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(54) SYSTEM, DEVICE, AND METHOD FOR DETERMINATION OF INTRAOCULAR PRESSURE

SYSTEM, VORRICHTUNG UND VERFAHREN ZUR BESTIMMUNG DES AUGENINNENDRUCKS

SYSTÈME, DISPOSITIF, ET PROCÉDÉ DE DÉTERMINATION DE LA PRESSION INTRAOCULAIRE

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(73) Proprietors:
- **Brockman Holdings LLC**
  Louisville, Kentucky 40207 (US)
- **University Of Kentucky Research Foundation**
  Lexington, Kentucky 40506-0033 (US)

(72) Inventors:
- **HASTINGS, Jeffrey Todd**
  Lexington
  Kentucky 40502 (US)
- **BROCKMAN, E. Britt**
  Louisville
  Kentucky 40207 (US)
- **ST. OMER, Ingrid L.**
  Lexington
  Kentucky 40514 (US)
- **WRIGHT, John C.**
  Louisville
  Kentucky 40241 (US)

(74) Representative: **Müller-Boré & Partner**
Patentanwälte PartG mbB
Friedenheimer Brücke 21
80639 München (DE)

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Description

[0001] The present invention relates to systems, devices, and methods for measuring pressure. More particularly, the present invention relates to systems, devices, and methods for measuring intraocular pressure based on an intraocular pressure sensor.

[0002] Devices that measure intraocular pressure (IOP) by measuring the applanation of the cornea are known in the art. Ophthalmologists use such devices to measure IOP in a physician's office. However, these single-point measurements remain insufficient to fully manage eye disease, particularly glaucoma. IOP peaks are missed in office hours measurements, IOP fluctuations may be an independent risk factor, and a majority of glaucoma patients require changes to their topical and/or surgical management approach after multiple IOP measurements on a single day. Infrequent measurements also make it difficult to evaluate treatment effectiveness and/or to assess patient compliance. However, more frequent, longer term tonometry is labor intensive, impractical, expensive, and often conducted only upon admission to an academic hospital. Tonometers that can be used by the patient are know in the art, but these devices often cause discomfort, have proven difficult for patients to repeatably administer, and have demonstrated unacceptable error in clinical studies.

[0003] Implantable electronic devices for more frequent measurement of intraocular pressure are known in the art. Readout of passive electronic sensors has proven problematic because inductively coupling to tiny receivers in the sensor is difficult. Active sensors overcome this problem, but require implantable power sources or power storage systems, implanted integrated circuits, and large antennas. As a result, both passive and active systems have so far proven too large and complex, mostly irreversible, risky with regard to biocompatibility, and/or error prone.

[0004] US 2004/254438 A1 discloses methods, apparatus and systems for measuring pressure and/or for quantitative or qualitative measurement of analytes within the eye or elsewhere in the body.

[0005] US 2007/123768 A1 discloses ophthalmic instruments, systems and methods especially adapted for conducting simultaneous tonometry and pachymetry measurements.

[0006] US 2008/154114 A1 discloses a device and a method for use in non-invasive measurement of a patient's intra-ocular pressure (IOP).

[0007] According to one aspect of the invention, a system for determination of intraocular pressure includes: an intraocular pressure sensor; a light source illuminating the intraocular pressure sensor with one or more wavelengths of light; and a detector that measures reflected and/or emitted light from the sensor.

[0008] According to the present invention, the intraocular pressure sensor includes a substrate member, a spacer member, and a flexible membrane. The substrate member, the spacer member and the flexible membrane define a sealed cavity. The flexible membrane is configured to move or deform in response to intraocular pressure changes, wherein the movement of the flexible membrane can be measured optically. The flexible membrane is configured to both transmit and reflect light, and the substrate member is configured to reflect light, wherein the light reflected by the substrate member interferes either constructively or destructively with light reflected from the flexible membrane to create an interference pattern, and wherein the resulting interference pattern corresponds to intraocular pressure.

[0009] In accordance with one implementation, the system further includes a processing device in communication with the detector. Then, the flexible membrane both transmits and reflects the one or more wavelengths of light, the substrate member reflects the one or more wavelengths of light transmitted by the flexible membrane, the light reflected by the substrate member interferes with light reflected from the flexible membrane to create an interference pattern, and the interference pattern corresponds to intraocular pressure. According to this implementation, the detector is an electronic imaging device capturing an image of the interference pattern, and the processing device performs a phase calculation on the image of the interference pattern to determine phase angles of the interference pattern, and correlates the phase angles with intraocular pressure.

[0010] The processing device may further perform the phase calculation using an integral transform and may calculate the phases at one or more spatial frequencies corresponding to peaks in an absolute value of the integral transform.

[0011] Also, the processing device may use the values of the spatial frequencies corresponding to peaks in the absolute value of the integral transform to correct for errors which arise from angular deviation of a sensor normal from an optical axis of a readout system.

[0012] Still further, each wavelength emitted by the light source may have a coherence length longer than the twice the separation between the flexible membrane and the substrate member.

[0013] According to this implementation, the system may further include an optical filter positioned between the intraocular pressure sensor and at least one of the light source and the electronic imaging device. The optical filter provides an optical coherence length greater than twice the distance from the flexible membrane to the substrate member.

[0014] The light source may be modulated in time to allow for lock-in detection of the interference pattern.

[0015] Further, the light source may emit multiple wavelengths of light, either simultaneously or sequentially, and the dimensions of the flexible membrane may allow a phase change in the interference pattern of greater than 2π for at least one of the multiple wavelengths of light.

[0016] In accord with another implementation, the sys-

tem further includes a processing device in communication with the detector, a coating containing a fluorescent material coated on at least one of the substrate member and the flexible membrane, and a filter positioned between the intraocular pressure sensor and the detector. An external light source excites the fluorescent material of the coating, the fluorescent material of the coating emits a light of a different second wavelength, the emission of the light of the second wavelength being the result of excitation of the fluorescent material, and the proximity of the flexible membrane to the substrate member modulates the intensity of the emitted light of a different second wavelength. The detector is a light intensity sensor. The filter allows only the second wavelength to reach the detector. Then, the processing device correlates the detected intensity at the second wavelength with intraocular pressure.

[0017] According to another aspect of the invention, a device for measuring intraocular pressure includes: the above-defined intraocular pressure sensor; an anchoring member attached to the intraocular pressure sensor for immobilizing the intraocular pressure sensor in an eye; a protective member attached to the anchoring member and covering the intraocular pressure sensor to prevent contact between the flexible membrane and portions of the eye; and a second intraocular pressure sensor having at least one of a different diameter, shape, membrane thickness, membrane material, and substrate material, the intraocular pressure sensor and the second intraocular pressure sensor providing at least one of redundant pressure measurement, failure detection, compensation for temperature fluctuations in the eye, increased pressure measurement sensitivity, and increased pressure measurement dynamic range.

[0018] In accordance with one implementation, the anchoring member comprises a plate for insertion in a scleral pocket and for immobilizing the device, and an arm for entering an anterior chamber of the eye through a scleral tunnel. The plate may include holes for suturing the plate to the eye, and/or holes for assisting wound healing.

[0019] In accordance with another implementation, the anchoring member includes a pair of pincers to enclavate an iris of the eye.

[0020] The anchoring member and the protective member may be formed from a biocompatible material selected from a group consisting of polymethylmethacrylate, other acrylic plastics, silicone, other biocompatible plastics, biocompatible metals, and biocompatible metal alloys.

[0021] In accordance with one implementation, the sealed cavity of the intraocular pressure sensor has a pressure below one atmosphere.

[0022] Herein, material and dimensions of the flexible membrane may provide a number of periods in the interference pattern to estimate phase within ± 0.03 radians such that intraocular pressure can be measured with an accuracy of 1 mm Hg over a range of 610 to 820 mmHg absolute pressure.

[0023] Also according to this implementation, the material and dimensions of the flexible membrane may prevent the membrane from contacting the bottom of the sealed cavity under pressures encountered in the intraocular environment.

[0024] Further in accord with this implementation, the materials and dimensions of the flexible membrane may limit pressure measurement errors to less than 1 mm Hg in the presence of temperature fluctuations from 32°C to 36°C typically encountered in the intraocular environment.

[0025] Still further in accord with this implementation, the material and dimensions of the flexible membrane and the thickness of the spacer member provide an interference pattern without using a light source that relies on laser action.

[0026] This implementation may further include a layer of additional material coated on the external side of the membrane, with the thickness and refractive index of the additional material equalizing the reflection from the flexible membrane and the substrate member.

[0027] Additionally, the material and dimensions of the membrane of this implementation may limit the phase change in the interference pattern to less than 2π over a range of 610 to 820 mmHg absolute pressure.

[0028] In accordance with another implementation, the intraocular pressure sensor includes a coating containing a fluorescent material, the coating being coated on at least one of the substrate member and the flexible membrane. An external light source excites the fluorescent material of the coating, and the fluorescent material of the coating emits a light of a different second wavelength, the emission of the light of the second wavelength being the result of excitation of the fluorescent material. The proximity of the flexible membrane to the substrate member modulates the intensity of the emitted light of a different second wavelength and the detected intensity of the emitted light of the different second wavelength is used to determine the pressure.

[0029] This implementation may further include a scattering medium coated on at least one of the flexible membrane and the substrate member.

[0030] Also, in accordance with this implementation, the coating may further include a second fluorescent material, and the external light source may further excite the second fluorescent material of the coating to emit a light of a different third wavelength. Then, the difference in detected intensity of the emitted light at the second and third wavelengths may be used to determine the pressure.

[0031] Basically, a method for determination of intraocular pressure includes placing an intraocular pressure sensor in an eye, the intraocular pressure sensor including a substrate member, a spacer member, and a flexible membrane, the substrate member, the spacer member and the flexible membrane defining a sealed cavity wherein the flexible membrane moves and/or deforms in

response to intraocular pressure changes. The method further includes illuminating, with a light source, the intraocular pressure sensor with one or more wavelengths of light, and detecting, with a detector, a resultant light that contains information about intraocular pressure.

[0032] In accordance with one implementation, the flexible membrane both transmits and reflects the one or more wavelengths of light, the substrate member reflects the one or more wavelengths of light transmitted by the flexible membrane, and the light reflected by the substrate member interferes with light reflected from the flexible membrane to create an interference pattern. The interference pattern corresponds to intraocular pressure.

[0033] According to this implementation, detecting the resultant light includes capturing, with an electronic imaging device, an image of the interference pattern, and the method further includes: performing a phase calculation on the image of the interference pattern to determine phase angles of the interference pattern; and correlating the phase angles with intraocular pressure.

[0034] Then, this implementation may further include positioning an optical filter between the intraocular pressure sensor and at least one of the light source and the electronic imaging device, the optical filter providing an optical coherence length greater than twice the distance from the flexible membrane to the substrate member.

[0035] According to this implementation, the step of illuminating the intraocular pressure sensor includes modulating the light source in time to allow for lock-in detection of the interference pattern by the electronic imaging device.

[0036] In accordance with another implementation, the method further includes coating a layer containing fluorescent material on at least one of the substrate member and the flexible membrane. Illuminating the intraocular pressure sensor includes exciting the fluorescent material of the coating with a light source such that the fluorescent material of the coating emits a light of a different second wavelength, the emission of the light of the second wavelength being the result of excitation of the fluorescent material. Then, the proximity of the flexible membrane to the substrate member modulates the intensity of the emitted light of a different second wavelength. Additionally, detecting the resultant light includes detecting an intensity of the emitted light of the different second wavelength to determine the pressure.

[0037] In accordance with another implementation, placing the intraocular pressure sensor in the eye includes immobilizing the intraocular pressure sensor in the eye using an anchoring member attached to the intraocular pressure sensor. The anchoring member may include a plate and an arm, and the immobilizing the intraocular pressure sensor in the eye may further include: inserting the plate into a scleral pocket of the eye; and inserting the arm into an anterior chamber of the eye through a scleral tunnel. Also, immobilizing the intraocular pressure sensor in the eye may include suturing the plate to the eye using holes in the plate.

[0038] Basically, a method for the determination of intraocular pressure uses an interference pattern produced by an intraocular pressure sensor. The intraocular pressure sensor includes a substrate member, a spacer member, and a flexible membrane. The substrate member, the spacer member and the flexible membrane define a sealed cavity; wherein the flexible membrane moves and/or deforms in response to intraocular pressure changes. The movement or deformation of the flexible membrane is measured optically. Light from a light source, emitting one or more wavelengths of light either simultaneously or sequentially, is both transmitted and reflected by the flexible membrane, and reflected by the substrate member. The light reflected by the substrate member interferes with light reflected from the flexible membrane to create an interference pattern. The method includes: performing, by a processing device, a phase calculation on the interference pattern to determine phase angles of the interference pattern, and correlating the phase angles with pressure. The phase calculation may be performed using an integral transform and the phases may be calculated at one or more spatial frequencies corresponding to peaks in an absolute value of the integral transform. Additionally, values of the spatial frequencies corresponding to the peaks in the absolute value of the integral transform may be used to correct for errors which arise from angular deviation of a sensor normal from an optical axis of a readout system.

[0039] Other features and advantages of the invention will be set forth in, or apparent from, the detailed description of exemplary embodiments of the invention found below.

[0040] These and other features, aspects, and advantages of the present invention will become better understood with regard to the following description, appended claims, and accompanying drawings where:

FIG. 1 is a functional block diagram of an exemplary system for determination of intraocular pressure, according to the invention;

FIG. 2A and FIG. 2B are schematic cross-sectional views of exemplary intraocular pressure sensors according to the invention;

FIG. 3A is a representation of an image of an exemplary interference pattern;

FIG. 3B is a graph of an absolute value of an integral transform of the exemplary interference pattern of FIG. 3A;

FIG. 3C is a graph of an experimentally measured relationship between phase of an interference pattern and liquid pressure for an exemplary intraocular pressure sensor;

FIG. 4A is another representation of an image of an exemplary interference pattern;

FIG. 4B is a graph of an absolute value of an integral transform of the exemplary interference pattern of FIG. 3A;

FIG. 5A is a schematic perspective view of an ex-

emplary embodiment of a device for measuring intraocular pressure according to the invention;
FIG. 5B is a schematic sectional view of an eye with the device of FIG. 5A implanted therein;
FIG. 6A is a schematic plan view of another exemplary embodiment of a device for measuring intraocular pressure according to the invention;
FIG. 6B is a schematic plan view of an eye with the device of FIG. 6A implanted therein;
FIG. 7A through FIG. 7D are schematic cross-sectional views of exemplary intraocular pressure sensors according to the invention further comprising a coating containing a fluorescent material;
FIG. 8A and FIG. 8B are representations of interference patterns having a phase change of 2π;
FIG. 9A and FIG. 9B are representations of interference patterns associated with multiple, sequentially emitted wavelengths;
FIG. 9C and FIG. 9D are graphs of the absolute value of integral transforms of the interference patterns of FIG. 9A and FIG. 9B, respectively;
FIG. 10A is a representation of an interference pattern associated with multiple, simultaneously emitted wavelengths;
FIG. 10B is a graph of the absolute value of the integral transform of the interference pattern of FIG. 10A;
FIG. 11A through FIG. 11D are graphs showing a calculated ratio of resultant light power to incident light power as a function of membrane-fluorescent coating separation;
FIG. 12 is a flow chart of an exemplary method for determination of intraocular pressure according to the invention;
FIG. 13 is a flowchart of an exemplary method for the determination of pressure from an interference pattern produced by an intraocular pressure sensor according to the invention; and
FIG. 14A and FIG. 14B are schematic perspectives view of further exemplary embodiments of a device for measuring intraocular pressure according to the invention.

[0041] FIG. 1 shows an exemplary system **100** for frequent measurement of intraocular pressure using an intraocular (i.e., inside or within an eye) pressure sensor **101** which, in use, would be implanted in an eye. The pressure is measured optically by the system **100** using a light source **102** to illuminate the intraocular pressure sensor **101** with one or more wavelengths of incident light **103.** A resultant light **113** (comprising reflected light or a combination of reflected and emitted light) is captured by a detector **106** and the signal from the detector **106** is processed by a processing device **107** to determine the intraocular pressure.

[0042] The exemplary system **100** further comprises an objective lens **110,** a beam splitter **104,** an illuminating lens **111,** and a diffuser **112.** The objective lens **110** performs at least one of the functions of collecting light from the intraocular pressure sensor **101** and forming an image of the intraocular pressure sensor **101** on the detector **106.** The beam splitter **104** allows light from the source **102** to reach the intraocular pressure sensor **101** and the reflected light from the intraocular pressure sensor **101** to reach the detector **106.** The illuminating lens **111** and diffuser **112** provide well controlled, uniform illumination of the intraocular pressure sensor **101.** The exemplary system **100** further comprises an atmospheric pressure sensor **109.** The atmospheric pressure sensor **109** communicates with the processing device **107** to allow measurement of intraocular pressure with respect to atmospheric pressure. The atmospheric pressure sensor **109** can be an optical pressure sensor **101** as described here or one of several atmospheric pressure sensors known to those skilled in the art of pressure measurement.

