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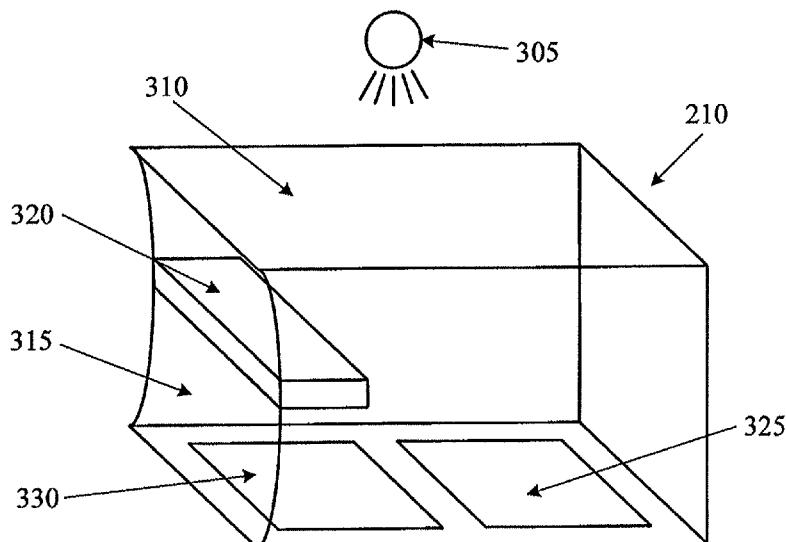


Fig. 4

(57) Abstract: An implantable intraocular pressure sensor system has a sealed geometric shape with an internal pressure at a first value. The sealed geometric shape has a first light permitting surface and a second flexible surface. A pair of photocells is located in the sealed geometric shape. A light shield is coupled to the second flexible surface. When the second flexible surface is deflected, a light measurement by the pair of photocells indicates an intraocular pressure condition.

INTRAOCULAR PRESSURE SENSOR

BACKGROUND OF THE INVENTION

5 The present invention relates to a device for monitoring intraocular pressure and more particularly to an implantable pressure sensor.

Glaucoma, a group of eye diseases affecting the retina and optic nerve, is one of the leading causes of blindness worldwide. Glaucoma results when the intraocular 10 pressure (IOP) increases to pressures above normal for prolonged periods of time. IOP can increase due to an imbalance of the production of aqueous humor and the drainage of the aqueous humor. Left untreated, an elevated IOP causes irreversible damage the optic nerve and retinal fibers resulting in a progressive, permanent loss of vision.

15 The eye's ciliary body epithelium constantly produces aqueous humor, the clear fluid that fills the anterior chamber of the eye (the space between the cornea and iris). The aqueous humor flows out of the anterior chamber through the uveoscleral pathways, a complex drainage system. The delicate balance between the production 20 and drainage of aqueous humor determines the eye's IOP.

25 Open angle (also called chronic open angle or primary open angle) is the most common type of glaucoma. With this type, even though the anterior structures of the eye appear normal, aqueous fluid builds within the anterior chamber, causing the IOP to become elevated. Left untreated, this may result in permanent damage of the optic nerve and retina. Eye drops are generally prescribed to lower the eye pressure. In 30 some cases, surgery is performed if the IOP cannot be adequately controlled with medical therapy.

35 Only about 10% of the population suffers from acute angle closure glaucoma. Acute angle closure occurs because of an abnormality of the structures in the front of the eye. In most of these cases, the space between the iris and cornea is more narrow than normal, leaving a smaller channel for the aqueous to pass through. If the flow of aqueous becomes completely blocked, the IOP rises sharply, causing a sudden angle closure attack.

Secondary glaucoma occurs as a result of another disease or problem within the eye such as: inflammation, trauma, previous surgery, diabetes, tumor, and certain

medications. For this type, both the glaucoma and the underlying problem must be treated.

