An Exploration of a Through-the-Eyelid Intraocular Pressure Measurement Device

by

Flora T. Chiu

Submitted to the Department of Electrical Engineering and Computer Science
in Partial Fulfillment of the Requirements for the Degree of
Master of Engineering in Electrical Engineering
at the Massachusetts Institute of Technology

May 19, 2005
[June 2005]

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ABSTRACT

Glaucoma, caused by an elevated intraocular pressure (IOP), is one of the leading causes of blindness. As constant monitoring of IOP is essential in the treatment of glaucoma, the IOP measurement techniques described in patents and patent applications since 1950 are examined. None of the methods provides a simple and comfortable approach for patients to self monitor their IOPs at different times throughout the day. A through-the-eyelid tonometry method is proposed to address the deficiencies of the previous techniques. Two through-the-eyelid tonometers are designed, and parts of the prototypes are built.

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Chapter 1 Introduction

Glaucoma, one of the most common and severe eye disorder, is caused by an increase in intraocular pressure (IOP) “resulting either from a malformation or malfunction of the eye's drainage structures” [1]. If untreated, an elevated IOP can lead to permanent vision loss.

There are two types of glaucoma: acute glaucoma (also known as angle closure glaucoma) and chronic glaucoma (also known as open angle glaucoma). In both cases, the circulation of the aqueous humor, a fluid that is constantly produced by the ciliary body, is blocked. In a healthy eye, the aqueous circulates from behind the iris, through the pupil and into the anterior chamber between the iris and the cornea. Then the fluid drains out of the eye through the drainage angle, a network of tissue between the iris and the cornea, and into a channel that leads to a network of small veins on the outside of the eye [2]. An increase in IOP occurs when an imbalance between the production and the draining of the aqueous exists: either the aqueous flows out slowly or fails completely to flow out of the drainage angle. In acute glaucoma, the drainage angle becomes blocked suddenly; in chronic glaucoma, the drainage angle becomes blocked gradually over a period of years.

The extra pressure caused by the blocked drainage angle exerts on the vitreous humor, the jelly-like fluid that fills the posterior cavity of the eyeball, via the lens. The pressure of the vitreous humor on the retina collapses the blood vessels that nourish the ganglion cells of the retina, and the fibers of the optic nerve. When the cells and the nerve fibers die due to the lack of oxygen and nutrients, vision deteriorates. Figure 1.1 illustrates the anatomy of the eye.

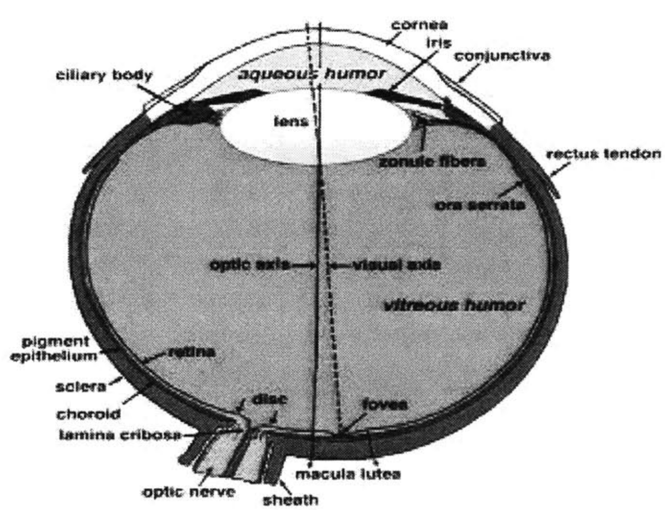


Figure 1.1: Anatomy of the Eye [3]

Monitoring IOP is important for detecting glaucoma. A normal IOP ranges from 12 to 22 mmHg; therefore, an IOP above 22mmHg could be an indication of the onset of glaucoma. Currently, clinicians measure patients' IOPs at their offices. Unfortunately, the one-time IOP measurement is difficult to predict the true IOP because many studies have shown that IOP changes throughout the day with the highest IOP occurring in the morning and the lowest IOP in the early afternoon [4]. One study has even indicated that the average diurnal range of IOP is 10mmHg +/- 2.9 mmHg and acquiring a true IOP would require averaging several IOP measurements taken throughout the day [5].

Tonometry, the technique used to measure IOP, and tonometers, the clinical devices to measure IOP, will be detailed in Chapter 2 and 3. Presently, clinicians use different tonometers at their offices: indentation, applanation, and non-contact air jet tonometers. Though non-contact air jet tonometers are the most commonly used devices, these instruments are only used as initial glaucoma screening devices because they are not as accurate as contact tonometers [6]. Direct contact on the cornea using indentation and applanation tonometers may cause patient discomfort and nervousness.

The technique being investigated is to measure IOP through-the-eyelid. The main advantage of the proposed method is that deformation through the closed eyelid would increase patient comfort and prevent cornea infection. Furthermore, if the proposed through-the-eyelid tonometer is calibrated to the accepted "gold standard" tonometer – the Goldmann tonometer, patients may perform self-tonometry at home at different times of the day to acquire a true IOP reading.

1.1 Anatomy

To understand the through-the-eyelid tonometry technique, basic mechanical properties of the cornea and the eyelid are examined.