[0043] FIG. 2A shows an exemplary intraocular pressure sensor **101** comprising a substrate member **200,** a spacer member **201,** and a flexible membrane **202** which define a sealed cavity **203.** The flexible membrane **202** deflects in response to changes in intraocular pressure and these changes can be measured optically. The incident light **103** is both transmitted and reflected by the flexible membrane **202,** and reflected by the substrate member **200.** The light reflected by the substrate member **200** interferes either constructively or destructively with light reflected from the flexible membrane **202** such that the resultant light **113** (FIG. 1) comprises an interference pattern **300,** as shown in FIG. 3A.

[0044] The interference pattern **300** consists of bright and dark regions that are referred to as interference fringes. The brightest and darkest levels of the interference pattern **300** are shown as solid and dashed contour lines in FIG. 3A. These interference fringes change position when the flexible membrane **202** deflects in response to intraocular pressure changes as described in more detail below. Thus, the interference pattern **300** corresponds to intraocular pressure.

[0045] The interference pattern **300** is captured using the detector **106** (FIG. 1). In an embodiment the detector **106** is an electronic imaging device such as a digital camera or photodetector array. In an embodiment, the detector **106** communicates with a processing device **107** which performs a phase calculation on the image of the interference pattern **300** and correlates the calculated phase angles with intraocular pressure.

[0046] FIG. 3C shows the experimentally measured relationship between the phase of the interference pattern **300** and liquid pressure for an intraocular pressure sensor **101** with a silicon substrate member **200,** a silicon nitride flexible membrane **202,** illuminated with a light emitting diode light source **102** at a wavelength of similar to 800 nm.

[0047] As shown in FIG. 3B, the processing device **107** (FIG. 1) performs the phase calculation using an integral transform and calculates the phase at one or more spatial frequencies corresponding to peaks **301** in an absolute

value of the integral transform **302.** This calculation further allows for correction of pressure readings for angular deviations between the optical axes of the detector **106** and the intraocular pressure sensor **101,** as described in more detail below.

[0048] FIG. 4A shows an interference pattern **300** from a sensor **101** whose optical axis is tilted about the y-axis effectively compressing the pattern along the x-direction.

[0049] FIG. 4B, discussed below, shows the absolute value of an integral transform **302** of the interference pattern **300.**

[0050] In an embodiment each wavelength emitted by the light source **102** (FIG. 1) has a coherence length longer than twice the separation between the flexible membrane **202** and the substrate member **200** (FIGS. 2A and 2B). Having a sufficiently long coherence length ensures that the interference pattern **300** (FIG. 3A) can be clearly captured by the detector **106** (FIG. 1). A shorter coherence length could be contemplated, but would reduce the visibility of the interference pattern **300** and thus reduce the signal to noise ratio of the detector **106** signal.

[0051] In an embodiment the light source **102** is a light emitting diode. A light emitting diode is preferred because it emits a narrow range of wavelengths such that the coherence length of the incident light **103** and resultant light **113** is between 1μm and 1000 μm. This is appropriate for the range of sealed cavity **203** thicknesses described in more detail below. Laser light sources also offer sufficiently long coherence lengths, but light emitting diodes offer greater eye safety.

[0052] In the exemplary system **100** shown in FIG. 1, an optical filter **105** is positioned between the intraocular pressure sensor **101** and at least one of the light source **102** and the detector **106.** The optical filter **105** increases the coherence length of at least one of the incident light **103** and resultant light **113.** The optical filter **105** is required if the light source **102** does not have an intrinsically long enough coherence length. In a preferred embodiment the filter is positioned immediately in front of the detector so as to block other light not at the wavelength of the resultant light **113.**

[0053] In a preferred embodiment the wavelengths of the incident light **103** are in the infrared spectral region so that the incident light **103** remains invisible to the patient.

[0054] In an embodiment, the light source **102** is modulated in time by a modulator **108** which also communicates with the processing device **107.** The modulator modulates the light source by at least one of electrical or mechanical means or some combination of electrical and mechanical means. The modulator **108** has a frequency such that many cycles are contained in a single intraocular pressure measurement. The modulating signal can be any of several periodic signals, such as a sine wave or square wave, that are familiar to those skilled in the art. The signal from the modulator **108** is also routed to the processing device **107** where it is combined with the signal from the detector **106** for phase-locked (or "lock-in") detection, a technique well known to those skilled in the art of low-level signal measurements. This detection method reduces noise that could be introduced by light sources, for example room lights, other than the resultant light **113.**

[0055] In an embodiment the light source **102** emits multiple wavelengths of light in order to improve at least one of the precision and dynamic range of the pressure measurement. This is particularly important for designs of the intraocular pressure sensor **101** in which the deflection of the flexible membrane **202** yields a phase change of greater than 2π.

[0056] FIG. 8A and FIG. 8B show interference patterns **300** having a phase change of 2π.

[0057] A single wavelength measurement of a single intraocular pressure sensor **101** (FIG. 1) would exhibit pressure ambiguities if the phase changes by more than 2π, as described in more detail below.

[0058] FIG. 9A and FIG. 9B show interference patterns **300** associated with each wavelength captured by the detector **106** in an embodiment where multiple wavelengths are emitted sequentially. The processing device **107** (FIG. 1) calculates the phase angle of each interference pattern **300** at spatial frequencies corresponding to the illuminating wavelengths as described in more detail below.

[0059] As shown in FIG. 10A, in an alternative embodiment the light source **102** emits the multiple wavelengths simultaneously, and a more complex interference pattern **300** is generated. The processing device **107** now calculate the phase angles from a single interference pattern **300** but at multiple spatial frequencies, each spatial frequency corresponding to a different wavelength, as described in more detail below.

[0060] In yet another embodiment, as shown in FIG. 7A and FIG. 7B respectively, the intraocular pressure sensor **101** further comprises a coating **700** containing a fluorescent material, the coating **700** being coated on at least one of the substrate member **200** and the flexible membrane **202.** As used herein, a fluorescent material is a material which absorbs electromagnetic energy of a specific first wavelength and re-emits energy at different (but equally specific) additional wavelengths. A fluorophor is a component, such as a fluorescent dye molecule, of a fluorescent material which absorbs electromagnetic energy of a specific first wavelength and re-emits energy at different (but equally specific) second wavelength. A fluorescent material may contain one or more fluorophors. The incident light **103** excites the fluorescent material of the coating **700,** and the fluorescent material of the coating **700** emits light of a different second wavelength, the emission of the light of the second wavelength being the result of excitation of the fluorescent material. After passing back through the flexible membrane, and perhaps being further modulated, the emitted light of a different second wavelength becomes the resultant light **113.**

[0061] In an embodiment, the proximity of the flexible

membrane **202** to the substrate member **200** modulates the intensity of the resultant light **113.** In an embodiment the intensity of the resultant light **113** from the intraocular pressure sensor **101** is modulated based on several phenomena described in more detail below. In an embodiment the detector **106** is one or more light intensity sensors. The light intensity sensors may be at least one of photodiodes or photomultipler tubes. The signal from the detector **106** corresponds to intraocular pressure, and the processing device **107** processes the signal to determine intraocular pressure. In an embodiment the optical filter **105** is placed between the intraocular pressure sensor **101** and the detector **106** such that only the second wavelength in the resultant light **113** reaches the detector **106.**

[0062] Movement of the intraocular pressure sensor **101** with respect to the assembly containing the detector **106** must be considered. The assembly may be at least one of a handheld unit, a head mounted unit, and an eye glass mounted unit. The assembly may or may not contain the light source **102.**

[0063] In an embodiment relative motion is limited by providing a target at which the patient gazes while the pressure measurement is acquired. The target can be real structure or a virtual image created using optics within the assembly. Those skilled in the art have found that angular motions are limited to less than 0.2 degrees during visual fixation.

[0064] In an embodiment an eye cup can be added to the assembly containing the detector **106.** The eye cup contacts the face during the pressure measurement in order to physically limit movement of the intraocular pressure sensor **101** with respect to the detector **106.**

[0065] In an embodiment, at least one of autofocus mechanisms or image stabilization mechanisms, familiar to those skilled in the art, are added to the assembly to minimize the movement of the sensor **101** image and the detector **106.**

[0066] In an embodiment the detector **106** is an electronic image sensor with a frame rate in excess of 100 frames per second. The frame rate allows images to be captured during times when the sensor is in focus and within the field of view of the electronic image sensor.

[0067] The processing device **107** is preferably at least one of a dedicated electronic circuit, a microprocessor, a digital signal processor, or a programmable logic device. The processing device **107** may be either internal or external to the assembly containing the detector **106.** The processing device is connected to the detector by at least one of a physical electrical connection, a wireless connection, or a network connection all of which are familiar to those skilled in the art.

[0068] FIG. 5A shows a device for measuring intraocular pressure comprising an intraocular pressure sensor **101** and an anchoring member **500.** The anchoring member comprises a protective member **501,** a plate **502,** and an arm **503.**

[0069] FIG. 5B shows an eye **505** with the device implanted through the sclera **508** such that the intraocular pressure sensor **101** is located in the anterior chamber **506** and is visible through the cornea **507.** The protective member **501** prevents the intraocular pressure sensor **101** from contacting the cornea **507** in case of movement of the sensor toward the cornea **507.** The dimensions of the plate **502** are chosen so that it can be fixed in a scleral pocket. Although other dimensions could be contemplated, a long dimension of 1 to 5 mm and a short dimension of 1 to 3 mm are appropriate.

[0070] In one embodiment the plate **502** contains holes **504** for suturing the anchoring member **500** to the sclera **508.** Although other dimensions could be contemplated, the diameter of the holes should be greater than approximately 50μm to permit an atraumatic needle and suture to pass.

[0071] In an embodiment the plate **502** contains holes **504** to assist in wound healing. In this case the sclera **508** closes through the holes to promote both healing and immobilization of the device. The dimensions of the arm **503** are such that the arm can extend through a scleral tunnel placing the intraocular pressure sensor **101** in a position within the anterior chamber **506** such that the intraocular pressure sensor **101** is visible through the cornea **507.** Other dimensions could be contemplated, but an arm width of 1 to 2 mm and an arm length of 2 to 7 mm are acceptable.

[0072] In an embodiment shown in FIG. 6A and FIG. 6B, the anchor member **500** comprises a pair of **600** on at least one end such that it can be attached to the iris **601** rather than fixed in the sclera **508.** In this embodiment the anchor member **500** along with the attached intraocular pressure sensor **101** is inserted into the anterior chamber **506** and placed on the iris **601** such that it does not block the pupil **602.** The tissue of the iris is enclavated by the pincers **600** to immobilize the anchor member **500** in the eye **505.**

[0073] In an embodiment shown in FIG. 14A two or more intraocular pressure sensors **101** can be included in the same device. This provides redundant pressure measurements that increase confidence in the pressure reported by the intraocular pressure measurement system **100.** In addition, if one sensor fails, the deviation in readings between the first sensor and any additional sensors will serve as an indication of the failure.

[0074] In an embodiment shown in FIG. 14B, the second intraocular pressure sensor **101** has at least one of a different diameter, shape, flexible membrane **202** thickness, flexible membrane **202** material, and substrate member **200** material. The two or more pressure sensors **101** provide at least one of redundant pressure measurement, failure detection, compensation for temperature fluctuations in the eye, increased pressure measurement precision, increased pressure measurement dynamic range. In this embodiment, the flexible membrane **202** deflection due to temperature changes and the flexible membrane **202** deflection due to pressure changes are different for the two different sensors **101.** Thus, the

pressure and temperature can be separately measured by solving a set of simultaneous equations of the form:

$$(\theta_1 - \theta_{01}) = S_{1T}(T - T_0) + S_{1P}(P - P_0)$$

$$(\theta_2 - \theta_{02}) = S_{2T}(T - T_0) + S_{2P}(P - P_0)$$

where θ_1, and θ_2 are the phases for the interference pattern **300** or the intensities associated with the fluorescence for the first and second sensor respectively. θ_{01} and θ_{02} are known reference phases for the interference pattern **300** or known reference intensities associated with the fluorescence for the first and second sensor respectively. S_{1T} and S_{2T} are the sensitivities of the first and second sensor to changes in temperature, for example in radians/°C or intensity/°C, S_{1P} and S_{2P} are the sensitivities of the first and second sensor to changes in pressure, for example in radians/mmHg or intensity/mmHg, T is the temperature and T_0 is a known reference temperature, and P is the pressure and P_0 is a known reference pressure.

[0075] An exemplary device with two intraocular pressure sensors **101** includes one sensor with diameter similar to 300 um and another with diameter similar to 400 um. The flexible membrane **202** thickness is similar to 1.5 μm for both sensors. The sensitivities of the two intraocular pressure sensors **101** to changes in pressure are similar to 0.020 radians/mmHg and 0.037 radians/mmHg respectively for intraocular pressure ranges from 730 mmHg to 780 mmHg (10 to 50 mmHg above atmospheric pressure at sea level). The sensitivity of the two sensors **101** to changes in temperature are similar to 0.014 radians/°C and 0.023 radians/°C respectively. Thus, the interference patterns **300** from the two sensors allow differentiation between changes in pressure and temperature.

[0076] In an embodiment, the flexible membrane **202** deflection due to pressure changes is different for two sensors **101.** Pressure is determined by measuring the phase angles of the interference patterns **300** from both sensors. If the phase change for at least one of the interference patterns **300** exceeds 2π the pressure can still be determined uniquely based on the phase of the other interference pattern. In addition, if the desired dynamic range is kept constant, the use of two sensors with higher sensitivity, but at least one with total phase change greater than 2π, can improve sensitivity and thus sensing precision and accuracy.

[0077] An exemplary device with two intraocular pressure sensors **101** includes one sensor **101** with diameter similar to 300 um and flexible membrane thickness similar to 1.5 μm and another sensor **101** with flexible membrane **202** diameter similar to 600 um and flexible membrane **202** thickness similar to 200 nm. The sensitivity of the two sensors **101** to changes in pressure are 0.020 radians/mmHg and 0.074 radians/mmHg respectively from 730 mmHg to 780 mmHg. For a desired dynamic range of 610 to 820 mmHg the first sensor undergoes a total phase change of similar to 4.8 radians and the second sensor undergoes a total phase change similar to 16 radians. In this exemplary case the first sensor **101** provides a coarse measurement of pressure with no ambiguity over the entire pressure range, and the second sensor **101** provides a more sensitive measurement of pressure with ambiguity among several pressures within the range. However, the first sensor **101** removes this ambiguity. Using two sensors **101** allows intraocular pressure to be measured with greater sensitivity without sacrificing dynamic range. Other sensor designs can be contemplated that would expand dynamic range without sacrificing sensitivity.

[0078] The anchoring member **500** is formed from materials that are biocompatible when implanted in the eye. Possible materials include polymethylmethacrylate, other acrylic plastics, and silicone. These materials are commonly used for intralocular lenses. In addition, biocompatible metals and metal alloys containing elements such as gold or titanium are possible materials for the anchoring member.

[0079] As discussed above, FIG. 2A shows an intraocular pressure sensor **101** comprising a substrate member **200,** a spacer member **201,** a flexible membrane **202** which define a sealed cavity **203.** The flexible membrane **202** deflects in response in response to intraocular pressure changes and the deflection of the flexible membrane **202** can be measured optically. The substrate member **200** consists of at least one biocompatible metal, semiconductor, or insulator material. The spacer member **201** consists of at least one biocompatible metal, semiconductor, or insulator material. The spacer member **201** prevents fluid from penetrating into the sealed cavity **203.** In an embodiment the spacer member **200** material is at least one of silicon, silicon nitride, and silicon dioxide. The spacer member **201** can be formed by one of several processes familiar to those skilled in the art of micro fabrication including at least one of etching or deposition.

[0080] In a preferred embodiment the sealed cavity **203** has a pressure below one atmosphere. The reduced cavity pressure reduces the temperature sensitivity of the device because expansion or contraction of the gas inside the cavity will not create large changes in the separation of the flexible membrane **202** from the substrate member **200.** A sealed cavity **203** with reduced pressure can be formed by one of several processes familiar to those skilled in the art of microfabrication including at least one of vacuum contact bonding, vacuum anodic bonding, vacuum adhesive bonding, thermal annealing, etching through release holes and low pressure chemical vapor deposition sealing of these holes, and gettering of residual gas in the cavity.

[0081] The flexible membrane **202** is substantially impermeable to gas or liquid in order to maintain the integrity

of the sealed cavity **203** over the life of the intraocular pressure sensor **101.** In a preferred embodiment, the flexible membrane **202** consists of silicon nitride. Silicon nitride is one of the best known moisture and gas barriers, with no measurable permeation, even at 1100°C.

[0082] In an embodiment, an incident light **103** (FIG. 1) strikes the intraocular pressure sensor **101** and is partially reflected and partially transmitted by the flexible membrane **202.** The transmitted light is partially reflected by the substrate member **200.** Reflected light from the flexible membrane **202** and the substrate member **200** combine to form a resultant light **113.** Light reflected by the substrate member **200** interferes either constructively or destructively with light reflected from the flexible membrane **202** to create an interference pattern **300** (FIG. 3). The resulting interference pattern **300** corresponds to intraocular pressure, as described in more detail below.

