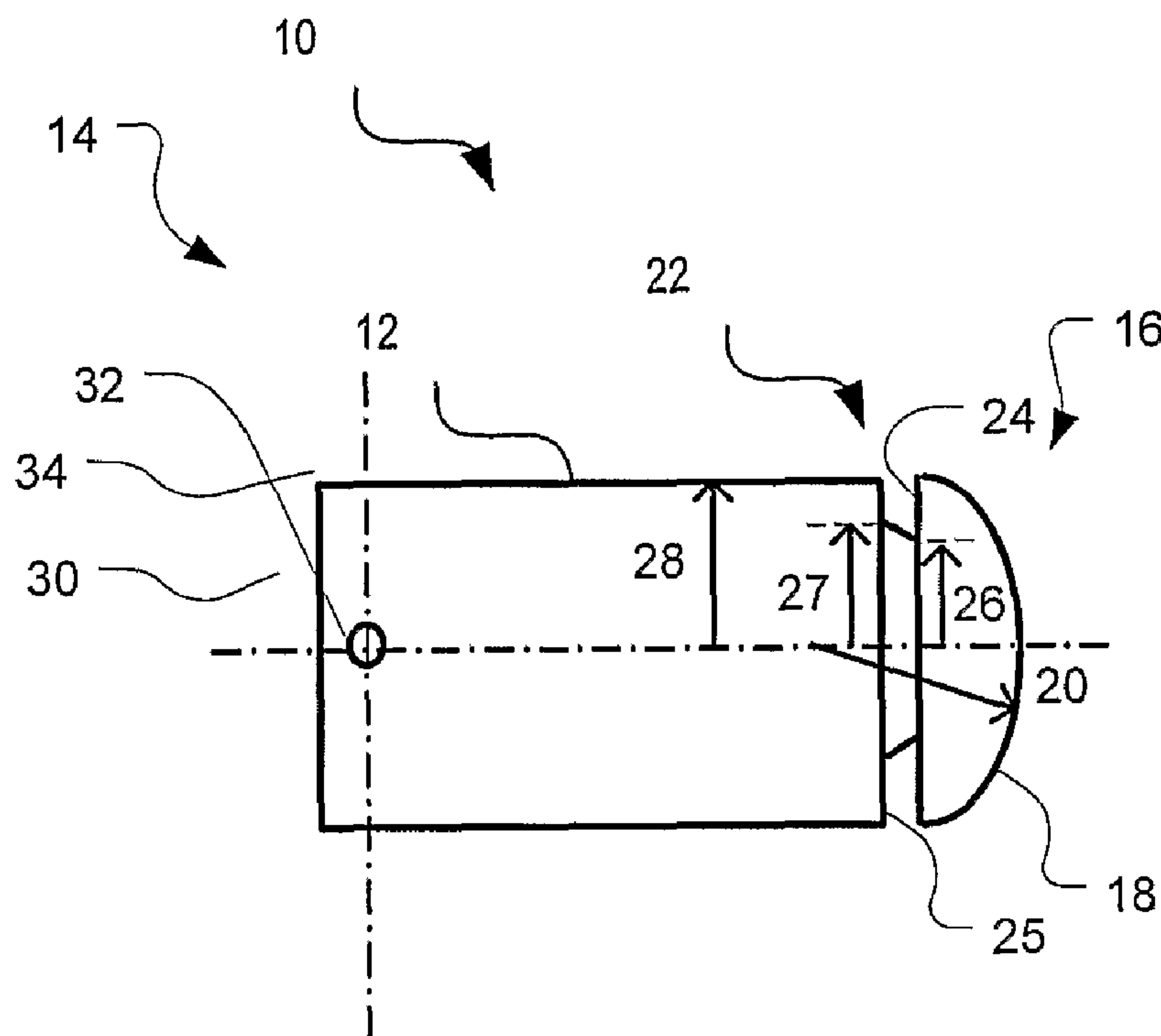




(86) Date de dépôt PCT/PCT Filing Date: 2004/11/09
(87) Date publication PCT/PCT Publication Date: 2005/05/26
(85) Entrée phase nationale/National Entry: 2006/04/27
(86) N° demande PCT/PCT Application No.: US 2004/041166
(87) N° publication PCT/PCT Publication No.: 2005/047938
(30) Priorité/Priority: 2003/11/10 (US60/518,826)

(51) Cl.Int./Int.Cl. *A61F 9/008* (2006.01),
A61B 18/20 (2006.01)
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(54) Titre : PROCÉDES ET DISPOSITIFS DE TEST DE L'ALIGNEMENT EN TORSION D'UN DISPOSITIF DE
DIAGNOSTIC AVEC UN SYSTEME A REFRACTION LASER
(54) Title: METHODS AND DEVICES FOR TESTING TORSIONAL ALIGNMENT BETWEEN A DIAGNOSTIC DEVICE
AND A LASER REFRACTIVE SYSTEM



(57) **Abrégé/Abstract:**

The present invention provides methods and test devices for aligning a diagnostic device with a laser refractive system. In one embodiment, the device comprises a body comprising a proximal portion and a distal portion. The proximal portion defines a radiused corneal surface and an iris, and the distal portion defines a retinal surface. The test devices of the present invention typically have visual and optical characteristics that are similar to a human eye.



(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
26 May 2005 (26.05.2005)

PCT

(10) International Publication Number
WO 2005/047938 A2

(51) International Patent Classification⁷: **G02B**

(21) International Application Number:
PCT/US2004/041166

(22) International Filing Date:
9 November 2004 (09.11.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/518,826 10 November 2003 (10.11.2003) US

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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declaration under Rule 4.17:

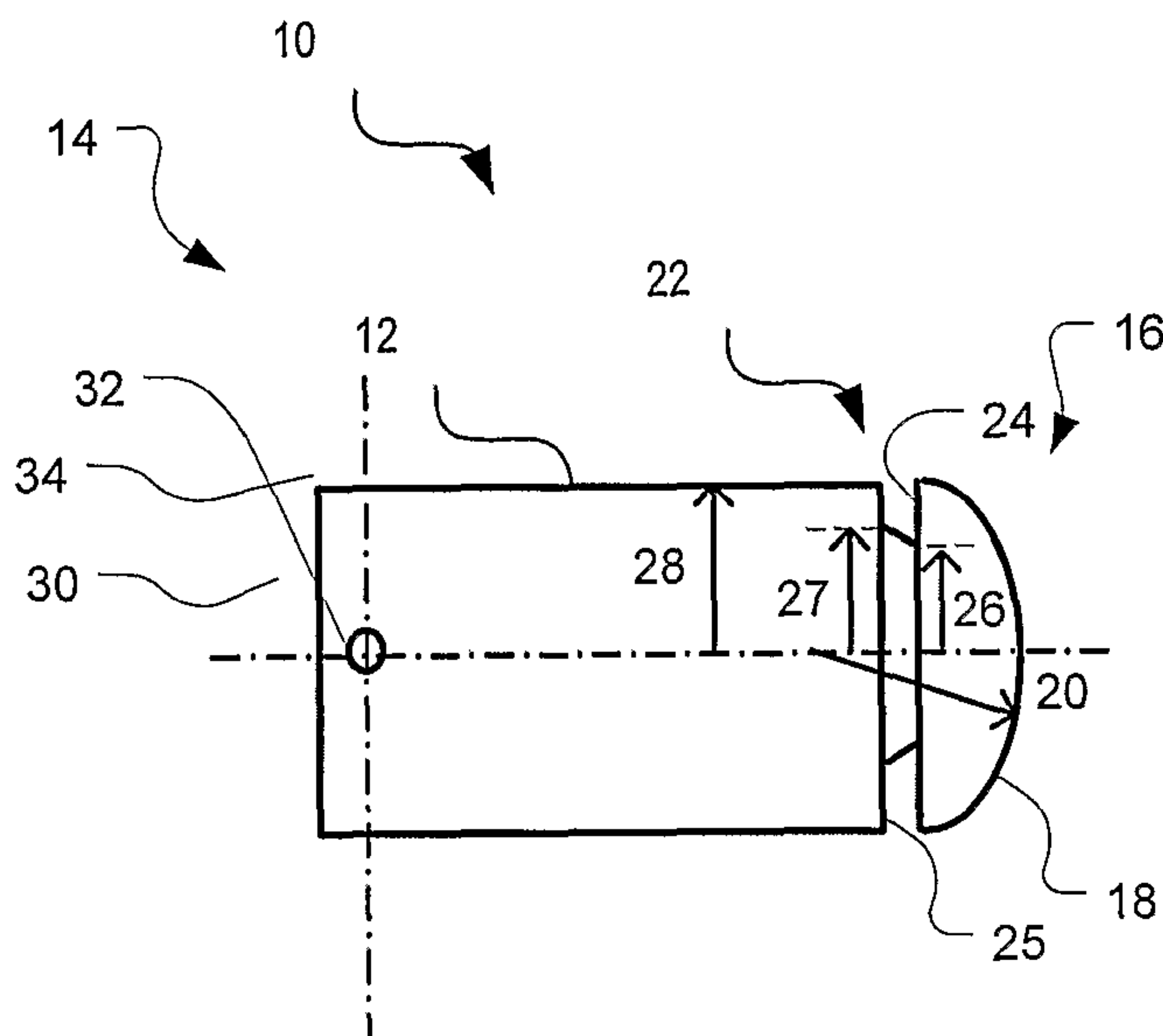
— of inventorship (Rule 4.17(iv)) for US only

Published:

— without international search report and to be republished upon receipt of that report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: METHODS AND DEVICES FOR TESTING TORSIONAL ALIGNMENT BETWEEN A DIAGNOSTIC DEVICE AND A LASER REFRACTIVE SYSTEM



(57) Abstract: The present invention provides methods and test devices for aligning a diagnostic device with a laser refractive system. In one embodiment, the device comprises a body comprising a proximal portion and a distal portion. The proximal portion defines a radiused corneal surface and an iris, and the distal portion defines a retinal surface. The test devices of the present invention typically have visual and optical characteristics that are similar to a human eye.

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METHODS AND DEVICES FOR TESTING TORSIONAL ALIGNMENT BETWEEN A DIAGNOSTIC DEVICE AND A LASER REFRACTIVE SYSTEM

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] The present application claims the benefit of U.S. Patent Application
5 No. 60/518,826, filed on November 10, 2003, the complete disclosure of which is
incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0002] The present application relates generally to methods and devices for
testing the accuracy of a torsional misalignment measurement between two torsionally
10 misaligned images. More specifically, the present invention relates to methods and devices
that are used to compare a measured torsional misalignment to an actual torsional
misalignment between two different images taken of the test device.

[0003] Known laser eye procedures generally employ an ultraviolet or
infrared laser to remove a microscopic layer of stromal tissue from the cornea of the eye to
15 alter the refractive characteristics of the eye. The laser removes a selected shape of the
corneal tissue, often to correct refractive errors of the eye. Ultraviolet laser ablation results in
photo-decomposition of the corneal tissue, but generally does not cause thermal damage to
adjacent and underlying tissues of the eye. The irradiated molecules are broken into smaller
volatile fragments photochemically, directly breaking the intermolecular bonds.

20 [0004] Laser ablation procedures can remove the targeted stroma of the cornea
to change the cornea's contour for varying purposes, such as for correcting myopia,
hyperopia, astigmatism, and the like. Control over the distribution of ablation energy across
the cornea may be provided by a variety of systems and methods, including the use of
ablatable masks, fixed and moveable apertures, controlled scanning systems, eye movement
25 tracking mechanisms, and the like. In known systems, the laser beam often comprises a
series of discrete pulses of laser light energy, with the total shape and amount of tissue
removed being determined by the shape, size, location, and/or number of a pattern of laser
energy pulses impinging on the cornea. A variety of algorithms may be used to calculate the
pattern of laser pulses used to reshape the cornea so as to correct a refractive error of the eye.
30 Known systems make use of a variety of forms of lasers and/or laser energy to effect the
correction, including infrared lasers, ultraviolet lasers, femtosecond lasers, wavelength
multiplied solid-state lasers, and the like. Alternative vision correction techniques make use

of radial incisions in the cornea, intraocular lenses, removable corneal support structures, thermal shaping, and the like.