1.1.1 Cornea

As shown in Figure 1.1, the cornea is at the front of the globe of the eye, bulging outward to transmit and focus light into the eye. It has five layers - epithelium, Bowman's layer, stroma, Descemet's membrane, and endothelium - and it is spherical within approximately 1.5 mm of the center with a curvature in the range from 5.5 mm to 9.5 mm [7]. Moreover, it has an average thickness of 0.55 mm [9], and an average ocular rigidity of 0.0245 V-1 [7]. Ocular rigidity is defined as "the resistance offered by the eyeball to a change in intraocular volume, manifested as a change in IOP" [7]. It relates applied pressure to deformation volume, which measures the distensibility of the eye. In addition, cornea properties are affected by race, gender, and age [11]. Due to the cornea variations, a tonometry technique must be independent of the cornea properties.

1.1.2 Eyelid

The eyelid has four planes of tissue: (1) cutaneous (the skin); (2) muscular (a striated muscle layer); (3) fibrous (a fibrous tissue layer); and (4) conjuctival (the thin mucus membrane on the underside of the eyelid) [12]. The part of the eyelid which covers the eye has an average thickness of 2 mm, and is delicate, and elastic. Though it is quite uniform in layers, it is composed of many layers of cells. Due to the difficulty in modeling these complicated layers, it is therefore crucial that the IOP measurement technique is independent of the properties of the eyelid. Figure 1.2 illustrates the anatomy of the eyelid.

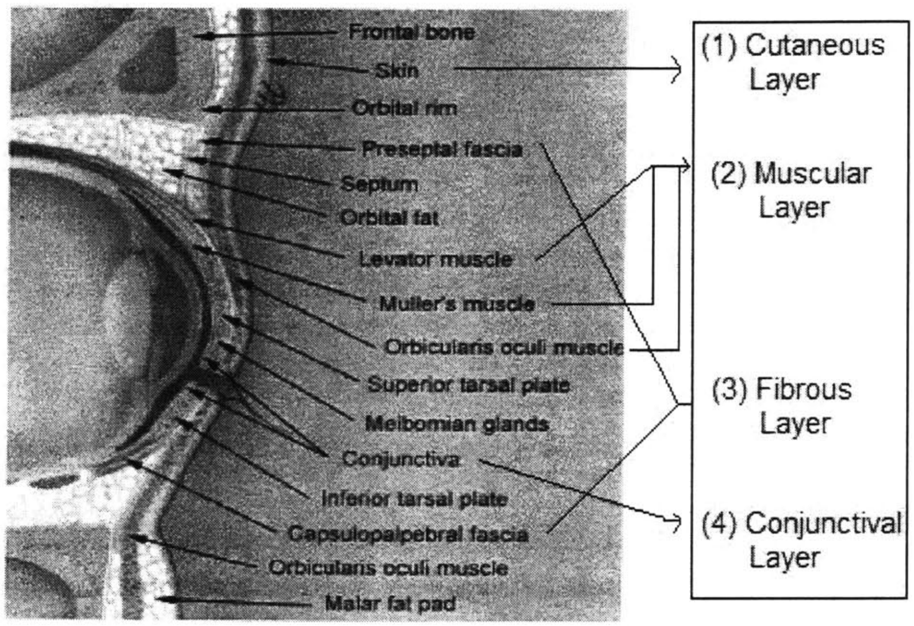


Figure 1.2: Anatomy of the Eyelid [12]

Chapter 2 Tonometry (1950 – 1979)

Tonometry is the technique used to measure IOP; tonometers are the clinical devices to measure IOP. In the early 1900s, indentation tonometry was developed. In the 1950s, applanation tonometry was originated. In the 1970s, non-contact tonometry was created. These three tonometry techniques are described in this chapter. Appendix A lists expired patents from 1950 to 1980. Appendix B summarizes expired patents in their respective categories.

2.1 Indentation Tonometry

In indentation tonometry, a specific weight (a known force) is applied on the cornea and the corresponding indentation depth is measured. The most common indentation tonometer, the Schiotz tonometer, as shown in Figure 2.1, was developed in the early 1900s. A Schiotz tonometer consists of a scale, a needle, a holder, a freely sliding plunger which is attached to a weight, and a footplate. The indentation depth varies inversely to IOP and is influenced by individual cornea rigidity. Repeated readings increase aqueous outflow, thus decreasing IOP.

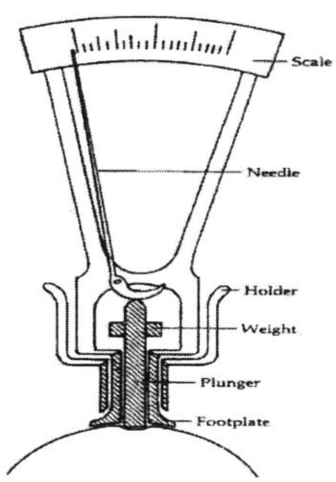


Figure 2.1: Schiotz Tonometer [7]

Figure 2.2 illustrates the Schiotz tonometer in use. The tonometer is placed on the anesthetized cornea of a patient who is lying down and the footplate is sterilized after each use to prevent cross infections.

Figure 2.2: Tonometer in Use [12]

~~2.2~~ Applanation Tonometry

In applanation tonometry, the amount of force is measured to minimally flatten a specific area on the cornea. The Goldmann tonometer, developed in 1957, uses the applanation technique. Imbert - Fick's principle states that when a flat surface is pressed against a dry, flexible, elastic, and infinitely thin spherical surface of a container with a given pressure, equilibrium will be attained when the force exerted is balanced by the internal pressure of the sphere exerted over the area of contact. Mathematically speaking, the equation is

$$P = F / A$$

where P is the pressure, F is the force, and A is the area.

