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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
10 May 2007 (10.05.2007)

PCT

(10) International Publication Number
WO 2007/053826 A2

(51) International Patent Classification:
A61B 3/10 (2006.01)

(21) International Application Number:
PCT/US2006/060381

(22) International Filing Date: 31 October 2006 (31.10.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/731,756 31 October 2005 (31.10.2005) 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, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, 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, LT, LU, LV, 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).

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— *as to the identity of the inventor (Rule 4.17(i))*
— *of inventorship (Rule 4.17(iv))*

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

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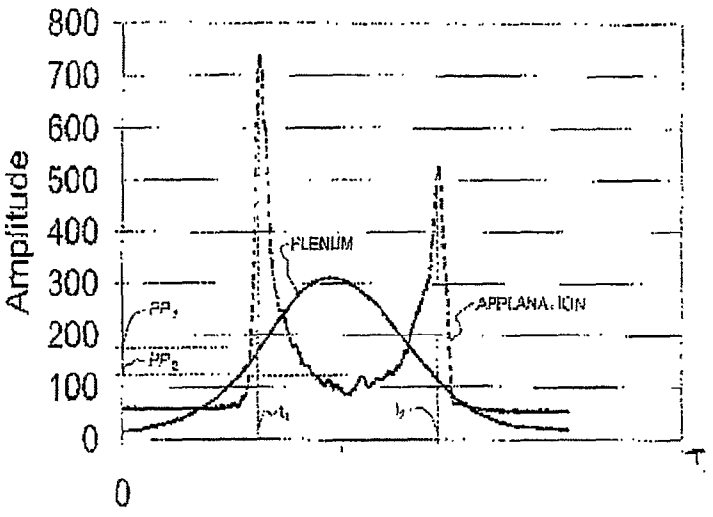
(54) **Title:** METHOD AND APPARATUS FOR MEASURING THE DEFORMATION CHARACTERISTICS OF AN OBJECT



(57) **Abstract:** Embodiments of the invention are generally directed to apparatus and methods for measuring a deformation characteristic of a deformable target surface. The measurement principles of the invention may be applied to a large variety of organic (e.g., human, animal or plant tissue) and inorganic materials having a surface that can be deformed by an applied non-contact force. The surface may be light diffusing and non-transparent or non-diffusing and transparent. An illustrative embodiment of the invention is directed to a device for measuring a deformation characteristic of a cornea. The device comprises a corneal topographer and a non-contact tonometer that is operationally integrated with the corneal topographer. In an aspect, the corneal topographer is a rasterstereography-based topographer. Use of the inventive device enables a method for measuring a deformation characteristic of the cornea. In addition to the measurable deformation characteristics listed above, dioptric power, intraocular pressure, corneal hysteresis, corneal elasticity, corneal viscosity and various known corneal topography characteristics can be measured.

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METHOD AND APPARATUS FOR MEASURING THE DEFORMATION CHARACTERISTICS OF AN OBJECT

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to US Provisional Application Serial Number 60/731,756 filed on October 31, 2005.

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0002] Embodiments of the invention generally relate to methods and apparatus for measuring characteristics of a deformable object through changes in the surface of the object during a deformation interval. More particularly, embodiments of the invention relate to the measurement of physical and biomechanical characteristics of a live cornea.

2. Description of Related Art

[0003] The measurement of the surface characteristics of an object can reveal much information about the physical and mechanical properties of the object. If the surface of the object is deformable in response to an applied force, measurement of the changes in characteristics of the surface may provide further useful information. There exists numerous organic and inorganic objects having deformable surfaces whose measurement may be of interest in various fields. A particularly interesting, exemplary object is the cornea of a human eye. The widespread interest in understanding the physical, biomechanical, optical and all other characteristics of the eye is obviously

motivated. Over the years, different theories have been presented about the structural and dynamic properties of the eye, particularly the cornea. Earlier theories modeling the cornea as a solid structure have more recently given way to understanding the cornea as a layered, biodynamically responsive structure that to this day is not completely understood.