[0083] The substrate member **200** consists of a material with the correct optical properties and surface finish to at least partially reflect light at the illumination wavelength. The substrate member **200** material is chosen from a group including at least one of biocompatible metals, semiconductors, or insulators. In an embodiment, the substrate member **200** is made of polished silicon which is partially reflective throughout the visible and near-infrared spectral region. In another embodiment the substrate member **200** is made from a glass, plastic, semiconductor, or oxide material. In another embodiment, the substrate member **200** material is optically transparent for visible wavelengths but is reflective at infrared wavelengths. In another embodiment, the substrate member **200** is coated with another layer of material or multiple layers of materials to render it reflective in the infrared. In this way the sensor is transparent in the visible spectral region but reflective in the infrared region to improve the aesthetics of the sensor.

[0084] The flexible membrane **202** consists of a material with the correct optical properties and correct thickness to partially, but not entirely, reflect an incident light **103.** In this way an optical cavity is formed and an optical interference pattern **300** is generated. In one embodiment a flexible membrane **202** consists of at least one of silicon, silicon nitride, and silicon dioxide. A flexible membrane **202** can be formed by one of several processes familiar to those skilled in the art of micro fabrication including at least one of implantation, oxidation, physical vapor deposition, chemical vapor deposition, and etching.

[0085] The interference pattern **300** consists of bright and dark regions that are often referred to as interference fringes. These interference fringes change position when the flexible membrane **202** deflects with respect to the substrate member. The separation of these rings depends on the curvature of the flexible membrane **202** surface. If the separation of the flexible membrane **202** and the substrate member **200** changes then the rings shift in radial position. If the curvature of the flexible membrane **202** surface changes then the spacing of the rings changes. The visibility, the difference in intensity between brightest and darkest points divided by sum of the intensities between the brightest and darkest points, of the rings at the detector **106** is determined by the separation of the substrate member **200** and the flexible membrane **202** and the coherence length of the resultant light **113.**

[0086] The materials and dimensions of the flexible membrane allow a number of periods in the interference pattern **300** and sufficient deflection to detect clinically important changes in intraocular pressure. In it known that intraocular pressure changes of 1 mmHg have clinical significance in managing glaucoma. In an exemplary sensor the flexible membrane **202** is circular with a diameter of 300 μm and a thickness of 1.5 μm. The sealed cavity **203** contains a vacuum. The spacer member is greater than 5μm thick but less than twice the coherence length of the incident light **103.** At 820 mmHg absolute pressure (60 mmHg above atmospheric pressure at sea level) the flexible membrane **202** deflects similar to 3.6 μm at its central point. This gives rise to 9 periods in the interference pattern **300** when illuminated with an incident light **103** of 800 nm wavelength. To measure intraocular pressure from 10 to 60 mmHg with respect to atmospheric pressure at elevations from sea level to 2000 m the sensor **101** measures absolute pressures from 610 mmHg to 820 mmHg. For a light source **102** emitting a single wavelength, the interference pattern **300** is limited to a maximum phase change of 2π over this pressure range. Thus the intraocular pressure measurement system **100** must measure the phase to ± 0.03 radians to maintain an accuracy of 1 mmHg. With a signal to noise ratio as low as 1, the standard deviation of the phase estimate is similar to 0.01 radians when the signal is captured using only 200 x 200 pixel electronic image sensor. We define signal to noise ratio as the square of the amplitude of the interference pattern **300** modulation divided by the variance of an additive Gaussian noise. This noise level is much larger and the image resolution much smaller than what would be typically encountered in practice, thus the precision of the phase measurement is sufficient to detect clinically relevant changes in intraocular pressure.

[0087] The material and dimensions of the flexible membrane **202** and the dimensions of the spacer layer **201** prevent the membrane **202** from contacting the bottom of the sealed cavity **203** under pressures encountered in the intraocular environment. In an exemplary sensor **101** the flexible membrane **202** consists of non-stoichiometric, low-stress silicon nitride with an elastic modulus similar to 200 GPa and a Poisson ratio similar to 0.27. The flexible membrane **202** diameter is 300 μm and the flexible membrane **202** thickness is 1.5 μm. The sealed cavity **203** contains a vacuum. At 820 mmHg absolute pressure (60 mmHg above atmospheric pressure at sea level) the flexible membrane **202** deflects similar to 3.6 μm toward the substrate member **200** at its center. If the spacer member **201** is greater than 3.6 μm thick

then the flexible membrane **202** will not contact the substrate member **200.** Other dimensions and materials could be contemplated that also prevent contact between the flexible membrane **202** and the substrate member **200.**

[0088] In a preferred embodiment an intraocular pressure sensor **101** limits pressure measurement errors to 1 mmHg in the presence of temperature fluctuations from 32° to 36°. This range represents the approximate range of corneal temperature variation for ambient temperatures ranging from 18°C to 27°C. It is known that variations in corneal temperature represent an upper bound on variations in the anterior chamber. In an exemplary sensor **101** the flexible membrane **202** consists of non-stoichiometric, low-stress silicon nitride with an elastic modulus similar to 200 GPa, a Poisson ratio similar to 0.27, and a coefficient of thermal expansion similar to 2.3×10^{-6}/°C. One skilled in the art of micro fabrication will understand that the mechanical properties of silicon nitride thin films can vary depending on deposition conditions and stoichiometry, and that other mechanical properties could be contemplated that would yield similar behavior. The flexible membrane **202** diameter is 500 μm and the flexible membrane **202** thickness is 0.5 μm. The sealed cavity **203** contains a vacuum. The substrate member **200** and the spacer member **201** consist of silicon with a coefficient of thermal expansion of 2.6×10^{-6}/°C. The spacer member is greater than 11μm thick. The illumination wavelength is 800 nm. At a normal intraocular pressure of 15 mmHg (735 mmHg absolute pressure at sea level) the pressure measurement error with change in temperature is similar to 0.12 mmHg/°C. This restricts the measurement error to less than ±0.25 mmHg under the anterior chamber temperature fluctuations described above. In an embodiment, the intraocular pressure measurement system **100** indicates the pressure measurement is potentially erroneous if extreme ambient temperatures are detected. In an embodiment, the pressure sensor **101** is calibrated for extreme ambient temperatures. Other dimensions and materials could be contemplated that also reduce temperature dependence to acceptable levels.

[0089] In a preferred embodiment an intraocular pressure sensor **101** has a spacer member **201** with a thickness that provides an interference pattern **300** without using a light source that relies on laser action. The coherence length of the incident light **103** must be longer than twice the thickness of the sealed cavity **203.** The spacer member **201** has a thickness that ensures the separation of the flexible membrane **202** and the substrate member **200** is less than half the coherence length of the incident light **103.** Laser light sources typically have coherence lengths of greater than 1mm. However, eye safety concerns when using lasers indicate that a light emitting diode light source is preferred. Light emitting diodes have coherence lengths ranging from approximately 1μm to 1000μm. In an embodiment, an optical filter **105** is used to further increase the coherence length of at least one of the incident light **103** or the resultant light **113.** In an exemplary sensor the spacer member is less than 50 μm thick so that the separation between the flexible membrane **202** and the substrate member **200** does not exceed 50 um and thus an incident light **103** with a coherence length of less than 25μm can be used to form the interference pattern **300.** For an infrared light source **102** with a center wavelength of 800 nm this corresponds to a spectral bandwidth of approximately 25 nm. Other dimensions could be contemplated that also allow light sources **102** not employing laser action to be used. One skilled in the art of interferometry will understand that there are subtle differences in definition of coherence length and spectral bandwidth depending on the spectral shape of the light, the criterion for bandwidth, and the criterion for coherence. As such, one skilled in the art will understand that the numbers given are representative and that other criteria for coherence length could be conceived.

[0090] In one embodiment, shown in FIG. 2B, the intraocular pressure sensor **101** further comprises one or more layers **204** of additional material coated on the external side of the flexible membrane **202.** This additional material has refractive index and thickness such that reflection from the membrane **202** is substantially equal to the reflection from the substrate member **200.** Equalizing the reflection from the membrane **202** and substrate member **200** provides the greatest interference pattern **300** visibility, where visibility is defined as the ratio of the differences in the maximum and minimum intensity in the interference pattern **300** to the sum of the maximum and minimum intensity. As a result, the signal to noise ratio of the captured interference pattern **300** will be maximized if all other conditions are equal. It is important to note that for certain combinations of flexible membrane **202** thickness and refractive index the additional layer **204** is unnecessary because the reflection is intrinsically balanced. However, the thickness of the flexible membrane **202** is often determined by the pressure range and sensitivity required, and cannot be freely adjusted based on optical considerations. In an exemplary intraocular pressure sensor **101** the substrate member **200** is silicon with refractive index similar to 3.7, the flexible membrane **202** is low stress silicon nitride with refractive index similar to 2.2 and thickness similar 350 nm, the additional layer **204** is one of several poly(p-xylylene) polymers with a refractive index similar to 1.6 and a thickness similar to 150 nm, and the illumination wavelength is similar to 800 nm. In this example the interference pattern **300** visibility improves from 0.48 without the additional layer **204** to 0.75 with the additional layer **204** in place. Other materials with different refractive indices and thicknesses could be conceived to achieve a similar improvement.

[0091] In the case of a single intraocular pressure sensor **101** illuminated by a single wavelength of light, the phase change of the interference pattern **300** is restricted to the less than 2π over the range of pressures to be measured. In an exemplary sensor the flexible mem-

brane diameter is 300 μm and the flexible membrane thickness is 1.5 μm. The wavelength of illumination is 800 nm. Over a range of absolute pressures from 610 mmHg to 820 mmHg the sensor's **101** sensitivity is similar to 0.02 radians/mmHg and the interference pattern **300** undergoes a phase change of less than 2π. As a result, there is no ambiguity in the pressure measurements between 610 mmHg and 820 mmHg. Other dimensions and materials for the flexible membrane **202** could be contemplated that also restrict the phase change to 2π over a desired pressure range.

[0092] In the embodiment shown in FIG. 7A, the intraocular pressure sensor **101** further comprises a coating **700** containing a fluorescent material on the substrate member **200.** A light source **102** excites the fluorescent material of the coating **700** and the fluorescent material of the coating emits a light of a different second wavelength. The proximity of the flexible membrane **202** to the substrate member **200** modulates the intensity of the emitted light of a different second wavelength and the detected intensity of the emitted light of the different second wavelength is used to determine the pressure. The coating **700** can be any material that is intrinsically fluorescent or that has been dyed with a fluorescent component. An example coating could be a polymer, such as poly-methyl methacrylate (PMMA), dyed with fluoresecent molecules, such as the near-infrared polymethine dyes. In an embodiment both the polymer and the dye are be transparent in the visible part of the spectrum for aesthetic reasons. In an embodiment, both excitation and emission wavelengths are in the near infrared to prevent the patient from seeing the incident light **103** or resultant light **113** while the pressure is being measured. In another embodiment shown in FIG. 7B, the intraocular pressure sensor **101** further comprises a coating **700** containing a fluorescent material on the flexible membrane **202.**

[0093] The intensity of the resultant light **113** from the pressure sensor **101** is modulated based on several phenomena. First the intensity of incident light **103** that reaches the fluorescent coating **700** is modulated. This occurs because of wave optical effects typically described in terms of (1) interference of optical reflections from the membrane surfaces, the fluorescent material surfaces, and the substrate and (2) optical near-field and evanescent coupling across the sealed cavity when the separation of the membrane and substrate are on the order of the wavelength of light. When light is transmitted through two or more partially reflective surfaces it can interfere constructively and destructively depending on the separation of the surfaces. As a result, the transmitted power in the resultant light **103** depends on the separation of the surfaces. In the pressure sensor **101** there are at least four partially reflected surfaces: the two surfaces of the flexible membrane **202;** the interface of the fluorescent coating **700** with the sealed cavity **203;** and the interface of the substrate member **200** with the fluorescent coating **700.** First, the transmission of incident light **103** to the fluorescent coating **700** is modulated by the separation between the flexible membrane **203,** which is partially reflective, and the fluorescent coating **700** on the substrate member **200.** As the transmitted power at the excitation wavelength changes, the light emission from the fluorescent coating **700** is modulated as well.

[0094] The same effects that modulate the intensity of incident light **103** reaching the fluorescent coating **700** also modulates the resultant light **113.** In addition, a significant fraction of the light emitted by the fluorescent coating **700** is reflected back into the material by total internal reflection. If the refractive index of the fluorescent coating **700** is greater than the underlying substrate member **200,** then this light is completely trapped in the fluorescent layer. In either case, the evanescent electric field from the internally reflected light extends a short distance beyond the interface between the fluorescent coating **700** and the sealed cavity **203.** If the flexible membrane **203** is sufficiently close to the fluorescent coating **700** (separation similar to wavelength) then light that would otherwise be totally internally reflected in the fluorescent coating **700** will couple into the flexible membrane **202.** The strength of this coupling is strongly dependent on the separation of the two layers; thus, a change in pressure that deflects the flexible membrane **202,** alters the fluorescent membrane **202** -fluorescent coating **700** separation, and the light emission. Moreover, light will be trapped in the flexible membrane **202** by total internal reflection.

[0095] In an exemplary pressure sensor **101,** a substrate member **200** is coated with a fluorescent coating **700** with real refractive index 1.7 and that is sufficiently thick and absorbing to absorb all of the excitation light. A flexible membrane **202** is separated from the fluorescent coating **202** by a sealed cavity **203** containing vacuum. The pressure sensor **101** is excited with the incident light **113** at wavelength of 770 nm in the near infrared and the fluorescent coating **700** emits at 800 nm. For explanatory purposes, the incident light **103** is normally incident, unpolarized, and collimated, and the fluorescence yield (or quantum efficiency) is 1. The resultant light **113** emitted from the fluorescent coating **700** is unpolarized and has a diffuse (Lambertian) distribution.

[0096] FIG. 11A shows a calculated ratio of resultant light **113** power to incident light **103** power as a function of membrane **202**-fluorescent coating **700** separation. This ratio is a direct measure of membrane **202** deflection and thus a measure of pressure.

[0097] The pressure sensor **101** need not operate with collimated incident light **103** or with normally incident light **103.** However, the output of the pressure sensor **101** is dependent on the angle of illumination, ϕ.

[0098] FIG. 11B shows a calculated ratio of resultant light **113** power to incident light **103** power as a function of membrane **202**-fluorescent coating **700** separation with an illumination angle of 10 degrees from normal. The relationship is different and this angle dependence must either be calibrated out of the pressure reading or eliminated by a more sophisticated sensor design de-

scribed in more detail below.

[0099] In an embodiment shown in FIG. 7C, the flexible membrane **203** is also coated with a scattering medium **701** on the side of the membrane external to the sealed cavity **203** to enhance light emission from the sensor **101** and minimize illumination angle dependence, as further described below. An example of such a scattering medium is polytetrafluoroethylene. Modulation of the incident light **103** reaching the fluorescent layer and modulation of the resultant light **113** exiting the sensor are both governed by the phenomena described above. The scattering medium **701** serves two purposes. First the scattering medium **701** randomizes the angle of incident light **103** to reduce output dependence on the angle of illumination. Secondly, the scattering medium **701** serves to extract light from the flexible membrane **202** and the fluorescent coating **700** that would otherwise be trapped by total internal reflection. This both increases the total amount of light emitted by the sensor and alters the relationship between the amount of resultant light **113** and the flexible membrane **202** - fluorescent coating **700** gap.

[0100] In an alternative embodiment, shown in FIG. 7D, the scattering medium **701** is placed on the surface of the flexible membrane **202** inside the sealed cavity **203.** This configuration can improve light extraction from the fluorescent material because the scattering medium **701** is in a region of greater evanescent electric field strength.

[0101] In an exemplary sensor a scattering medium **701** is coated on the flexible membrane **202** surface external to the sealed cavity **203.** Both incident light **103** and emitted light are diffusely (Lambertian) scattered at the membrane surface. As a result, the ratio of incident light **103** power to resultant light **113** power is no longer dependent on angle of illumination. However, the angle of illumination will affect the total input power coupled into to the sensor.

[0102] FIG. 11C plots the calculated ratio of resultant light **113** power to incident light **103** power as a function of flexible membrane **202** -fluorescent coating **700** separation with the scattering medium **701** on the external side of the flexible membrane **202.** This relationship is independent of illumination angle.

[0103] In an embodiment, the fluorescent coating **700** is placed in the flexible membrane **202,** rather than on the substrate member **200,** as shown in FIG. 7B. This embodiment is governed by the same phenomena; however, interference effects, near field effects, and evanescent coupling are all modified by the position of the fluorescent coating **700** in relation to the other sensor components. Specifically, light is trapped in the combined structure of the fluorescent coating **700** and the flexible membrane **202,** and is evanescently coupled to the substrate member **200** depending on the fluorescent coating **700** - substrate member **200** separation.

[0104] In another embodiment of the exemplary intraocular pressure sensor **101,** two different fluorophors are contained in the fluorescent coating **700,** and the two fluorophors emit light at two different wavelengths. The detector **106** measures the ratio of optical power at the two different wavelengths. In an embodiment the detector comprises a dichroic beam splitter and two light sensors. Each light sensor detects only one wavelength. In another embodiment, the detector comprises a beam splitter, two optical filters, and two light sensors. Again, each light sensor detects only one wavelength. By measuring the difference in detected optical power between the two sensors, the pressure measurement system **101** can compensate for different excitation and emission efficiencies that occur when the eye moves relative to the light source **102** and the detector **106** during or between measurements.