[0005] Known corneal correction treatment methods have generally been successful in correcting standard vision errors, such as myopia, hyperopia, astigmatism, and the like. However, as with all successes, still further improvements would be desirable. Toward that end, diagnostic devices, such as wavefront measurement systems are now available to measure the refractive characteristics of a particular patient's eye. By customizing an ablation pattern based on wavefront measurements, it may be possible to correct minor refractive errors so as to reliably and repeatably provide visual acuities greater than 20/20. Alternatively, it may be desirable to correct aberrations of the eye that improve visual acuity to better than 20/20. Unfortunately, these measurement systems are not immune from measurement error. Similarly, the calculation of the ablation profile, the transfer of information from the measurement system to the ablation system, and the operation of the ablation system all provide opportunities for the introduction of errors, so that the actual visual acuities provided by real-world wavefront-based correction systems may not be as good as might be theoretically possible.

[0006] For example, one potential problem with the use of wavefront measurements is aligning the customized laser ablation pattern that is based on the wavefront measurements with the real-time position of the patient's eye during the ablation treatment. In order to achieve precise registration between the customized ablation pattern delivered to the patient's eye, the real-time position of the eye should share a common coordinate system with the ablation pattern. However, in order to provide the common coordinate system, the software algorithms of the laser refractive system should be able to accurately locate and track the position and cyclotorsional orientation of the patient's eye.

[0007] In light of the above, it would be desirable to provide methods and test devices that may be used to measure the accuracy of the tracking algorithms of the laser refractive system.

BRIEF SUMMARY OF THE INVENTION

[0008] The present invention provides methods, systems, and test devices for measuring an accuracy of a cyclotorsional algorithm. In particular, the present invention may calculate the accuracy of the cyclotorsional algorithm by comparing a known torsional misalignment angle between a test device in two images to a calculated torsional

misalignment angle between the test device two images that is calculated by the cyclotorsional algorithm.

[0009] In one aspect, the present invention provides a test device for testing an accuracy of a misalignment measurement between a diagnostic device and a laser refractive system. The device comprises a body comprising a proximal portion and a distal portion. The proximal portion defines a radiused corneal surface and an iris, and the distal portion defines a retinal surface. The test devices of the present invention typically have visual and optical characteristics that are similar to a human eye. Consequently, the test devices of the present invention may be used with existing commercial diagnostic devices and laser refractive systems without having to alter the diagnostic devices and laser refractive systems.

[0010] Embodiments of the test device of the present invention are typically comprised of a material that has similar optical characteristics to a human eye. In one embodiment, the test device is composed of cast polymethylmethacrylate (PMMA). PMMA has dispersion characteristics that are similar to that of the human eye. As can be appreciated, the test devices of the present invention may be composed of other optical materials. For example, other material that may be used, include but are not limited to, glass, other plastics, or any optically clear material that can be ablated with a UV laser.

[0011] The iris of the test device is typically an annular region of the proximal portion that is substantially adjacent the radiused corneal surface. The iris surface may comprise one or more texture patches or markings that provides a unique marking that allows the cyclotorsional algorithm of the present invention to identify the iris and thereafter determine the torsional offset between the two images of the test device. The iris texture patches may be created during manufacturing by scratching, scraping or otherwise processing the iris surface to create radial striations or other markings on the iris surface.

[0012] The retinal surface positioned in the distal portion of the test device typically defines a diffuse surface that absorbs light. In one embodiment, the retinal surface is manufactured to be optically "flat." The retinal surface may thereafter be polished to create an optically diffuse surface. Thereafter, a material may be applied to the diffuse surface to provide the light absorbing characteristics. One material that may be applied is a flat dark gray paint.

[0013] Optionally, the test device may comprise an alignment reference that allows the user to visually assess the torsional rotational offset of the test device in the images of the test device. The alignment reference may also be used by the cyclotorsional algorithms of the present invention to determine the torsional offset between the alignment reference in

the images of the test device. The alignment reference may take on a variety of forms. In one embodiment, the alignment reference comprises an alignment pin that is positioned in a hole in the test device. The alignment pin may extend radially from a longitudinal axis of the test device and is viewable in the images of the test device. In other embodiments, the alignment reference may take the form of a flattened surface, a protrusion, marking, or the like.

[0014] In another aspect, the present invention provides a method that comprises obtaining an image of the test device with the diagnostic device. To obtain the first image, the test device may be positioned within an optical axis of the diagnostic device in a first orientation. A second image of the test device may be obtained with the laser refractive system by positioning the test device in a second orientation within an optical axis of a laser refractive system. The second orientation may be in a torsionally offset orientation from the first orientation so as to provide a known torsional misalignment. The first and second images of the test device are compared to provide a measured torsional misalignment between the images of the test device. The measured torsional misalignment is compared to the known misalignment to determine the accuracy of the measured misalignment.

[0015] The methods of the present invention may (1) determine the cyclotorsional rotational offset between the diagnostic devices and the laser refractive system, (2) measure the ability of the algorithm to locate and match iris markers in the test device, and/or (3) demonstrate cyclotorsional compensation by removing high order aberrations from the test device.

[0016] In some embodiments, the diagnostic device is used to obtain measurement of the aberrations of the eye and may be an autorefractor or an aberrometer such as a wavefront sensor. For example, aberrometers using a Hartmann-Shack device, Tscherning device, ray-tracing technology and the like may be employed.

[0017] In another aspect, the present invention provides a method of manufacturing a test device. The method comprises providing a body that comprises a first optical surface and a second, radiused optical surface. The body is treated to form a textured annular iris surface. The first optical surface is treated to create a pupil surface.

[0018] The textured annular iris surface may include unique patterns of striations and imperfections and may be created by polishing, scraping or otherwise enhancing the iris surface.

[0019] To create the pupil surface, the first optical surface may be polished to produce a diffuse back scattering surface and a material that absorbs light may be applied to

the polished surface. For example, in one configuration, an 0.3 micron Al_2O_3 grit may be used to polish the first optical surface and a flat dark gray paint may be applied to the polished surface.

[0020] In a further aspect, the present invention provides a kit. The kits may include any of the test devices described herein. The kits may further include instructions for use setting forth any of the methods described herein. The kits may also include packaging suitable for containing the test device and the instructions for use. Exemplary packaging includes pouches, trays, boxes, tubes, and the like. The instructions for use may be provided on a separate sheet of paper or other medium. Optionally, the instructions may be printed in whole or in part on the packaging.

[0021] These and other aspects of the invention will become more apparent from the following detailed description of the invention when taken in conjunction with the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0022] FIGS. 1 and 1A illustrate different views of one embodiment of a test device that is encompassed by the present invention.

[0023] FIG. 1B illustrates a geometry of one test device encompassed by the present invention.

[0024] FIG. 2 schematically illustrates a simplified method of the present invention.

[0025] FIG. 3 illustrates one embodiment of a test holder that is encompassed by the present invention.

[0026] FIGS. 3A to 3D illustrate torsional registration fixtures that may be used to position the test device in an optical axis of a laser refractive system.

[0027] FIG. 4 illustrates an image of a test device taken by a camera of a wavefront sensor system.

[0028] FIGS. 5 and 6 illustrate images of the same test device taken by a camera of a laser refractive system.

[0029] FIG. 7 is a graph showing the torsional offset between the images of FIGS. 4 and 6.

[0030] FIG. 8 illustrates a kit of the present invention.

[0031] FIG. 9 schematically illustrates a simplified method of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0032] FIGS. 1 and 1A illustrate one embodiment of a test eye or test device 10 that is encompassed by the present invention. Test device 10 comprises a body 12 that has a distal end 14 and a proximal end 16. The illustrated embodiment of test device is substantially cylindrical, but it should be appreciated that the test device may also be such as substantially spherical, or the like.

[0033] Test device 10 may be comprised of a transparent optical material, such as cast polymethylmethacrylate (PMMA). Applicants have found that cast PMMA machines easily with a lathe and also provides a variation in its refractive index at different wavelengths (i.e., dispersion) that closely matches the index of refraction properties of the optical tissues of the human eye. While PMMA is one preferred material, other clear optical materials that can be ablated with a UV laser may be used. For example, glass may be used if spherical aberrations are desired to be incorporated into the test fixture.

[0034] Test device 10 may be composed of a single piece of material or may be composed of multiple pieces of machined pieces. A single piece test device 10 is preferred so that the test device 10 will be free of joints, thus ensuring a clear optical path.

[0035] Proximal end 16 of body 12 may include a radiused surface 18 that defines a proximal radius 20. In one embodiment, radiused surface has a radius of about 7.8 mm. Radiused surface 18 may have a curvature that coincides with a shape of a cornea of a human eye. Radiused surface 18 may have a smooth surface. If the surface is too rough, the diagnostic device may not be able to measure the surfaces of the test device.

[0036] Test fixture 10 may be manufactured to have a gap 22 in the proximal end 16 of body 12 adjacent the radiused surface 18. Gap 22 defines a front, annular shaped surface 24 and a back, annular shaped surface 25. The front, annular shaped surface 24 is substantially opposed to the radiused surface 18 on the proximal end 16 of body 12 and may be used to define an iris surface.

[0037] Test device 10 comprises a beveled surface within gap 22 in which a radius 27 measured from a longitudinal axis of test device, of beveled surface adjacent back, annular shaped surface 27 is larger than a radius 26 of the beveled surface adjacent the front, annular shaped surface 24. An outer radius 18 of body 12 will define an outermost radius of test device 10 and may be used to define an outer radius of the iris. The inner radius 26 of annular surface 24 may be used to define an inner surface of the iris and a pupil diameter.

[0038] The iris surface 24 may be manufactured so that it is rough and contains irregular marks/patches so as to provide a unique surface when imaged. Such

irregular markings may be used by an alignment algorithm of the present invention as "markers" so as to assist in finding a match for an eye and determining a torsional misalignment of the images of the test fixture taken by the different imaging devices (e.g., diagnostic device and laser refractive system). In some embodiments, iris surface 24 may be enhanced by scraping or otherwise treating iris surface 24 to create a realistic appearance of the iris in near infrared light. For example, a curved needle, carbon paper, carbon-based ink, such as a Sharpie pen or other comparable substances that are visible in infrared light, or the like, may be used to create texture patches, radial striations or other irregular types of imperfections on iris surface 24, so as to provide a surface that visually and optically reflects an iris of a human eye.

[0039] A distal surface 30 of body 12 may be configured to provide a surface that acts as a retinal surface 30. Retinal surface 30 may be finished in a variety of ways to provide the retinal surface. In one embodiment, retinal surface 30 is treated to create a diffuse surface that absorbs light. For example, the retinal surface 30 may be treated with a single point diamond lathe finish to provide an optically flat surface. The retinal surface may be polished with a 0.3 micron Al_2O_3 grit to produce a diffuse back scattering surface, and thereafter painted a flat dark gray so as to absorb light that is directed through body 12. One paint that may be used to produce the flat dark gray is a "weather black" Floquil model railroad paint. As can be appreciated however, the present invention is not limited to this one embodiment and other types of treatments, polish, and paints may be used.

[0040] It should be appreciated that while the distal surface 30 is illustrated as a distal most surface, other surfaces within body 12 may be treated to create a retinal surface, and the present invention is not limited to the retinal surface 30 being positioned on the distal most surface.

[0041] In some embodiments, a drilled hole 32 may be formed in the test fixture 10 at or near the distal end 14. Drilled hole 32 may have any diameter, but one preferred embodiment has a diameter of about 0.159 mm. In the illustrated embodiment, drilled hole 32 is about 4 mm away from the distal end of body 14. As can be appreciated, the distance the drilled hole 32 from the distal end may vary. An alignment pin 34 may be positioned within drilled hole 32 so as to provide a rotational alignment feature that is independent of the iris markings. The alignment pin 34 will have a diameter that substantially matches the diameter of the drilled hole 32 and may be press fit into drilled hole 32. In the illustrated embodiment, alignment pin comprises a stainless steel rod that is about 7 mm in length and extends radially from a longitudinal axis of body 12.