[0004] Increased understanding of the structure of the cornea and its interaction with other components of the eye has been achieved by measuring various topographical characteristics of the cornea. These topographical characteristics include corneal curvature and surface elevation with respect to a reference surface, as well as others known in the art. Corneal topography measuring devices are alternatively referred to as topographers, keratographers or keratometers (a topographer is a generic term referring to an apparatus for measuring the topographical characteristics of an object surface, while keratographer and keratometer more specifically refer to measurements of the cornea). Different devices use different measuring principles to determine various topographical characteristics of the cornea. For example, some devices use Placido-based reflective image analysis. Placido-based devices can measure curvature parameters of the cornea but typically lack the capability to directly measure surface elevation. The Orbscan® anterior segment analyzer (Bausch & Lomb Incorporated) is a topography characteristic measuring device that utilizes a scanning optical slit. Device software provides for direct measurement of surface elevation and corneal thickness as well as surface curvature. Another commercial device developed by Par Technology Corporation is known as the PAR CTS™ Corneal Topography

System (PAR). The PAR imaging system utilizes a raster photography method. The PAR CTS imaging system projects a known grid geometry onto the anterior corneal surface that is viewed by a camera from an offset axis. Other topography characteristic measuring techniques include confocal microscopy, optical coherence tomography, ultrasound, optical interferometry and others, all of which are well known in the art.

[0005] While the measurement of various topographical characteristics of the cornea provide a wealth of information about vision and the effects of corneal shape on visual performance, corneal topography by itself cannot reveal the physical and biomechanical properties of the cornea necessary for a thorough understanding of its structure and function. In order to better understand the biomechanical and biodynamic properties of the cornea, it is necessary to know something about the elastic and viscoelastic properties of the cornea. One technique used to explore these properties is to deform the cornea with a known force and measure the response of the cornea to the force. An illustrative apparatus of this type is known in the art as a tonometer. Tonometers for measuring intraocular pressure (IOP) where originally developed as contact-type instruments, meaning that a portion of the instrument is brought into contact with the cornea during the measurement procedure. A well known instrument of this type is the Goldmann applanation tonometer (GAT) originally developed in the 1950s. The GAT measures the force required to flatten ("applanate") a known area of the cornea, and is used today as a standard against which other types of tonometers are compared to assess measurement accuracy.

[0006] Patient discomfort caused by contact tonometers such as the GAT led to the development of "non-contact" tonometers, which operate by directing an air pulse generated by a pump mechanism through a discharge tube aimed at the cornea to cause applanation. As the cornea is deformed by the fluid pulse, an optoelectronic system monitors the cornea by detecting corneally reflected light from a beam obliquely incident upon the cornea. A peak detector signal occurs at the moment of applanation when the reflecting surface of the cornea is flat. During a non-contact IOP measurement, the cornea is actually deformed from its original convex state through a first state of applanation to a slightly concave state and is allowed to return from concavity through a second state of applanation to convexity as the air pulse decays.

[0007] A method for measuring IOP and a non-contact tonometer are disclosed in U.S. Patent Nos. 6,419,631 and 6,875,175, the disclosures of which are hereby incorporated by reference in their entireties to the fullest extent allowed by applicable laws and rules. This technology is commercially known as the Reichert (Depew, New York) Ocular Response Analyzer™. According to posted information accessible at *http://ocularresponse.reichertoi.com*, the Reichert Ocular Response Analyzer utilizes a dynamic bidirectional applanation process to measure a cornea tissue property called corneal hysteresis. The term corneal hysteresis refers to the difference in pressure values of the air pulse at the inward moving applanation point and the outward moving applanation point during a measurement interval (inward moving refers to an initial convex corneal shape moving to a flattened condition, while the outward applanation point refers to the post air pulse concave corneal surface moving towards the

applanation point on its return to a normal convex surface shape). Since corneal hysteresis appears to be a repeatable measurement, it may provide a metric that is useful for identifying and categorizing various conditions of the cornea. For example, measurement of corneal hysteresis is alleged to aid in identifying and classifying conditions such as corneal ectasia and Fuch's Dystrophy, and as helping in the diagnosis and management of glaucoma. Differences in hysteresis measurements for different corneal conditions may better inform about the biomechanical and biodynamical properties of the cornea. Because corneal hysteresis measurement is credited for presenting a complete characterization of the cornea's biomechanical state, it is believed to have additional potential uses in screening refractive surgery candidates as well as predicting and controlling surgical outcomes. The interested reader is directed to the aforementioned website address for further information provided by the manufacturer.

