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(71) Applicant: **HADASIT MEDICAL RESEARCH SERVICES AND DEVELOPMENT LTD.** [IL/IL]; Jerusalem BioPark, Hadassah Ein Kerem Medical Center, P.O.B. 12000, 9112001 Jerusalem (IL).

(72) Inventors: **NGUEDIA VOFO, Brice**; c/o Hadasit Medical Research Services and Development Ltd. Jerusalem BioPark, Hadassah Ein Kerem Medical Center, P.O.B. 12000, 9112001 Jerusalem (IL). **BADUM, Lukas**; Ludwigstr. 35, 91301 Forchheim (DE).

(74) Agent: **BEIDER, Joel**; c/o Jerusalem Business Center, Hillel 24 - 5th Floor, 9458124 Jerusalem (IL).

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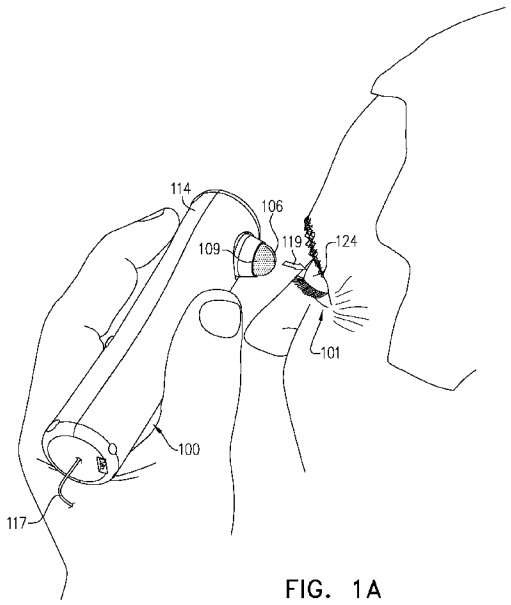

FIG. 1A

(57) **Abstract:** An apparatus (100) for measuring an intraocular pressure of an eye (101) includes a deformation capsule (106) containing a fluid (109) and configured to deform as the deformation capsule is pressed against an eyelid (124) of the eye while the eye is closed, thereby causing a change in a pressure of the fluid. The apparatus further includes at least one pressure sensor (110) configured to connect to the deformation capsule and to output a pressure-sensor signal indicative of the change in the pressure of the fluid, and a force sensor (102) configured to connect to the deformation capsule and to output a force-sensor signal indicative of a force with which the deformation capsule is pressed against the eyelid. The intraocular pressure is derivable from the change in the pressure of the fluid and the force. Other embodiments are also described.

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HANDHELD APPARATUS FOR MEASURING INTRAOCULAR PRESSURE

CROSS-REFERENCE TO RELATED APPLICATIONS

The present application claims priority from US Provisional Application 63/472,358, entitled "Hand-held intraocular pressure measurement device," filed June 12, 2023, whose disclosure is incorporated herein by reference.

FIELD OF EMBODIMENTS OF THE INVENTION

The present disclosure is related generally to the field of ophthalmology, and specifically to the measurement of intraocular pressure.

BACKGROUND

Glaucoma is an eye condition in which the optic nerve, which carries visual information from the eye to the brain, is progressively damaged. According to the World Health Organization, glaucoma is the leading cause of irreversible blindness and the second-leading cause of blindness worldwide, affecting approximately 80 million people. It is more common in older adults, but it can affect people of any age. In the United States, it is estimated that more than 3 million people have glaucoma, and that number is expected to increase as the population ages. However, with early detection and treatment, the progression of glaucoma can often be slowed or stopped, and vision loss can be prevented. Regular eye exams can help to detect glaucoma early, so that treatment can be started before significant vision loss occurs.

Risk factors for glaucoma include age, family history, high intraocular pressure, diabetes, and a history of eye injuries. Glaucoma treatment is typically aimed at reducing intraocular pressure, e.g., using medication or surgery (e.g., laser surgery).

Intraocular pressure can be measured using a device called a tonometer. Some tonometers measure deformation of the cornea when pressure is applied thereto. The most common corneal technique, which is also the gold standard for intraocular-pressure measurement, is the Goldmann applanation technique, which uses a small, weighted probe to flatten a small area of the cornea. The amount of force required to flatten the area of the cornea is used to calculate intraocular pressure, based on the Imbert-Fick principle. Other corneal techniques include non-contact tonometry (air-puff tonometry) and rebound tonometry. Some of these techniques are applied transpalpebrally, i.e., over the eyelid, thereby obviating the

need for topical anesthesia to numb the eye.

SUMMARY

There are several problems with conventional tonometry techniques. For example, some techniques, such as the Goldmann applanation technique, require the eye to be open and focused on a target. As a result, some subjects, such as older adults, may have difficulty with traditional tonometry tests. Furthermore, even with conventional transpalpebral tonometry, the test needs to be administered by a healthcare professional, and it is sometimes difficult for the subject to cooperate. In general, there is a need for an easy-to-use, non-invasive, affordable tonometer that can be used by a subject, such as a glaucoma patient, to monitor her intraocular pressure in the comfort of her home.

To address this need, embodiments of the present invention provide an affordable handheld transpalpebral tonometer that can be used, safely and comfortably, even by an individual who is not a healthcare professional, such as the subject herself, at home. The tonometer is configured to measure the intraocular pressure of an eye of the subject, e.g., to facilitate the detection (e.g., early detection) of glaucoma. Typically, the tonometer is further configured to display the intraocular pressure, record the intraocular pressure, and/or communicate the intraocular pressure to an external device, such as a device belonging to the subject's ophthalmologist.

In some embodiments, the tonometer comprises a deformation capsule, which is typically made of a flexible material such as an elastomer, and which contains a fluid such as gel, water, and/or air. The tonometer further comprises a pressure sensor and a force sensor, each of which is connected to the deformation capsule. To use the tonometer, the subject presses the deformation capsule against the eyelid of the subject's eye while the eye is closed, thereby causing the deformation capsule to deform and, hence, a change in the pressure of the fluid. The pressure sensor outputs a pressure-sensor signal indicative of the change in the pressure of the fluid, and the force sensor outputs a force-sensor signal indicative of the force with which the deformation capsule is pressed against the eyelid. An internal or external computation unit receives the two signals, derives the pressure change and the force from the signals, and then derives the intraocular pressure from the change in the pressure of the fluid and the force.

For example, in some embodiments, the two signals are sampled frequently so as to derive a curve representing the relationship between the pressure change and the force.

Typically, this relationship is approximately linear, i.e., the magnitude of the pressure change increases, approximately linearly, with increasing force. Furthermore, the slope of this linear relationship, which represents the sensitivity of the pressure change to the applied force, is a function (e.g., a linear function) of the intraocular pressure of the eye. Hence, in some embodiments, the computation unit linearly regresses the pressure change on the force (or linearly regresses the force on the pressure change), and then computes the intraocular pressure from the slope.

It is noted that, in view of the functionality of the computation unit described briefly above and further described below, the present application, in addition to the verb "measure," uses other verbs, such as "derive," "estimate," "calculate," and "compute," to describe the measurement of the intraocular pressure.

There is therefore provided, in accordance with some embodiments of the present invention, an apparatus for measuring an intraocular pressure of an eye. The apparatus includes a deformation capsule containing a fluid and configured to deform as the deformation capsule is pressed against an eyelid of the eye while the eye is closed, thereby causing a change in a pressure of the fluid. The apparatus further includes at least one pressure sensor configured to connect to the deformation capsule and to output a pressure-sensor signal indicative of the change in the pressure of the fluid, and a force sensor configured to connect to the deformation capsule and to output a force-sensor signal indicative of a force with which the deformation capsule is pressed against the eyelid. The intraocular pressure is derivable from the change in the pressure of the fluid and the force.