[0042] As may be appreciated, in other embodiments of the present invention other conventional alignment references known in the art may be used to determine the torsional orientation of test fixture 10, such as a flattened surface, printed image, pins, cutoffs, flats, or the like. Furthermore, other embodiments of test fixture 10 may not need alignment mechanisms, since the cyclotorsional algorithms used in the present invention may use the iris markings to compare the torsional differences between images of the test fixture 10.

[0043] Referring now to FIG. 1B, embodiments of test device 10 typically have a geometry that provides a visible pupil size 2VP and a physical pupil size diameter 2P. The visible pupil size differs from the physical pupil size due to the magnification caused by the PMMA material. The following chart provides some examples of suitable diameters for a pupil of the test device 10:

Visible pupil diameter (mm)	Physical pupil diameter (mm)
3.000	2.559
4.000	3.424
5.000	4.301
6.000	5.194
7.000	6.109
8.000	7.054

[0044] As shown in FIG. 1B, due to the refractive properties and shape of the test device 10, the visible pupil diameter 2VP (i.e., the pupil size that the diagnostic device will image) differs from the physical pupil 2P diameter (i.e., the true, non-refractive pupil size). In particular, a principal ray 40 is shown passing from a center of the objective lens 42 of an imaging system to a radiused surface 18 of the test device 10 where it is refracted and passed into the test eye. Principal ray 40 strikes an edge of the physical pupil radius P at a distance P from the optical axis 46. The principal ray 40 is directed through test device 10 and makes an angle U with the optical axis 46 so that at one focal length f of the objective lens 42, its distance from the optical axis 46 is the visible pupil radius VP. The imaging system is assumed to be positioned so that the focal plane is 0.5 mm anterior to the plane of the physical pupil P. Distance P (e.g., physical pupil radius) is found by tracing this chosen

ray through the optical system and finding where it strikes a plane at a distance A from the front surface vertex.

[0045] FIG. 2 schematically illustrates the method of manufacturing the test device 10 encompassed by the present invention. At 100, the method comprises shaping the body of the test device. The material may be shaped by creating the radiused front surface and a substantially flat back surface. The front surface may be shaped by a contact lens lathe (or other similar shaping devices) to create a smooth spherical surface that corresponds to the cornea of the human eye. Similarly, the back surface may be shaped to be optically flat. One exemplary contact lens lathe that may be used to create the front surface is ALM-OTT lathe system by DAC International of Capenteria, California.

[0046] At 102, the iris surface may be formed. The iris surface may be formed by creating an annular space in a proximal portion of the body 12 so as to create a front and back annular surface (FIG. 1).

[0047] At 104, the surfaces of the test device may be processed to create the desired characteristics. For example, the retinal surface may be polished to create an optically diffuse surface. The optically diffuse surface may thereafter be painted to create a surface that absorbs light. The corneal surface may be left untreated if it was originally created with a contact lens lathe. If however, the corneal surface was created with a conventional lathe, the corneal surface may be smoothed with a contact lens lathe to create an optically smooth spherical surface. To create the unique iris patches on the front annular surface 24 (FIG. 1), the iris surface may be treated with a conventional lathe. Additionally or alternatively, the iris surface may be enhanced with a material, such as a carbon paper, to scrape or scratch the iris surface to create radial striations, imperfections or other markings.

[0048] FIG. 3 illustrates a test device holder 200 that may be used to position the test device 10 of the present invention in an optical path of an diagnostic device. In use, the user may examine the head rest support columns of the instrument (e.g., diagnostic device and/or laser refractive system) and determine how far from the support columns (in a horizontal direction), the normal eye location would be if a person's forehead was against the head rest and was looking into optical axis of the instrument. Some head-rest designs place the eye farther from the head-rest supports than others. If the proper eye position is close to the supports, it is best to place a round horizontal rod 202 of the test eye holder 200 on the side of the head-rest supports opposite from the instrument. If the eye position is much closer to the instrument than the head-rest supports, then it is best to place the horizontal rod 202 on the side of the supports closest to the instrument.

[0049] Having chosen the side of head rest support to place the horizontal bar 202, the bar may be held with the eye holding block 204 attached against the head-rest supports. A horizontal slot 206 in the eye holding block 204 that orients the test device 10 on the 0 axis side is shown in FIG. 3. The horizontal alignment slot 206 may be used to ensure
5 that the test device 10 is positioned in substantially the same orientation during each of the placements of the test device in the optical axis of the diagnostic device.

[0050] To attach the holder 200 to the instrument, an end of the horizontal rod with a paper sleeve 208 around may be attached it to the head rest support with an elastic band (not shown), or other conventional attachment means, such as velcro straps, buckles, or
10 the like. To adjust the horizontal position and rotational position of the eye holding block 204 (and the test device 10) about the horizontal rod, the user may actuate knob 210, such as a thumb screw, to loosen the eye holding block 204 from its original position.

[0051] The test holding block 204 may include one or more bubble levels 212 to assist in the positioning of the test device 10. To level the device in the horizontal
15 orientation, one or both ends of rod 202 may be moved vertically until the proper leveling is achieved. Bubble levels may give an idea of the precision of the leveling. For example, if the test holder 200 is moved from having the bubble exactly centered to having the outer edge of the bubble touching the outer ring, the holder will be tipped about 3/4 degree. The holding block 204 may be rotated until the bubble in a level 212 shows that it is approximately
20 upright. The test eye holder may be moved horizontally until it is at a proper horizontal position for measurement. After horizontally and rotationally repositioning the eye holding block 204, knob 210 may be tightened to lock the eye holding block 204 into its position relative to horizontal bar 202.

[0052] With the test eye holder 200 properly centered and leveled, the test
25 device 10 may be inserted into the rear of the test eye block 204 with its pupil facing the instrument. The alignment pin 34 on the test device 10 slides in the alignment slot 206 in the holder. When the test device is in position, measurement with the diagnostic device may be carried out just as if a human eye were positioned in the optical axis of the diagnostic device.

[0053] FIGS. 3A to 3D illustrate some embodiments of an embodiment of a
30 torsional registration fixture 250 that may be used to hold the test device 10 in an optical path of a laser refractive system. Torsional registration fixture 250 may be positioned on a headrest 252 so as to place the test device 10 in a position that is a similar position to where a human eye would be positioned in the optical axis of the laser refractive system. Torsional registration fixture 250 may include a base 254 that is fixed to the headrest 252 that is of a

height that vertically positions the test device 10 to a position where a patient's eye would typically be positioned. A rotatable platform 255 may be rotatably coupled to the base so as to allow the test device 10 to be rotated about an axis that coincides with the optical axis of the laser refractive system. Platform 255 may rotate the test device over any desired angles
5 so as to impart a torsional misalignment. In the illustrated embodiment, the test device is allowed to be torsionally rotated ± 10 degrees. Platform 255 typically includes an opening 256 sized and shaped to receive the test device 10. Opening 256 may include an alignment slot (not shown) that receives the alignment pin 34 of the test device so as to position the test device 10 in a known orientation within registration fixture 250. Torsional registration
10 fixture 250 may include a handle 257 and a torsional scale 258, such as a protractor, on its top surface that allows the user to torsionally position the test device 10 to a known torsional angle from its angle under the diagnostic device (i.e., 0 degrees).

[0054] FIG. 9 illustrates schematically illustrates one embodiment of a method that is incorporated by the present invention. At 400, the test device 10 is positioned in an
15 optical axis of a diagnostic device in a first orientation. For the embodiments illustrated in FIG. 3, the alignment pin 34 of the test device is positioned in the 0 degree position. The 0 degree position in the test holder 200 may correspond to the 0 degree orientation in the registration fixture 250. At 402, the test device 10 is imaged by the diagnostic device. At 404, the test device is positioned in an optical axis of a laser refractive system. The test
20 device 10 may be placed in a second orientation that is torsionally misaligned from the first orientation. For the embodiments illustrated in FIGS. 3A to 3D, the user may rotate platform 255 so that the test device is at a known torsional misalignment from the first orientation (i.e., any angle except the 0 degree angle, as shown by the readout on scale 258). Once the test device 10 is positioned at the desired torsional misalignment, an image of the misaligned test
25 device may be obtained by the laser refractive system 406. At 408, the cyclotorsional algorithm of the present invention may be used to measure the torsional misalignment between the test device in the first image and the test device in the second image. At 410, the measured torsional misalignment and the actual misalignment (as shown by scale 258) are compared to determine the accuracy of the cyclotorsional algorithm. The tests may be
30 repeated a plurality of times at a variety of different torsional misalignment angles to determine the accuracy of the cyclotorsional algorithms at different angles.

[0055] Thereafter, the cyclotorsional algorithm of the laser refractive system may be modified to compensate for the differences between the measured misalignment and the known misalignment, if desired.

[0056] Appearance of the test device in an image of the diagnostic device and laser refractive system is shown in FIGS. 4 to 6. In particular, FIG. 4 illustrates test device 10 in an image taken by an eye camera of a wavefront instrument, such as the VISX WaveScan[®] System. FIGS. 5 and 6 are images of test device 10 that are obtained by a camera of a laser refractive system, such as the VISX STAR S4[™] laser system. As shown in all three images, alignment pin 34 is visible in the images and acts as a fixed physical alignment reference that illustrates the difference in orientation of the test device in the different images of the two devices. Using the cyclotorsional algorithm of the present invention, the two images of the test device may be analyzed to determine the amount of torsional misalignment between the test device under the diagnostic device and the laser refractive system. A comparison of the actual and measured amount of torsional misalignment between the two images will tell the user how accurate the cyclotorsional algorithm is and thereafter allow the laser refractive system to be correctly calibrated for use in subsequent laser treatments.

[0057] A full description of one cyclotorsional algorithm is more fully described in co-pending and commonly owned U.S. Patent Application No. 10/300,714 filed November 19, 2002, the complete disclosure of which is incorporated herein by reference. Because the test device has similar optical characteristics of a human eye and because the position of the test device 10 is placed in a position that the human eye would be in, the diagnostic device and laser refractive system do not have to be altered to determine the misalignment between the two instruments.

[0058] FIG. 7 shows an output of the cyclotorsional algorithm of an analysis of the images of FIGS. 4 and 6. The calculated amount of cyclotorsional rotation was computed to be about 7.68 degrees, which matched the actual cyclotorsional rotation to a precision of better than 1/4 degree. The cyclotorsional algorithm was based on matching patches of prominent iris texture between the two images from the diagnostic device and the laser refractive system. Because the manufacturing process of the test device 10 produces unique patterns of striations and imperfections on the iris, the algorithm is able to analyze test device 10 as it would a real eye.

[0059] FIG. 8 illustrates a kit of the present invention. The kit 300 includes a test device 10 and instructions for use 302. The test device 10 and IFU 302 may be disposed within a packaging 304. Test device 10 will generally be as described above, and the instruction for use (IFU) 302 will set forth any of the methods described above. Package 304 may be any conventional medical device packaging, including pouches, trays, boxes, tubes,

or the like. The instructions for use 302 will usually be printed on a separate piece of paper, but may also be printed in whole or in part on a portion of the package 304.

[0060] The kits of the present invention may also include a torsional registration fixture 250 and a test eye holder 200 that positions the test device 10 in a path of at least one of the diagnostic device and the laser refractive system.

[0061] A variety of modifications are possible within the scope of the present invention. For example, the test device of the present invention may be ablated by the laser refractive system to create a known aberration into the surface of the test device. Thereafter, the test device may be imaged by a diagnostic device to test the diagnostic devices ability to measure the known aberrations. If the measurement from the diagnostic device matches the known aberration, the diagnostic device will not have to be calibrated. If however, the measurement from the diagnostic device does not match the known aberration, then the diagnostic device may be calibrated. Moreover, once the aberration has been measured, the test device may be positioned in the optical axis of the laser refractive system so as to deliver a corrective ablation pattern to the test device. Advantageously, the ability of the cyclotorsional algorithm of the present invention to track the torsional alignment of the "eye" may be tested by positioning the test device in a torsionally misaligned orientation. After the corrective ablation pattern has been delivered to the test device, the test device may be placed in the optical axis of the diagnostic device to determine how well the ablation pattern was delivered.