[0008] In view of the foregoing described techniques, capabilities and apparatus for measuring corneal parameters such as topography characteristics and hysteresis, for example, the inventor has recognized that additional benefits could be obtained by a combination of the techniques and integration of the different apparatus. The inventor has further recognized the need for new and improved methods and apparatus that are capable of more efficiently measuring properties of the cornea, resulting in a better understanding of corneal biomechanics and biodynamics.

SUMMARY OF THE INVENTION

[0009] Embodiments of the invention are generally directed to apparatus and methods for measuring a deformation characteristic of a deformable target surface. It is to be understood that the measurement principles of the invention may be applied to a large variety of organic (e.g., human, animal or plant tissue) and inorganic materials having a surface that can be deformed by an applied non-contact force. The surface may be light diffusing and non-transparent or non-diffusing and transparent. Apparatus suitable for measuring the surface topography characteristics of a deformable target surface during or over a deformation interval, that incorporate a component which can supply a non-contact force that deforms the target surface over the deformation interval, are considered to be within the scope of the claimed invention. As such, an embodiment of the invention is directed to a device for measuring a deformation characteristic of a deformable target surface that includes a topographer and a non-contact target surface deformer that is operationally integrated with the topographer and is located along a first operational axis of the device. According to an aspect, the topographer includes a high speed camera located along a second, operational axis of the device. A suitable camera or detector is required to capture sequential images or still images of specific deformation events during the deformation interval. The device also includes an optical system including a grid object and a light source for projecting a grid image, aligned along a third, operational axis of the device. In a particular aspect, at least one of the second and third axes are offset from the first axis. More particularly, all of the axes are directionally independent.

[0010] In a related aspect in which the target object is a live cornea of an eye, the topographer advantageously is a computer-assisted videokeratography-based topographer (referred to herein as a corneal topographer). In a particular aspect, the corneal topographer is a modified PAR CTS imaging device. According to an aspect, the non-contact target surface deformer is an air pressure pulse-based apparatus. In a particular aspect, the non-contact target surface deformer is a non-contact tonometer.

[0011] According to a related method embodiment for measuring a deformation characteristic of a deformable target surface, a device including a topographer for making a topography characteristic measurement of the target surface and a non-contact force producing component apparatus is provided. The target surface to be measured is suitably positioned with respect to the device. The target surface subjected to the force and experiences responsive deformation over a deformation interval. A plurality of topography characteristic measurements are made during the deformation interval. Exemplary topography characteristic measurements may include, but are not limited to, surface curvature, surface elevation, surface indentation, surface deformation symmetry, surface deformation shape, surface deformation area, surface deformation hysteresis and elasticity, viscosity and pressure.

[0012] An illustrative and particularly advantageous embodiment of the invention is directed to a device for measuring a deformation characteristic of a cornea. The device comprises a corneal topographer and a non-contact tonometer that is operationally integrated with the corneal topographer. In a particularly advantageous

aspect, the corneal topographer is a rasterstereography-based topographer. More particularly, the corneal topographer is a modified PAR CTS imaging device.

[0013] Use of the aforementioned device enables a method for measuring a deformation characteristic of the cornea. In addition to the measurable deformation characteristics listed above, dioptric power, intraocular pressure, corneal hysteresis, corneal elasticity, corneal viscosity and various known corneal topography characteristics can be measured.

[0014] Additional features and advantages of the invention will be set forth in the detailed description which follows, and in part will be readily apparent to those skilled in the art from that description or recognized by practicing the invention as described herein, including the claims as well as the appended drawings.

[0015] It is to be understood that both the foregoing general description and the following detailed description are merely exemplary of the invention, and are intended to provide an overview or framework for understanding the nature and character of the invention as it is claimed. The accompanying drawings are included to provide a further understanding of the invention, and are incorporated in and constitute a part of this specification. The drawings illustrate various embodiments of the invention, and together with the description serve to explain the principles and operation of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] FIG. 1 is a schematic plan view of a device according to an embodiment of the invention;

[0017] FIG. 2A is a schematic force diagram of a cornea at a first moment of applanation;

[0018] FIG. 2B is a schematic force diagram of a cornea at a second moment of applanation;

[0019] FIG. 3 is a graph showing applanation detection and plenum pressure signals for a deformation characteristic measurement according to an embodiment of the invention;

[0020] FIG. 4 is a top view of a projected PAR CTS grid on a simulated cornea before air puff deformation of the corneal surface;

[0021] FIG. 5 is a top view of a projected PAR CTS grid on a simulated cornea after an air puff deformation of the corneal surface;

[0022] FIG. 6 is a schematic side view of corneal indentation corresponding to the deformation shown in FIG. 5; and

[0023] FIG. 7 is a schematic side view of corneal indentation showing a narrower, deeper corneal indentation that that shown in FIG. 6.

DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION

[0024] An embodiment of the invention is generally directed to a device for measuring a deformation characteristic of a deformable target surface. An exemplary embodiment of the invention is directed to a device 10, as shown in Figure 1, for measuring a deformation characteristic of a live cornea. Wherever possible, the same reference numbers will be used throughout the drawings to refer to the same or like

parts. The device 10 includes a corneal topographer 20 and a non-contact tonometer 30 that are operationally and physically integrated components of the device.

[0025] The corneal topographer 20 of the device shown in Figure 1 is a rasterstereography-based topographer that is modeled after a PAR CTS corneal topography system. Such a system is disclosed in US Patent Nos. 4,995,716 and 5,159,361, the disclosures of which are incorporated herein by reference to the fullest allowable extent as though fully set forth in their entireties. The corneal topographer 20 includes a high speed camera/detector 32 located along a second, operational axis 76 of the device 10 and an optical system 42, including a grid object 44 and a light source 45, for projecting a grid image, aligned along a third, operational axis 78 of the device 10. The target object, in this case the cornea 87 of an eye 88, is located along a central device axis 82 in a measurement plane illustrated by dotted line 98. Various lenses and filters that are components of the PAR CTS corneal topographer 20 are not shown.

[0026] The exemplary device 10 also includes a non-contact tonometer 52 located along a first operational axis 72. Axis 72 and axis 82 are coplanar. Second and third operational axes 76, 78 are thus off-set. In an illustrative aspect, non-contact tonometer 52 is a Reichert Ocular Response Analyzer, a description of which is set forth in aforementioned U.S. Patent Nos. 6,419,631 and 6,875,175. Once the cornea is suitably positioned in the measurement plane 98, measurement begins with generation of a metered air pulse directed at the cornea. The impulse energy imparted to the cornea by the air pulse reversibly deforms the cornea from its original state of convexity through a first state of applanation, P_1, to a state of concavity. As the air pulse decays

or is controllably diminished by de-energizing the pump solenoid, the cornea returns from concavity back through a second state of applanation, P_2, to its original state of convexity. This deformation occurs over a deformation interval T referenced in Figure 3. Figures 2A and 2B are simplified diagrams showing the forces acting on a cornea C at the moment (t_1) of first applanation (Figure 2A) and second (t_2) applanation (Figure 2B) during the measurement interval, while ignoring dynamic effects. In the figures, F_1 represents the inwardly directed force of an incident air pulse, F_2 represents the force required to bend the corneal tissue itself, and F_3 represents the outwardly directed force attributed to intra-ocular pressure.

[0027] Based upon the operational principles of the Ocular Response Analyzer, the corneal topographer 20 can conveniently be triggered off of event P_1 at time t_1, event P_2 at time $t_{2,}$, at peak plenum pressure and/or at any predetermined trigger points over the deformation interval T to obtain a plurality of deformation characteristic measurements.

[0028] According to the exemplary apparatus embodiment, use of the PAR CTS system modified to incorporate a high speed camera/detector as the corneal topographer 20 in device 10 is advantageous because the off-set axes 76, 78 of the camera 32 and optical system 42 provide for a centralized location of the tonometer 52. Although a Placido-based topographer may not allow the tonometer to be centrally located, other topography characteristic measuring apparatus may provide a suitable physical arrangement to be used in device 10.

[0029] Figures 4 and 5 show simulated PAR CTS grid images before and after, respectively, an air puff deformation of a corneal surface. Figure 6 illustrates a wide, shallow corneal indentation corresponding to that in Figure 5. For comparative illustration, Figure 7 shows a narrower and deeper corneal indentation than that shown in Figure 6. The figures illustrate that softer or stiffer corneas may respond differently to an applied deformation force.

[0030] Various deformation characteristics can be measured with the device embodiment described above. For example, the magnitude, the symmetry or asymmetry, the shape and the area of the surface deformation could be measured during the deformation interval, as well as applanation depth, corneal curvature, elevation, hysteresis, corneal elasticity and viscosity, and IOP.