In some embodiments, the fluid includes a gel.

In some embodiments, the fluid includes water.

In some embodiments, the fluid includes air.

In some embodiments, the deformation capsule includes a wall configured to contact the eyelid as the deformation capsule is pressed against the eyelid, and the wall has a non-uniform thickness.

In some embodiments, the deformation capsule is shaped to define multiple cavities, each of which cavities contains some of the fluid, and the apparatus includes multiple pressure sensors configured to connect to the cavities, respectively, and to output multiple pressure-sensor signals.

In some embodiments, the multiple cavities include a central cavity and a peripheral cavity, which surrounds the central cavity.

In some embodiments, the deformation capsule is disposable.

In some embodiments, the apparatus further includes a casing that contains the pressure sensor and the force sensor, and the deformation capsule is insertable into and removable from the casing.

In some embodiments, the apparatus further includes a computation unit configured to:

receive the pressure-sensor signal and the force-sensor signal,

derive the change in the pressure of the fluid from the pressure-sensor signal and the force from the force-sensor signal, and

derive the intraocular pressure from the change in the pressure of the fluid and the force.

In some embodiments,

the change in the pressure of the fluid and the force vary as the deformation capsule is pressed against the eyelid,

the computation unit is configured to derive multiple pressure-change values of the change in the pressure of the fluid and corresponding force values of the force, and

the computation unit is configured to derive the intraocular pressure from the pressure-change values and force values.

In some embodiments, the computation unit is configured to derive the intraocular pressure by:

calculating a slope of a regression line that results from a linear regression of the pressure-change values and force values on one another, and

computing the intraocular pressure based on the slope.

In some embodiments, the computation unit is configured to derive the intraocular pressure by applying a machine-learned model to the pressure-change values and force values.

In some embodiments, the apparatus further includes a casing that contains the pressure sensor, the force sensor, and the computation unit.

In some embodiments, the apparatus further includes a feedback device configured to produce an output indicating that the deformation capsule should be removed from the eyelid.

In some embodiments, the feedback device includes a vibration motor configured to produce the output by vibrating.

In some embodiments, the feedback device includes a speaker configured to produce the output by outputting a sound.

There is further provided, in accordance with some embodiments of the present invention, a method for measuring an intraocular pressure of an eye. The method includes, while a deformation capsule, which contains a fluid, is pressed against an eyelid of the eye while the eye is closed, receiving, from at least one pressure sensor connected to the deformation capsule, a pressure-sensor signal indicative of a change in a pressure of the fluid, which results from a deformation of the deformation capsule, and receiving, from a force sensor connected to the deformation capsule, a force-sensor signal indicative of a force with which the deformation capsule is pressed against the eyelid. The method further includes deriving the intraocular pressure from the change in the pressure of the fluid and the force.

There is further provided, in accordance with some embodiments of the present invention, a method for measuring an intraocular pressure of an eye. The method includes holding a handheld apparatus, which includes a deformation capsule containing a fluid, at least one pressure sensor connected to the deformation capsule, and a force sensor connected to the deformation capsule. The method further includes, while holding the handheld apparatus, pressing the deformation capsule against an eyelid of the eye while the eye is closed, such that the deformation capsule deforms, thereby causing a change in a pressure of the fluid, the pressure sensor outputs a pressure-sensor signal indicative of the change in the pressure of the fluid, the force sensor outputs a force-sensor signal indicative of a force with which the deformation capsule is pressed against the eyelid, and a computation unit derives the intraocular pressure from the change in the pressure of the fluid and the force.

There is further provided, in accordance with some embodiments of the present invention, an apparatus including a deformation capsule containing a fluid and configured to deform as the deformation capsule is pressed, at least one pressure sensor configured to connect to the deformation capsule, and a force sensor configured to connect to the deformation capsule.

The present invention will be more fully understood from the following detailed description of embodiments thereof, taken together with the drawings, in which:

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1A is a schematic illustration of a method for measuring the intraocular pressure of an eye of a subject, in accordance with some embodiments of the present invention;

Figs. 1B and 1C are schematic illustrations, from two different perspectives, of an apparatus for measuring the intraocular pressure of an eye of a subject, in accordance with some embodiments of the present invention;

Fig. 2 schematically illustrates a cross-section through an apparatus for measuring an intraocular pressure of an eye of a subject, in accordance with some embodiments of the present invention;

Figs. 3A, 3B, 3C, and 3D are schematic illustrations of deformation capsule, in accordance with various embodiments of the present invention; and

Figs. 4A and 4B show experimental results obtained by using the apparatus described herein, in accordance with some embodiments of the present invention.

DETAILED DESCRIPTION

Reference is initially made to Figs. 1A, which is a schematic illustration of a method for measuring the intraocular pressure of an eye 101 of a subject, and to Figs. 1B-1C, which are schematic illustrations, from two different perspectives, of an apparatus 100 for measuring the intraocular pressure, in accordance with some embodiments of the present invention.

Apparatus 100 comprises a deformation capsule 106 containing a fluid 109 comprising, for example, air, water, and/or gel. To use apparatus 100, deformation capsule 106 is pressed, by the subject or by another person, against the eyelid 124 of eye 101 while the eye is closed, as indicated in Fig. 1A by a pressing indicator 119. Deformation capsule 106, which is typically made of a flexible material such as an elastomer, is configured to deform as the deformation capsule is pressed against eyelid 124, thereby causing a change in the pressure of fluid 109. As further described below with reference to the subsequent figures, the intraocular pressure of eye 101 is estimated based on the magnitude of this pressure change and on the magnitude of the force with which the deformation capsule is pressed against eyelid 124.Typically, apparatus 100 further comprises a casing 114, which contains the various components of the apparatus described below with reference to the subsequent figures. Typically, to facilitate holding and using the apparatus, casing 114 is shaped ergonomically. For example, in some embodiments, casing 114 is shaped to facilitate placing the index finger

directly behind the deformation capsule, as shown in Fig. 1A. Alternatively or additionally, the casing is angled obliquely, relative to the deformation capsule, such that the casing is held at an incline as the apparatus is used.

In some embodiments, apparatus 100 further comprises a display 103 configured to display the pressure change, the force, the estimated intraocular pressure, any other relevant parameters, and/or any instructions related to use of the apparatus. Typically, display 103 is integrated with casing 114. In some embodiments, display 103 is positioned directly behind the deformation capsule, as shown in Figs. 1B-1C. In other embodiments, display 103 is offset from this position, e.g., so as not to interfere with the index finger of the subject as the index finger presses the deformation capsule against the eyelid.

In some embodiments, apparatus 100 further comprises one or more knobs 105 configured for user interaction, e.g., to accept input from the subject as the subject uses the apparatus to measure the intraocular pressure of eye 101. Alternatively or additionally, display 103 comprises a touch screen for such interaction.

In some embodiments, apparatus 100 further comprises at least one cable 117, such as a universal serial bus cable or a power cord, configured to connect the apparatus to an external device and/or to an external power supply.

Reference is now made to Fig. 2, which schematically illustrates a cross-section through apparatus 100, in accordance with some embodiments of the present invention.

Apparatus 100 comprises at least one pressure sensor 110 configured to connect to deformation capsule 106 and to output a pressure-sensor signal indicative of the change in the pressure of fluid 109. In some embodiments, pressure sensor 110 connects directly to the deformation capsule, i.e., the pressure sensor contacts the capsule. In other embodiments, the pressure sensor connects to the deformation capsule one or more other components. For example, in some embodiments, apparatus 100 comprises a pressure-sensor adapter 140 shaped to define a lumen 141 configured for fluid communication with the fluid-filled cavity of deformation capsule 106, e.g., such that fluid 109 fills lumen 141 even before the deformation capsule is deformed. Pressure sensor 110 is coupled, e.g., glued, to adapter 140 such that the pressure sensor occludes the end of lumen 141. As the deformation capsule is deformed, the fluid exerts increased pressure on pressure sensor 110, and the signal output by the pressure sensor indicates this increase.