[0062] Hence, the scope of the present application is not limited to the specifics of the embodiments described herein, but is instead limited solely by the appended claims.

WHAT IS CLAIMED IS:

- 1 1. A method comprising:
2 positioning a test device in an optical axis of the diagnostic device in a first
3 orientation;
4 obtaining a first image of the test device with the diagnostic device;
5 positioning the test device in an optical axis of a laser refractive system in a
6 second orientation that is torsionally offset from the first orientation so as to provide a known
7 torsional misalignment;
8 obtaining a second image of the test device with the laser refractive system;
9 measuring a torsional misalignment of the test device in the first image and the
10 test device in the second image; and
11 comparing the measured misalignment with the known misalignment to
12 determine the accuracy of the measured misalignment.
- 1 2. The method of claim 1 wherein the diagnostic device comprises an
2 aberrometer.
- 1 3. The method of claim 2 wherein the aberrometer comprises a
2 Hartmann-Shack device, Tscherning device, or a ray tracing device.
- 1 4. The method of claim 2 wherein the aberrometer comprises a wavefront
2 measurement sensor.
- 1 5. The method of claim 1 wherein positioning the test device within the
2 optical axis comprises coupling the test device to a head rest.
- 1 6. The method of claim 1 wherein comparing the first image of the test
2 device to the second image of the test device comprises determining a cyclotorsional rotation
3 between the first image and the second image.
- 1 7. The method of claim 1 wherein the test device comprises a proximal
2 portion that defines a radiused corneal surface and an iris, and a distal portion that defines a
3 retinal surface.

1 8. The method of claim 1 wherein the test device is positioned within the
2 optical axes of at least one of the diagnostic device and the laser refractive system with a
3 holder.

1 9. The method of claim 1 wherein the test device has visual and optical
2 characteristics of a human eye.

1 10. A method comprising:
2 providing a test device comprising a corneal surface, an iris and a retinal
3 surface in a first orientation with the diagnostic device;
4 obtaining a first image of the test device with the diagnostic device;
5 obtaining a second image of the test device that is positioned in a second
6 orientation with the laser refractive system; and
7 comparing the first image of the test device to the second image of the test
8 device to measure a torsional misalignment between the test device in the first orientation and
9 the test device in the second orientation; and
10 determining an accuracy of the measured misalignment by comparing the
11 measured misalignment to a known misalignment.

1 11. A test device for testing an alignment measurement between a
2 diagnostic device and a laser refractive system, the device comprising:
3 a body comprising a proximal portion and a distal portion;
4 wherein the proximal portion defines a corneal surface and an iris, and the
5 distal portion defines a retinal surface.

1 12. The device of claim 11 wherein the corneal surface is radiused.

1 13. The device of claim 11 wherein the iris surface comprises one or more
2 texture patches.

1 14. The device of claim 11 wherein the retinal surface defines a diffuse
2 surface.

1 15. The device of claim 14 wherein the diffuse surface absorbs light.

1 16. The device of claim 11 wherein the test device defines a visible pupil
2 diameter between about 3 mm and about 8 mm.

1 17. The device of claim 11 wherein the body comprises a material that
2 disperses different wavelengths of light at a substantially same rate as a human eye.

1 18. The device of claim 17 wherein the material comprises
2 polymethylmethacrylate (PMMA) or glass.

1 19. The device of claim 11 wherein the body further comprises an
2 alignment reference.

1 20. The device of claim 19 wherein the alignment reference comprises an
2 alignment pin that extends radially from a longitudinal axis of the body.

1 21. The device of claim 19 wherein the alignment reference comprises a
2 flattened surface along at least one of the proximal portion and distal portion of the body.

1 22. A device that tests alignment between a diagnostic device and a laser
2 refractive system, the device comprising:

3 a body;
4 means for providing optical alignment markers; and
5 means for providing a retinal surface.

1 23. A method of manufacturing a test device, the method comprising:
2 providing a body that comprises a first optical surface and a second, radiused
3 optical surface;

4 treating the body to form a textured annular iris surface;
5 treating the first optical surface to create a pupil surface.

1 24. The method of claim 23 wherein treating the body comprises creating a
2 unique pattern of striations and imperfections.

1 25. The method of claim 23 wherein treating the first optical surface
2 comprises:

3 polishing the first optical surface to produce a diffuse back scattering surface;
4 and

5 applying a material that absorbs light to the polished surface.

1 26. The method of claim 25 wherein polishing is carried out with 0.3
2 micron Al₂O₃ grit.

1 27. The method of claim 25 wherein the material comprises a flat dark
2 gray paint.

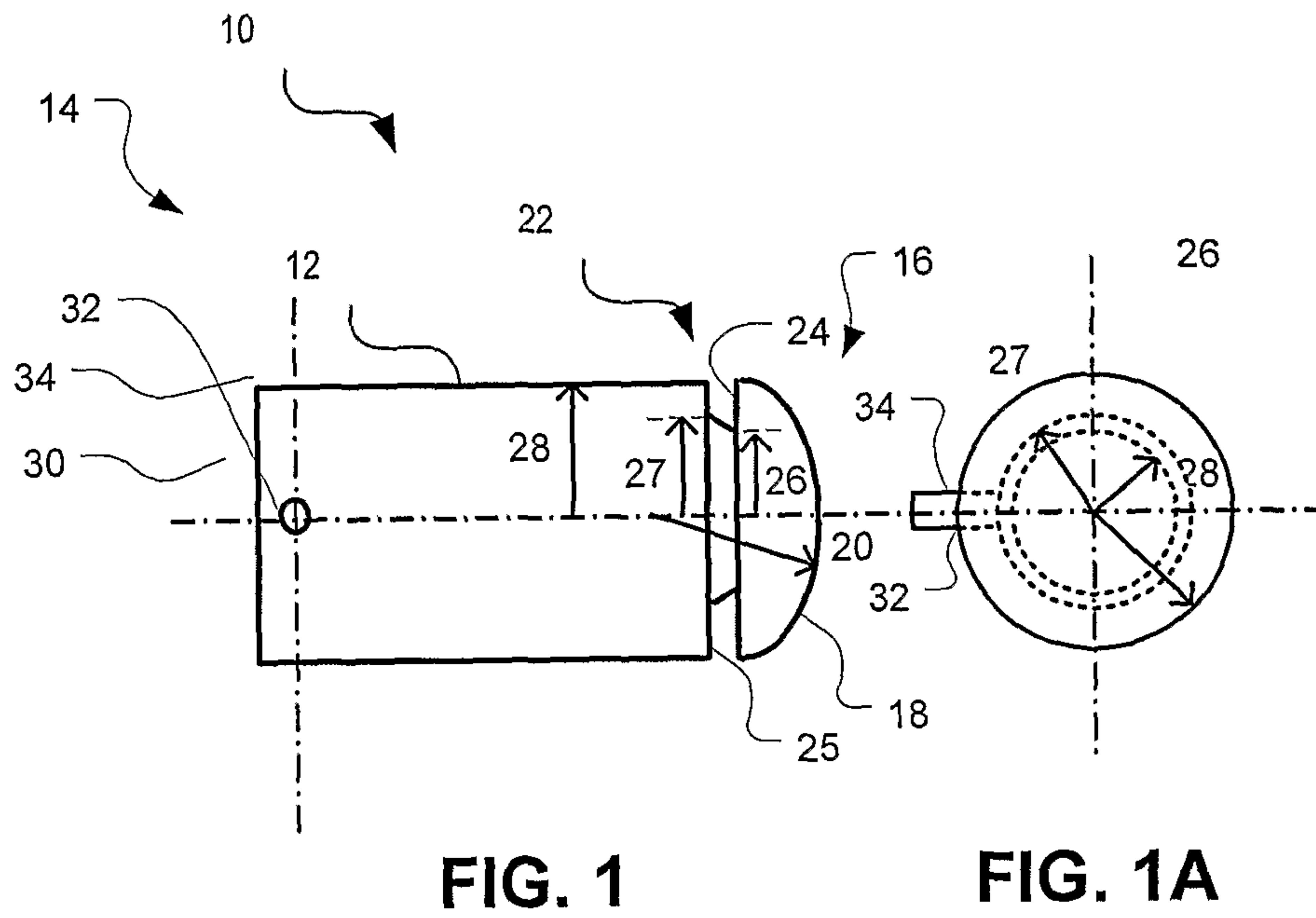
1 28. A kit for testing an alignment between a diagnostic device and a laser
2 refractive system, the kit comprising:
3 a test device;
4 instructions for use comprising placing the test device in a first orientation and
5 obtaining a first image of the test device with the diagnostic device, placing the test device in
6 a second orientation that is torsional offset from the first orientation, obtaining a second
7 image of the test device with the laser refractive system, and comparing a known torsional
8 misalignment between the test device with a measured torsional misalignment that is
9 calculated by comparing the first image of the test device to the second image of the test
10 device; and
11 a package to hold the test device and instructions for use.

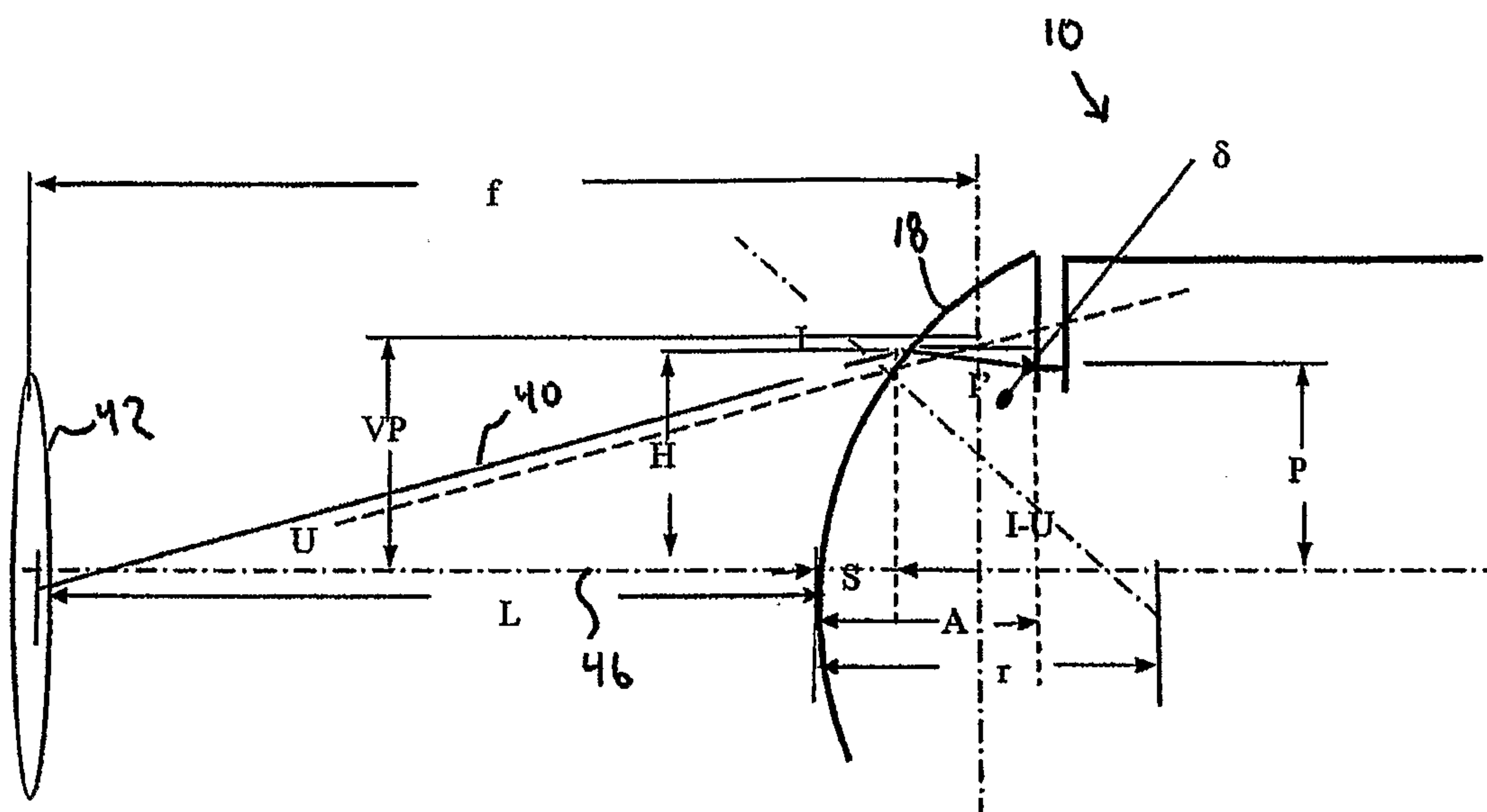
1 29. The kit of claim 28 wherein the test device comprises a body
2 comprising a proximal portion and a distal portion, wherein the proximal portion defines a
3 corneal surface and an iris, and the distal portion defines a retinal surface.