Because the cornea is not perfectly spherical, and the wall is not infinitely thin, Goldmann adjusted the above formula to the following modified Imbert - Fick law:

$$P = (F + M - N) / A$$

where P is the IOP, F is the tonometer applied force, M is the surface tension between the applanation surface and the team film, N is the force needed to overcome the cornea rigidity, and A is the area of inner corneal flattening. The predetermined applanation area of 7.35 mm^2 (diameter equals 3.06mm) is chosen such that the opposing forces - M and N - cancel out. With this area flattened, the force measured in grams is related to IOP in mmHg by 10:1. For example, 1 gram of force = 10 mmHg. Figure 2.3 illustrates the area of corneal flattening.

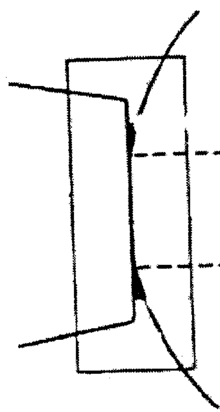


Figure 2.3: Area of Corneal Flattening [7]

Acquiring IOP with a Goldmann tonometer requires three steps: 1) adding a fluorescein dye and an anesthetic to the eye; 2) aligning a biprism (two triangular prisms fused together to form an optical device for obtaining interference fringes [8]) to aid in determining the endpoint; and 3) setting up the slit-lamp to magnify the eye structures. Figure 2.4 illustrates the Goldmann tonometer mounted on a slit-lamp.

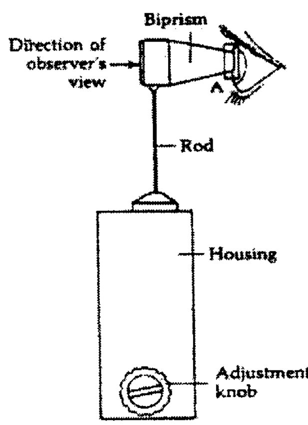


Figure 2.4: Goldmann Tonometer Mounted on a Slit-Lamp [7]

2.3 Non-Contact Tonometry

Non-contact tonometry (NCT), developed in 1970s, eliminates the mechanical contact and the topical anesthesia on the cornea by bursting an air puff towards the eye. NCT is mounted on a table and involves three subsystems – an alignment system, an opto-electronic applanation monitoring system, and a pneumatic system – to measure IOP.

When the cornea is properly aligned, the operator of the instrument triggers the pneumatic system to generate a puff of air. The force of the air pulse increases linearly with time, which progressively flattens the cornea. The higher the IOP, the more time will be required for the applanation of the cornea. Because NCT measurement is usually made in 1-3 milliseconds (1/500 of the cardiac cycle), and is random with respect to the phase of the cardiac cycle, the ocular pulse becomes a significant source of variation [13]. In other words, the probability of acquiring an IOP at the same phase in a subsequent cardiac cycle is minute; thus, the repeatability is low. As a result, consecutive readings are taken for each eye until a cluster of three within a 3 mmHg spread is obtained [13]. Furthermore, though IOPs acquired using older NCTs are quite different from IOPs acquired using the Goldmann tonometer, newer NCTs produce more comparable results. For example, in a recent study of a NCT model NT- 4000, “more than 80% of the results from the NT - 4000 were within 3 mmHg of those from the Goldmann tonometry” [14]. Figure 2.5 illustrates how IOP is measured using NCT.

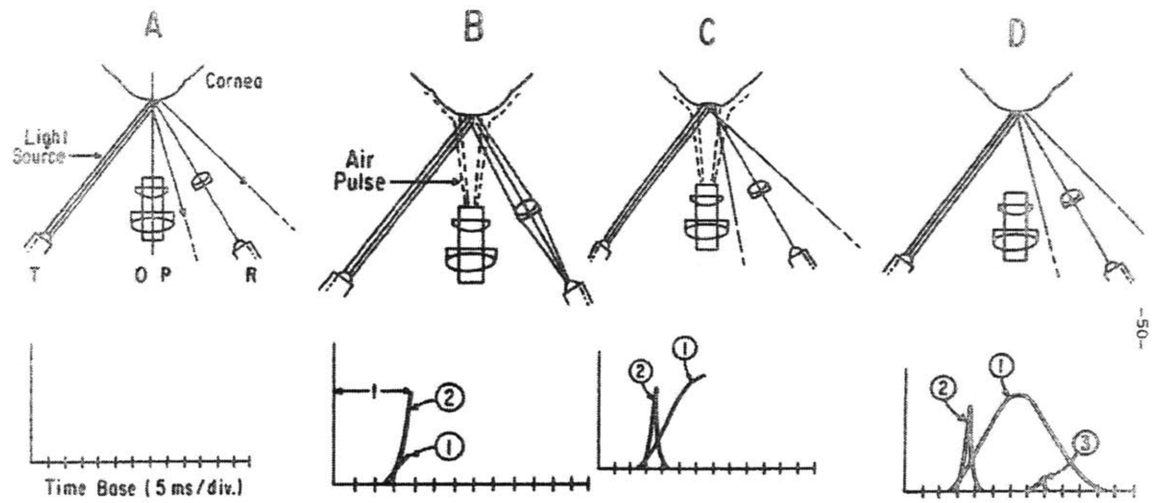


Figure 2.5: NCT Tonometer

A: Light source from transmitter (T) is reflected from undisturbed cornea toward receiver (R), while cornea is aligned with optical system (O). B: Air pulse (1) from pneumatic system (P) applanated cornea, causing maximum number of light rays (2) to be received and detected by R. Time interval (t) from internal reference point to moment of applanation is converted to IOP and displayed in mm. Hg on digital readout. C: Continued air pulse produces momentary concavity of cornea, causing shape reduction in number of rays received by R. D: As cornea returns to undisturbed state, a second moment of applanation causes another light peak [15].