Typically, apparatus 100 further comprises a deformation-capsule casing 111

configured to hold (and stabilize) the deformation capsule. In some embodiments, deformation-capsule casing 111 is attached (e.g., bonded) to the deformation capsule. In other embodiments, deformation-capsule casing 111 is not attached to the deformation capsule. For embodiments in which apparatus 100 comprises adapter 140, deformation-capsule casing 111 is typically configured to couple to adapter 140 (e.g., by snapping into the adapter) such that the fluid-filled cavity of deformation capsule 106 is in fluid communication with lumen 141.

Typically, deformation capsule 106, e.g., together with deformation-capsule casing 111, is a separable component of apparatus 100. For example, in some embodiments, deformation capsule 106, e.g., together with deformation-capsule casing 111, is insertable into and removable from casing 114. In some such embodiments, deformation capsule 106, e.g., together with deformation-capsule casing 111, is disposable, such that the deformation capsule can be replaced between subjects and/or between successive uses by a single subject.

Alternatively, the deformation capsule is not disposable and, in some embodiments, is not a separable component. Nonetheless, optionally, the materials from which the deformation capsule is made, and the geometry of the deformation capsule, are such that the deformation capsule can be disinfected between subjects and/or between successive uses by a single subject.

In some embodiments, in the absence of any force applied to deformation capsule 106, fluid 109 is at the ambient pressure. In other embodiments, the fluid is at an elevated pressure, which can be provided during the manufacturing process, for example, by pumping the fluid into the deformation capsule, by moving an object into the sealed cavity of the deformation capsule after the deformation capsule has been filled with the fluid, or by deforming the deformation capsule after it has been sealed.

In some embodiments, deformation capsule 106 is configured for maximum sensitivity at typical intraocular pressures, such as pressures between 5 and 50 mmHg. This configuration can be achieved by tailoring the geometry of the deformation capsule, the properties (e.g., hardness) of the material from which the capsule is made, and/or the properties (e.g., compressibility) of the fluid.

Apparatus 100 further comprises a force sensor 102 configured to connect, directly or via one or more other components, to deformation capsule 106, and to output a force-sensor signal indicative of the force with which the deformation capsule is pressed against the eyelid. The intraocular pressure of the eye is then derivable from the change in the pressure of the

fluid and the force.

Typically, force sensor 102 is connected at one end to casing 114 and at the other end to deformation capsule 106, such that deformation capsule 106 is connected to casing 114 via force sensor 102. Thus, the pressing force applied to the deformation capsule is transferred to the force sensor. For example, in some embodiments, force sensor 102 is connected directly (e.g., glued) to pressure sensor 110, deformation capsule 106, deformation-capsule casing 111, or adapter 140. Alternatively, the force sensor is connected to the deformation capsule via a connecting part 112, which is connected directly (e.g., glued) to pressure sensor 110, deformation capsule 106, deformation-capsule casing 111, or adapter 140.

For example, in some embodiments, force sensor 102 comprises a load cell 113 that is connected to casing 114 and to connecting part 112 via connectors 116 or via glue. In some such embodiments, load cell 113 comprises a strain-gauge load cell. As the deformation capsule is pressed against the eyelid, the force applied to load cell 113 causes a change in the resistance of the load cell, and the signal from the force sensor indicates this difference. In other embodiments, load cell 113 comprises a hydraulic, pneumatic, capacitive, or piezoelectric load cell. Alternatively, force sensor 102 comprises a suspended mechanical element that is displaced or deformed as force is applied thereto, the signal from the force sensor indicating the magnitude of this displacement or deformation.

Typically, apparatus 100 further comprises a computation unit 104 configured to receive the pressure-sensor signal and the force-sensor signal, to derive the change in the pressure of fluid 109 from the pressure-sensor signal, and to derive the force from the force-sensor signal. The computation unit is further configured to derive the intraocular pressure of the eye from the change in the pressure of the fluid and the force. This derivation is possible by virtue of the dependency of the fluid pressure on the applied force and the intraocular pressure of the eye.

In some embodiments, computation unit 104 is contained within casing 114. For example, in some embodiments, casing 114 contains an electronics board 115 (e.g., a printed circuit board) connected, via electrical connectors 120 comprising wires or cables, to pressure sensor 110 and force sensor 102. Computation unit 104 is connected (directly, or via an electrical connector 120) to board 115 such that the computation unit receives the pressure-sensor signal and force-sensor signal via board 115.

In other embodiments, computation unit 104 is external to casing 114. For example, in

some embodiments, computation unit 104 comprises a processor of a smartphone, a laptop computer, a desktop computer, a cloud-based server, or any other external device. In some such embodiments, apparatus 100 comprises a wireless communication device, which is connected to board 115 for example, configured to communicate the pressure-sensor signal and force-sensor signal to the computation unit. Alternatively, cable 117 is configured to connect to the external device, and the signals are communicated via the cable.

Typically, the computation unit is configured to compute the pressure-change and force values relative to the pressure and force at the time of the initial contact of the deformation capsule with the eyelid, which the computation unit identifies based on the spike in the pressure and force that occurs at this time. The computation unit thus compensates for any deviations, between measurements, in the initial pressure and force, which can be due to factors such as the angle at which the apparatus is held and the altitude of the location of the subject, as well as manufacturing nonuniformities.

In some embodiments, apparatus 100 further comprises a feedback device 118 configured to produce an output indicating that the deformation capsule should be removed from the eyelid so as to end the intraocular-pressure measurement. In some embodiments, feedback device 118 comprises a vibration motor configured to produce the output by vibrating. Alternatively or additionally, feedback device 118 comprises a speaker configured to produce the output by outputting a sound. Alternatively or additionally, feedback device 118 comprises a visual indicator, such as a light emitting diode, configured to produce a visual output, such as light.

For example, in some embodiments, feedback device 118 is configured to produce the output in response to the pressure-sensor signal indicating that the change in the pressure of the fluid exceeds a predefined pressure-change threshold and/or in response to the force-sensor signal indicating that the force exceeds a predefined force threshold. Thus, advantageously, the feedback device helps prevent the subject from accidentally inflicting harm on the subject's eye. Alternatively or additionally, feedback device 118 is configured to produce the output in response to the deformation capsule having been pressed against the eyelid for a threshold amount of time sufficient for an intraocular-pressure measurement. In some embodiments, this threshold is between 0.2 and 2 seconds.

In some embodiments, alternatively or additionally to indicating that the intraocular-pressure measurement should be ended, feedback device 118 is configured to indicate that the intraocular-pressure measurement should start, and/or to provide any other useful feedback to

the subject.

In some embodiments, computation unit 104 drives feedback device 118 to provide feedback, e.g., in response to ascertaining that the pressure change exceeds the pressure-change threshold and/or that the force exceeds the force threshold, or in response to ascertaining that the threshold amount of time has been reached. In other embodiments, feedback device 118 is connected to separate circuitry, such as comparator circuitry, configured to receive the pressure-sensor signal and/or the force-sensor signal, and to trigger the feedback device in response to a property (e.g., the amplitude) of the signal(s) indicating that the measurement can be ended.

In some embodiments, apparatus 100 further comprises a power supply 126, such as a battery, configured to supply power (e.g., via board 115) to other components of apparatus 100 such as computation unit 104 and feedback device 118. In some embodiments, power supply 126 is rechargeable via cable 117 and/or wirelessly.