Figure 1 is a diagram of the front portion of an eye that helps to explain the processes of glaucoma. In Figure 1, representations of the lens 110, cornea 120, iris 130, ciliary bodies 140, trabecular meshwork 150, and Schlemm's canal 160 are pictured. Anatomically, the anterior chamber of the eye includes the structures that cause glaucoma. Aqueous fluid is produced by the ciliary bodies 140 that lie beneath the iris 130 and adjacent to the lens 110 in the anterior chamber. This aqueous humor washes over the lens 110 and iris 130 and flows to the drainage system located in the angle of the anterior chamber. The angle of the anterior chamber, which extends circumferentially around the eye, contains structures that allow the aqueous humor to drain. The first structure, and the one most commonly implicated in glaucoma, is the trabecular meshwork 150. The trabecular meshwork 150 extends circumferentially around the anterior chamber in the angle. The trabecular meshwork 150 seems to act as a filter, limiting the outflow of aqueous humor and providing a back pressure producing the IOP. Schlemm's canal 160 is located beyond the trabecular meshwork 150. Schlemm's canal 160 has collector channels that allow aqueous humor to flow out of the anterior chamber. The two arrows in the anterior chamber of Figure 1 show the flow of aqueous humor from the ciliary bodies 140, over the lens 110, over the iris 130, through the trabecular meshwork 150, and into Schlemm's canal 160 and its collector channels.

In glaucoma patients, IOP can vary widely during a 24 hour period. Generally, IOP is highest in the early morning hours before medication is administered upon waking. Higher pressures damage the optic nerve and can lead to blindness. Accordingly, it would be desirable to measure IOP over time in order to assess the efficacy of various treatments. The present invention provides an IOP measuring device.

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SUMMARY OF THE INVENTION

In one embodiment consistent with the principles of the present invention, the present invention is an implantable intraocular pressure sensor system that has a sealed geometric shape with an internal pressure at a first value. The sealed geometric shape has a first light permitting surface and a second flexible surface. A pair of photocells is located in the sealed geometric shape. A light shield is coupled

to the second flexible surface. When the second flexible surface is deflected, a light measurement by the pair of photocells indicates an intraocular pressure condition.

5 In another embodiment consistent with the principles of the present invention, the present invention is an implantable intraocular pressure sensor system that has a sealed geometric shape with an internal pressure at a first value. The sealed geometric shape has a first light permitting surface and a second flexible surface. A pair of photocells is located in the sealed geometric shape. A light shield is coupled to the second flexible surface. When the second flexible surface is deflected, a light measurement by the pair of photocells indicates an intraocular pressure condition.

10 The system also has a processor coupled to a power source and memory. The processor is configured to read the measured resistance and write values corresponding to intraocular pressure to the memory.

15 It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are intended to provide further explanation of the invention as claimed. The following description, as well as the practice of the invention, set forth and suggest additional advantages and purposes of the invention.

20

BRIEF DESCRIPTION OF THE DRAWINGS

25 The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate several embodiments of the invention and together with the description, serve to explain the principles of the invention.

Figure 1 is a diagram of the front portion of an eye.

30 Figure 2 is a block diagram of an IOP measuring system according to the principles of the present invention.

Figure 3 is a perspective view of an IOP sensor according to the principles of the present invention.

35 Figure 4 is a perspective view of an IOP sensor according to the principles of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Reference is now made in detail to the exemplary embodiments of the invention, examples of which are illustrated in the accompanying drawings.

5 Wherever possible, the same reference numbers are used throughout the drawings to refer to the same or like parts.

Figure 2 is a block diagram of an IOP measuring system 200 according to the principles of the present invention. In Figure 2, the IOP measuring system includes

10 power source 205, IOP sensor 210, processor 215, memory 220, data transmission module 225, and optional speaker 230.

Power source 205 is typically a rechargeable battery, such as a lithium ion or lithium polymer battery, although other types of batteries may be employed. In

15 addition, any other type of power cell is appropriate for power source 205. Power source 205 provides power to the system 200, and more particularly to processor 215. Power source can be recharged via an RFID link or other type of magnetic coupling.

Processor 215 is typically an integrated circuit with power, input, and output

20 pins capable of performing logic functions. In various embodiments, processor 215 is a targeted device controller. In such a case, processor 215 performs specific control functions targeted to a specific device or component, such as a data transmission module 225, speaker 230, power source 205, or memory 220. In other embodiments, processor 215 is a microprocessor. In such a case, processor 215 is programmable so

25 that it can function to control more than one component of the device. In other cases, processor 215 is not a programmable microprocessor, but instead is a special purpose controller configured to control different components that perform different functions.