Chapter 3 Tonometry (1980 - 2005)

Since 1980, a variety of new tonometry techniques have been patented in addition to continual improvements on the applanation and the non-contact tonometry techniques. Appendix C lists tonometry-related patents since 1985. Appendix D summarizes different patents in their respective categories. Appendix E lists patent applications since 2001. Appendix F summarizes patent applications in their respective categories. The new tonometry techniques are highlighted in this chapter.

3.1 High Frequency Light/Sound Waves

A new type of NCT involves sending ultrasound or high frequency waves into the eye. The benefit of ultrasound NCT is that it does not create sounds or air surges like the air puff NCT which has the possibility of causing physical or psychological discomfort in some patients.

Three patents are highlighted from the patent summaries in Appendix D: (1) Hsu; (2) Chechersky et al.; and (3) Sinha et al. These patents illustrate different techniques to measure IOP using ultrasound waves.

In Hsu's patent (US 4,928,697), low frequency sound waves (10 - 500 Hz) are sent to perturb a given corneal area and high frequency sound waves (10KHz to 1MHz) are directed toward the perturbed corneal area. The curvature of the cornea is dependent on IOP. When IOP is high, the cornea bulges more. Therefore, the incident high frequency waves are more diverged as they are reflected towards the receiver, and the collector collects less of the beams. The reflected waves are amplitude modulated as the surface is perturbed by low frequency waves and the output signals are directly related to IOP. Figure 3.1 shows the ultrasound NCT arrangement from Hsu's patent.

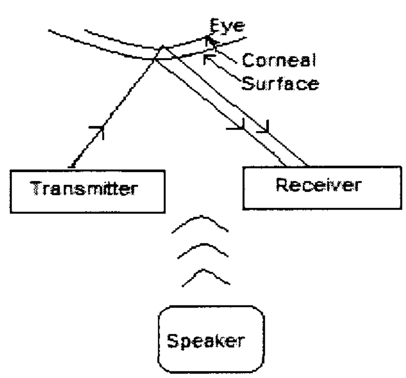


Figure 3.1: Ultrasound NCT Arrangement [16]

In Chechersky et al.'s patent (US 6,030,343), an ultrasonic transducer emits a single ultrasonic beam of appropriate frequency and power to deform the glove of the eye. IOP is calculated based on the phase shift between the incident and reflected beams.

Sinha et al. in US patent 5,375,595 calculates IOP based on the principle of the eye's resonant frequency. An ultrasonic transducer sweeps a range of audio frequencies in which human eyes can resonate onto the eye and a fiber-optic reflection vibration sensor detects the resonant vibrations of eye to determine IOP. Changes in IOP can be determined after a reference pressure is established.

The above comparison highlights that even though many patents use ultrasound waves in their inventions, their methods of calculating IOP may differ.

3.2 Through-the-Eyelid Tonometry

Through-the-eyelid tonometry is another new tonometry technique. As the name suggests, IOP measurement is performed through-the-eyelid to increase patient comfort. Five through-the-eyelid tonometers have been patented up-to-date: Fedorov et al. in 1993, Suzuki in 1994, Fresco in 1998, Ballou in 1998, and Kontiola in 2000. Three patent applications have been filed: Ahmed in 2003, Cuzzani in 2003, and Moore in 2004. These patents and patent applications do not detail how the eyelid affects the measured IOP and the described methods are non-specific.

Two methods are illustrated in the patents and patent applications: applanation, and vibration. Applanation involves applying a force through-the-eyelid on the eye. Because the compliances of the eyelid and the eye are different, a gradient change is predicted in a graph of applied force versus indented distance as the applanation probe applies a force on the eye after the eyelid is completely flattened. The point at the gradient change is used to calculate IOP. The proposed through-the-eyelid IOP measurement device also utilizes the applanation approach and is illustrated in detail in Chapter 4. Figure 3.2 illustrates the applanation on the eyelid.

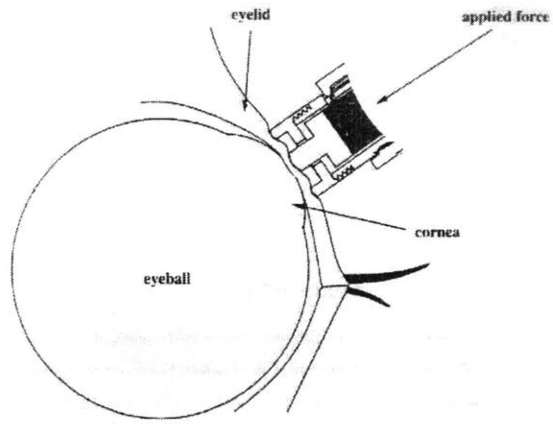


Figure 3.2: Applanation on Eyelid [17]

3.2.1 Vibrational Approach

As described in Cuzzani's patent publication (US 2003/0187343 A1), a vibrator transmits vibrational energy into an eyeball through the eyelid while a force transducer coupled to the vibrator measures the force or phase response in the eyeball. Vibrational energy, which may be derived from a solenoid, must be capable of producing constant amplitude and a range of frequencies for inducing vibration in at least a portion of an underlying eyeball. In order to ensure the eyeball is vibrated and a vibrational response will be detected by the force transducer, a static force sensor can be applied to the eyelid. By using acoustic energy to obtain IOP, the volume of the eye does not change during measurement and the pressure is not affected. It is also predicted that the response of the eyelid is not a substantial factor in determining the response of the eyeball.