In some embodiments, the computation unit is configured to display (e.g., on display 103) at least one of the pressure change, the force, the estimated intraocular pressure, any other relevant parameters, and any instructions related to use of the apparatus. Alternatively or additionally, the computation unit is configured to save such data on the apparatus (e.g., on a memory card mounted onto board 115). Alternatively or additionally, the computation unit is configured to transfer the data, via cable 117 or a wireless communication device, to one or more external devices such as a smartphone or another device of the subject, a device of the subject's ophthalmologist, and/or a cloud-storage device.

In some embodiments, alternatively or additionally to the components described above, board 115 is connected to other components such as cable 117, display 103, and/or knobs 105.

In general, computation unit 104 may be embodied as a single processor, or as a cooperatively networked or clustered set of processors. The functionality of computation unit 104 may be implemented solely in hardware, e.g., using one or more fixed-function or general-purpose integrated circuits, Application-Specific Integrated Circuits (ASICs), and/or Field-Programmable Gate Arrays (FPGAs). Alternatively, this functionality may be implemented at least partly in software. For example, computation unit 104 may be embodied as a programmed processor comprising, for example, a central processing unit (CPU) and/or a Graphics Processing Unit (GPU). Program code, including software programs, and/or data may be

loaded for execution and processing by the CPU and/or GPU. The program code and/or data may be downloaded to the processor in electronic form, over a network, for example. Alternatively or additionally, the program code and/or data may be provided and/or stored on non-transitory tangible media, such as magnetic, optical, or electronic memory. Such program code and/or data, when provided to the processor, produce a machine or special-purpose computer, configured to perform the tasks described herein.

Reference is now made to Figs. 3A-3D, which are schematic illustrations of deformation capsule 106, in accordance with various embodiments of the present invention.

Deformation capsule 106 comprises a wall 121 configured to contact eyelid 124 (Fig. 1A) as the deformation capsule is pressed against the eyelid. In some embodiments, as shown in Fig. 3A, wall 121 has a uniform thickness. In other embodiments, as shown in Fig. 3B, wall 121 has a non-uniform thickness.

In some embodiments, as shown in Figs. 3A-3B, deformation capsule 106 is shaped to define a single cavity 108, which contains fluid 109 (Fig. 2). In other embodiments, deformation capsule 106 is shaped to define multiple cavities, each of which contains some of the fluid. In such embodiments, typically, the apparatus comprises multiple pressure sensors configured to connect to the cavities, respectively, and to output multiple pressure-sensor signals. For example, Fig. 3C shows an embodiment in which the deformation capsule is shaped to define a central cavity 108c and a peripheral cavity 108p, which surrounds central cavity 108c.

In some embodiments, as shown in Figs. 3A-3C, wall 121 is spherical. In other embodiments, wall 121 has another shape, such as an ellipsoidal or planar shape. In some embodiments, as shown in Fig. 3D, wall 121 is non-smooth, e.g., textured, spiked, or wavy. Wall 121 can be convex, as shown in Figs. 3A-3D, or concave.

Reference is now made to Figs. 4A-4B, which show experimental results obtained by using the apparatus described herein, in accordance with some embodiments of the present invention.

Typically, as the deformation capsule is pressed against the eyelid, the pressing force, and hence also the pressure of the fluid, vary. Computation unit 104 (Fig. 2) is configured to derive multiple pressure-change values from the pressure-sensor signal, along with corresponding force values from the force-sensor signal. Typically, the computation unit samples the signals (simultaneously) at a high frequency, e.g., 10-50 Hz, while the

deformation capsule is pressed against the eyelid, e.g., at least until a threshold force is reached, a threshold pressure change is reached, and/or a threshold amount of time has transpired. Subsequently to obtaining the pairs of corresponding force and pressure-change values, the computation unit derives the intraocular pressure from these values.

In some embodiments, the force and pressure sampling continues during the withdrawal of the apparatus from the eye. In some such embodiments, this additional sampling facilitates an assessment of corneal hysteresis.

Experimentally-obtained values for the force and pressure change are plotted in Fig. 4A for five eyes having intraocular pressures of 10.7 mmHg, 14 mmHg, 20 mmHg, 26 mmHg, and 35 mmHg, respectively, as measured using the Goldmann technique. As can be seen in Fig. 4A, the pressure change increases, with the applied pressing force, at a rate that is an increasing function of the intraocular pressure. Thus, these experimental data demonstrate that the relationship between the pressure change and the force is indicative of the intraocular pressure.

In some embodiments, the computation unit derives the intraocular pressure by applying a machine-learned model to the pressure-change values and force values.

In other embodiments, the computation unit performs the derivation based on the fact that, as shown in Fig. 4A, the relationship between the pressure change and the force is approximately linear. In particular, the computation unit calculates the slope of a regression line 123 that results from a linear regression of the pressure-change values and force values on one another. (In other words, the computation unit linearly regresses the pressure change on the force, or vice versa, to obtain the regression-line slope.) The computation unit then computes the intraocular pressure based on the slope. Thus, for example, assuming the pressure change is regressed on the force, a larger slope yields a larger intraocular-pressure estimate, while a smaller slope yields a smaller intraocular-pressure estimate.

In some embodiments, the computation unit looks up the intraocular pressure in a reference database (e.g., a lookup table), in which multiple regression slopes are stored with corresponding intraocular pressures. Such a database can be constructed from clinical tests performed on multiple subjects having a range of intraocular pressures. Given that the fluid pressure depends on properties of the deformation capsule, such as the type of material from which the capsule is made and the geometry of the capsule, all the clinical tests use the same type of deformation capsule. For each subject, the subject's intraocular pressure is measured

using a conventional technique, such as Goldmann tonometry. In addition, apparatus 100 is used to obtain a force-pressure curve, such as the curves shown in Fig. 4A, and the regression slope of the curve is recorded, in the database, in association with the intraocular pressure.

In other embodiments, the computation unit calculates the intraocular pressure analytically, by applying a predefined function to the slope. For example, Fig. 4B shows the slopes obtained by linearly regressing the curves shown in Fig. 4A, along with several other curves not shown in Fig. 4A. The slopes are plotted against the intraocular pressures measured using the Goldmann technique. As can be seen, the slope increases, in an approximately linear manner, with the intraocular pressure. Thus, Fig. 4B demonstrates that the computation unit can estimate the intraocular pressure by applying a linear function to the regression slope. The linear function is learned from clinical tests performed on multiple subjects having a range of intraocular pressures, as described in the paragraph above.

In some embodiments, for greater accuracy, several measurements are performed, and the reported intraocular pressure is a statistic, such as the average, of these measurements.

In some embodiments, prior to every measurement or at pre-defined intervals, the apparatus is tested on a calibration object, such as an elastomeric half-sphere, the hardness of which mimics the intraocular pressure of an eye. In particular, the apparatus is applied to the calibration object until a force-pressure curve is obtained. The computation unit then compares the force-pressure curve with a reference force-pressure curve that was previously obtained from the same calibration object. (This reference curve can be stored on the apparatus, e.g., on a memory card mounted onto board 115 (Fig. 2), or accessed via cable 117 (Fig. 2) or a wireless communication device.) If the curves differ from one another by more than a predefined tolerance, the computation unit corrects the force and/or pressure-change values of the subsequent in-situ measurements performed on the subject. Alternatively or additionally, the computation unit outputs an alert (e.g., on display 103 (Fig. 2)) indicating that the deformation capsule, the force sensor, and/or other components of the apparatus require replacement or repair.

It will be appreciated by persons skilled in the art that the present invention is not limited to what has been particularly shown and described hereinabove. Rather, the scope of the present invention includes both combinations and subcombinations of the various features described hereinabove, as well as variations and modifications thereof that are not in the prior art, which would occur to persons skilled in the art upon reading the foregoing description.