1 30. The kit of claim 28 wherein the body further comprises an alignment
2 reference.

1 31. The method of claim 1 wherein the measured misalignment is carried
2 out with a cyclotorsional measurement algorithm.

1 32. The method of claim 31 further comprising calibrating the
2 cyclotorsional measurement algorithm based on a difference between the measured
3 misalignment and the known misalignment.




$$VP = (\text{visible pupil diameter})/2$$

P = physical pupil radius

f = focal length of objective lens = about 80 mm

A = distance of physical pupil from the front surface vertex = about 3.5 mm

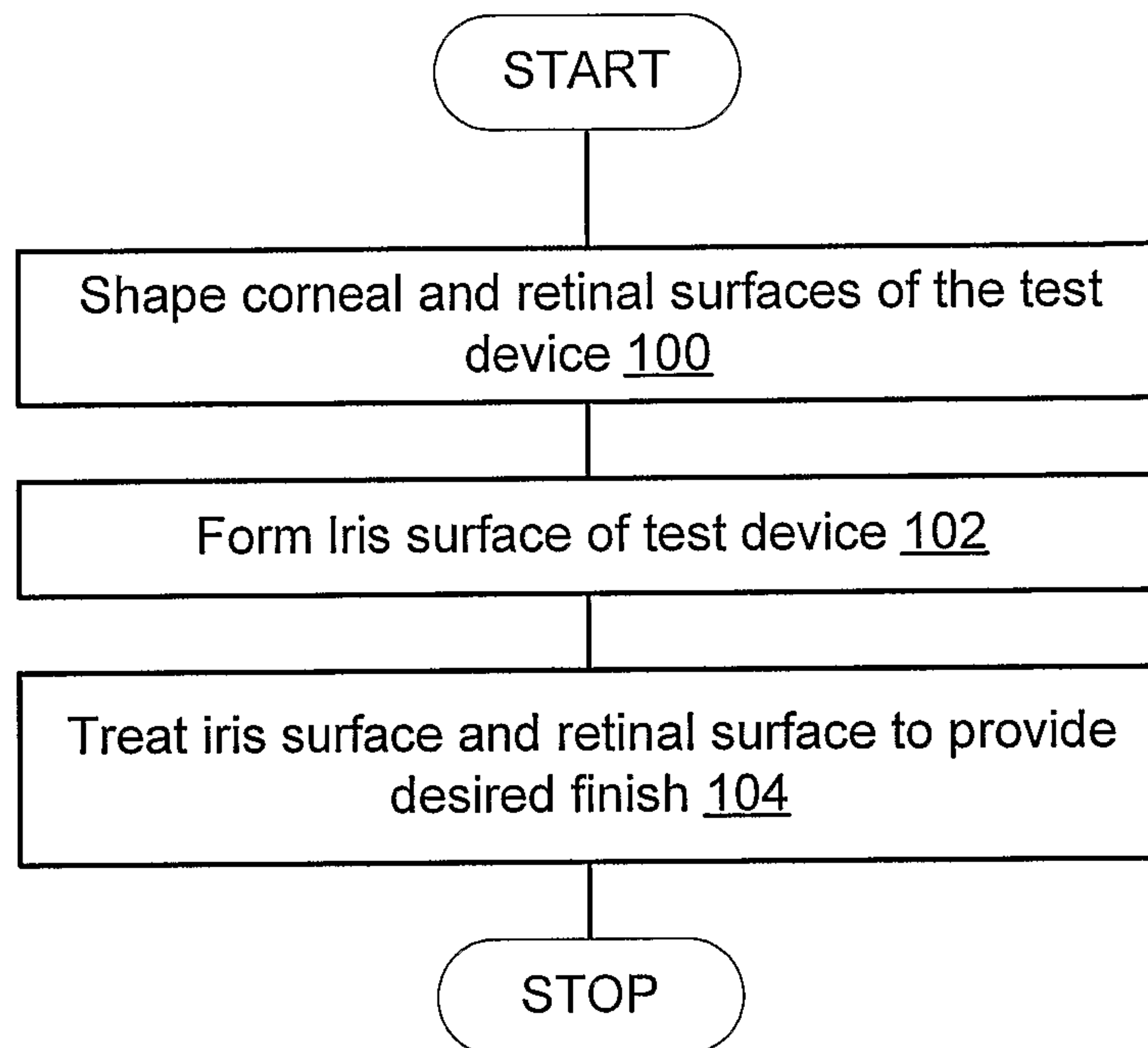
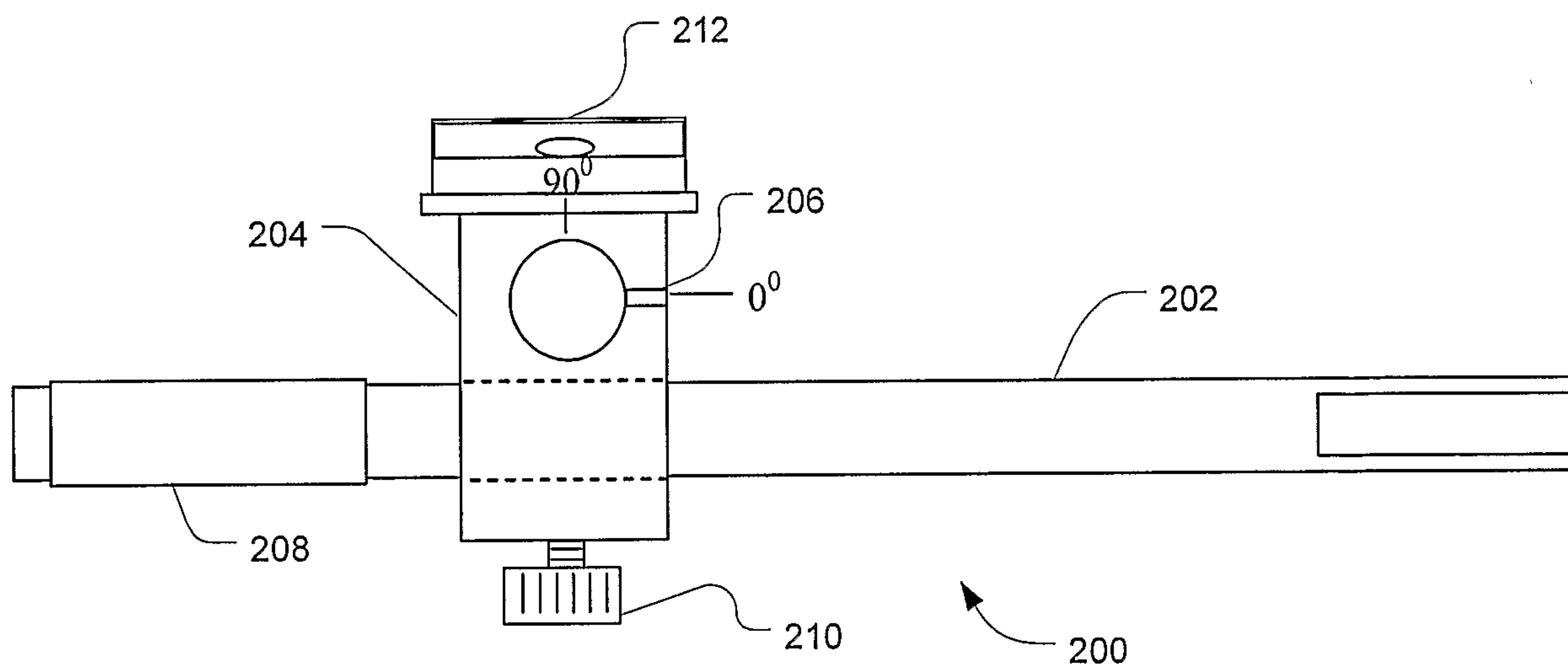
L = distance of objective lens from the front surface vertex

r = radius of curvature of the front surface = about 7.8 mm

n = index of refraction of the test eye material = about 1.493

$$U = \text{atan}(VP/f)$$
$$L = f - 3\text{mm}$$
$$\sin(T) = \sin(U)(L+r)/r$$
$$H = r \sin(I-U)$$
$$S = r(I - \cos(I - U))$$
$$\sin(I') = \sin(I)/n$$
$$d = I \cdot U \cdot T'$$
$$P = H - (A - S) \tan(d)$$