[0031] It will be apparent to those skilled in the art that various modifications and variations can be made to the present invention without departing from the spirit and scope of the invention. Thus, it is intended that the present invention cover the modifications and variations of this invention provided they come within the scope of the appended claims and their equivalents.

I Claim:

1. A device for measuring a deformation characteristic of a cornea, comprising:

a corneal topographer; and

a non-contact tonometer operationally integrated with the corneal topographer.

2. The device of claim 1, wherein the corneal topographer includes a high speed camera located along an operational axis of the device.

3. The device of claim 1, wherein the non-contact tonometer is an air puff-based tonometer.

4. The device of claim 3, wherein the tonometer provides a metered, collimated air pulse.

5. The device of claim 1, wherein the tonometer is located along a first, operational axis of the device, further wherein the corneal topographer includes a high speed camera located along a second, operational axis of the device and an optical system including a grid object and a light source for projecting a grid image, aligned along a third, operational axis of the device, further wherein all of the axes are directionally independent.

6. The device of claim 5, wherein the first, operational axis is intermediate the second and third operational axes.

7. The device of claim 6, wherein the first, operational axis is a central operational axis of the device.

8. The device of claim 1, wherein the corneal topographer is a rasterstereography-

based topographer.

9. The device of claim 1, wherein the corneal topographer is a modified PAR CTS imaging device.

10. A device for measuring a deformation characteristic of a deformable target surface, comprising:

a topographer; and

a non-contact target surface deformer operationally integrated with the topographer, located along a first operational axis of the device.

11. The device of claim 10, wherein the topographer is a computer-assisted videokeratography-based topographer.

12. The device of claim 11, wherein the topographer is a posterior apical radius (PAR) imaging device.

13. The device of claim 10, wherein the topographer includes a high speed camera/detector located along a second, operational axis of the device and an optical system including a grid object and a light source for projecting a grid image, aligned along a third, operational axis of the device, further wherein at least one of the second and third axes are offset from the first axis.

14. The device of claim 13, wherein all of the axes are directionally independent.

15. The device of claim 10, wherein the non-contact target surface deformer is an air pressure pulse-based apparatus.

16. The device of claim 15, wherein the non-contact target surface deformer is a non-contact tonometer.

17. The device of claim 10, wherein the first, operational axis of the device is a central operational axis of the device.

18. The device of claim 10, wherein the topographer is adapted to measure elevational data of the target surface.

19. The device of claim 10, wherein the target surface is light diffusing and non-transparent.

20. The device of claim 10, wherein the target surface is light non-diffusing and transparent.

21. The device of claim 20, wherein the target surface is a cornea.

22. A method for measuring a deformation characteristic of a deformable target surface, comprising:

providing a device including a topographer for making a topography characteristic measurement of the target surface;

positioning the target surface in a suitable measurement position;

providing a non-contact target surface deformation force apparatus operationally integrated with the device that is capable of deforming the target surface, and deforming the target surface over a deformation interval; and

making a plurality of the topography characteristic measurements over the deformation interval.

23. The method of claim 22, comprising providing a symmetrical surface deformation force.

24. The method of claim 22, comprising providing an air pressure pulse as the

surface deformation force.

25. The method of claim 22, wherein making a plurality of the topography characteristic measurements over the deformation interval comprises triggering the topographer at a selected time or by a selected event over the deformation interval.

26. The method of claim 25, wherein the selected time or event includes at least one of a state of corneal convexity, a first state of applanation, a state of corneal concavity and a second state of applanation.

27. The method of claim 22, wherein the measured deformation characteristic of the deformable target surface is a magnitude of surface indentation during the deformation interval.

28. The method of claim 22, wherein the measured deformation characteristic of the deformable target surface is a measure of the symmetry or asymmetry of the target surface during the deformation interval.

29. The method of claim 22, wherein the measured deformation characteristic of the deformable target surface is a measure of surface indentation shape during the deformation interval.

30. The method of claim 22, wherein the measured deformation characteristic of the deformable target surface is a measure of surface indentation area during the deformation interval.

31. The method of claim 22, wherein the measured deformation characteristic of the deformable target surface is a measure of hysteresis.

32. The method of claim 22, wherein the deformable target surface is a cornea.

33. The method of claim 32, wherein the measured deformation characteristic of the cornea is a measure of intraocular pressure (IOP).