[0105] In an exemplary sensor **101** the fluorescent coating **700** emits at two wavelengths, 800 nm and 900 nm. When both fluorophors are excited, the ratio of the detected intensity between the two wavelengths corresponds to intraocular pressure. In this way we need not know the excitation power for any given measurements.

[0106] FIG. 11D plots the ratio of light detected at 800 nm to that detected at 900 nm as a function of the flexible membrane **202** - fluorescent coating **700** separation.

[0107] As shown in FIG. 12, an exemplary method **1200** for determination of intraocular pressure, includes the steps of: **S1202** placing an intraocular pressure sensor **101** (FIG. 1) in an eye (e.g., eye **505** of FIG. 5B), the intraocular pressure sensor **101** including a substrate member **200,** a spacer member **201,** and a flexible membrane **202,** the substrate member **200,** the spacer member **201** and the flexible membrane **202** defining a sealed cavity **203** wherein the flexible membrane **202** moves and/or deforms in response to intraocular pressure changes; **S1204** illuminating, with a light source **102,** the intraocular pressure sensor **101** with one or more wavelengths of light; and **S1206** detecting, with a detector, a resultant light that contains information about intraocular pressure.

[0108] In an embodiment, the flexible membrane **202** (FIG. 2) both transmits and reflects the one or more wavelengths of light, the substrate member **200** reflects the one or more wavelengths of light transmitted by the flexible membrane **202,** the light reflected by the substrate member **200** interferes with light reflected from the flexible membrane **202** to create an interference pattern **300,** and the interference pattern **300** corresponds to intraocular pressure.

[0109] In an embodiment, the step **S1206** detecting the resultant light includes capturing, with an electronic imaging device, an image of the interference pattern **300,** and the method further comprises a step **S1208** performing a phase calculation on the image of the interference pattern **300** to determine phase angles of the interference pattern **300;** and a step **S1210** correlating the phase angles with intraocular pressure.

[0110] In an embodiment, the method further comprises a step **S1212** positioning an optical filter **105** between the intraocular pressure sensor **101** and at least one of

the light source **102** and the electronic imaging device, the optical filter **105** providing an optical coherence length greater than twice the distance from the flexible membrane **202** to the substrate member **200.**

[0111] In an embodiment, the step of **S1204** illuminating the intraocular pressure sensor includes modulating the light source **102** in time to allow for lock-in detection of the interference pattern **300** by the electronic imaging device.

[0112] In an embodiment, the method further comprises a step **S1214** coating a coating **700** containing fluorescent material on at least one of the substrate member **200** and the flexible membrane **202,** wherein the step **S1204,** illuminating the intraocular pressure sensor, includes exciting the fluorescent material of the coating **700** with a light source **102** such that the fluorescent material of the coating **700** emits a light of a different second wavelength, the emission of the light of the second wavelength being the result of excitation of the fluorescent material, wherein the proximity of the flexible membrane **202** to the substrate member **200** modulates the intensity of the resultant light **113** of a different second wavelength, and wherein the step **S1206** detecting the resultant light, includes detecting an intensity of the resultant light **113** of the different second wavelength to determine the pressure.

[0113] In an embodiment, the step **S1202,** placing the intraocular pressure sensor in an eye, further includes immobilizing the intraocular pressure sensor **101** in the eye **505** using an anchoring member **500** attached to the intraocular pressure sensor **101.**

[0114] In an embodiment, the anchoring member **500** comprises a plate **502** and an arm **503,** and immobilizing the intraocular pressure sensor **101** further includes inserting the plate **502** into a scleral pocket of the eye **505;** and inserting the arm **503** into an anterior chamber **506** of the eye through a scleral tunnel.

[0115] In an embodiment, immobilizing the intraocular pressure sensor in the eye further includes suturing the plate **502** to the eye using holes **504** in the plate **502.**

[0116] As shown in FIG. 13, an exemplary method 1300 for the determination of pressure from an interference pattern **300** produced by an intraocular pressure sensor **101** comprising a substrate member **200;** a spacer member **201;** and a flexible membrane **202;** the substrate member **200,** the spacer member **201** and the flexible membrane **202** defining a sealed cavity **203;** wherein the flexible membrane **202** moves and/or deforms in response to intraocular pressure changes and the movement or deformation of the flexible membrane **202** is measured optically, wherein light from a light source **102,** emitting one or more wavelengths of light either simultaneously or sequentially, is both transmitted and reflected by the flexible membrane **202,** and reflected by the substrate member **200,** and wherein the light reflected by the substrate member **200** interferes with light reflected from the flexible membrane **202** to create an interference pattern **300,** the method includes the steps of: **S1302** performing, by a processing device **107,** a phase calculation on the interference pattern **300** to determine phase angles of the interference pattern **300;** and **S1304** correlating the phase angles with pressure.

[0117] An exemplary interference pattern **300** has intensity, I, that is periodic with the square of the spatial variables. An exemplary signal of this type is $I(x, y) = A\cos(k_x x^2 + k_y y^2) + B$ where A is the amplitude of the fringe modulation, k_x and k_y are the spatial frequencies of the rings in the x- and y- directions, x and y are the spatial coordinates across the sensor surface, and B is constant offset of zero light level. In practice, this signal may be discretely sampled by an electronic imaging device so that the pixel value at the j^{th},k^{th} location in the image matrix is given by $I_{jk} = A\cos(k_x x_j^2 + k_y y_k^2) + B$.

[0118] To determine the phase of the interference pattern **300,** the two-dimensional image is multiplied by a kernel of the form $K(k_x,k_y,x,y) = \exp[-ik_x x^2 - ik_y y^2]$. For each value of k_x and k_y the product of the signal and kernel is integrated over x and y to yield the integral transform given by $F(k_x,k_y) = \iint I(x,y)\exp[-jk_x x^2 - jk_y y^2]dxdy$. FIG. 3B shows the absolute value of the integral transform **302,** $|F(k_x,k_y)|$. As can be seen in FIG. 3B, there is a peak value **301** in $|F(k_x,k_y)|$ at a particular non-zero pair of values for k_x and k_y. At this peak value **301,** the phase angle of the transform,

$$\phi\left(k_x, k_y\right) = \arctan\left(\frac{\mathrm{Im}\left\{F\left(k_x, k_y\right)\right\}}{\mathrm{Re}\left\{F\left(k_x, k_y\right)\right\}}\right),$$

will relate to how the rings are spatially positioned. Because the spatial position of the rings in the interference pattern **300** is related to the deflection of the flexible membrane **202** with respect to the substrate member **200,** one can determine intraocular pressure from the phase of the transform at the spatial frequencies corresponding to the peak **301.** A change in the phase of the transform indicates a shift in position of the rings and thus a change in pressure. In an embodiment, the transform is computed discretely and becomes

$$\mathrm{F}\left(k_x, k_y\right) = \sum_{j=0}^{N}\sum_{k=0}^{M} I_{jk}\,\exp\left[-ik_x x_j^{\,2} - ik_y y_k^{\,2}\right]$$

where N is the number of pixels in the x-direction and M is the number of pixels in the y-direction.

[0119] In an embodiment, the spatial frequencies are known and the transform need only be computed for one value of k_x and one value of k_y. In an embodiment, the spatial frequencies are not known, and the integral transform is computed for a range of spatial frequencies, the peak **301** in the absolute value of the integral transform **302** is identified, and the phase is computed at the spatial frequencies corresponding to the peak **301.**

[0120] FIG. 3C plots the phase at the peak **301** of $|F(k_x, k_y)|$ as a function of pressure for experimentally obtained data. The sensor was placed in a sealed chamber with

water around it, and the pressure was varied with a syringe. The pressure values on the abscissa were measured with a commercial analog pressure sensor placed in the same test chamber as the optical sensor. It is apparent that phase is correlated with pressure, and that the sensor covers a range of physiologically relevant pressures found in the human eye (5-30 mmHg). In addition, this sensor design covers this range of pressures relative to atmospheric pressure without exceeding a phase change of 2π and there is no ambiguity in the phase-pressure relationship.

[0121] In an embodiment, the normal axis of the intraocular pressure sensor **101** is not required to be coincident with the optical axis of at least one of the light source **102** and detector **106.** The interference pattern **300** is spatially compressed along the direction associated with the tilt angle of the sensor **101.** For example, if the patient looks to the side during a pressure measurement, the sensor **101** will rotate about the y-axis and the interference pattern **300** will appear to compress in the x-direction. Compression of the interference pattern **300** in space shifts the peak **301** in $|F(k_x,k_y)|$ to a higher spatial frequency. Thus, one can determine the angle of the sensor **101** with respect to the optical axis of the readout system from the values of k_x and k_y. This allows one to correct for any error that would otherwise be introduced by the patient not looking directly along the optical readout axis. FIG. 4A shows an interference pattern **300** with the sensor rotated by 25 degrees about its y-axis. This rotation is extreme, but is used for exemplary purposes to make the fringe compression appear clear by visual inspection. FIG. 4B shows the absolute value of the integral transform 302, $|F(k_x,k_y)|$. In this case, the peak **301** shifts to higher values of k_x because of the rotation.

[0122] In an embodiment, at least one of a larger range of pressures needs to be measured or greater sensitivity, i.e. phase change with change in pressure, is required. Two wavelengths of light illuminate the sensor **101.** In an embodiment, the wavelengths illuminate the sensor sequentially so the interference pattern **300** from each wavelength is measured separately. FIG. 9A and FIG. 9B show two interference patterns **300** for sequential measurement of a sensor with wavelengths of 700 nm and 900 nm respectively. FIG. 9C and FIG. 9D show the absolute value of the integral transforms **302** for 700 nm and 900 nm wavelengths respectively. The peak values **301** occur at different spatial frequencies for the two different wavelengths. Calculating the phase at the spatial frequencies corresponding to each peak **301** in each transform allow unambiguous determination of the pressure even if the phase change of one or both interference patterns **300** exceeds 2π.

[0123] In an embodiment, the two wavelengths illuminate the sensor simultaneously, and a single interference pattern **300** is captured by the detector **106.** FIG. 10A shows the interference pattern **300** and FIG. 10B shows the absolute value of its integral transform **302** when the sensor is simultaneously illuminated with wavelengths of 700nm and 900nm. In this case the two wavelengths result in a peak **1000** for 900nm and a peak **1001** for 700 nm in a single integral transform. The shorter wavelength yields a higher spatial frequency. The two phases associated with the two wavelengths can be used to track phase changes larger than 2π without ambiguity in the relationship between phase and pressure. This method can increase the dynamic range of a sensor or allow a certain dynamic range to be maintained while redesigning the sensor for greater sensitivity.

[0124] Thus, the invention provides systems, devices, and methods for measuring intraocular pressure based on an intraocular pressure sensor. This detailed description, and particularly the specific details of the exemplary embodiment disclosed, is given primarily for clearness of understanding and no unnecessary limitations are to be understood therefrom. sequentially so the interference pattern **300** from each wavelength is measured separately. FIG. 9A and FIG. 9B show two interference patterns **300** for sequential measurement of a sensor with wavelengths of 700 nm and 900 nm respectively. FIG. 9C and FIG. 9D show the absolute value of the integral transforms **302** for 700 nm and 900 nm wavelengths respectively. The peak values **301** occur at different spatial frequencies for the two different wavelengths. Calculating the phase at the spatial frequencies corresponding to each peak **301** in each transform allow unambiguous determination of the pressure even if the phase change of one or both interference patterns **300** exceeds 2π.

[0125] In an embodiment, the two wavelengths illuminate the sensor simultaneously, and a single interference pattern **300** is captured by the detector **106.** FIG. 10A shows the interference pattern **300** and FIG. 10B shows the absolute value of its integral transform **302** when the sensor is simultaneously illuminated with wavelengths of 700nm and 900nm. In this case the two wavelengths result in a peak **1000** for 900nm and a peak **1001** for 700 nm in a single integral transform. The shorter wavelength yields a higher spatial frequency. The two phases associated with the two wavelengths can be used to track phase changes larger than 2π without ambiguity in the relationship between phase and pressure. This method can increase the dynamic range of a sensor or allow a certain dynamic range to be maintained while redesigning the sensor for greater sensitivity.

[0126] Thus, the invention provides systems, devices, and methods for measuring intraocular pressure. One of ordinary skill in the art will recognize that additional steps and configurations are possible without departing from the teachings of the invention. This detailed description, and particularly the specific details of the exemplary embodiment disclosed, is given primarily for clearness of understanding and no unnecessary limitations are to be understood therefrom, for modifications will become evident to those skilled in the art upon reading this disclosure and may be made without departing from the spirit or scope of the claimed invention.

Claims

1. An intraocular pressure sensor (101), comprising:

   a silicon substrate member (200);
   a spacer member (201); and
   a silicon nitride flexible membrane (202);
   the silicon substrate member (200), the spacer member (201) and the silicon nitride flexible membrane (202) defining a sealed cavity (203);
   the silicon nitride flexible membrane (202) configured to move or deform in response to intraocular pressure changes and wherein the movement of the silicon nitride flexible membrane (202) can be measured optically,
   the silicon nitride flexible membrane (202) configured to both transmit and reflect light, and the silicon substrate member (200) configured to reflect light,
   wherein the light reflected by the silicon substrate member (200) interferes either constructively or destructively with light reflected from the silicon nitride flexible membrane (202) to create an interference pattern (300), and
   wherein the resulting interference pattern (300) corresponds to intraocular pressure.

2. The intraocular pressure sensor (101) of claim 1, further comprising a layer (204) of additional material coated on the external side of the silicon nitride flexible membrane (202), the thickness and refractive index of the additional material equalizing the reflection from the silicon nitride flexible membrane (202) and the silicon substrate member (200).

3. The intraocular pressure sensor (101) of claim 1, further comprising a coating (700) containing a fluorescent material, the coating (700) being coated on at least one of the silicon substrate member (200) and the silicon nitride flexible membrane (202), wherein an external light source (102) excites the fluorescent material of the coating (700), and the fluorescent material of the coating (700) emits a light of a different second wavelength, the emission of the light of the second wavelength being the result of excitation of the fluorescent material, wherein the proximity of the silicon nitride flexible membrane (202) to the silicon substrate member (200) modulates the intensity of the emitted light of a different second wavelength and the detected intensity of the emitted light of the different second wavelength is used to determine the pressure.

4. The intraocular pressure sensor (101) of claim 3, further comprising a scattering medium (701) coated on at least one of the silicon nitride flexible membrane (202) and the silicon substrate member (200).

5. The intraocular pressure sensor (101) of claim 3, wherein the coating (700) further comprises a second fluorescent material, wherein the external light source (102) further excites the second fluorescent material of the coating (700) to emit a light of a different third wavelength, wherein the difference in detected intensity of the emitted light at the second and third wavelengths is used to determine the pressure.

6. A device for measuring intraocular pressure comprising:

   an intraocular pressure sensor (101) as defined in any one of claims 1 to 5;
   an anchoring member (500) attached to the intraocular pressure sensor (101) for immobilizing the intraocular pressure sensor (101) in an eye (505);
   a protective member (501) attached to the anchoring member (500) and covering the intraocular pressure sensor (101) to prevent contact between the silicon nitride flexible membrane (202) and portions of the eye (505); and
   a second intraocular pressure sensor (101) having at least one of a different diameter, shape, membrane thickness, membrane material, and substrate material, the intraocular pressure sensor (101) and the second intraocular pressure sensor (101) providing at least one of redundant pressure measurement, failure detection, compensation for temperature fluctuations in the eye (505), increased pressure measurement sensitivity, and increased pressure measurement dynamic range.

7. A system (100) for determination of intraocular pressure, the system (100) comprising:

   an intraocular pressure sensor (101) as defined in any one of claims 1 to 5; and a light source (102) illuminating the intraocular pressure sensor (101) with one or more wavelengths of light; and
   a detector (106) that measures reflected and/or emitted light from the sensor (101).

8. The system (100) of claim 7, further comprising a processing device (107) in communication with the detector (106),
   wherein the silicon nitride flexible membrane (202) both transmits and reflects the one or more wavelengths of light,
   wherein the silicon substrate member (200) reflects the one or more wavelengths of light transmitted by the silicon nitride flexible membrane (202), wherein the light reflected by the silicon substrate member (200) interferes with light reflected from the silicon nitride flexible membrane (202) to create an interfer-

ence pattern (300),
wherein the interference pattern (300) corresponds to intraocular pressure, wherein the detector (106) is an electronic imaging device capturing an image of the interference pattern (300), and
wherein the processing device (107) performs a phase calculation on the image of the interference pattern (300) to determine phase angles of the interference pattern (300), and correlates the phase angles with intraocular pressure.

9. The system (100) of claim 8, wherein the processing device (107) further performs the phase calculation using an integral transform (302) and calculates the phases at one or more spatial frequencies corresponding to peaks (301) in an absolute value of the integral transform (302).

10. The system (100) of claim 8, wherein the processing device (107) uses the values of the spatial frequencies corresponding to peaks (301) in the absolute value of the integral transform (302) to correct for errors which arise from angular deviation of a sensor normal from an optical axis of a readout system.