CLAIMS

1. An apparatus for measuring an intraocular pressure of an eye, the apparatus comprising:

a deformation capsule containing a fluid and configured to deform as the deformation capsule is pressed against an eyelid of the eye while the eye is closed, thereby causing a change in a pressure of the fluid;

at least one pressure sensor configured to connect to the deformation capsule and to output a pressure-sensor signal indicative of the change in the pressure of the fluid; and

a force sensor configured to connect to the deformation capsule and to output a force-sensor signal indicative of a force with which the deformation capsule is pressed against the eyelid,

the intraocular pressure being derivable from the change in the pressure of the fluid and the force.

2. The apparatus according to claim 1, wherein the fluid includes a gel.

3. The apparatus according to claim 1, wherein the fluid includes water.

4. The apparatus according to claim 1, wherein the fluid includes air.

5. The apparatus according to claim 1, wherein the deformation capsule comprises a wall configured to contact the eyelid as the deformation capsule is pressed against the eyelid, and wherein the wall has a non-uniform thickness.

6. The apparatus according to claim 1, wherein the deformation capsule is shaped to define multiple cavities, each of which cavities contains some of the fluid, and wherein the apparatus comprises multiple pressure sensors configured to connect to the cavities, respectively, and to output multiple pressure-sensor signals.

7. The apparatus according to claim 6, wherein the multiple cavities include a central cavity and a peripheral cavity, which surrounds the central cavity.

8. The apparatus according to claim 1, wherein the deformation capsule is disposable.

9. The apparatus according to any one of claims 1-8, further comprising a casing that contains the pressure sensor and the force sensor, wherein the deformation capsule is insertable into and removable from the casing.

10. The apparatus according to any one of claims 1-8, further comprising a computation unit configured to:

receive the pressure-sensor signal and the force-sensor signal,

derive the change in the pressure of the fluid from the pressure-sensor signal and the force from the force-sensor signal, and

derive the intraocular pressure from the change in the pressure of the fluid and the force.

11. The apparatus according to claim 10,

wherein the change in the pressure of the fluid and the force vary as the deformation capsule is pressed against the eyelid,

wherein the computation unit is configured to derive multiple pressure-change values of the change in the pressure of the fluid and corresponding force values of the force, and

wherein the computation unit is configured to derive the intraocular pressure from the pressure-change values and force values.

12. The apparatus according to claim 11, wherein the computation unit is configured to derive the intraocular pressure by:

calculating a slope of a regression line that results from a linear regression of the pressure-change values and force values on one another, and

computing the intraocular pressure based on the slope.

13. The apparatus according to claim 11, wherein the computation unit is configured to derive the intraocular pressure by applying a machine-learned model to the pressure-change values and force values.

14. The apparatus according to claim 10, further comprising a casing that contains the pressure sensor, the force sensor, and the computation unit.

15. The apparatus according to any one of claims 1-8, further comprising a feedback device configured to produce an output indicating that the deformation capsule should be removed from the eyelid.

16. The apparatus according to claim 15, wherein the feedback device comprises a vibration motor configured to produce the output by vibrating.

17. The apparatus according to claim 15, wherein the feedback device comprises a speaker configured to produce the output by outputting a sound.

18. A method for measuring an intraocular pressure of an eye, the method comprising:

while a deformation capsule, which contains a fluid, is pressed against an eyelid of the

eye while the eye is closed:

receiving, from at least one pressure sensor connected to the deformation capsule, a pressure-sensor signal indicative of a change in a pressure of the fluid, which results from a deformation of the deformation capsule, and

receiving, from a force sensor connected to the deformation capsule, a force-sensor signal indicative of a force with which the deformation capsule is pressed against the eyelid; and

deriving the intraocular pressure from the change in the pressure of the fluid and the force.

19. The method according to claim 18,

wherein the change in the pressure of the fluid and the force vary as the deformation capsule is pressed against the eyelid, and

wherein deriving the intraocular pressure comprises:

deriving multiple pressure-change values of the change in the pressure of the fluid and corresponding force values of the force, and

deriving the intraocular pressure from the pressure-change values and force values.

20. The method according to claim 19, wherein deriving the intraocular pressure from the pressure-change values and force values comprises:

calculating a slope of a regression line that results from a linear regression of the pressure-change values and force values on one another, and

computing the intraocular pressure based on the slope.

21. The method according to claim 19, wherein deriving the intraocular pressure comprises deriving the intraocular pressure by applying a machine-learned model to the pressure-change values and force values.

22. A method for measuring an intraocular pressure of an eye, the method comprising:

holding a handheld apparatus, which includes:

a deformation capsule containing a fluid,

at least one pressure sensor connected to the deformation capsule, and

a force sensor connected to the deformation capsule; and

while holding the handheld apparatus, pressing the deformation capsule against an eyelid of the eye while the eye is closed, such that:

the deformation capsule deforms, thereby causing a change in a pressure of the fluid,

the pressure sensor outputs a pressure-sensor signal indicative of the change in the pressure of the fluid,

the force sensor outputs a force-sensor signal indicative of a force with which the deformation capsule is pressed against the eyelid, and

a computation unit derives the intraocular pressure from the change in the pressure of the fluid and the force.

23. The method according to claim 22, wherein the fluid includes a gel.

24. The method according to claim 22, wherein the fluid includes water.

25. The method according to claim 22, wherein the fluid includes air.

26. The method according to claim 22, wherein a wall of the deformation capsule, which contacts the eyelid as the deformation capsule is pressed against the eyelid, has a non-uniform thickness.

27. The method according to claim 22, wherein the deformation capsule is shaped to define multiple cavities, each of which cavities contains some of the fluid, and wherein the apparatus includes multiple pressure sensors connected to the cavities, respectively.

28. The method according to claim 27, wherein the multiple cavities include a central cavity and a peripheral cavity, which surrounds the central cavity.

29. The method according to claim 22, wherein the deformation capsule is disposable.

30. The method according to claim 22, wherein the apparatus further includes a casing that contains the pressure sensor and the force sensor, wherein the deformation capsule is insertable into and removable from the casing.

31. The method according to any one of claims 22-30, wherein the apparatus further includes a feedback device configured to produce an output indicating that the deformation capsule should be removed from the eyelid.

32. The method according to claim 31, wherein the feedback device includes a vibration motor configured to produce the output by vibrating.

33. The method according to claim 31, wherein the feedback device includes a speaker configured to produce the output by outputting a sound.

34. An apparatus, comprising:

a deformation capsule containing a fluid and configured to deform as the deformation capsule is pressed;

at least one pressure sensor configured to connect to the deformation capsule; and

a force sensor configured to connect to the deformation capsule.