FIG. 1B

**FIG. 2****FIG. 3**

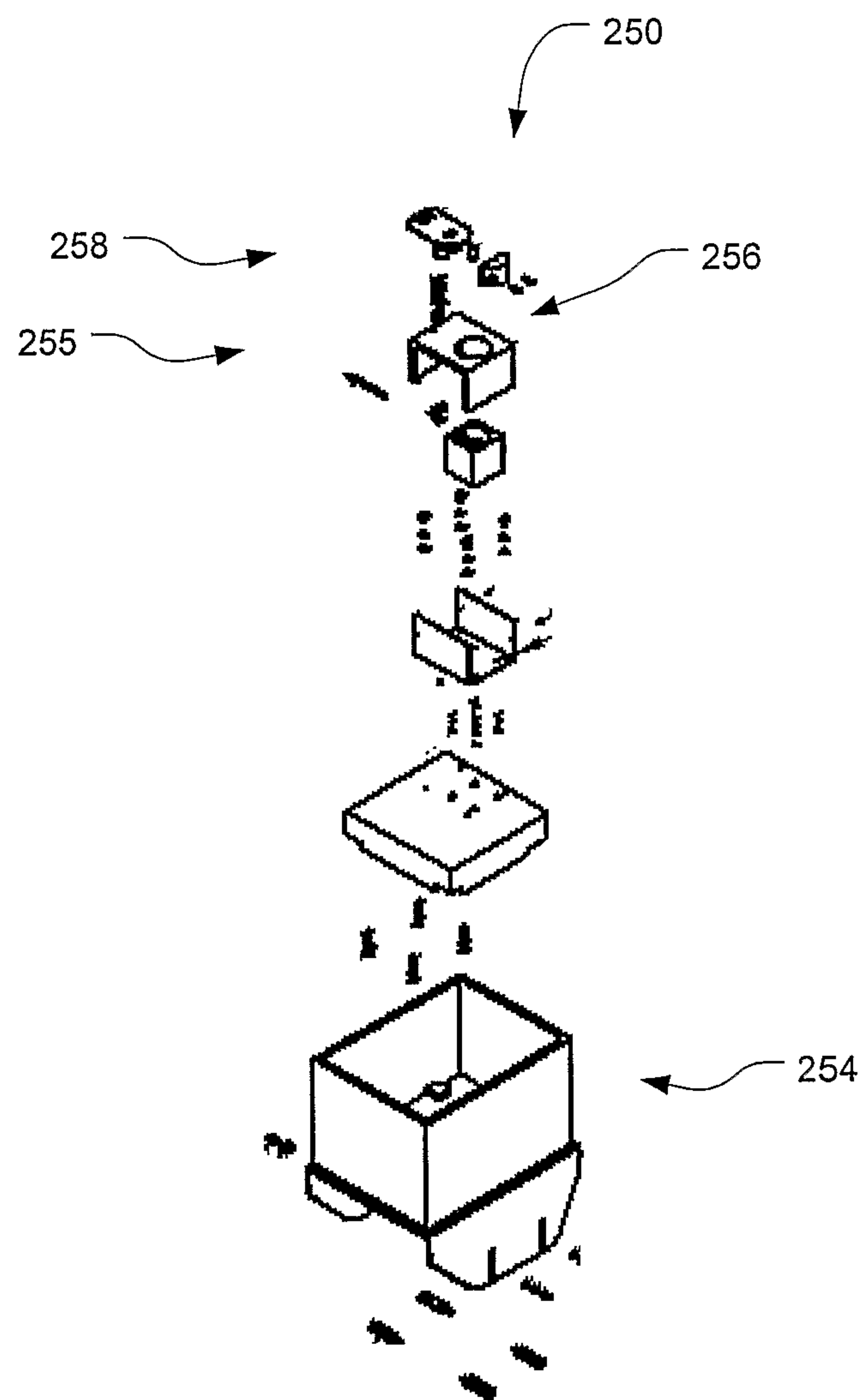


FIG. 3A

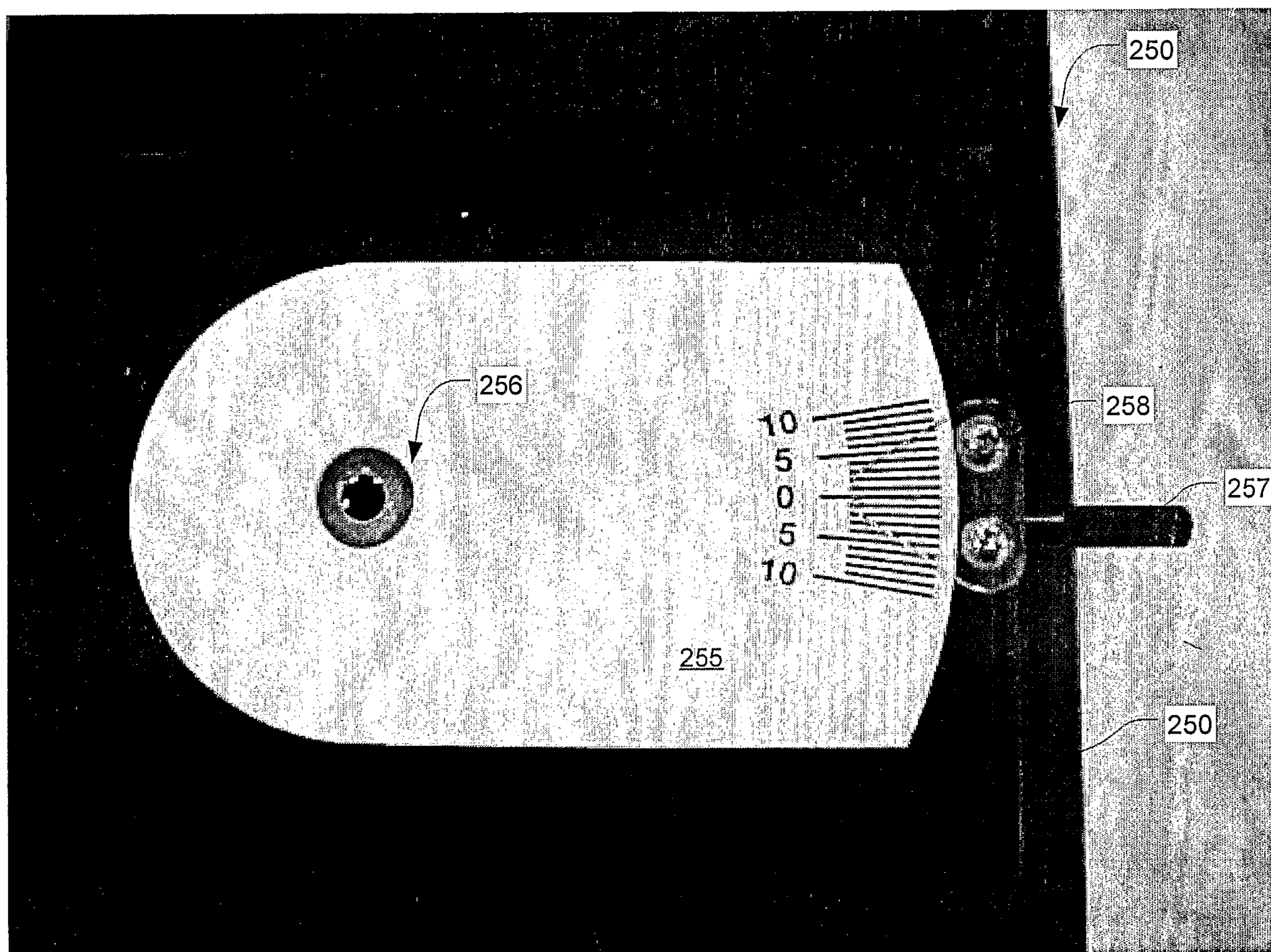


FIG. 3B

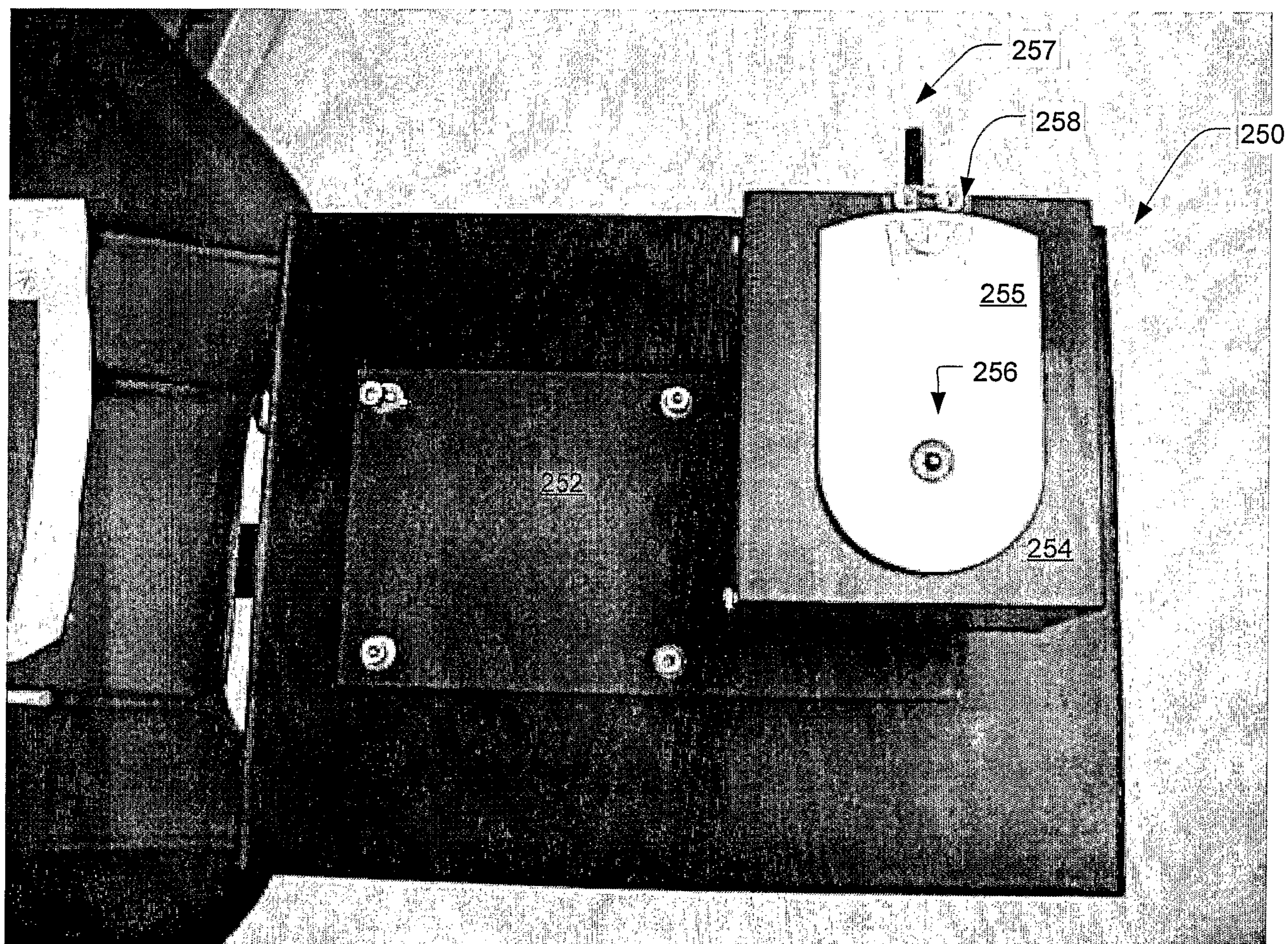


FIG. 3C