The vibrational impedance of the eye is calculated from the force or phase response. Vibrational impedance is characterized by the minimum point on the force vs. frequency graph and the maximum point on the phase vs. frequency graph. Once the vibrational impedance is attained, IOP is calculated as a function of V (eye volume, which is dependent on axial length), E (elastic modulus of the eye, which is a function of the thickness and the water content of the cornea), and Ri (biomechanical rigidity of the eye, which can be derived from the vibrational response of the eye). There seems to be less phase lag in a high IOP than a low IOP. Furthermore, the frequencies at which the amplitude of the force reaches a minimum and at which the phase reaches a maximum increase with increased IOP.

The IOP derived from the vibrational approach is then compared to the IOP obtained using the Goldmann method. Calibration factors are used if necessary to define the relationship between the vibration and Goldmann method for a specific patient. Additional eye properties, such as the axial length of the eye and the cornea thickness, may be gathered to normalize vibrational responses between different eyes. Figure 3.3 illustrates a vibrational tonometry arrangement.

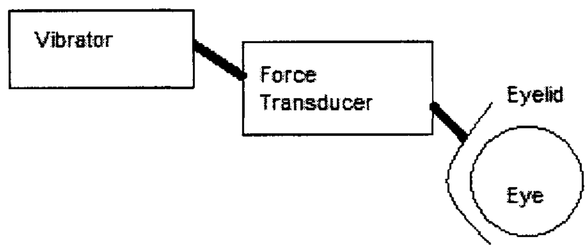


Figure 3.3: Vibrational Tonometry Arrangement [18]

3.3 Others

Others investigate the concept of a continuous IOP measurement device. Two ideas are suggested: (1) implants; and (2) contact lens with a strain gage. Proposed implant locations include the iris, the cornea, the sclera, and the lens. Figure 3.4 illustrates a Polysilicon Resonant Transducer implant in the cornea. Figure 3.5 shows the sclera contact lens. In both cases, external wireless devices communicate with the internal sensors and display the IOP to a user or a central monitoring station.

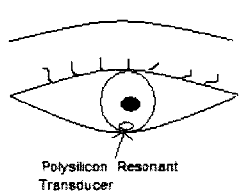


Figure 3.4: A Polysilicon Resonant Transducer Implant in the Cornea [19]

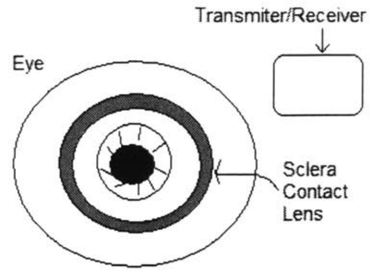


Figure 3.5: Sclera Contact Lens [20]

Chapter 4 Through-the-Eyelid Tonometry

The proposed through-the-eyelid tonometer has features that previous through-the-eyelid tonometers lack. Moreover, the eyelid mathematical model and the tonometer design are described in detail to show a better understanding of the effects of the eyelid on IOP measurements.

4.1 Eyelid Model

The cornea and the eyelid are idealized as two concentric, spherical shells in Figure 4.1. The applanation device has an area Aa, and the force is applied perpendicular to the shells, a critical criterion for achieving accurate IOPs when using the equations below. As the force flattens the eyelid, the probe's applanation area Aa equals the flattened eyelid's internal area Ae. When the force increases, the cornea will also be flattened and its internal area Ac will equal Ae and Aa. Once the eyelid is flattened, the additional force needed to flatten the cornea will not affect Ae. As a result, the above conditions should satisfy the inequality: Aa>=Ae>=Ac [21]. This inequality is pictorially shown in Figure 4.1.