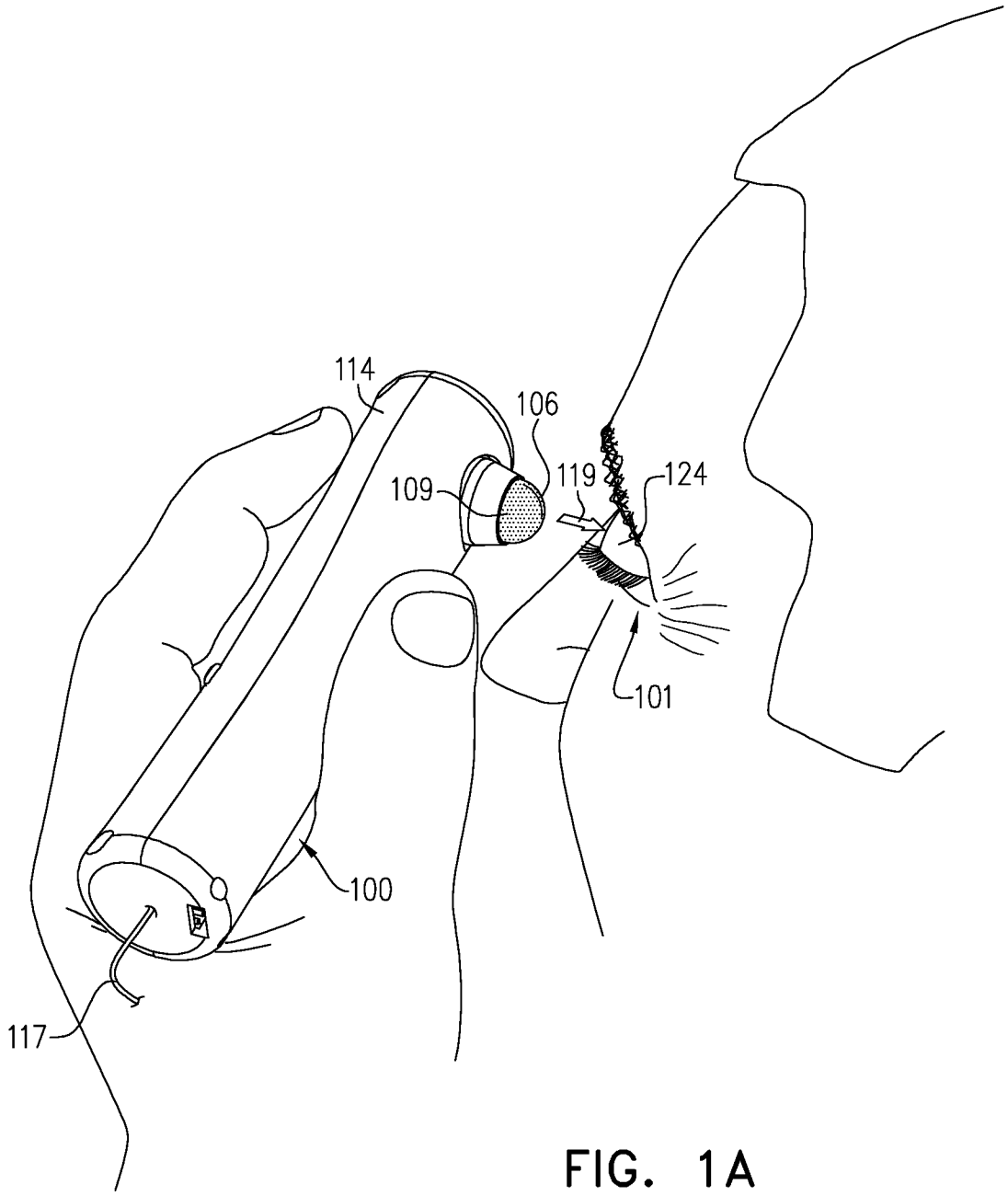


FIG. 1A

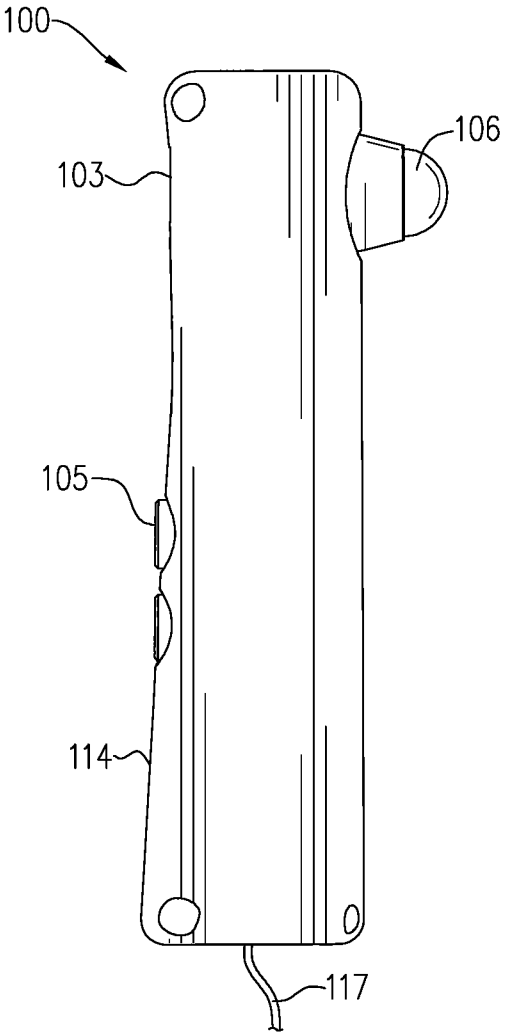


FIG. 1B

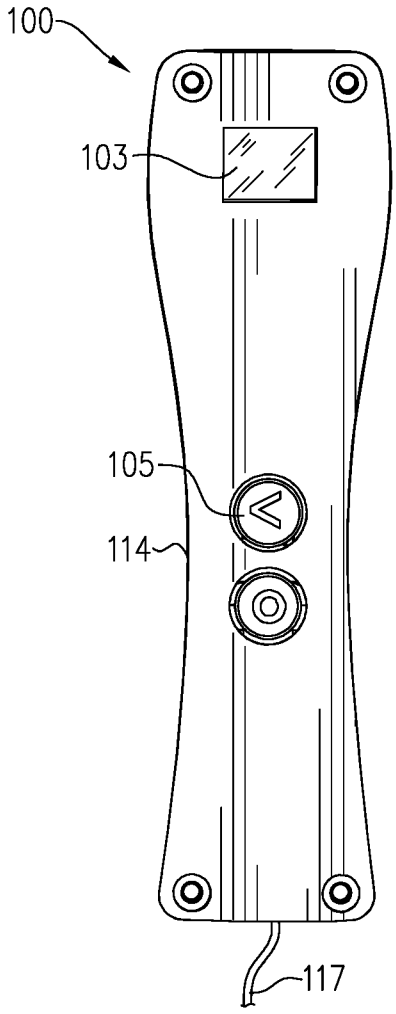
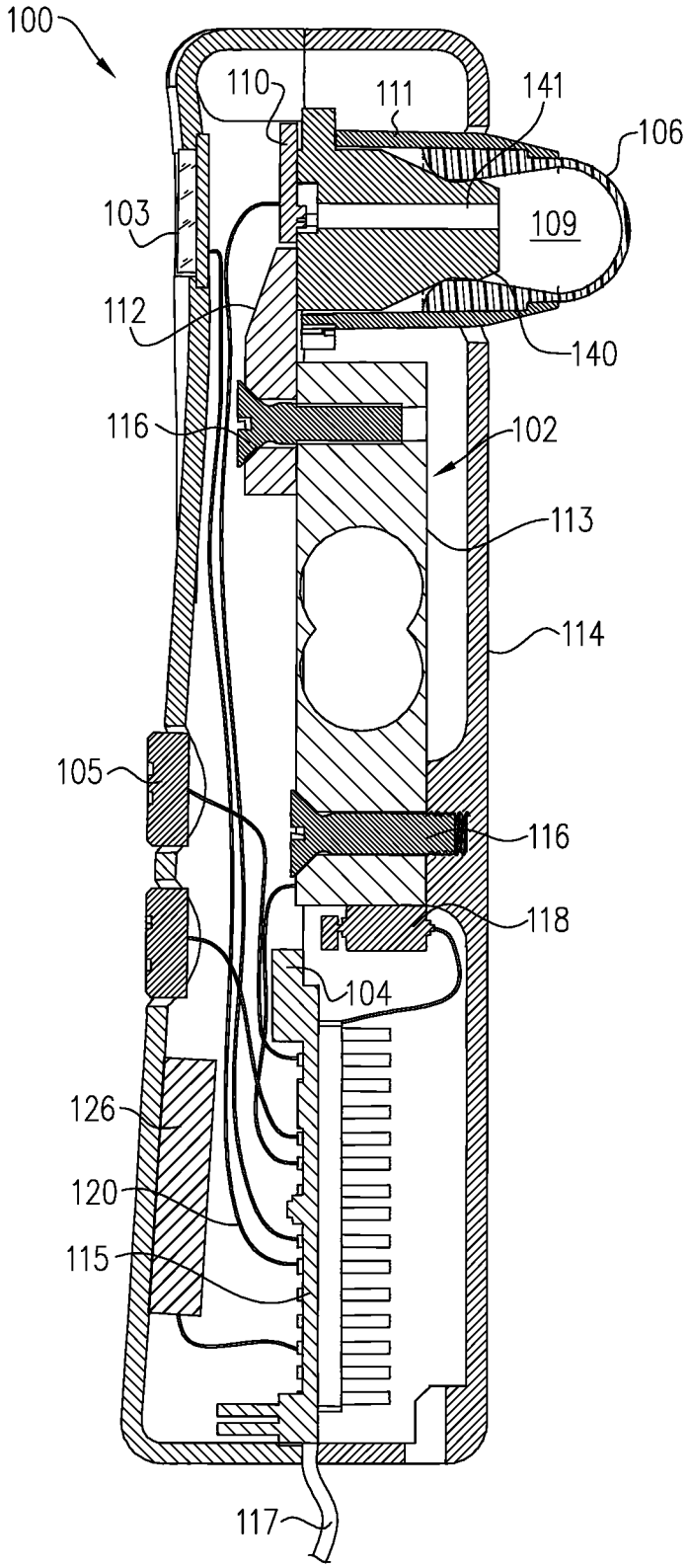