Memory 220 is typically a semiconductor memory such as NAND flash

30 memory. As the size of semiconductor memory is very small, and the memory needs of the system 200 are small, memory 220 occupies a very small footprint of system 200. Memory 220 interfaces with processor 215. As such, processor 215 can write to and read from memory 220. For example, processor 215 can be configured to read data from the IOP sensor 210 and write that data to memory 220. In this manner, a

35 series of IOP readings can be stored in memory 220. Processor 215 is also capable of performing other basic memory functions, such as erasing or overwriting memory 220, detecting when memory 220 is full, and other common functions associated with managing semiconductor memory.

5 Data transmission module 225 may employ any of a number of different types of data transmission. For example, data transmission module 225 may be active device such as a radio. Data transmission module 225 may also be a passive device
10 such as the antenna on an RFID tag. In this case, an RFID tag includes memory 220 and data transmission module 225 in the form of an antenna. An RFID reader can then be placed near the system 200 to write data to or read data from memory 220. Since the amount of data typically stored in memory 220 is likely to be small (consisting of IOP readings over a period of time), the speed with which data is transferred is not crucial. Other types of data that can be stored in memory 220 and transmitted by data transmission module 225 include, but are not limited to, power source data (e.g. low battery, battery defect), speaker data (warning tones, voices), IOP sensor data (IOP readings, problem conditions), and the like.

15 Optional speaker 230 provides a warning tone or voice to the patient when a dangerous condition exists. For example, if IOP is at a level that is likely to lead to damage or presents a risk to the patient, speaker 230 may sound a warning tone to alert the patient to seek medical attention or to administer eye drops. Processor 215 reads IOP measurements from IOP sensor 210. If processor 215 reads one or a series
20 of IOP measurements that are above a threshold, then processor 215 can operate speaker 230 to sound a warning. The threshold can be set and stored in memory 220. In this manner, an IOP threshold can be set by a doctor, and when exceeded, a warning can be sounded.

25 Alternatively, data transmission module may be activated to communicate an elevated IOP condition to a secondary device such as a PDA, cell phone, computer, wrist watch, custom device exclusively for this purpose, remote accessible data storage site (e.g. an internet server, email server, text message server), or other electronic device. In one embodiment, a personal electronic device uploads the data
30 to the remote accessible data storage site (e.g. an internet server, email server, text message server). Information may be uploaded to a remote accessible data storage site so that it can be viewed in real time, for example, by medical personnel. In this case, the secondary device may contain the speaker 230. For example, in a hospital setting, after a patient has undergone glaucoma surgery and had system 200 implanted, a secondary device may be located next to the patient's hospital bed. Since IOP fluctuations are common after glaucoma surgery (both on the high side and
35 on the low side which is also a dangerous condition), processor 215 can read IOP measurements made by an implanted IOP sensor 210. If processor 215 reads an

unsafe IOP condition, data transmission module 225 can alert the patient and medical staff via speaker 230 or by transmitting the unsafe readings to a secondary device.

Such a system is also suitable for use outside a hospital setting. For example, 5 if an unsafe IOP condition exists, processor 215 can operate speaker 230 to sound an audible warning. The patient is then alerted and can seek medical attention. The warning can be turned off by a medical professional in a number of ways. For example, when data transmission module 225 is an RFID tag, an RFID link can be established between an external device and system 200. This external device can 10 communicate with system 200 to turn off the speaker 230. Alternatively, an optical signal may be read by system 200. In this case, data transmission module 225 has an optical receptor that can receive a series of light pulses that represent a command – such as a command to turn off speaker 230.

15 System 200 is preferably in a small, implantable, integrated package. As such, all of the components of system 200 can be built on a substrate, such as a semiconductor wafer, by any of a number of different processes.