11. The system (100) of claim 8, wherein each wavelength emitted by the light source (102) has a coherence length longer than the twice the separation between the silicon nitride flexible membrane (202) and the silicon substrate member (200).

12. The system (100) of claim 8, further comprising an optical filter (105) positioned between the intraocular pressure sensor (101) and at least one of the light source (102) and the electronic imaging device, and providing an optical coherence length greater than twice the distance from the silicon nitride flexible membrane (202) to the silicon substrate member (200).

13. The system (100) of claim 8, wherein the light source (102) is modulated in time to allow for lock-in detection of the interference pattern (300).

14. The system (100) of claim 8, wherein the light source (102) emits multiple wavelengths of light, either simultaneously or sequentially, and wherein the dimensions of the silicon nitride flexible membrane (202) allow a phase change in the interference pattern (300) of greater than 2π for at least one of the multiple wavelengths of light.

15. The system (100) of claim 7, further comprising a processing device (107) in communication with the detector (106), a coating (700) containing a fluorescent material coated on at least one of the silicon substrate member (200) and the silicon nitride flexible membrane (202), and a filter (105) positioned between the intraocular pressure sensor (101) and the detector (106),
wherein an external light source (102) excites the fluorescent material of the coating (700), the fluorescent material of the coating (700) emits a light of a different second wavelength, the emission of the light of the second wavelength being the result of excitation of the fluorescent material, and the proximity of the silicon nitride flexible membrane (202) to the silicon substrate member (200) modulates the intensity of the emitted light of a different second wavelength,
wherein the detector (106) is a light intensity sensor,
wherein the filter (105) allows only the second wavelength to reach the detector (106), and
wherein the processing device (107) correlates the detected intensity at the second wavelength with intraocular pressure.

Patentansprüche

1. Intraokularer Drucksensor (101), umfassend:

ein Siliciumsubstratelement (200),
ein Abstandselement (201), und
eine flexible Siliciumnitridmembran (202),
wobei das Siliciumsubstratelement (200), das Abstandselement (201) und die flexible Siliciumnitridmembran (202) einen abgedichteten Hohlraum (203) definieren,
wobei die flexbile Siliciumnitridmembran (202) konfiguriert ist, sich in Antwort auf intraokulare Druckänderungen zu bewegen oder zu verformen und wobei die Bewegung des flexiblen Siliciumnitridmembran (202) optisch gemessen werden kann,
wobei die flexible Siliciumnitridmembran (202) konfiguriert ist, Licht sowohl zu transmittieren als auch zu reflektieren, und das Siliciumsubstratelement (200) konfiguriert ist, Licht zu reflektieren,
wobei das Licht, reflektiert durch das Siliciumsubstratelement (200), entweder konstruktiv oder destruktiv mit Licht, reflektiert von der flexiblen Siliciumnitridmembran (202), zu interferieren, um eine Interferenzmuster (300) zu bewirken, und
wobei das resultierende Interferenzmuster (300) einem intraokularen Druck entspricht.

2. Intraokularer Drucksensor (101) gemäß Anspruch 1, weiter umfassend eine Schicht (204) von zusätzlichem Material, beschichtet auf der äußeren Seite der flexiblen Siliciumnitridmembran (202), wobei die Dicke und der Brechungsindex des zusätzlichen Materials die Reflektion von der flexiblen Siliciumnitridmembran (202) und dem Siliciumsubstratelement (200) ausgleichen.

3. Intraokularer Drucksensor (101) gemäß Anspruch 1, weiter umfassend eine Beschichtung (700), enthaltend ein fluoreszierendes Material, wobei die Beschichtung (700) mindestens an einem von dem Siliciumsubstratelement (200) und der flexiblen Siliciumnitridmembran (202) beschichtet ist, wobei eine externe Lichtquelle (102) das fluoreszierende Material der Beschichtung (700) anregt, und das fluoreszierende Material der Beschichtung (700) ein Licht von einer unterschiedlichen, zweiten Wellenlänge emittiert, wobei die Emission des Lichts der zweiten Längenwelle das Ergebnis der Anregung des fluoreszierenden Materials ist, wobei die Nähe der flexiblen Siliciumnitridmembran (202) zu dem Siliciumsubstratelement (200) die Intensität des emittierten Lichts von einer unterschiedlichen, zweiten Wellenlänge moduliert und die detektierte Intensität des emittierten Lichts der unterschiedlichen, zweiten Wellenlänge verwendet wird, um den Druck zu bestimmen.

4. Intraokularer Drucksensor (101) gemäß Anspruch 3, weiter umfassend ein Streumedium (701), beschichtet auf mindestens einem von der flexiblen Siliciumnitridmembran (202) und dem Siliciumsubstratelement (200).

5. Intraokularer Drucksensor (101) gemäß Anspruch 3, wobei die Beschichtung (700) weiter ein zweites fluoreszierendes Material umfaßt, wobei die externe Lichtquelle (102) weiter das zweite fluoreszierende Material der Beschichtung (700) anregt, um ein Licht einer unterschiedlichen, dritten Wellenlänge zu emittieren, wobei der Unterschied in der detektierten Intensität des emittierten Lichts bei der zweiten und dritten Wellenlänge verwendet wird, um den Druck zu bestimmen.

6. Vorrichtung zum Messen des intraokularen Drucks, umfassend:

einen intraokularen Drucksensor (101), wie in einem der Ansprüche 1 bis 5 definiert,
ein Verankerungselement (500), angebracht an den intraokularen Drucksensor (101), zum Immobilisieren des intraokularen Drucksensors (101) in ein Auge (505),
ein Schutzelement (501), angebracht an das Verankerungselement (500) und den intraokularen Drucksensor (101) abdeckend, um Kontakt mit der flexiblen Siliciumnitridmembran (202) und Teilen des Auges (505) zu verhindern, und
einen zweiten intraokularen Drucksensor (101) mit mindestens einem von einem unterschiedlichen Durchmesser, Form, Membrandicke, Membranmaterial und Substratmaterial, wobei der intraokulare Drucksensor (101) und der zweite intraokulare Drucksensor (101) mindestens eines von redundanter Druckmessung, Fehlererkennung, Kompensation von Temperaturschwankungen in dem Auge (505), erhöhter Druckmeßempfindlichkeit und erhöhtem dynamischen Druckmessbereich bereitstellen.

7. System (100) zum Bestimmen des intraokularen Drucks, wobei das System (100) umfaßt:

einen intraokularen Drucksensor (101), wie in einem der Ansprüche 1 bis 5 definiert, und
eine Lichtquelle (102), welche den intraokularen Drucksensor (101) mit einer oder mehreren Wellenlängen des Lichts beleuchtet, und
einen Detektor (106), welcher reflektiertes und/oder emittiertes Licht von dem Sensor (101) misst.

8. System (100) gemäß Anspruch 7, weiter umfassend eine Verarbeitungsvorrichtung (107) in Verbindung mit dem Detektor (106),
wobei die flexible Siliciumnitridmembran (202) die eine oder die mehreren Wellenlängen des Lichts sowohl transmittiert als auch reflektiert,
wobei das Siliciumsubstratelement (200) die eine oder mehreren Wellenlängen des Lichts, transmittert durch die flexible Siliciumnitridmembran (202), reflektiert,
wobei das Licht, reflektiert durch das Siliciumsubstratelement (200), mit Licht, reflektiert von der flexiblen Siliciumnitridmembran (202), interferiert, um ein Interferenzmuster (300) zu bewirken,
wobei das Interferenzmuster (300) dem intraokularen Druck entspricht,
wobei der Detektor (106) eine elektronische Bildgebungsvorrichtung ist, die ein Bild des Interferenzmusters (300) aufnimmt, und
wobei die Verarbeitungsvorrichtung (107) eine Phasenberechnung an dem Bild des Interferenzmusters (300) durchführt, um Phasenwinkel des Interferenzmusters (300) zu bestimmen und die Phasenwinkel mit dem intraokularen Druck korreliert.

9. System (100) gemäß Anspruch 8, wobei die Verarbeitungsvorrichtung (107) weiter die Phasenberechnung unter Verwendung einer Integraltransformation (302) durchführt und die Phasen bei einer oder mehreren Ortsfrequenzen berechnet, die Peaks in einem Absolutwert der Integraltransformation entsprechen.

10. System (100) gemäß Anspruch 8, wobei die Verarbeitungsvorrichtung (107) die Werte der Ortsfrequenzen, die den Peaks (301) in dem absoluten Wert der Integraltransformation (302) entsprechen, um Fehler zu korrigieren, die sich aus einer Winkelabweichung einer Sensornormalen von einer opti-

schen Achse eines Auslesesystems ergeben.

11. System (100) gemäß Anspruch 8, wobei jede Wellenlänge, emittiert durch die Lichtquelle (102), eine Kohärenzlänge aufweist, die länger ist als der doppelte Abstand zwischen der flexiblen Siliciumnitridmembran (202) und dem Siliciumsubstratelement (200).

12. System (100) gemäß Anspruch 8, weiter umfassend einen optischen Filter (105), angeordnet zwischen dem intraokularen Drucksensor (101) und mindestens einem von der Lichtquelle (102) und der elektronischen Bildgebungsvorrichtung, und eine optische Kohärenzlänge lieferend, die größer ist als der doppelte Abstand von der flexiblen Siliciumnitridmembran (202) zu dem Siliciumsubstratelement (200).

13. System (100) gemäß Anspruch 8, wobei die Lichtquelle (102) zeitlich moduliert ist, um eine Erfassung des Interferenzmusters (300) zu ermöglichen.

14. System (100) gemäß Anspruch 8, wobei die Lichtquelle (102) mehrere Wellenlängen von Licht, entweder gleichzeitig oder nacheinander, emittiert, und wobei die Abmessungen der flexiblen Siliciumnitridmembran (202) eine Phasenänderung in dem Interferenzmuster (300) von mehr als 2π für mindestens eine der mehreren Wellenlängen von Licht zuläßt.

15. System (100) gemäß Anspruch 7, weiter umfassend eine Verarbeitungsvorrichtung (107) in Verbindung mit dem Detektor (106), eine Beschichtung (700), enthaltend ein fluoreszierendes Material, beschichtet auf mindestens einem von dem Siliciumsubstratelement (200) und der flexiblen Siliciumnitridmembran (202), und einen Filter (105), angeordnet zwischen dem intraokularen Drucksensor (101) und dem Detektor (106),
wobei eine externe Lichtquelle (102) das fluoreszierende Material der Beschichtung (700) anregt, wobei das fluoreszierende Material der Beschichtung (700) ein Licht einer unterschiedlichen, zweiten Wellenlänge emittiert, wobei die Emission des Lichts der zweiten Wellenlänge das Ergebnis der Anregung des fluoreszierenden Materials ist, und die Nähe der flexiblen Siliciumnitridmembran (202) zu dem Siliciumsubstratelement (200) die Intensität des emittierten Lichts einer unterschiedlichen, zweiten Wellenlänge moduliert,
wobei der Detektor (106) ein Lichtintensitätssensor ist,
wobei der Filter (105) zuläßt, dass nur die zweite Wellenlänge den Detektor (106) erreicht, und
wobei die Verarbeitungsvorrichtung (107) die detektierte Intensität bei der zweiten Wellenlänge mit dem intraokularen Druck korreliert.

Revendications

1. Capteur de pression intraoculaire (101) comprenant :

un élément de substrat en silicium (200) ;
un élément écarteur (201) ; et
une membrane flexible en nitrure de silicium (202) ;
l'élément de substrat en silicium (200), l'élément écarteur (201) et la membrane flexible en nitrure de silicium (202) définissant une cavité scellée (203) ;
la membrane flexible en nitrure de silicium (202) étant configurée pour se déplacer ou déformer en réponse à des changements de pression intraoculaire et dans lequel le mouvement de la membrane flexible en nitrure de silicium (202) peut être mesuré optiquement,
la membrane flexible en nitrure de silicium (202) étant configurée pour à la fois transmettre et refléter de la lumière, et l'élément de substrat en silicium (200) étant configuré pour refléter de la lumière,
dans lequel la lumière reflétée par l'élément de substrat en silicium (200) interfère de manière constructive ou destructive avec de la lumière reflétée depuis la membrane flexible en nitrure de silicium (202) pour créer un diagramme d'interférence (300), et
dans lequel le diagramme d'interférence résultant (300) correspond à la pression intraoculaire.

2. Capteur de pression intraoculaire (101) selon la revendication 1, comprenant en outre une couche (204) de matériau supplémentaire enduite sur le côté externe de la membrane flexible en nitrure de silicium (202), l'épaisseur et l'indice de réfraction du matériau supplémentaire égalisant la réflexion provenant de la membrane flexible en nitrure de silicium (202) et de l'élément de substrat en silicium (200).

3. Capteur de pression intraoculaire (101) selon la revendication 1, comprenant en outre un enrobage (700) contenant un matériau fluorescent, l'enrobage (700) étant enduit sur au moins un de l'élément de substrat en silicium (200) et la membrane flexible en nitrure de silicium (202), dans lequel une source lumineuse externe (102) excite le matériau fluorescent de l'enrobage (700), et le matériau fluorescent de l'enrobage (700) émet une lumière d'une deuxième longueur d'onde différente, l'émission de la lumière de la deuxième longueur d'onde étant le résultat de l'excitation du matériau fluorescent, dans lequel la proximité de la membrane flexible en nitrure de silicium (202) à l'élément de substrat en silicium (200) module l'intensité de la lumière émise d'une deuxiè-

me longueur d'onde différente et l'intensité détectée de la lumière émise de la deuxième longueur d'onde différente est utilisée pour déterminer la pression.

4. Capteur de pression intraoculaire (101) selon la revendication 3, comprenant en outre un milieu de dispersion (701) enduit sur au moins un de la membrane flexible en nitrure de silicium (202) et l'élément de substrat en silicium (200).

5. Capteur de pression intraoculaire (101) selon la revendication 3, dans lequel l'enrobage (700) comprend en outre un second matériau fluorescent, dans lequel la source lumineuse externe (102) excite en outre le second matériau fluorescent de l'enrobage (700) pour émettre une lumière d'une troisième longueur différente, dans lequel la différence d'intensité détectée de la lumière émise aux deuxième et troisième longueurs d'onde est utilisée pour déterminer la pression.

6. Dispositif de mesure de pression intraoculaire comprenant :

un capteur de pression intraoculaire (101) selon l'une quelconque des revendications 1 à 5 ;
un élément d'ancrage (500) connecté au capteur de pression intraoculaire (101) pour immobiliser le capteur de pression intraoculaire (101) dans un oeil (505) ;
un élément protecteur (501) connecté à l'élément d'ancrage (500) et recouvrant le capteur de pression intraoculaire (101) pour empêcher un contact entre la membrane flexible en nitrure de silicium (202) et des portions de l'oeil (505) ; et
un second capteur de pression intraoculaire (101) ayant au moins une caractéristique parmi un diamètre, une forme, une épaisseur de membrane, un matériau de membrane et un matériau de substrat différent, le capteur de pression intraoculaire (101) et le second capteur de pression intraoculaire (101) fournissant au moins un élément parmi une mesure de pression redondante, une détection de panne, une compensation de fluctuations de température dans l'oeil (505), une sensibilité de mesure de pression accrue et une plage dynamique de mesure de pression accrue.

7. Système (100) de détermination de pression intraoculaire, le système (100) comprenant :

un capteur de pression intraoculaire (101) selon l'une quelconque des revendications 1 à 5 ; et
une source lumineuse (102) éclairant le capteur de pression intraoculaire (101) avec une ou plusieurs longueurs d'onde de lumière ; et
un détecteur (106) qui mesure la lumière reflétée et/ou émise depuis le capteur (101).

8. Système (100) selon la revendication 7, comprenant en outre un dispositif de traitement (107) en communication avec le détecteur (106),
dans lequel la membrane flexible en nitrure de silicium (202) transmet et reflète à la fois la ou les longueurs d'onde de lumière,
dans lequel l'élément de substrat en silicium (200) reflète la ou les longueurs d'onde de lumière transmises par la membrane flexible en nitrure de silicium (202),
dans lequel la lumière reflétée par l'élément de substrat en silicium (200) interfère avec de la lumière reflétée depuis la membrane flexible en nitrure de silicium (202) pour créer un diagramme d'interférence (300),
dans lequel le diagramme d'interférence (300) correspond à la pression intraoculaire,
dans lequel le détecteur (106) est un dispositif d'imagerie électronique capturant une image du diagramme d'interférence (300), et
dans lequel le dispositif de traitement (107) réalise un calcul de phase sur l'image du diagramme d'interférence (300) pour déterminer des angles de phase du diagramme d'interférence (300) et met en corrélation les angles de phase avec la pression intraoculaire.

9. Système (100) selon la revendication 8, dans lequel le dispositif de traitement (107) réalise en outre le calcul de phase en utilisant une transformée intégrale (302) et calcule les phases à une ou plusieurs fréquences spatiales correspondant à des pics (301) d'une valeur absolue de la transformée intégrale (302).