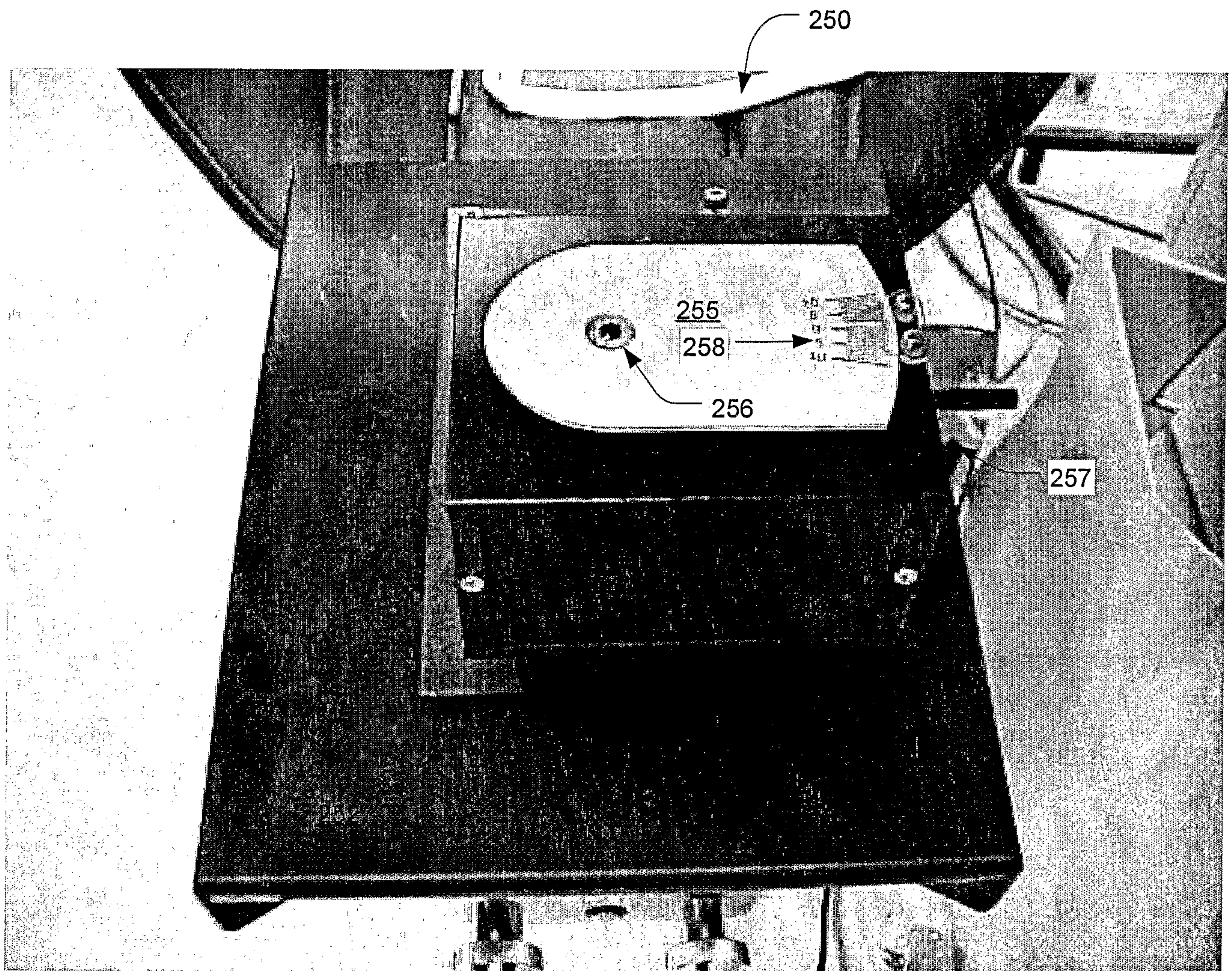


FIG. 3D

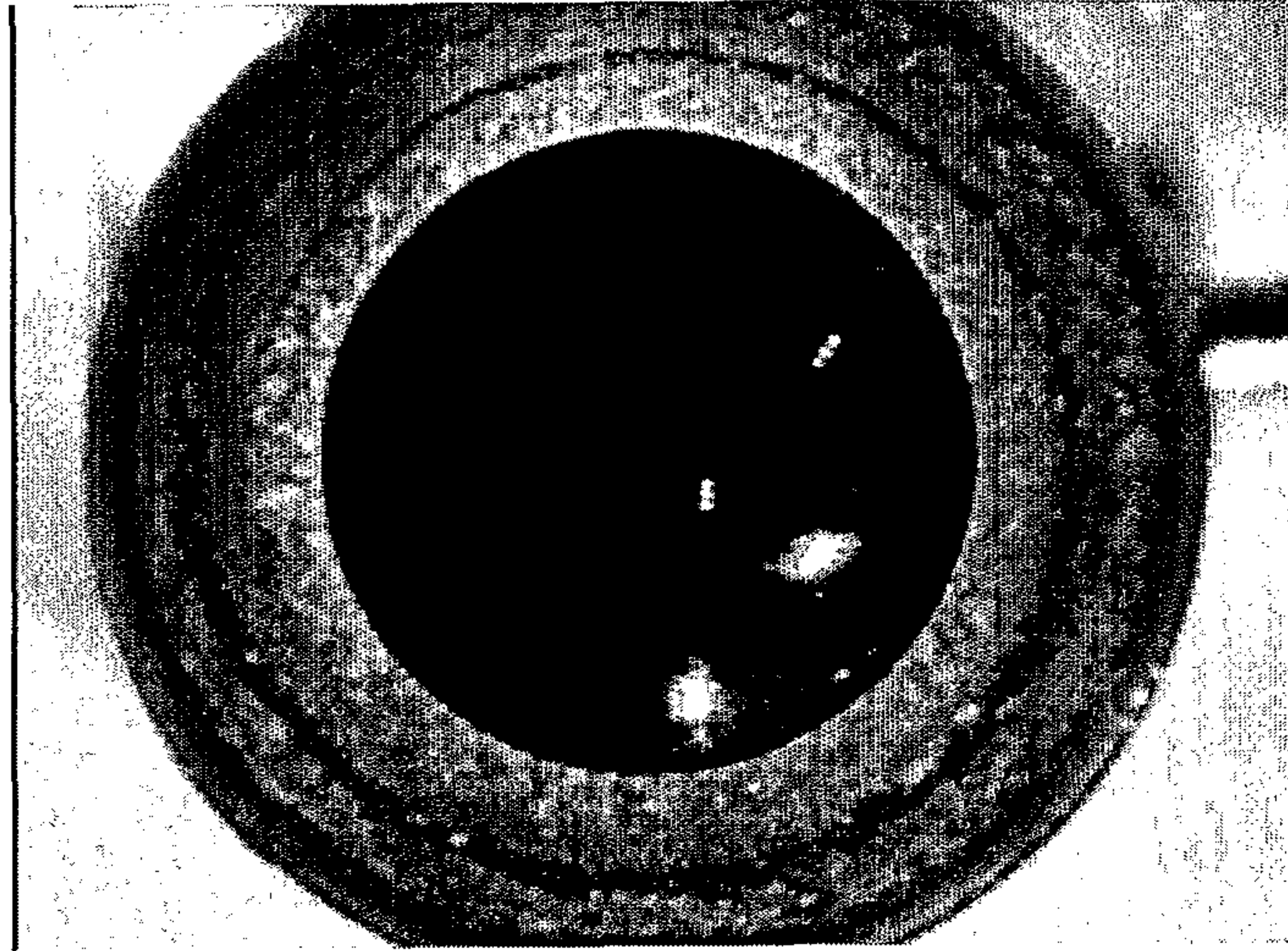


FIG. 4

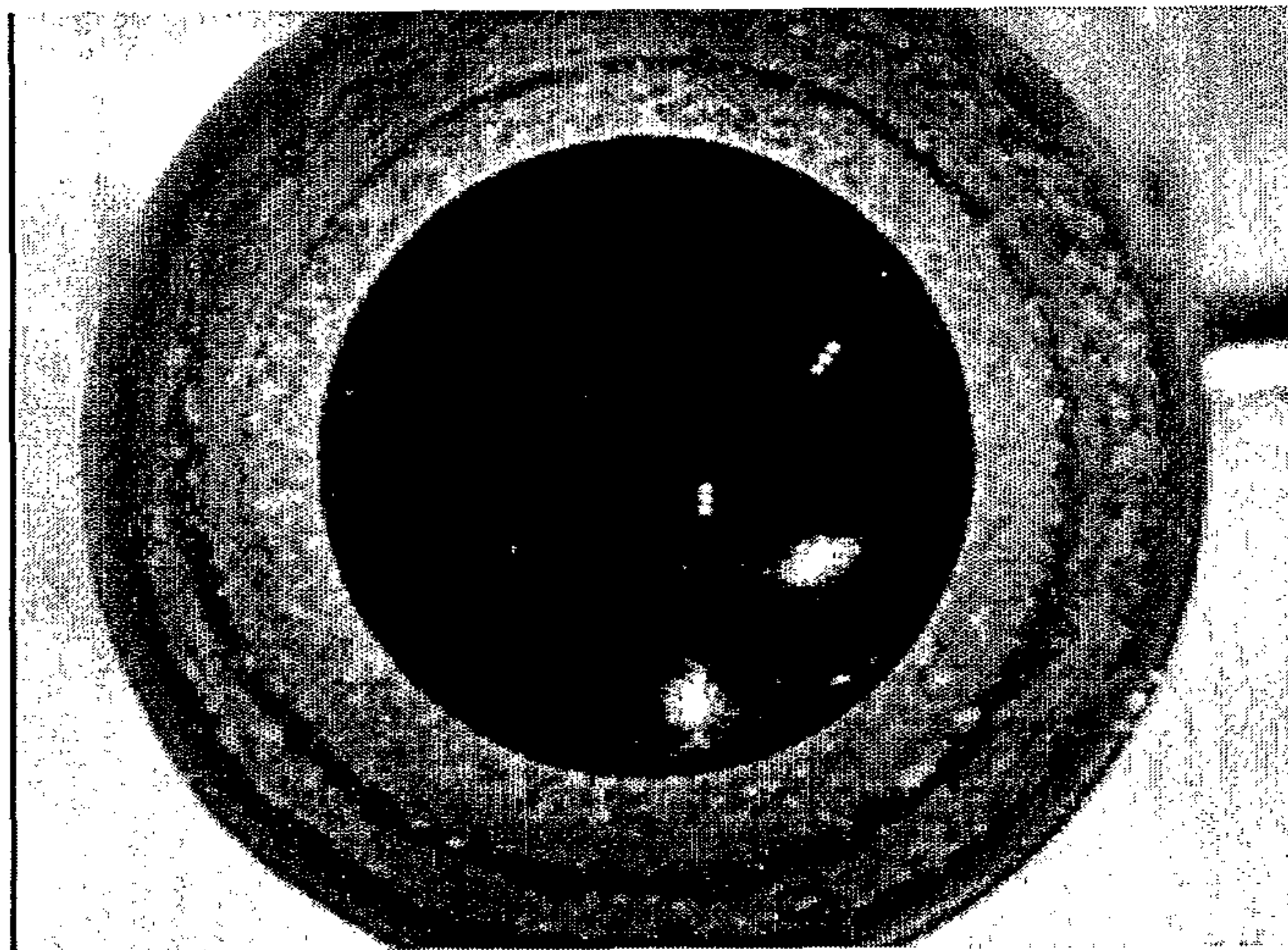


FIG. 5

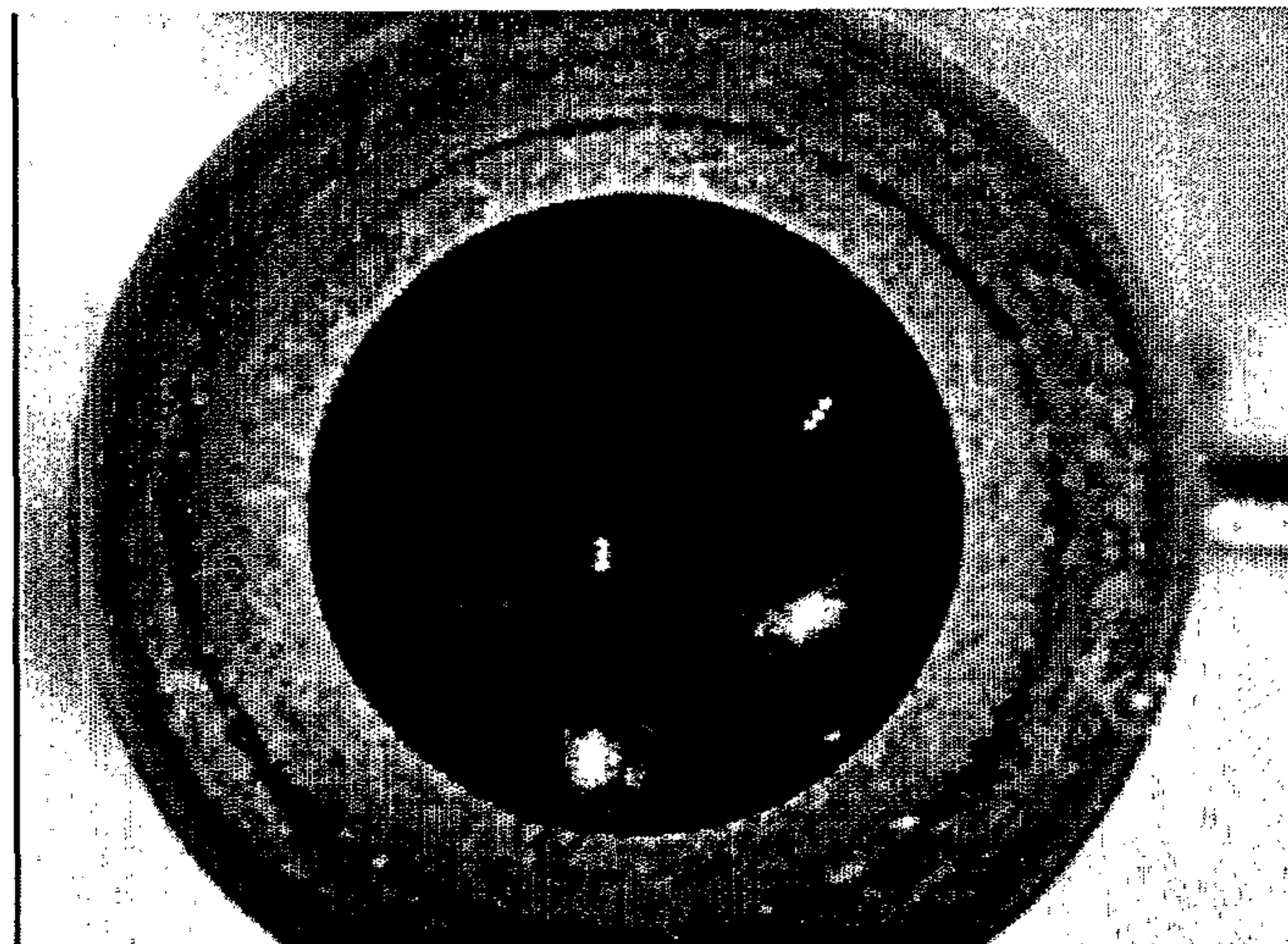