Figure 3 is a perspective view of an IOP sensor according to the principles of 20 the present invention. In Figure 3, IOP sensor 210 is a sealed cube with two photocells 325 & 330, a top surface 310, a side 315, a light shield 320 and an optional light source 305. Top surface 310 of IOP sensor allows light to enter the cube (e.g., it is transparent or translucent – a light permitting surface). Photocells 325 and 330 detect the amount of light entering the cube. Light shield 320 at least partially blocks 25 the light detected by photocell 330. Light shield 320 is fixed to side 315. Side 315 is flexible. Therefore, as side 315 moves in response to a pressure change, the amount of light blocked by light shield 320 changes and the amount of light detected by photocell 330 also changes. Side 315 may be thinner than the other sides, top 310, and bottom of the cube so that side 315 is more flexible. The top 310, bottom and 30 other sides (other than side 315) may be rigid or flexible. An optional light source 305, as described below, is provided. Alternatively, IOP sensor may use ambient light entering the eye. While described as a cube, IOP sensor 210 may be other geometric shapes that allow for deflection of side 315 and movement of attached shield 320.

35

The pressure inside the cube of IOP sensor 210 is determined during the manufacturing process and can be about 0 psig. The cube of IOP sensor 210 can be filled with any of a number of a variety of different gases, such as nitrogen, argon,

sulfur hexafluoride, or the like. When the internal pressure is 0 psig., side 315 will tend to deflect inward because the pressure inside the eye is higher than 0 psig. (as shown in Figure 4).

5 The configuration of photocells 325 & 330 shown in Figure 3 allows for a comparison between the light detected by photocell 325 and photocell 330 to be made. Since photocell 325 is not shielded by light shield 320, photocell 325 detects the “full amount” of light entering through top surface 310. Since photocell 330 is shielded by light shield 320, photocell 330 detects less than the “full amount” of light
10 entering through top surface 310. A comparison between the amount of light measured by photocells 325 and 330, therefore, can be used to determine the amount of deflection experienced by side 315. The higher the external pressure, the greater the deflection of side 315, and the less measured by photocell 330. Accordingly, the amount of light measured by photocell 330 indicates the amount of external pressure
15 (IOP). This use of two photocell (325 & 330) allows for the IOP sensor 210 to work under different light conditions (since ambient light conditions change).

20 For IOP measurements, calibrating the IOP sensor 210 is generally not critical. Since a change in the amount of light detected by photocell 330 can be correlated with a magnitude of IOP, a change in IOP can be easily detected. Generally, a series of light measurements taken over time corresponds to the relative magnitude of IOP over time. More precise calibration of IOP can be done in a doctor’s office, for example, by measuring IOP in a traditional manner and correlating that measurement with a quantity of light measured by photocell 325 and 330.

25 Optional light source 305 is typically an LED. Light source 305 may be mounted to or integrated with top surface 310 of IOP sensor 210. Alternatively, IOP sensor 210 may rely on ambient light (and light source 305 is absent). In another embodiment, a light source exterior to the eye can be used. For example, a light source may be attached to a hand held pressure reader and/or charger device that interfaces with IOP sensor 210. In this manner, an external light source (which can be calibrated) can be used to facilitate a pressure reading.

30 IOP sensor 210 can be manufactured via any of a number of different methods. For example, in a MEMS-based method, IOP sensor 210 is built in layers. In this manner, layers of a biocompatible material are deposited to build IOP sensor 210. Other vapor deposition methods, such as those used in the semiconductor industry, may also be employed.

Figure 4 is a perspective view of an IOP sensor according to the principles of the present invention. In Figure 4, side 315 of IOP sensor 210 is deflected inward. Accordingly, light shield 320 is also deflected inward to partially obscure light reaching photocell 330. In this manner, the internal pressure is less than the external pressure. The pressure difference determines how far light shield 320 moves and how much light photocell 330 detects. In other words, the distance that light shield 320 travels is dependent on the difference between the internal and external pressures. The distance that light shield 320 travels also determines the amount of light that is detected by photocell 330. Accordingly, the amount of light detected by photocell 330 (as compared to the amount of light detected by photocell 325) indicates the difference between the internal and external pressures. Such a light reading can be used to determine the change in IOP.