10. Système (100) selon la revendication 8, dans lequel le dispositif de traitement (107) utilise les valeurs des fréquences spatiales correspondant à des pics (301) de la valeur absolue de la transformée intégrale (302) pour corriger des erreurs qui surviennent à partir d'un écart angulaire d'une normale de capteur depuis un axe optique d'un système de lecture.

11. Système (100) selon la revendication 8, dans lequel chaque longueur d'onde émise par la source lumineuse (102) a une longueur de cohérence plus longue que le double de la séparation entre la membrane flexible en nitrure de silicium (202) et l'élément de substrat en silicium (200).

12. Système (100) selon la revendication 8, comprenant en outre un filtre optique (105) positionné entre le capteur de pression intraoculaire (101) et au moins un de la source lumineuse (102) et du dispositif d'imagerie électronique, et fournissant une longueur

de cohérence optique supérieure au double de la distance de la membrane flexible en nitrure de silicium (202) à l'élément de substrat en silicium (200).

13. Système (100) selon la revendication 8, dans lequel la source lumineuse (102) est modulée dans le temps pour permettre une détection synchrone du diagramme d'interférence (300).

14. Système (100) selon la revendication 8, dans lequel la source lumineuse (102) émet de multiples longueurs d'onde de lumière, simultanément ou séquentiellement, et dans lequel les dimensions de la membrane flexible en nitrure de silicium (202) permettent un changement de phase du diagramme d'interférence (300) supérieur à 2π pour au moins une des multiples longueurs d'onde de lumière.

15. Système (100) selon la revendication 7, comprenant en outre un dispositif de traitement (107) en communication avec le détecteur (106), un enrobage (700) contenant un matériau fluorescent enduit sur au moins un de l'élément de substrat en silicium (200) et la membrane flexible en nitrure de silicium (202), et un filtre (105) positionné entre le capteur de pression intraoculaire (101) et le détecteur (106),
dans lequel une source lumineuse externe (102) excite le matériau fluorescent de l'enrobage (700), le matériau fluorescent de l'enrobage (700) émet une lumière d'une deuxième longueur d'onde différente, l'émission de la lumière de la deuxième longueur d'onde étant le résultat de l'excitation du matériau fluorescent, et la proximité de la membrane flexible en nitrure de silicium (202) à l'élément de substrat en silicium (200) module l'intensité de la lumière émise d'une deuxième longueur d'onde différente,
dans lequel le détecteur (106) est un capteur d'intensité lumineuse,
dans lequel le filtre (105) permet uniquement à la deuxième longueur d'onde d'atteindre le détecteur (106), et
dans lequel le dispositif de traitement (107) met en corrélation l'intensité détectée à la deuxième longueur d'onde avec la pression intraoculaire.