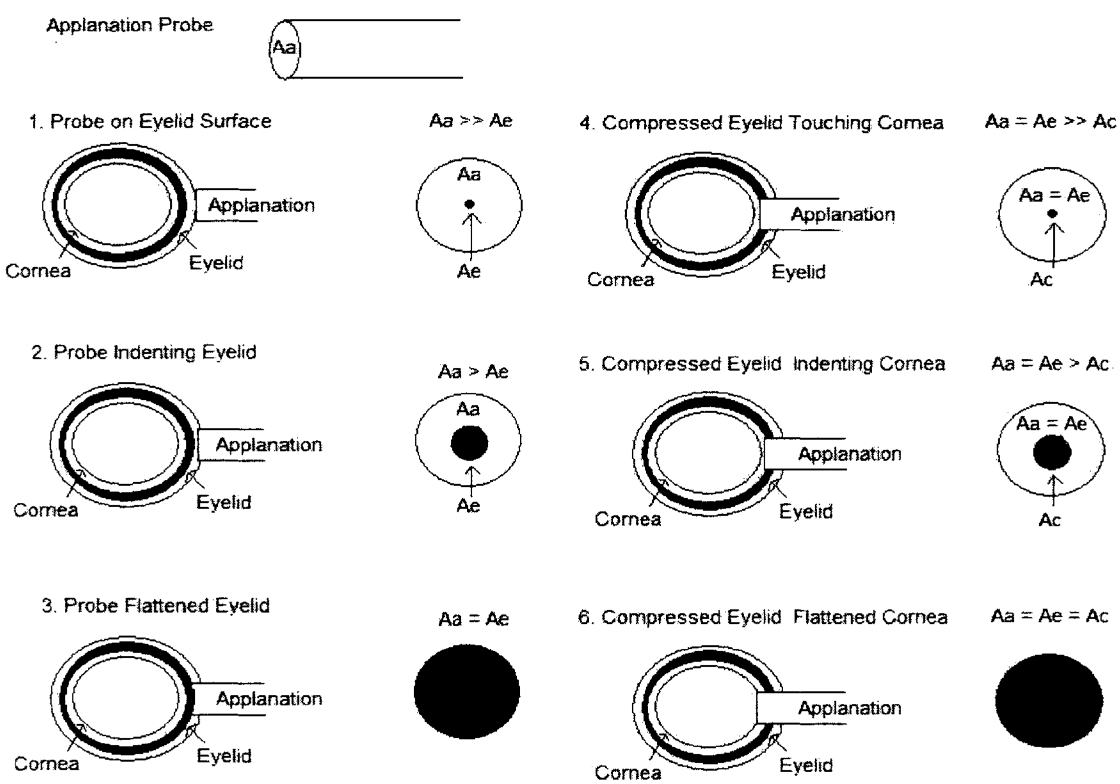


Figure 4.1: Eyelid-Eye Applanation Process

To find IOP, the following equations are used. Since the eyelid is elastic and delicate, it is assumed that the eyelid changes shape as soon as the probe begins to flatten it. Fe, the force needed to flatten Ae, is related to Pe, the pressure the eyelid exerts back onto the applanation surface Aa by

$$Pe = Fe / Aa \qquad (1)$$

When looking at the cornea equilibrium, the cornea rigidity must be accounted. Fc, the force needed to flatten Ac, is related to the IOP by

$$IOP = (Fc - N) / Ac \qquad (2)$$

where N is the force needed to overcome cornea rigidity. The total force Ft on the cornea and the eyelid is Fe + Fc. Fc is therefore Ft – Fe.

The surface tension M associated with the tear film is not taken into account in equation (2) because the applanation does not directly touch the cornea. Because the eyelid contacts the tear film and the contact has begun before the applanation, M is assumed to be already incorporated in Pe.

If IOP is calculated using Goldmann standards, Ac equals 7.35 mm^2 and N equals 0.415g. Therefore, only Ft and Fe are needed to calculate IOP:

$$IOP = (Ft - Fe - 0.415g) / (7.35mm^2) \qquad (3)$$

4.2 Force-Indentation Curve

One way to determine Ft and Fe is to generate a graph of applied force versus indentation depth of the eyelid and cornea in series such as Figure 4.2.

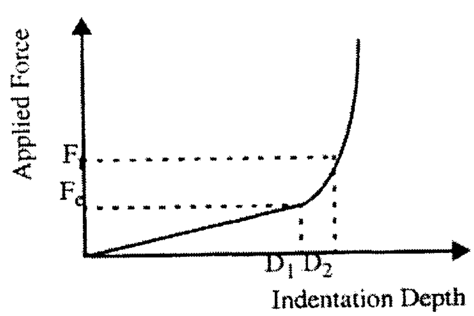


Figure 4.2: Force-Indentation Curve of Eyelid and Cornea [21]

The graph illustrates several important concepts of the eyelid model. First, the gradient from the indentation depth of 0 to D1 is smaller than the gradient after

D1. This is reasonable because the eyelid tissue is softer than the cornea tissue and the applied force can more easily indent the eyelid than the cornea. Second, the transition point from the eyelid to the eye is found at D1. D1 is the point at which the eyelid is completely flattened; the force applied to applanate the eye is Fe. Third, after D1, the applied force is used to flatten the cornea. The slope increases dramatically because the cornea is rigid. D2 is the point when the cornea is applanated; Ft corresponds to the total applied force.

If the above graph can be accurately constructed and the different significant points are found, IOP can be calculated.

4.3 Attempts by Previous Patents and Patent Applications

Creating a force-indentation plot is difficult because it requires a spatial reference. Previous patents and patent applications have attempted to find several points or to produce the entire graph to determine IOP. However, the described techniques have not provided conclusive and validating results. Fedorov in 1993 used the amount of ball rebound to determine IOP. The method is painful and the device is intimidating. Suzuki in 1994 tried to create a force-time curve with time relating to distance by using a probe sliding at a constant velocity into the eyelid. The system is dynamic, which increases the sources of errors, and the applanation location is situated at the intersection between the upper and the lower eyelid, an area which does not provide an even surface for data taking. Moore's patent application in 2004 illustrated the use of a linear voltage differential transducer to measure distance as a force sensor measures force. The tonometer is expensive in construction and the IOP measurement cannot be self performed by the patient himself or herself.

Chapter 5 Concept Generation and Product Development

5.1 Advantages of the Proposed Tonometer

The proposed tonometer addresses the above deficiencies. First, the device is inexpensive. Second, the tonometer is small, and it provides a comfortable non-slip grip. Third, the device automatically shuts off after a given time to save battery life. Fourth, self-tonometry can be easily performed. The tonometer has an electronic LCD display to show the measured IOP, and a buzzer system to signify the completion of the IOP measurement and to help with the initial tonometer alignment with the eyelid so the applied force will be perpendicular to the surface of the eyelid. Fifth and most importantly, the initial IOP acquired using the proposed tonometer is calibrated to an IOP obtained using the Goldmann tonometer. This saves the trouble of finding the important points in Figure 4.2.