Replacement Sheet 1/7

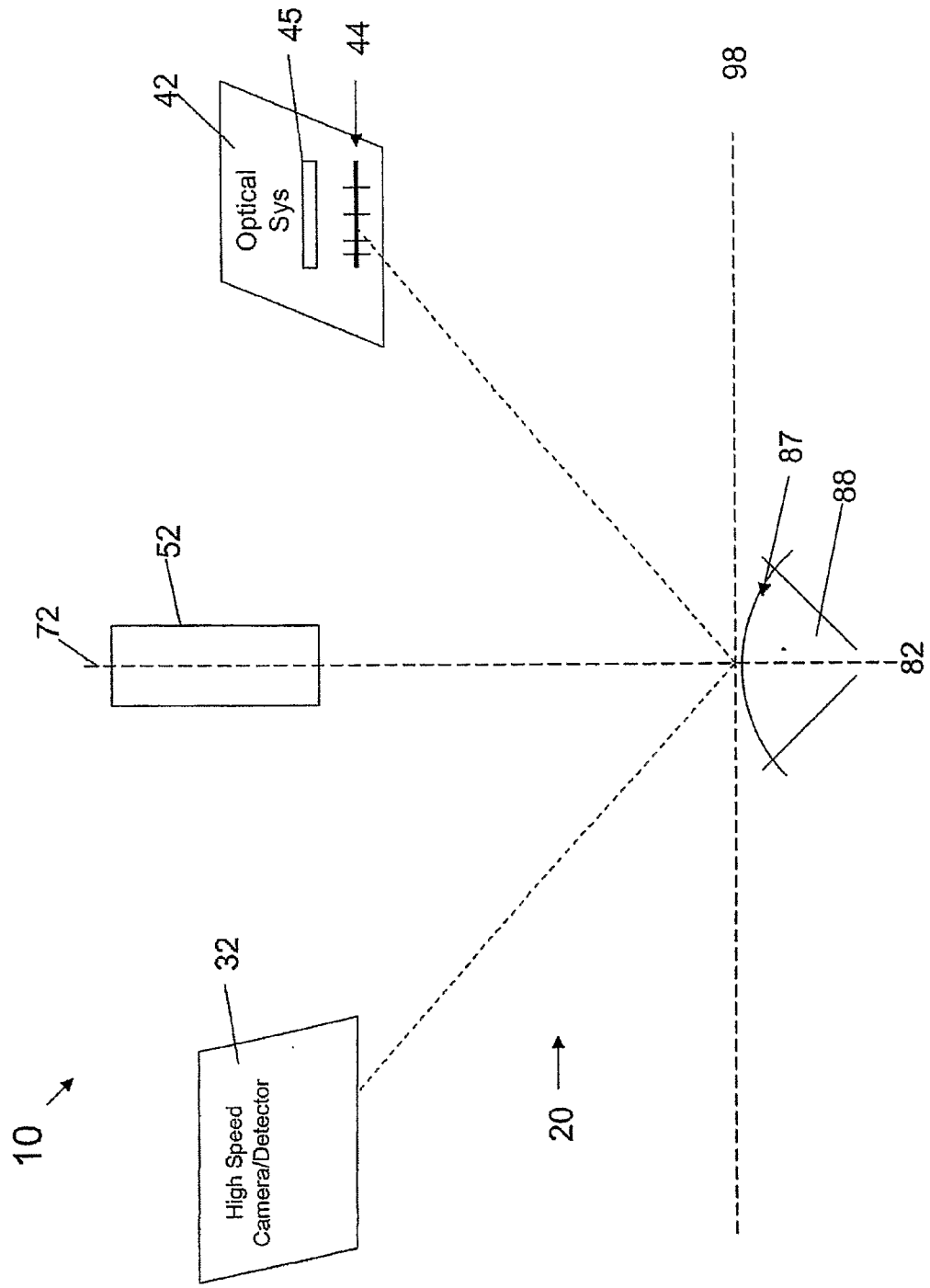


FIG. 1

Replacement Sheet 2/7

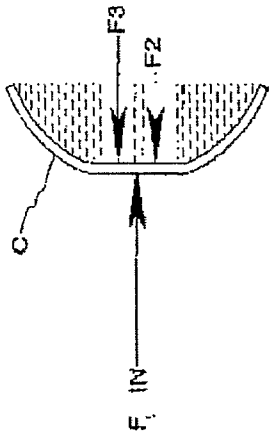


FIG. 2A

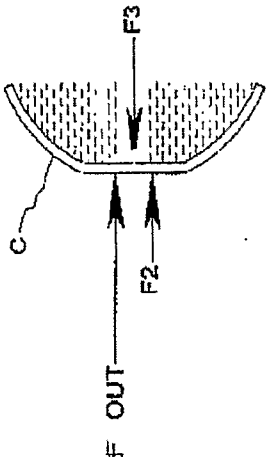
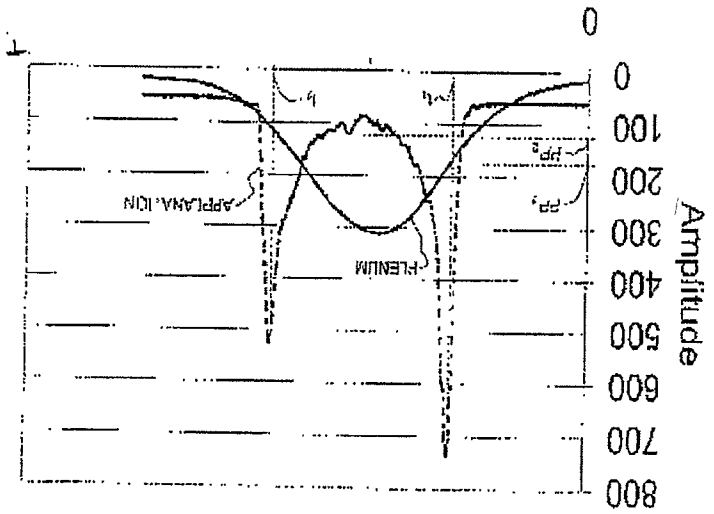


FIG. 2B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Amplitude
APPLANATION
PLENUM