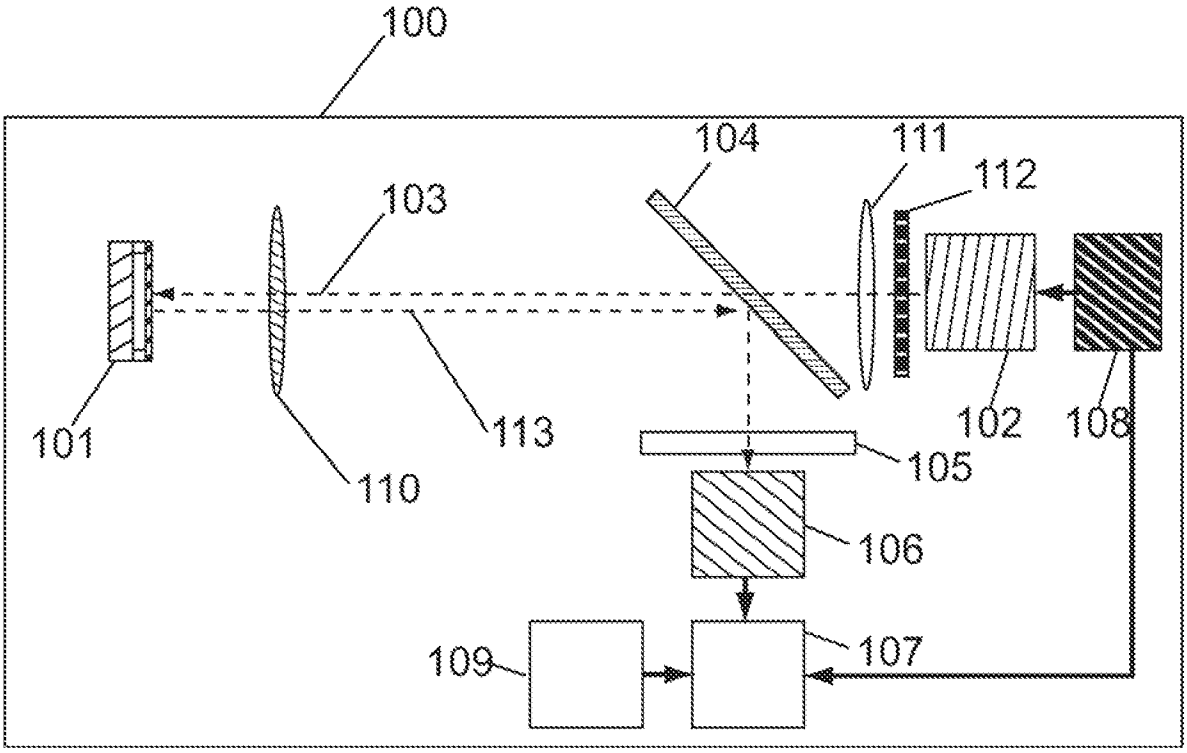


FIG. 1

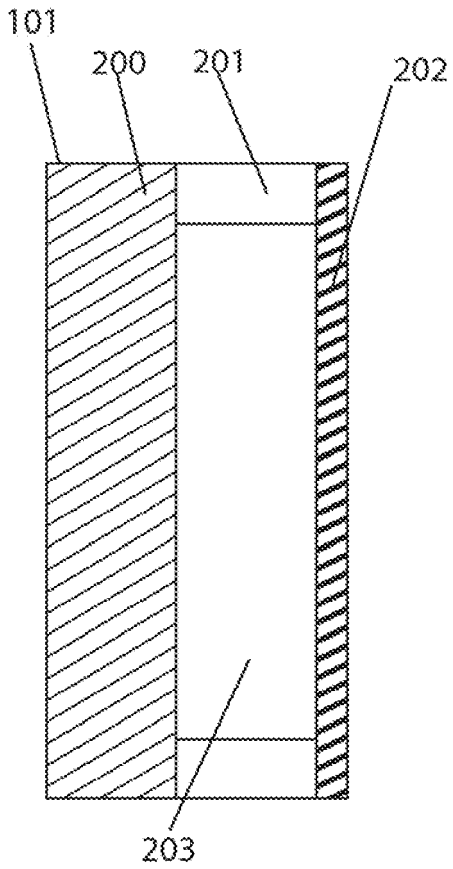


FIG. 2A

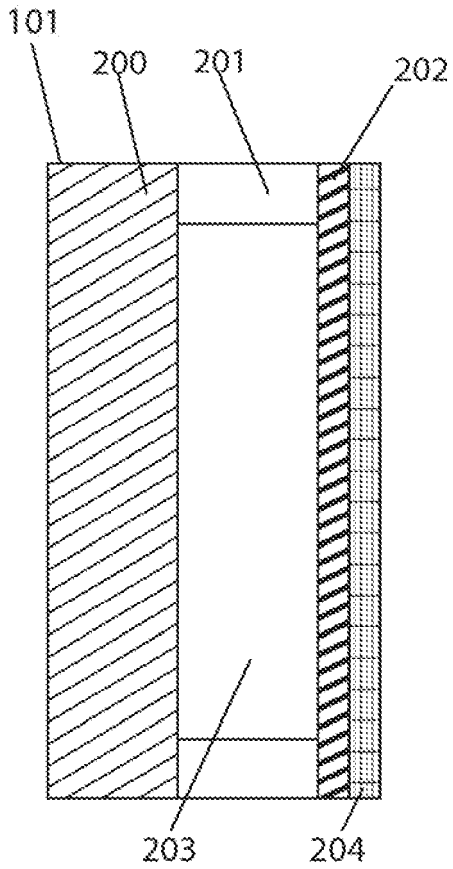


FIG. 2B

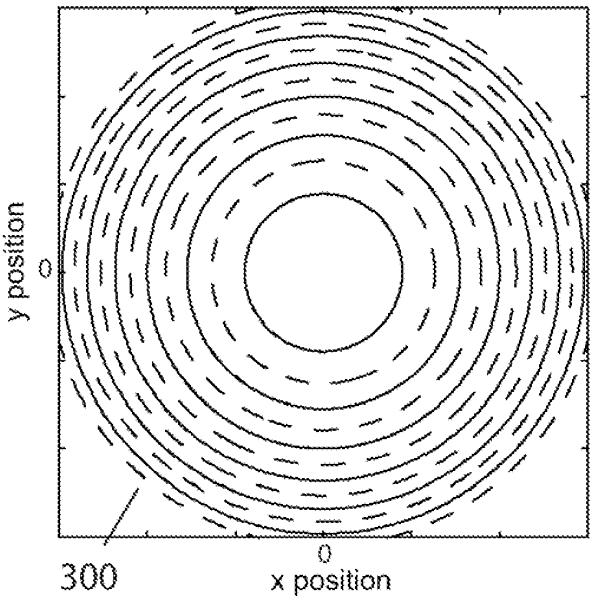


FIG. 3A

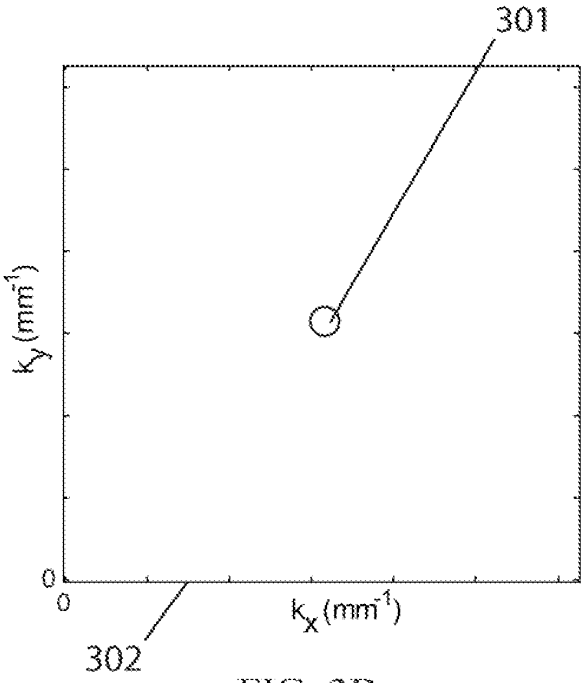


FIG. 3B

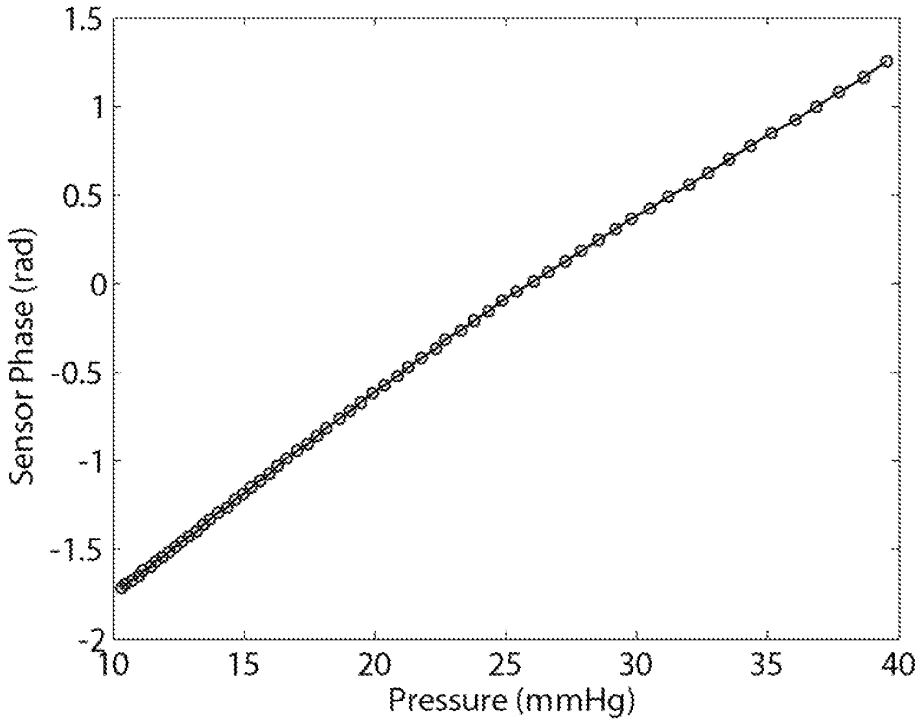


FIG. 3C

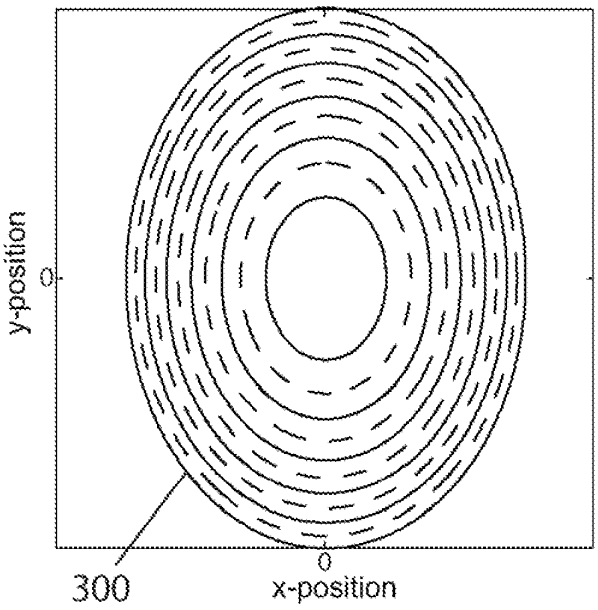


FIG. 4A

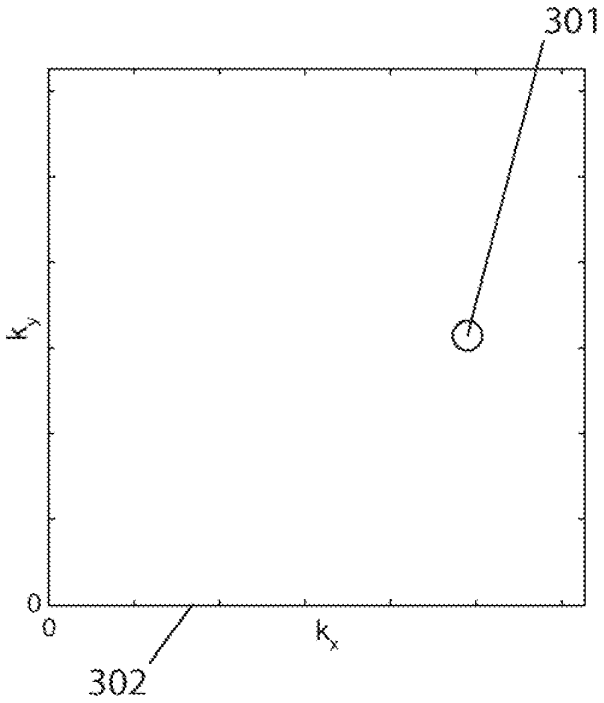


FIG. 4B

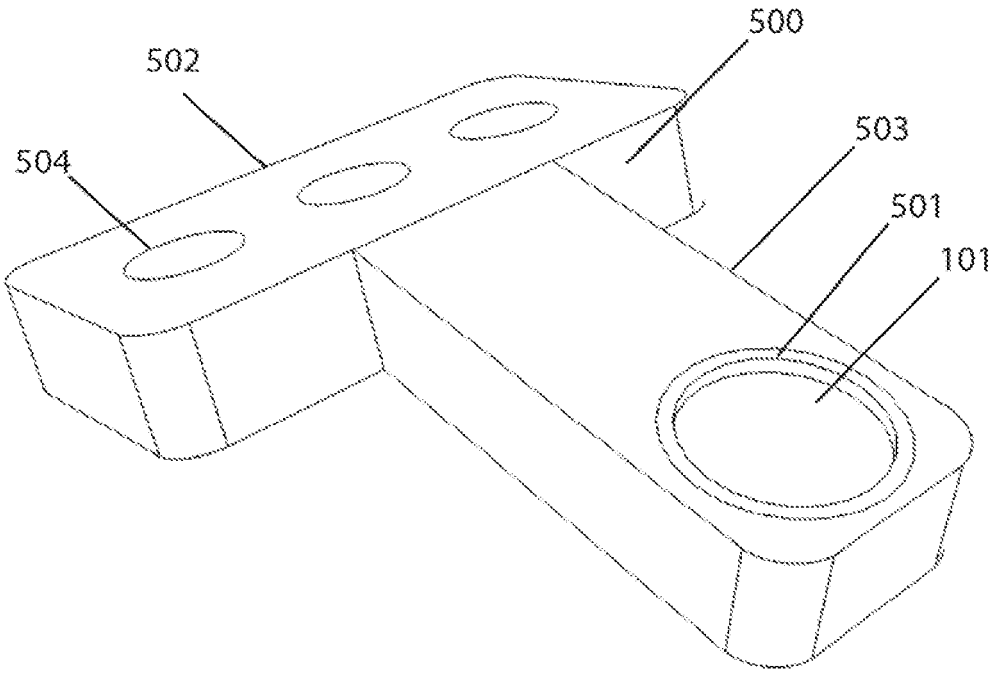


FIG. 5A

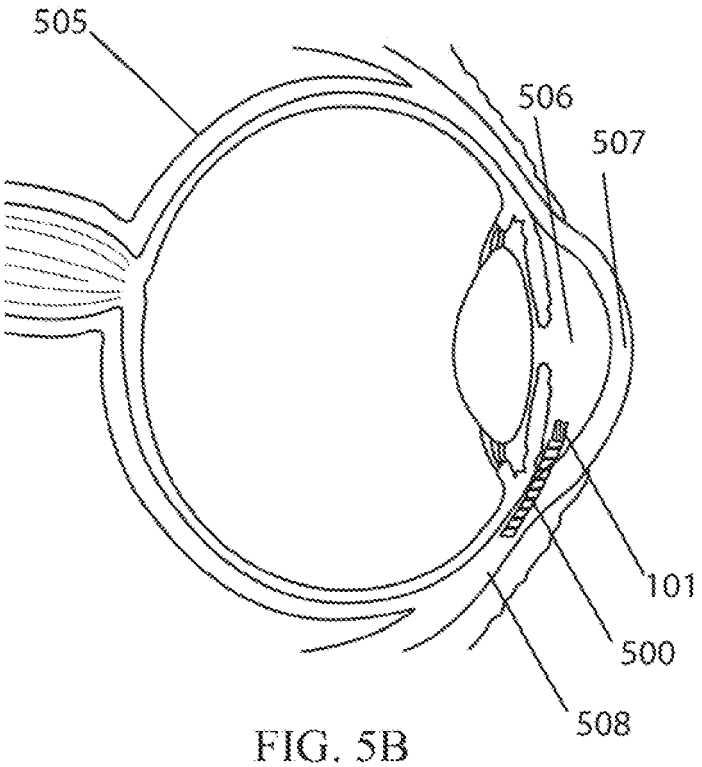


FIG. 5B

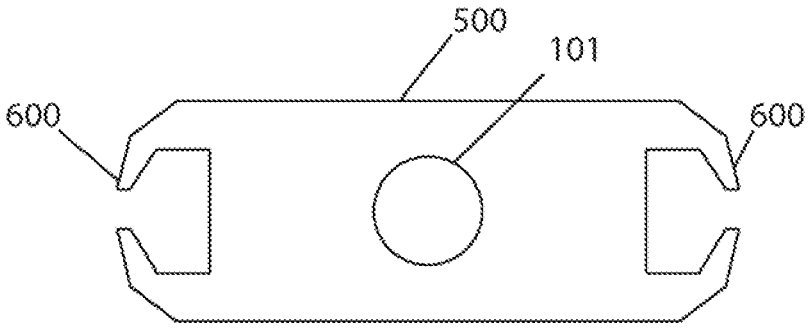


FIG. 6A

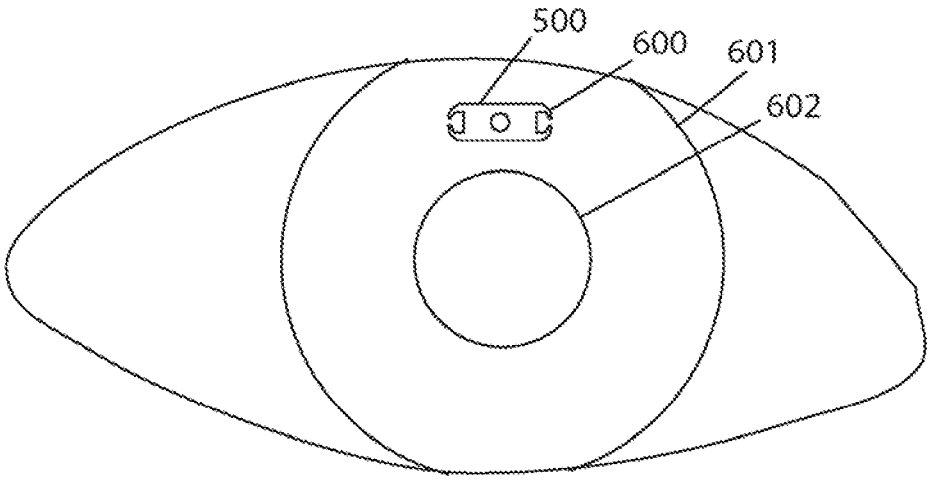


FIG. 6B

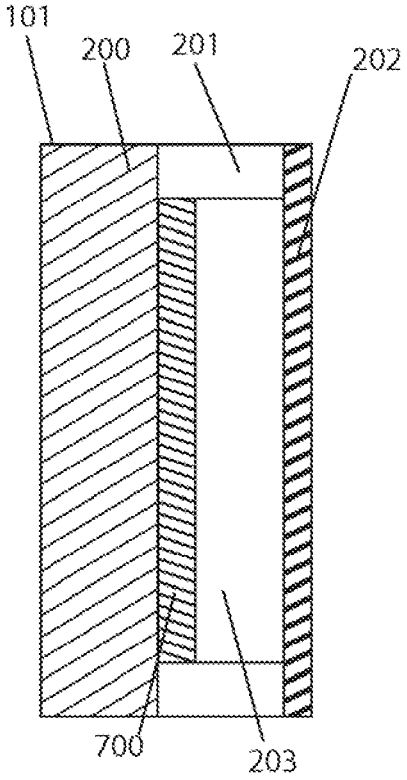


FIG. 7A

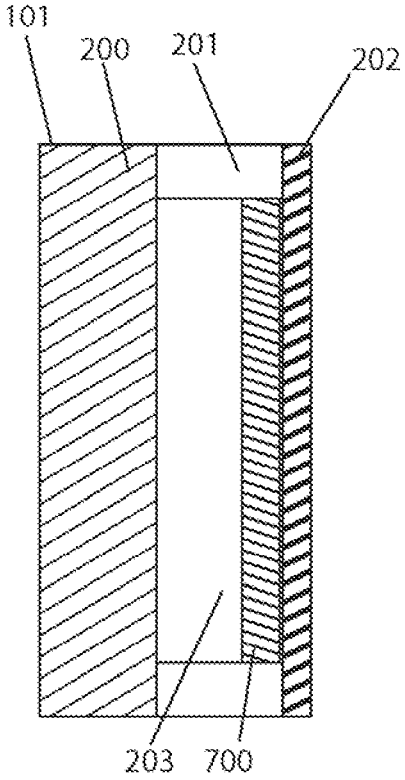


FIG. 7B

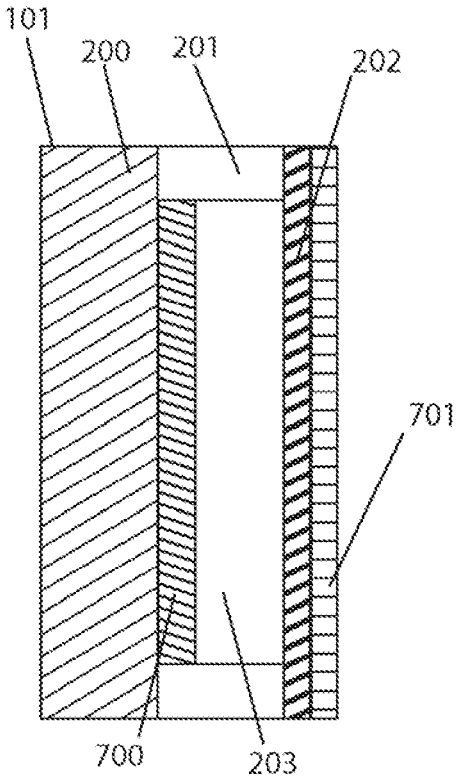


FIG. 7C

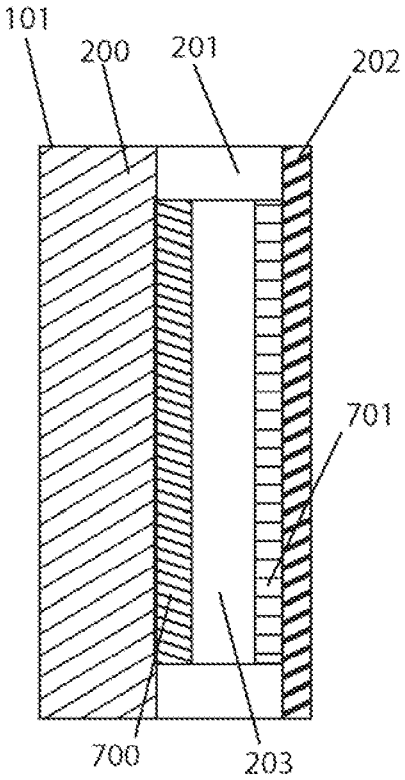


FIG. 7D

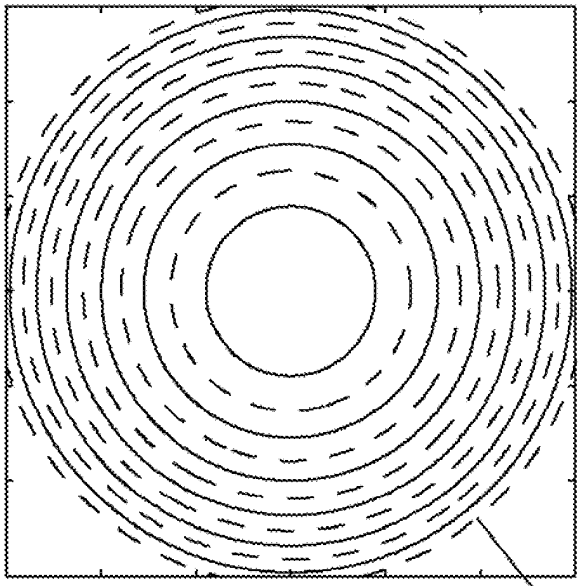


FIG. 8A

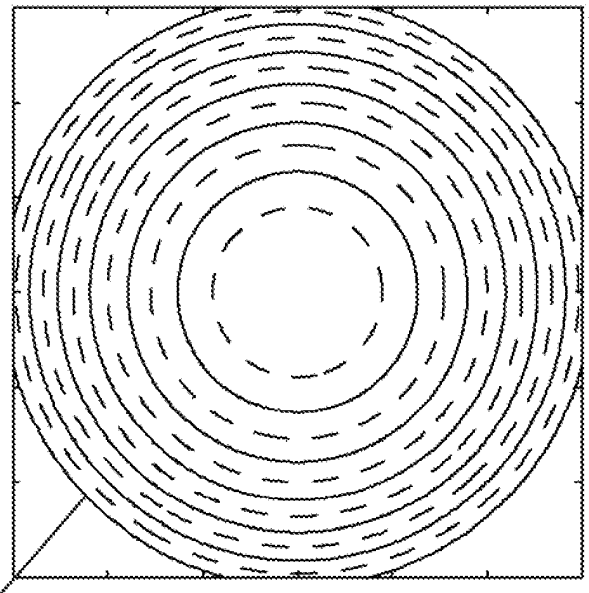


FIG. 8B

300

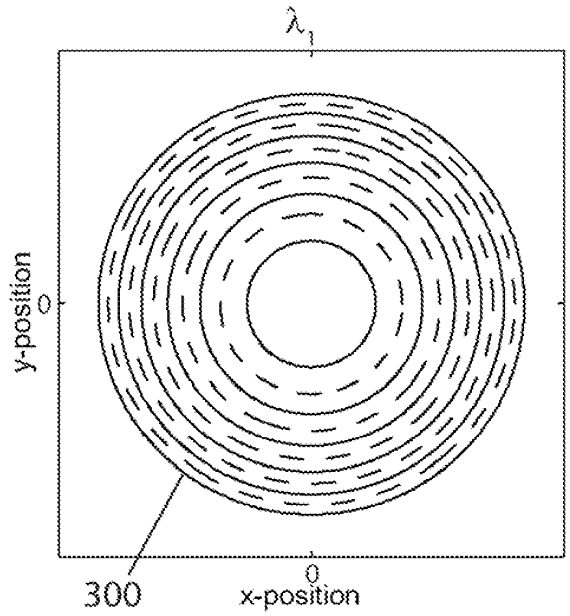


FIG. 9A

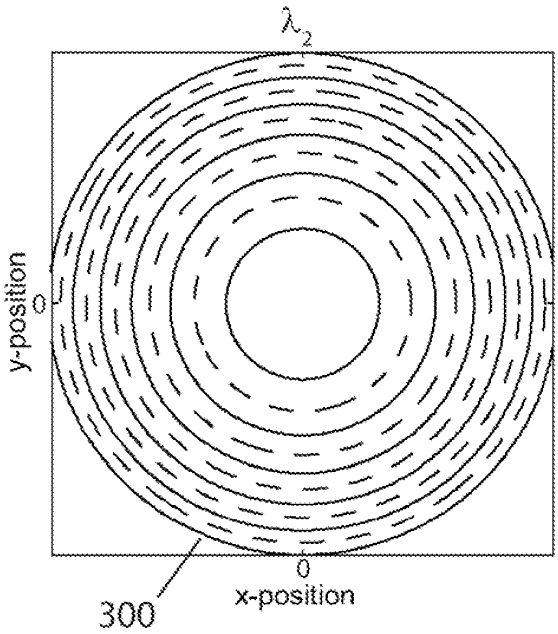


FIG. 9B

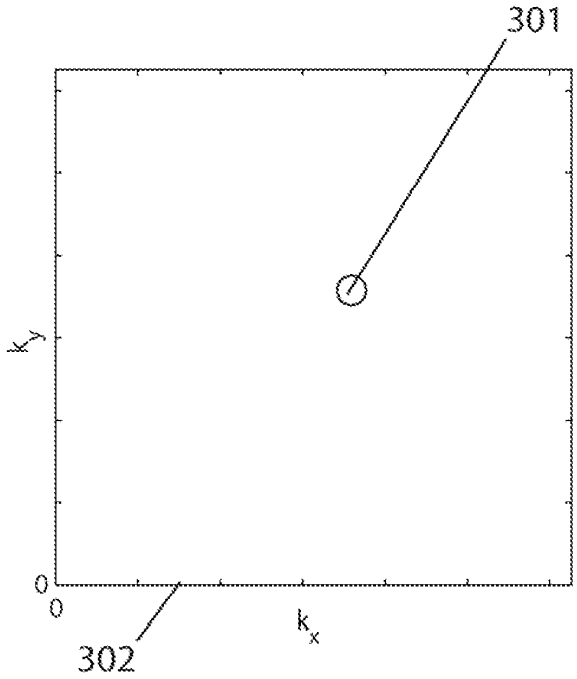


FIG. 9C

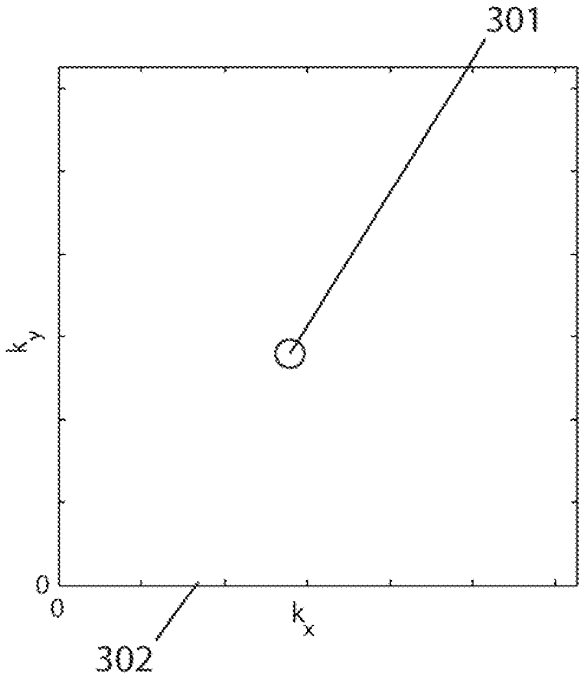


FIG. 9D

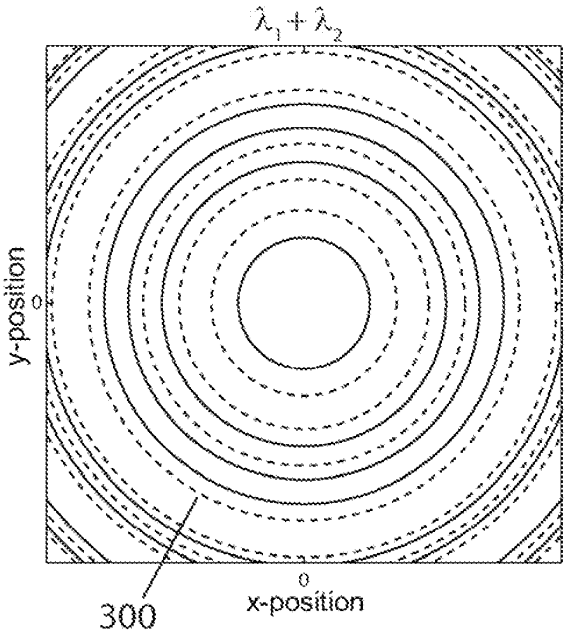


FIG. 10A

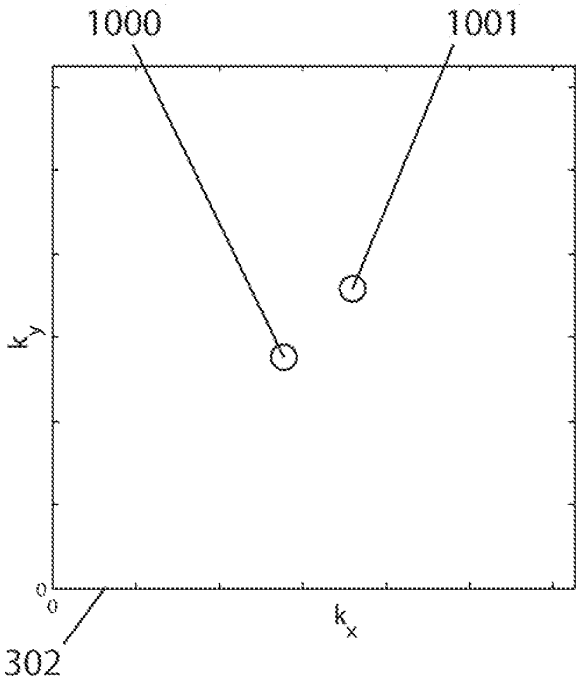


FIG. 10B

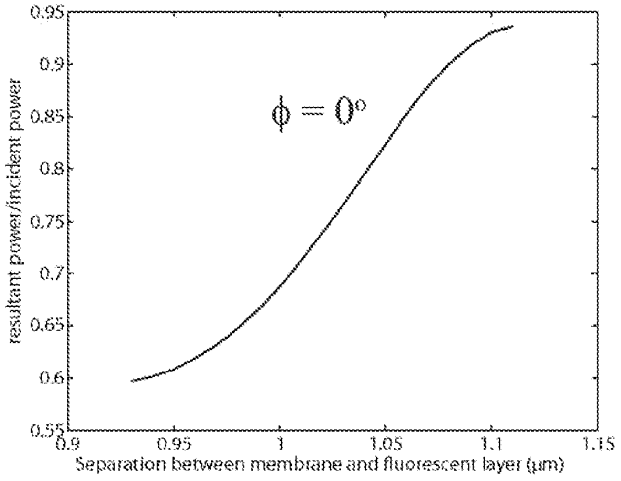


FIG. 11A

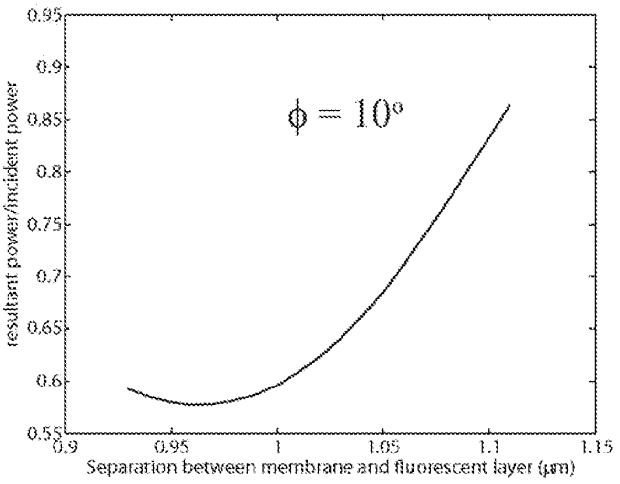


FIG. 11B

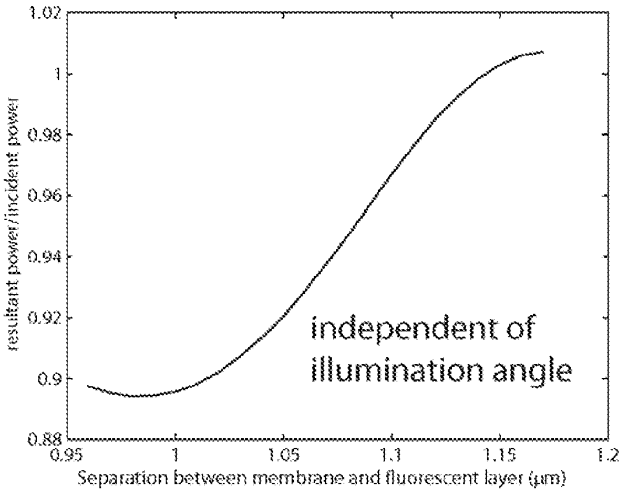


FIG. 11C

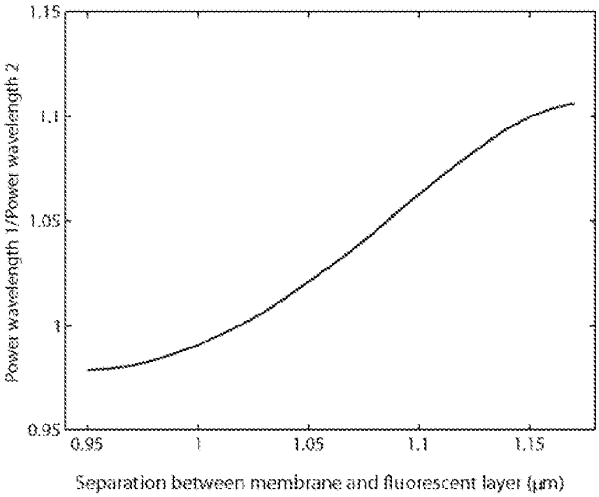


FIG. 11D

FIG. 12

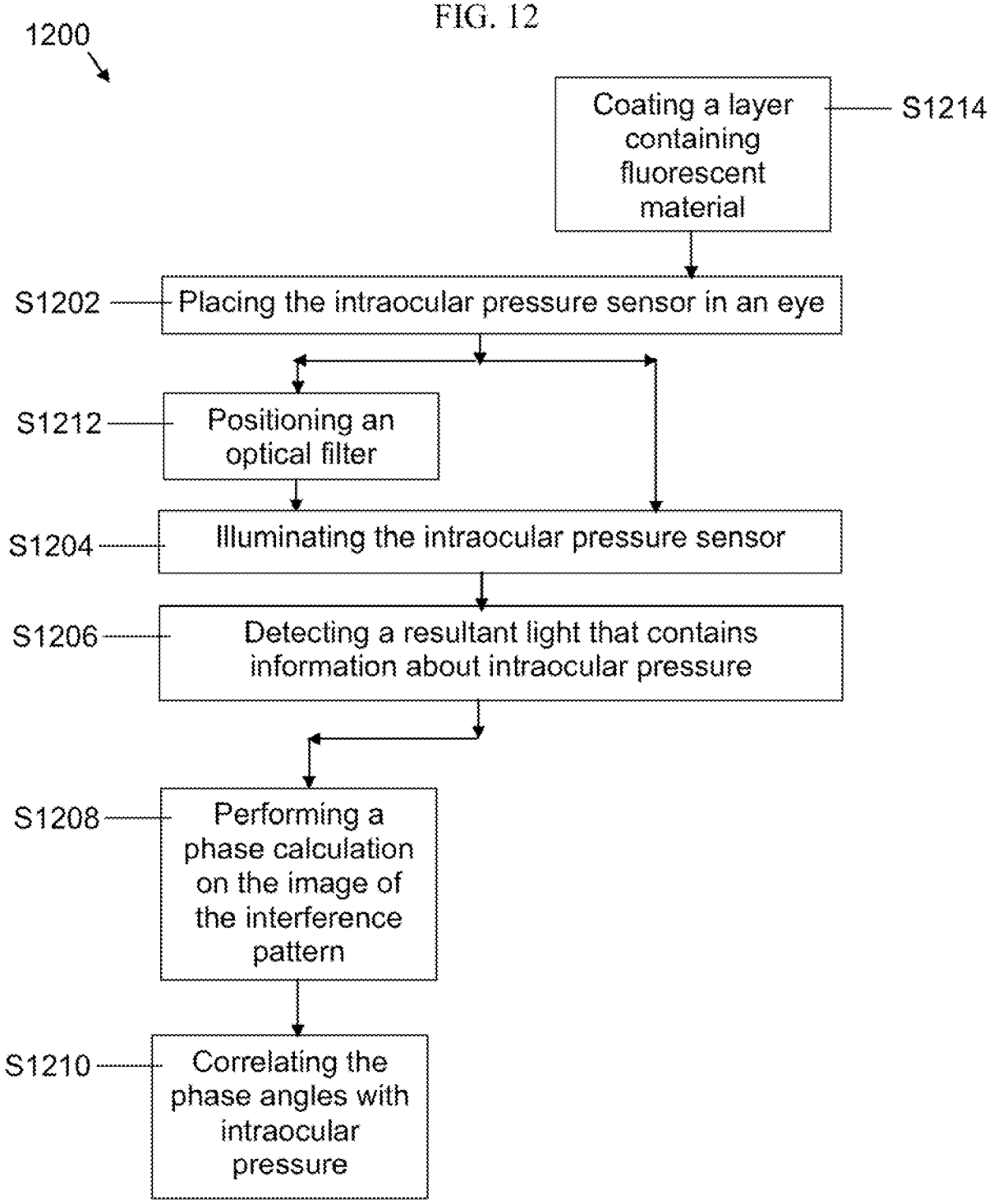
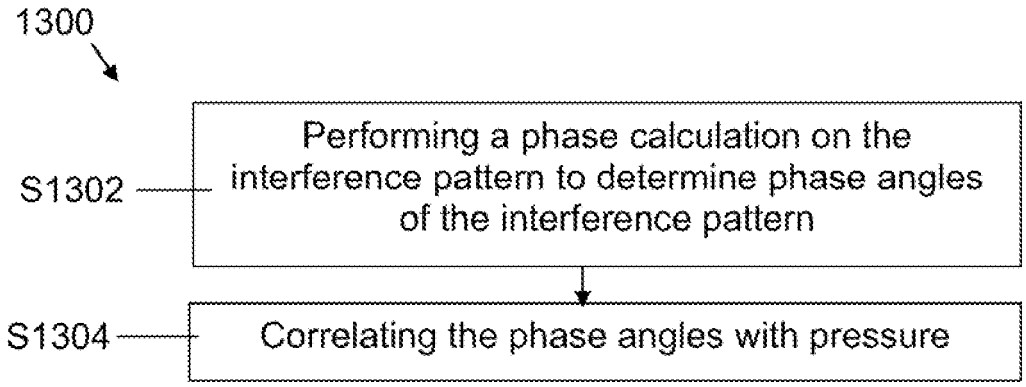

1200