In another embodiment of the present invention, an array of IOP sensors 210 (shown in Figs. 3 & 4) can be used together. In this configuration, more than one IOP sensor 210 is attached to a substrate and then implanted in the eye. Using more than one IOP sensor 210 allows for redundancy and more accurate measurement of IOP. As the number of IOP sensors 210 in array increases, the statistical variance of the resulting IOP measurement decreases (and thus accuracy increases). In another embodiment, multiple photodetector pairs can be used with a single light source to achieve redundancy.

From the above, it may be appreciated that the present invention provides a system measuring IOP. The present invention provides an IOP sensor and associated peripherals. The present invention is illustrated herein by example, and various modifications may be made by a person of ordinary skill in the art.

Other embodiments of the invention will be apparent to those skilled in the art from consideration of the specification and practice of the invention disclosed herein. It is intended that the specification and examples be considered as exemplary only, with a true scope and spirit of the invention being indicated by the following claims.

What is claimed is:

1. An implantable intraocular pressure sensor system comprising:
 - 5 a sealed geometric shape with an internal pressure at a first value, the sealed geometric shape having a first light permitting surface and a second flexible surface;
 - a pair of photocells located in the sealed geometric shape; and
 - a light shield coupled to the second flexible surface;
 - wherein when the second flexible surface is deflected, a light measurement by the pair of photocells indicates an intraocular pressure condition.
- 10 2. The pressure sensor system of claim 1 further comprising:
 - 15 a light source located such that light hits the first, light permitting surface.
3. The pressure sensor system of claim 1 further comprising:
 - 15 a processor;
 - a power source coupled to the processor; and
 - a memory coupled to the processor;
 - wherein the processor is configured to read the measured resistance.
- 20 4. The pressure sensor system of claim 3 wherein the processor writes values corresponding to an intraocular pressure condition to the memory.
5. The pressure sensor system of claim 3 further comprising:
 - 25 a data transmission module coupled to the processor.
6. The pressure sensor system of claim 5 wherein the data transmission module further comprises a radio.
- 30 7. The pressure sensor system of claim 5 wherein the data transmission module further comprises an RFID tag.
8. The pressure sensor system of claim 7 wherein data is transferred from the memory over an RFID link.
- 35 9. The pressure sensor system of claim 5 wherein the data transmission module transfers data from the memory to an external device.

10. The pressure sensor system of claim 3 further comprising:
a speaker coupled to the processor; wherein the speaker sounds a warning
when intraocular pressure is outside a safe range.
- 5 11. The pressure sensor system of claim 1 wherein the sealed geometric shape is
generally cubic.

12. An implantable intraocular pressure sensor system comprising:
an IOP sensor comprising:
a sealed geometric shape with an internal pressure at a first value, the
sealed geometric shape having a first light permitting surface and a second
5 flexible surface;
a pair of photocells located in the sealed geometric shape; and
a light shield coupled to the second flexible surface;
wherein when the second flexible surface is deflected, a light
measurement by the pair of photocells indicates an intraocular pressure
10 condition;
a processor;
a power source coupled to the processor; and
a memory coupled to the processor;
wherein the processor is configured to read the measured resistance and write
15 values corresponding to intraocular pressure to the memory.

13. The pressure sensor system of claim 12 further comprising:
a data transmission module coupled to the processor.

20 14. The pressure sensor system of claim 13 wherein the data transmission module
further comprises a radio.