FIG. 1C


100
110
111
141
106
103
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112
140
116
102
113
114
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116
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126
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115
117

FIG. 2

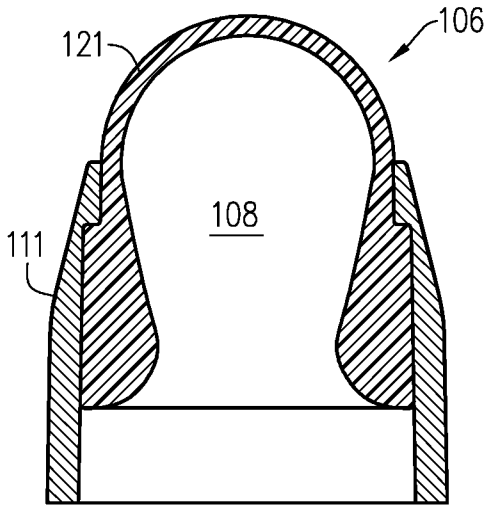

FIG. 3A

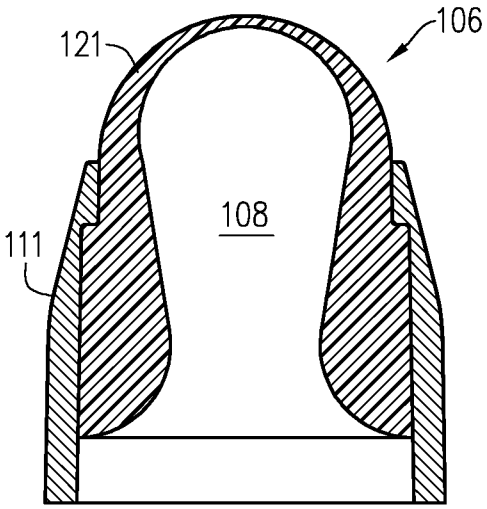

FIG. 3B

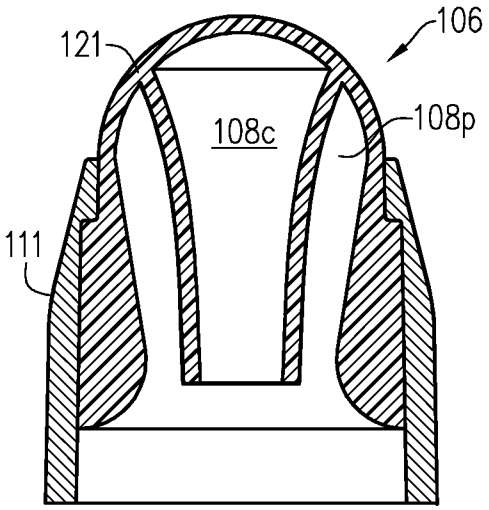

FIG. 3C

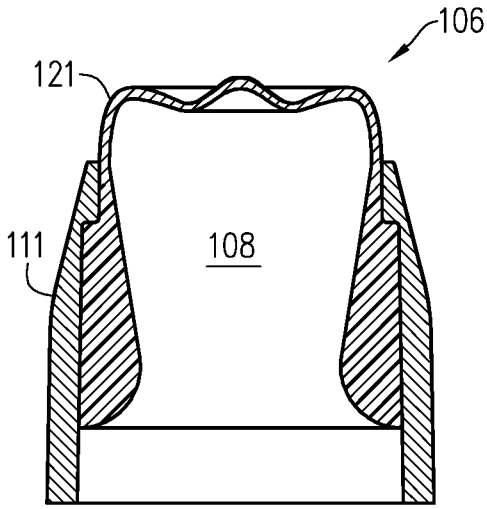

FIG. 3D

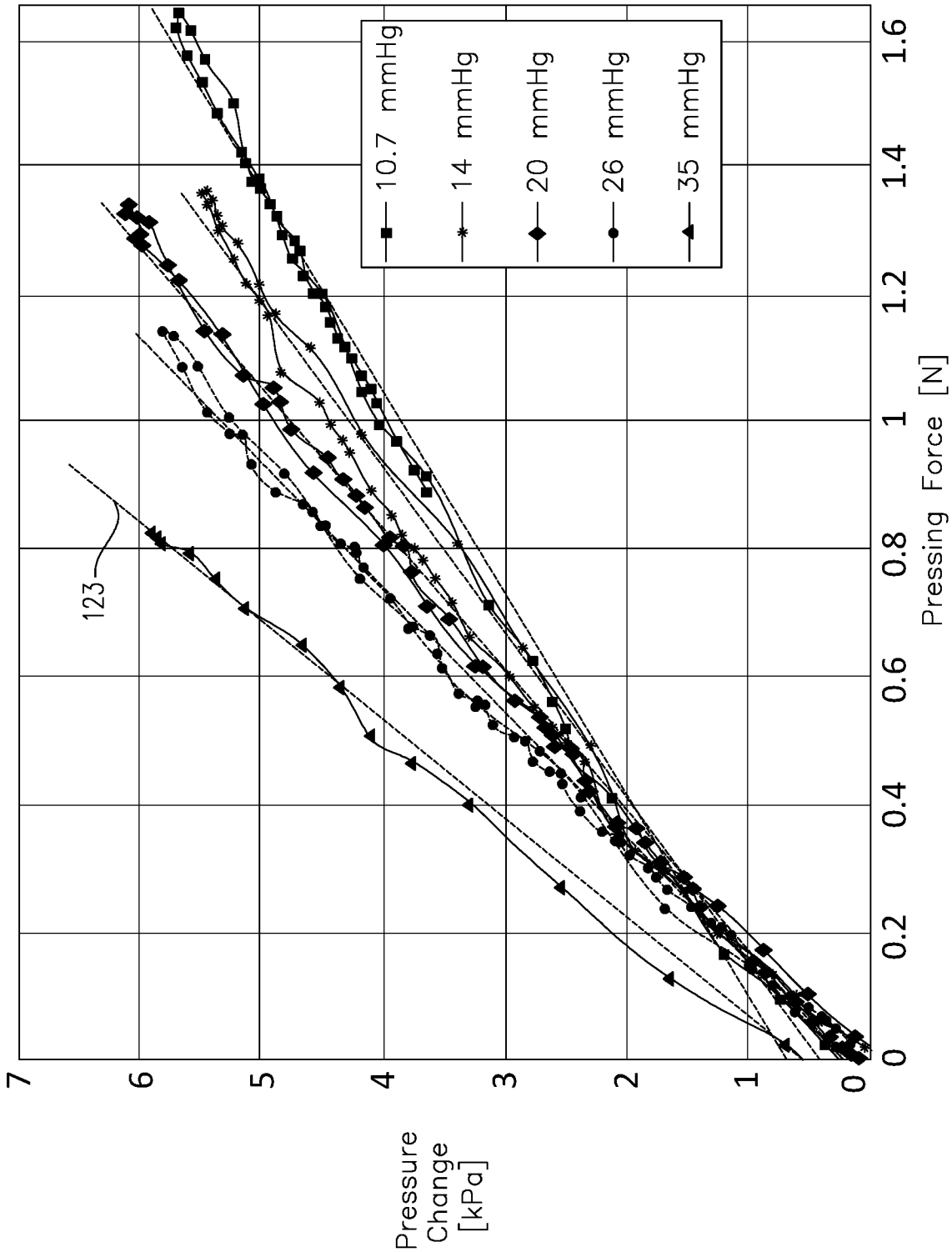
10.7 mmHg
14 mmHg
20 mmHg
26 mmHg
35 mmHg
123
Pressure Change [kPa]
Pressing Force [N]
0
1
2
3
4
5
6
7
0
0.2
0.4
0.6
0.8
1
1.2
1.4
1.6