Coating a layer containing fluorescent material
S1214
S1202
Placing the intraocular pressure sensor in an eye
S1212
Positioning an optical filter
S1204
Illuminating the intraocular pressure sensor
S1206
Detecting a resultant light that contains information about intraocular pressure
S1208
Performing a phase calculation on the image of the interference pattern
S1210
Correlating the phase angles with intraocular pressure

FIG. 13


1300
S1302
Performing a phase calculation on the interference pattern to determine phase angles of the interference pattern
S1304
Correlating the phase angles with pressure

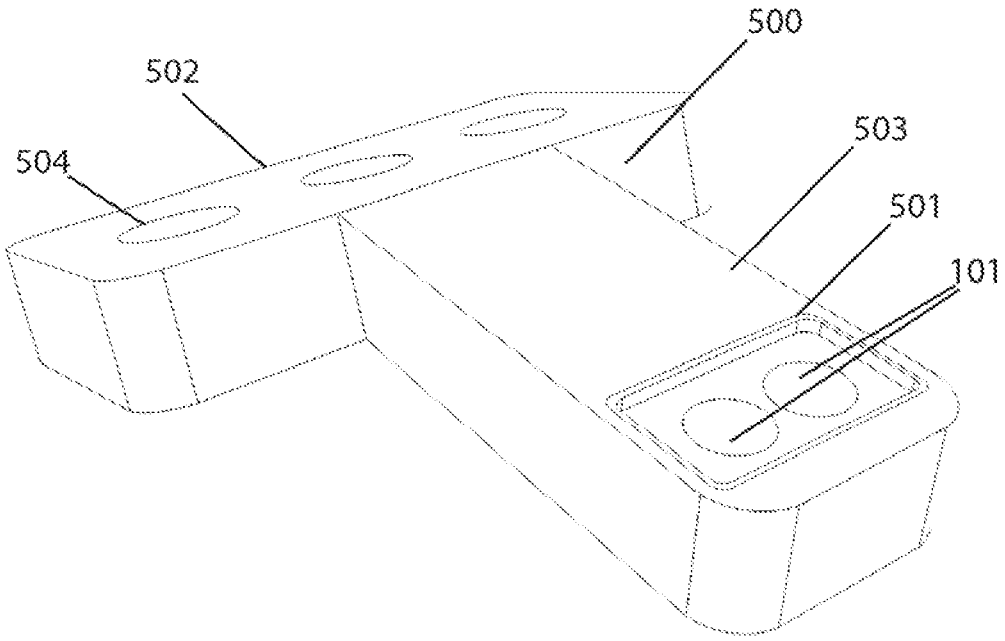


FIG. 14A

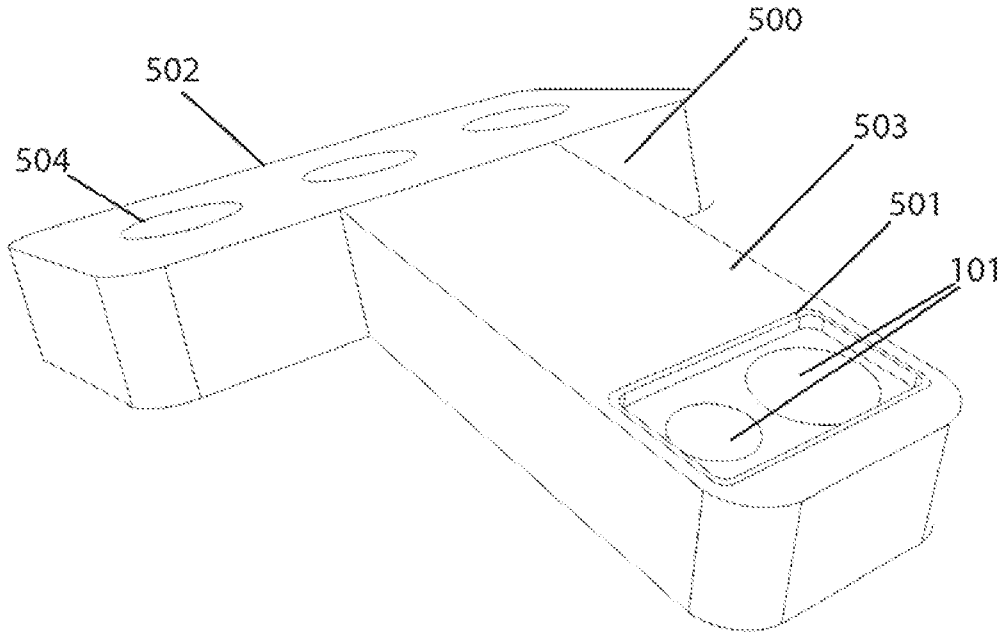


FIG. 14B

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- US 2004254438 A1 **[0004]**
- US 2007123768 A1 **[0005]**
- US 2008154114 A1 **[0006]**

专利名称(译)	用于确定眼内压的系统，装置和方法		
公开(公告)号	EP2519141B1	公开(公告)日	2018-09-05
申请号	EP2010841727	申请日	2010-12-30
[标]申请(专利权)人(译)	布罗克曼控股 肯塔基大学研究基金会		
申请(专利权)人(译)	布罗克曼控股有限公司 肯塔基州研究基金会大学		
当前申请(专利权)人(译)	布罗克曼控股有限公司 肯塔基州研究基金会大学		
[标]发明人	HASTINGS JEFFREY TODD BROCKMAN E BRITT ST OMER INGRID L WRIGHT JOHN C		
发明人	HASTINGS, JEFFREY TODD BROCKMAN, E. BRITT ST. OMER, INGRID L. WRIGHT, JOHN C.		
IPC分类号	A61B3/16 A61B5/00		
CPC分类号	A61B3/165		
优先权	61/291131 2009-12-30 US		
其他公开文献	EP2519141A4 EP2519141A2		
外部链接	Espacenet		

摘要(译)

一种用于确定眼压的系统包括：眼压传感器;用一个或多个波长的光照射传感器的光源;以及测量传感器发出的光的探测器。传感器包括基板构件，间隔构件和柔性膜，其限定密封腔。柔性膜响应于眼内压变化而移动。一种用于测量眼压的装置包括：传感器;附接到传感器的锚定构件，用于将传感器固定在眼睛中;保护构件附接到锚固构件并覆盖传感器以防止柔性膜和眼睛之间的接触。一种用于确定眼内压的方法包括：将传感器放置在眼睛中;用光源照射具有一个或多个波长的光的传感器;并且利用检测器检测包含关于眼内压的信息的合成光。