15. The pressure sensor system of claim 13 wherein the data transmission module
further comprises an RFID tag.

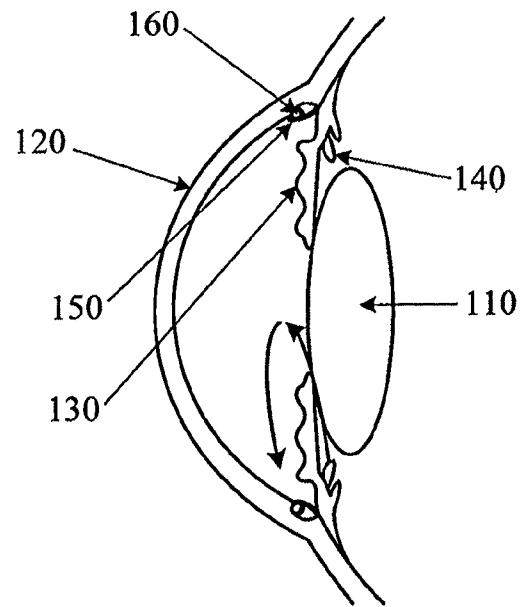
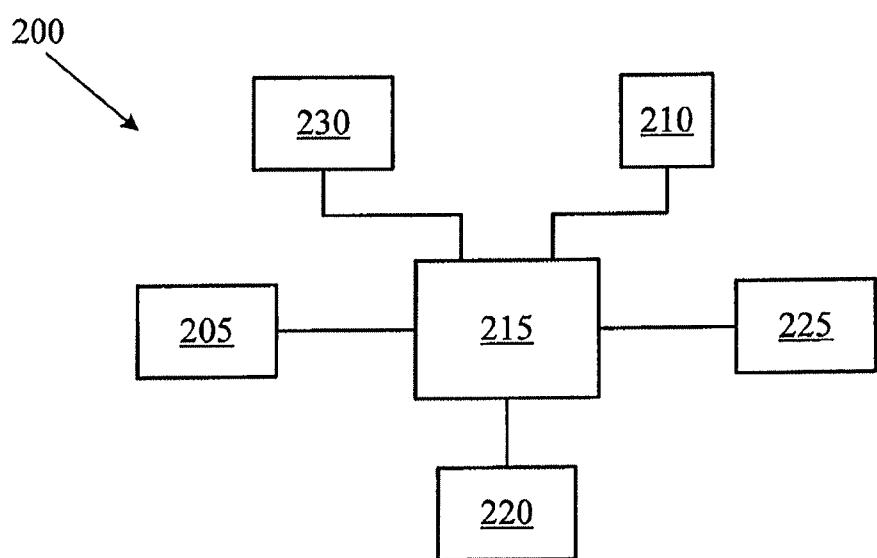
25 16. The pressure sensor system of claim 15 wherein data is transferred from the
memory over an RFID link.

17. The pressure sensor system of claim 13 wherein the data transmission module
30 transfers data from the memory to an external device.