5.2 Design Specifications

The advantages of the tonometer described in section 5.1 result in the following tonometer design constraints: (1) construction cost is as low as possible; (2) size is small; (3) applied force is as low as possible to increase patient comfort; (4) LCD display illustrates IOP measurement; (5) buzzer system to help with initial alignment; (6) microprocessor to turn off the battery.

5.3 First Design and Prototype

Figure 5.1 illustrates the cross section of the initial tonometer design in the lab book. Figure 5.2 shows the potentiometers in the design.

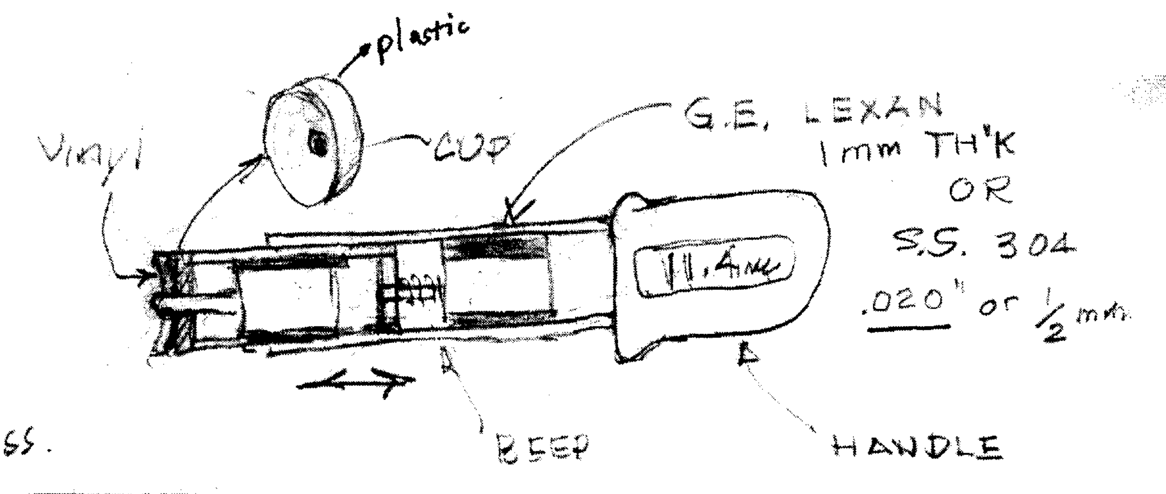


Figure 5.1: Initial Tonometer Design - Dated August 26, 2003

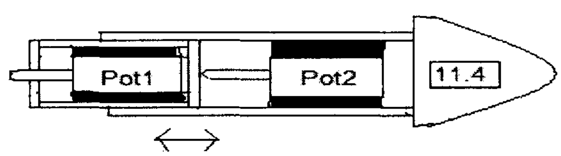


Figure 5.2: IOP Measurement Device

5.3.1 Exterior

Delrin, a plastic produced by Dupont [22], is used for the casing. Delrin is chosen because it is easy to machine, low in friction, cheap, light weight, and durable. Figure 5.3 shows the Delrin casing. Figure 5.4 illustrates the plastic cork stopper used for one end of the device.

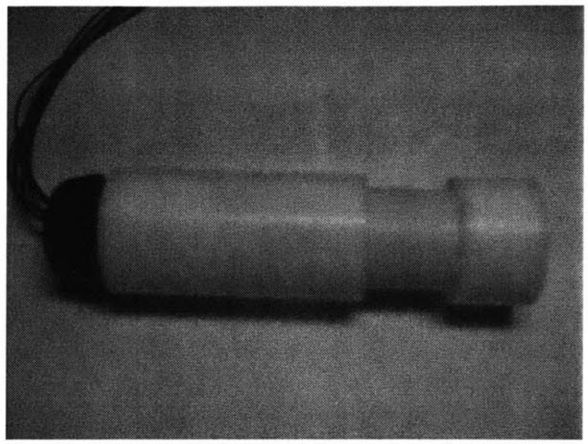


Figure 5.3: Delrin Casing

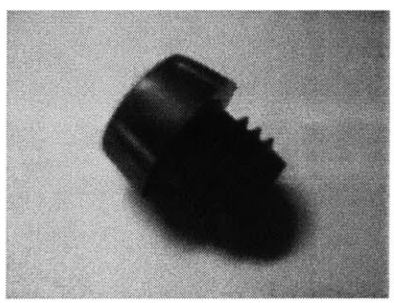


Figure 5.4: Plastic Cork Stopper

5.3.2 Interior

The main components of the device are linear potentiometers. Linear potentiometers are sensors that produce a resistance output proportional to the displacement or position. The resistance element is excited by either DC or AC voltage and the output voltage is ideally a linear function of the input displacement. Linear potentiometers are essentially variable resistors. They can be rectangular or cylindrical, and wire-wound or conductive plastic.

Figure 5.5 shows the linear potentiometer used for the device.