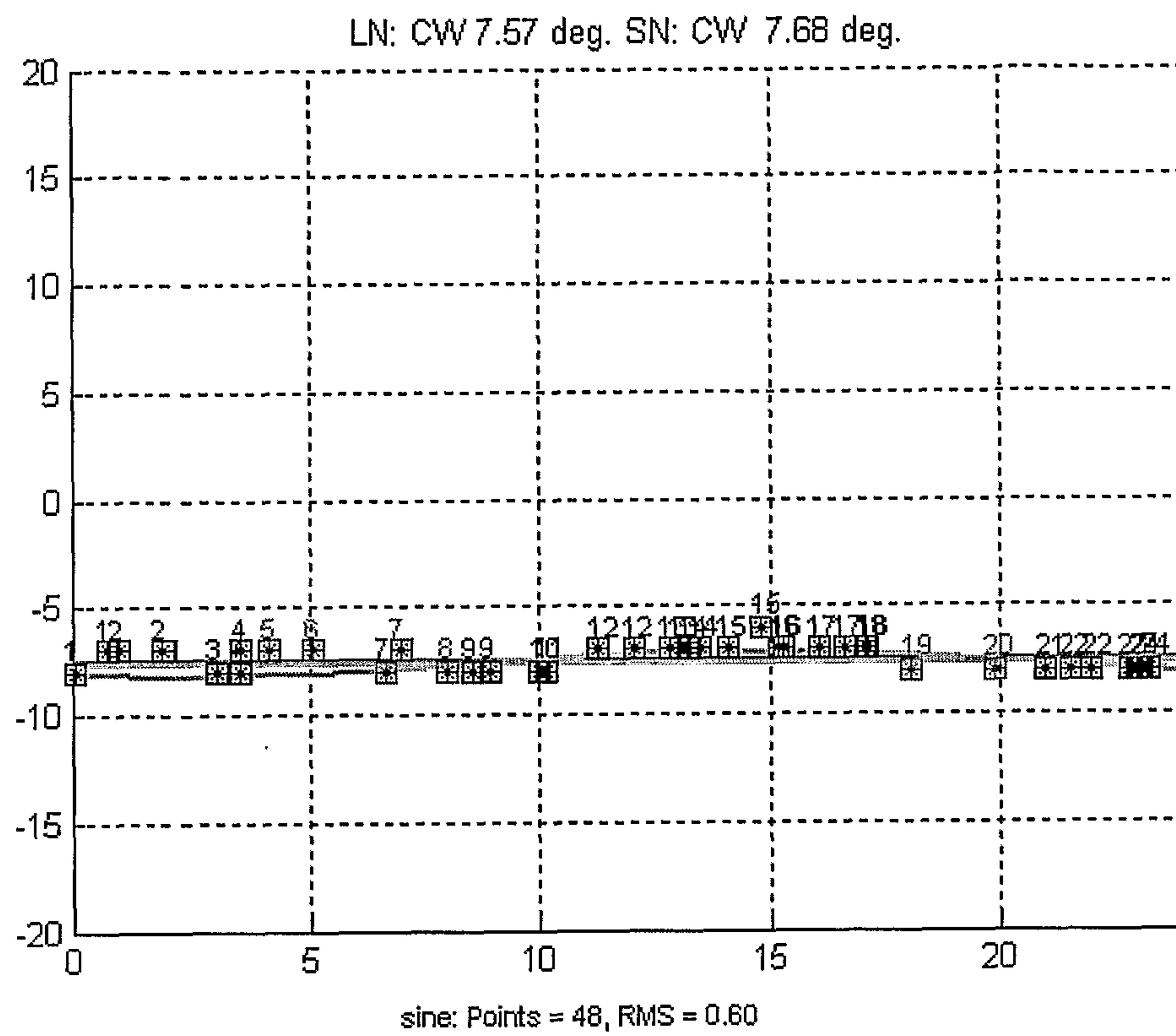
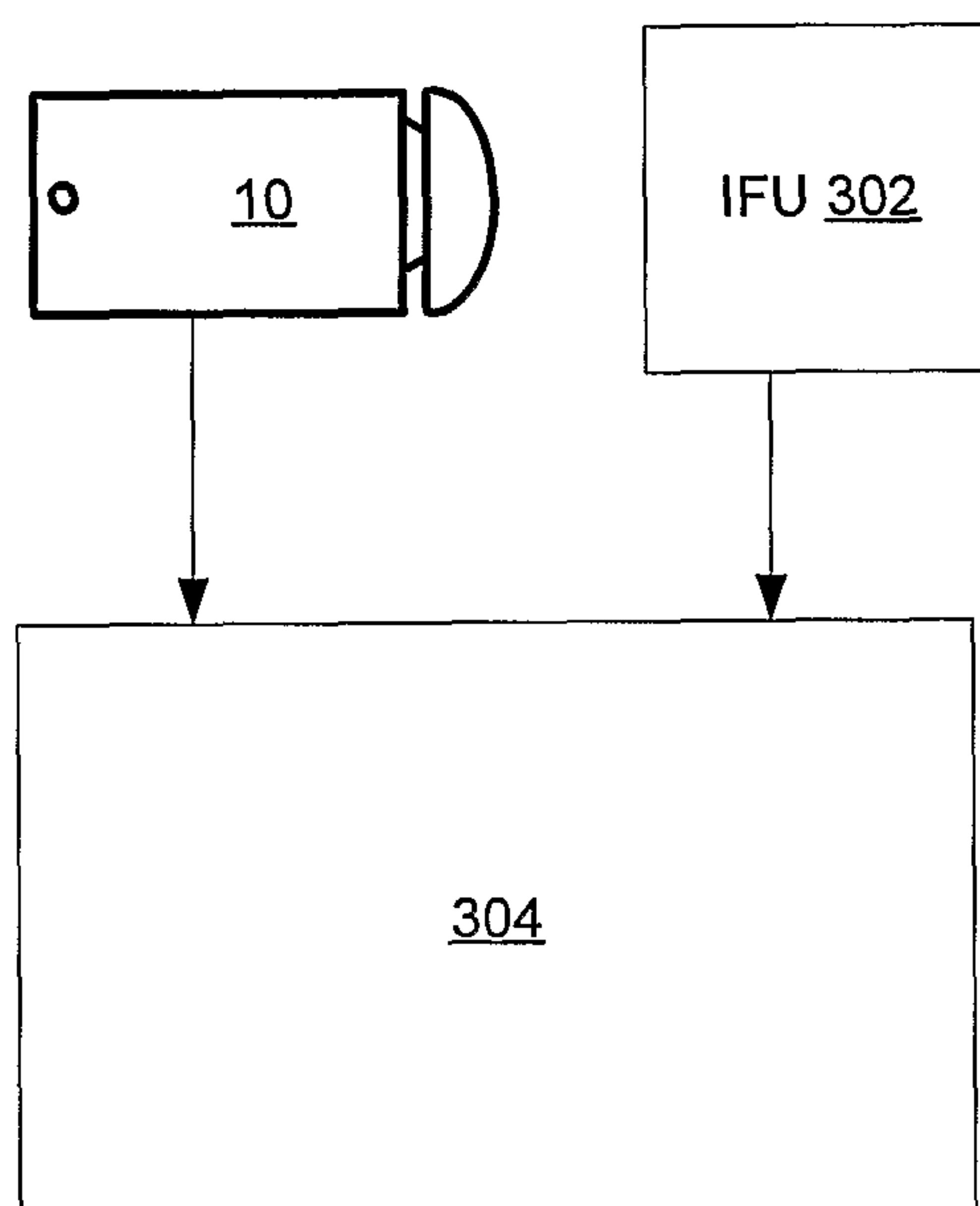
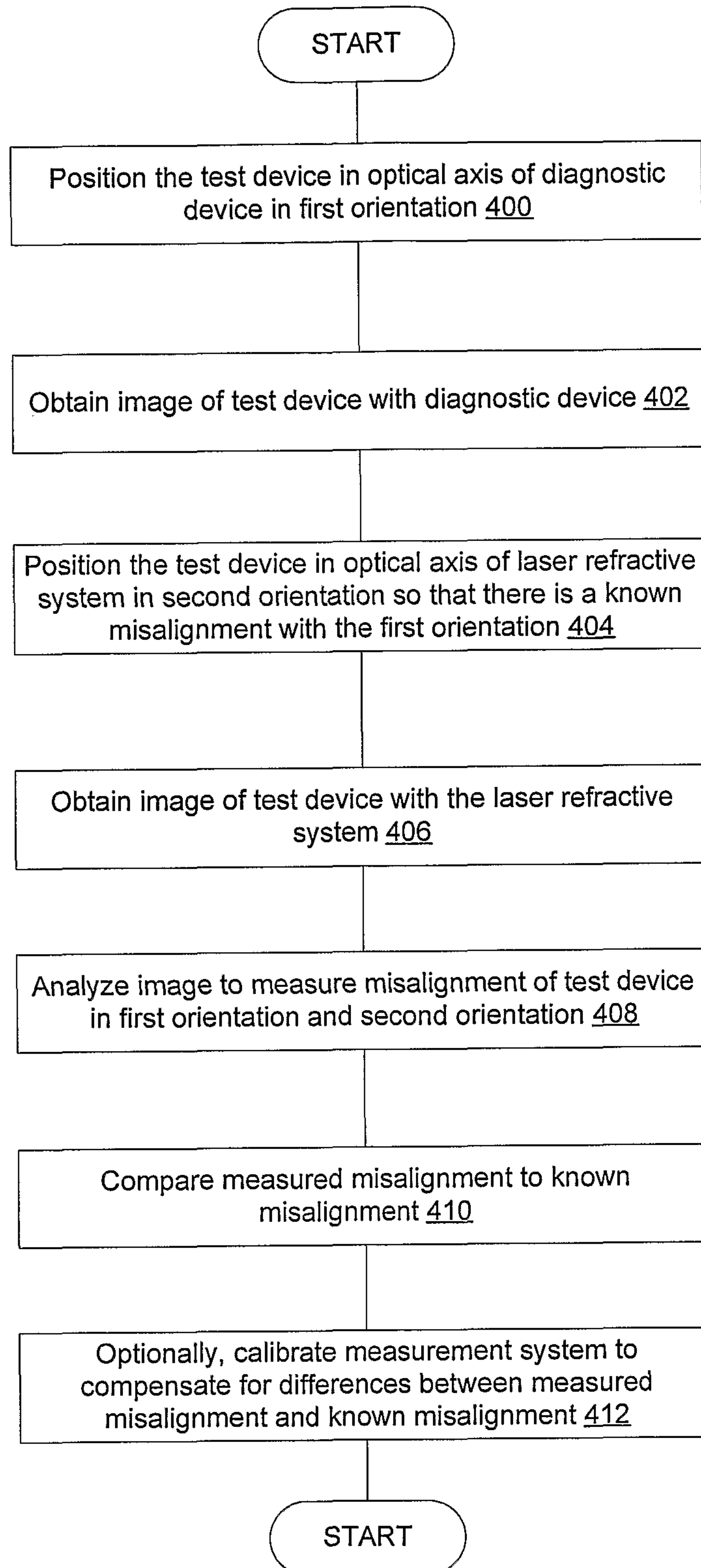


FIG. 6

**FIG. 7****FIG. 8**

**FIG. 9**