FIG. 4A

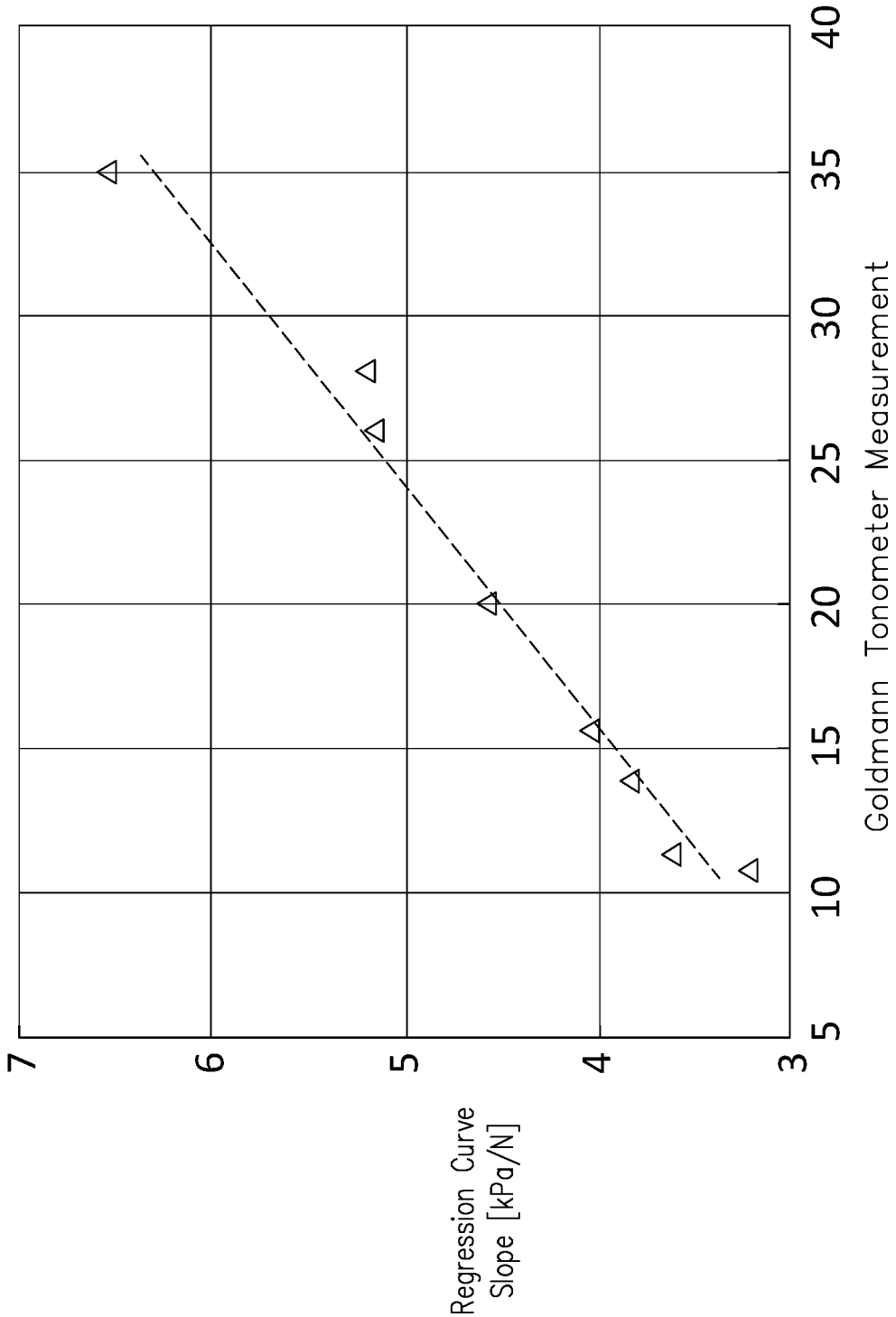
Regression Curve
Slope [kPa/N]
7
6
5
4
3
5
10
15
20
25
30
35
40
Goldmann Tonometer Measurement

FIG. 4B

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2024/055690

A. CLASSIFICATION OF SUBJECT MATTER

A61B 3/16(2024.01)i; ***A61B 3/02***(2024.01)i
CPC:A61B 3/16; A61B 3/02

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 3/16; A61B 3/02
CPC:A61B 3/16; A61B 3/02

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 practicable, search terms used)

Databases consulted: Google Patents, Orbit Search terms used: tonometer

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2006270925 A1 (TREATYOU MEDICAL TECHNOLOGY CO) 30 November 2006 (2006-11-30) fig.1-4, para.19, 24-29	1,2,4,5,7-14,16,18-23,25,28-30,32,34
X	DE 10227940 A1 (ALEXANDRESCU MIRCEA [DE]) 15 January 2004 (2004-01-15) fig.1-3	1-3,7,11-13,16, 18-23,28,32,34
X	US 2006020194 A1 (AHMED A M [US]) 26 January 2006 (2006-01-26) fig.1-4, para.29-36	1-3,5-7,10-24, 26-28,31-34

☐ Further documents are listed in the continuation of Box C. ☑ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"D" document cited by the applicant in the international application
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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
14 August 2024	**20 August 2024**

Name and mailing address of the ISA/IL	Authorized officer
Israel Patent Office **Technology Park, Bldg.5, Malcha, Jerusalem, 9695101,** **Israel** **Israel** Telephone No. **972-73-3927218** Email: **pctoffice@justice.gov.il**	**SHUSHAN Hadas** Telephone No.

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/IB2024/055690

Patent document cited in search report	Publication date (day/month/year)	Patent family member(s)	Publication date (day/month/year)
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DE 10227940 A1	15 January 2004	DE 10227940 A1	15 January 2004
US 2006020194 A1	26 January 2006	US 2006020194 A1	26 January 2006
		US 7288067 B2	30 October 2007
		US 2003097052 A1	22 May 2003
		US 6923765 B2	02 August 2005