FIG. 3

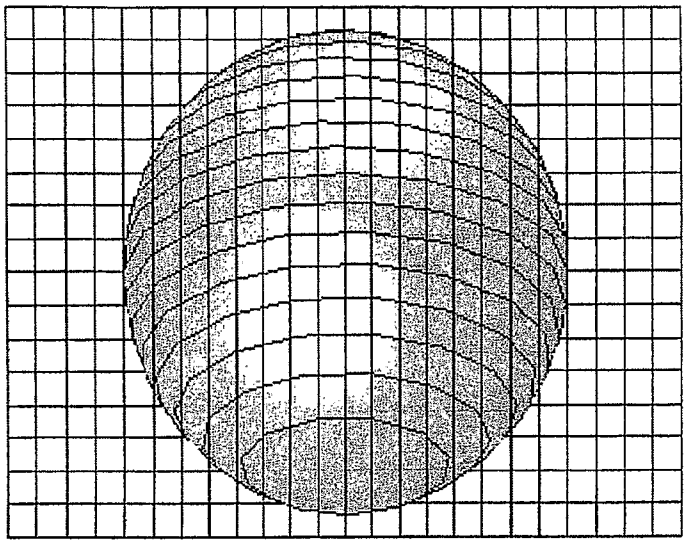

FIG. 4

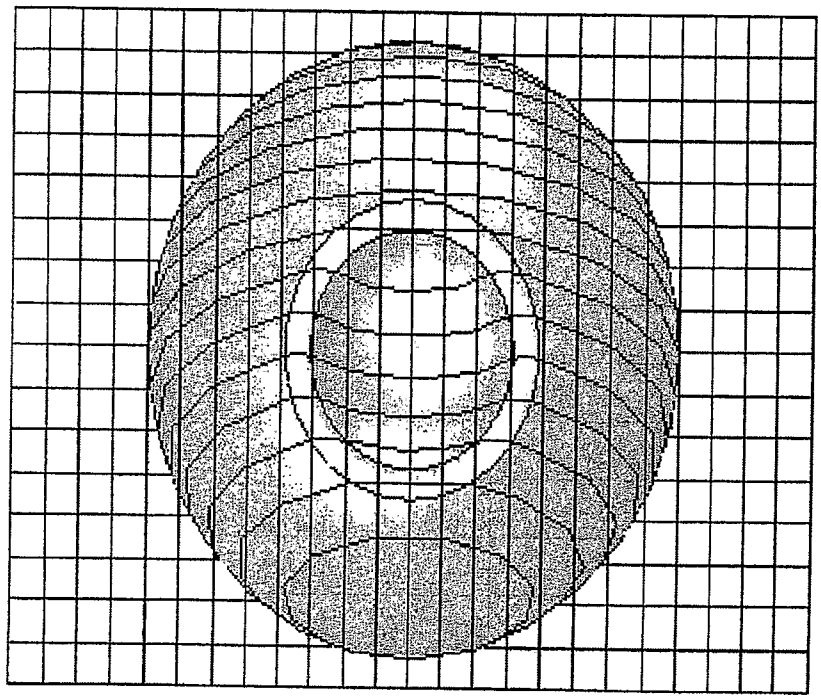