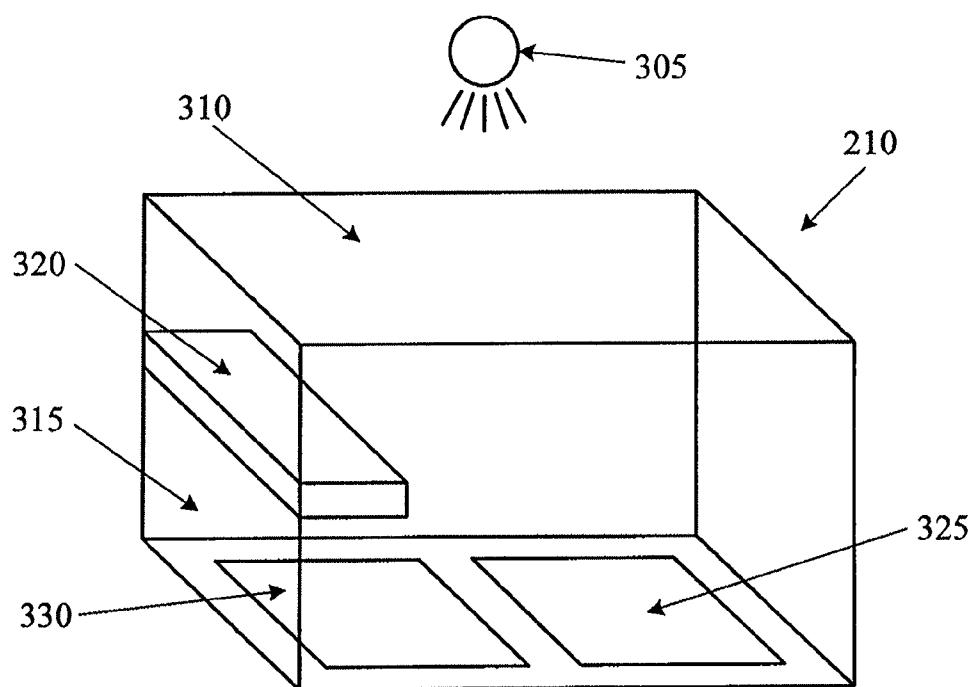
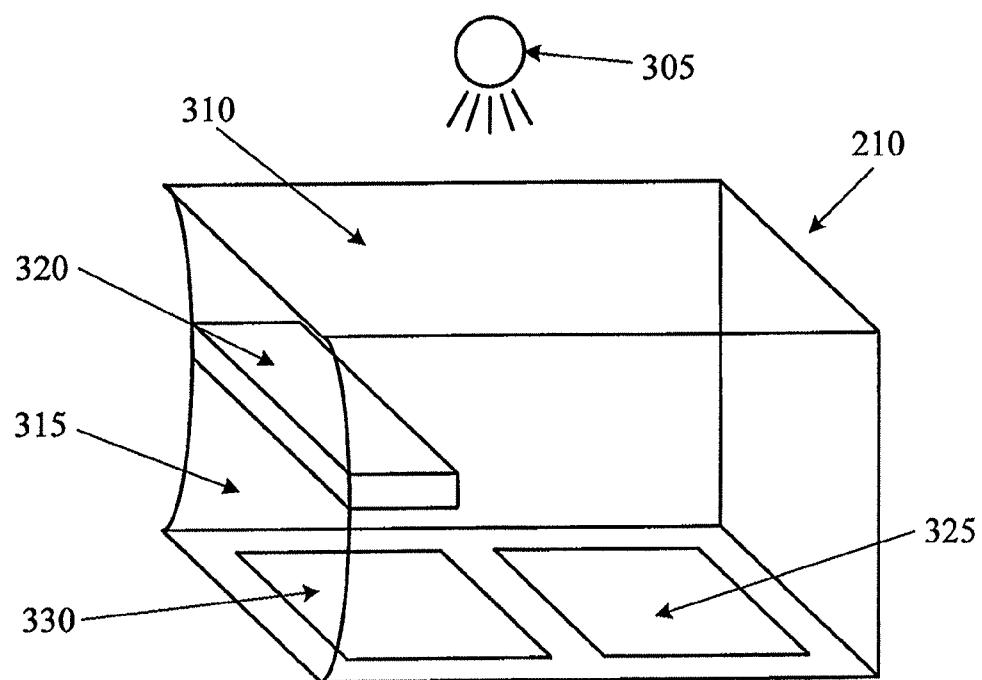
18. The pressure sensor system of claim 12 further comprising:
a speaker coupled to the processor;
wherein the speaker sounds a warning when intraocular pressure is outside a
35 safe range.

19. The pressure sensor system of claim 12 wherein the sealed geometric shape is
generally cubic.

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**Fig. 1****Fig. 2**

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**Fig. 3****Fig. 4**

INTERNATIONAL SEARCH REPORT

International application No

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A. CLASSIFICATION OF SUBJECT MATTER
 INV. A61B3/16 A61F2/14
 ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B A61F

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

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

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|---|-----------------------|
| X | US 2004/254438 A1 (CHUCK ROY S [US] ET AL) 16 December 2004 (2004-12-16) * abstract figures 1,2,3a,3b paragraphs [0021] - [0042] paragraphs [0015] - [0020] ----- | 1-19 |
| A | US 2004/116794 A1 (FINK WOLFGANG [US] ET AL FINK WOLFGANG [US] ET AL) 17 June 2004 (2004-06-17) * abstract figures 4,5a,6 paragraphs [0002], [0035] - [0048] ----- | 1-19 |

Further documents are listed in the continuation of Box C.

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INTERNATIONAL SEARCH REPORT**Information on patent family members**

International application No

PCT/US2010/033333

| Patent document cited in search report | | Publication date | | Patent family member(s) | | Publication date |
|--|----|------------------|----------|-----------------------------|--|--------------------------|
| US 2004254438 | A1 | 16-12-2004 | EP WO | 1589866 A2 2004062480 A2 | | 02-11-2005 29-07-2004 |
| US 2004116794 | A1 | 17-06-2004 | US | 2007112263 A1 | | 17-05-2007 |