FIG. 5

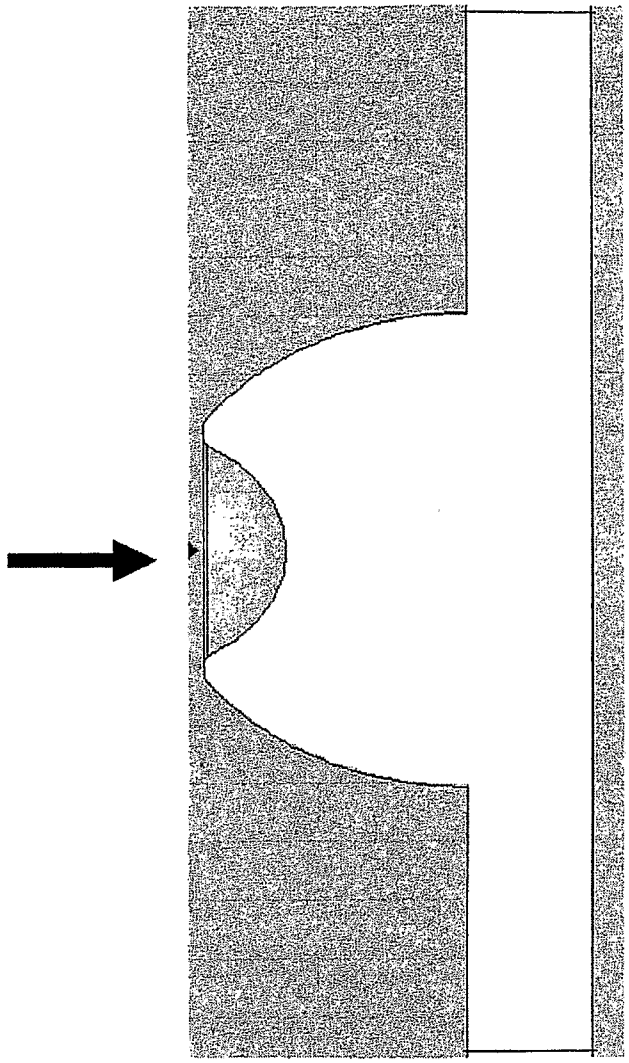

FIG. 6

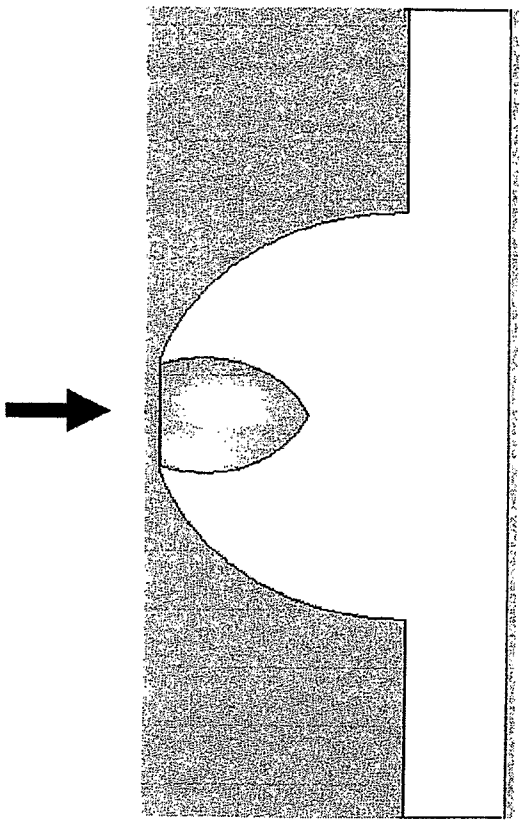

FIG. 7