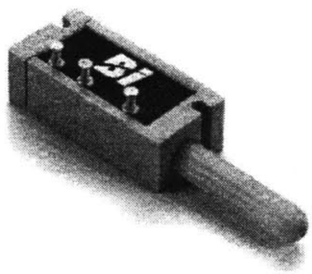


Figure 5.5: Linear Potentiometer with 10K Resistance [23]

Three leads are attached to a linear potentiometer. Two leads connect to the ends of the resistor, so the resistance between them is fixed. The third lead connects to a slider or wiper that travels along the resistor. The resistance between the third lead and each of the other two connections changes. The changes in resistance are related to changes in voltages. The special feature for each of these linear potentiometers is an internal spring. The internal spring serves to return the slider to its original extended position. Figure 5.6 demonstrates the potentiometer alignment inside the device.

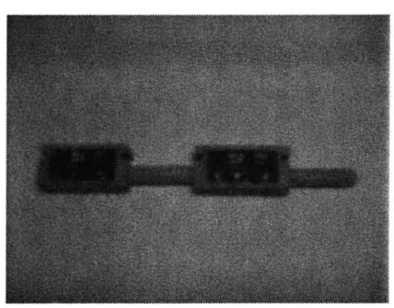


Figure 5.6: Potentiometers Aligned Inside

The first potentiometer is used to measure the IOP. The second potentiometer serves to define a reference force or reference point.

5.3.3 Explanation of Tonometer Design

There are two important systems in the tonometer design. First, an alignment system aligns the tonometer with the eyelid so the applied force is normal to the eyelid surface. The perpendicular condition must be met such that Imbert - Fick's equation can be used. Second, an IOP measuring system uses a consistent reference point to ensure IOP measurements are comparable.

5.3.3.1 Alignment System

To use Imbert-Fick's equation, the tonometer is positioned so that the applied force is perpendicular to the surface of the eyelid. Figure 5.7 shows the lateral view of the eye with the eyelids closed and the perpendicular condition indicated by the black lines. When the eyelids are closed, the eye is tilted slightly upward and the normal axis to the surface of the eyelid is not horizontal. As a result, an alignment system is needed to correctly position the tonometer. During the alignment period, because the patient cannot see, a buzzer system provides feedback to let the patient know whether or not the instrument is aligned.

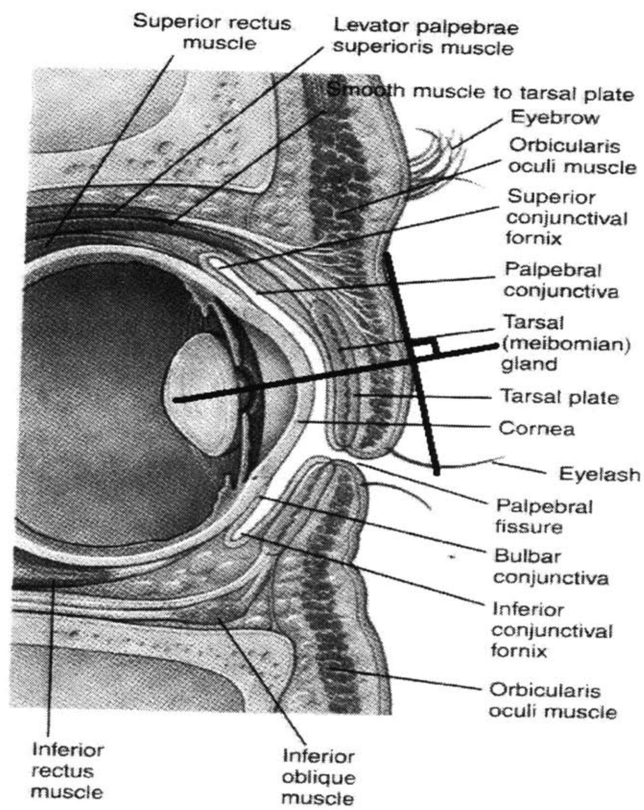


Figure 5.7: Lateral View with Eyelids Closed [14]

Black lines show the perpendicular condition.

One method to determine the proper alignment is to put three sensors on the rim of the cup similar to a tripod system as shown in Figure 5.8. The cup has an area of A2 and the force probe has an area of A1. The sensors, shown in black, may be force sensors to measure the force on the cup rim. When the tonometer is initially placed on the eyelid surface, a beep alarm is sounded. As the user tilts the tonometer to attempt alignment, the microprocessor constantly compares the forces on the three sensors. When the forces are equal, the alarm stops, indicating the instrument is properly aligned.

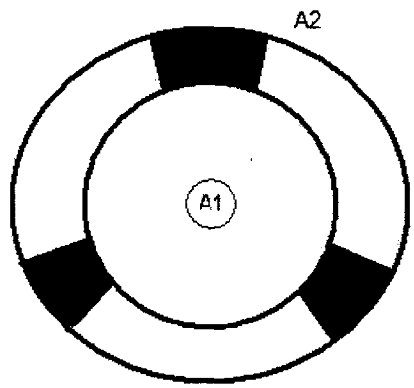


Figure 5.8: Sensors on Cup Rim

5.3.3.2 IOP Measuring System

The different components of the IOP measuring system are illustrated in this section. The normal axes to the surface of the eyelid are horizontal in the figures below to simplify the illustrations. Figure 5.7 above shows the actual normal axis direction.

5.3.3.2.a Mathematical Model

Figure 5.9 shows the front section of the system: the first potentiometer in the smaller section of the telescoping tubing. The cup is on the surface of the eyelid. The probe tip is perpendicular to the eyelid surface. The maximum probe movement is x1.

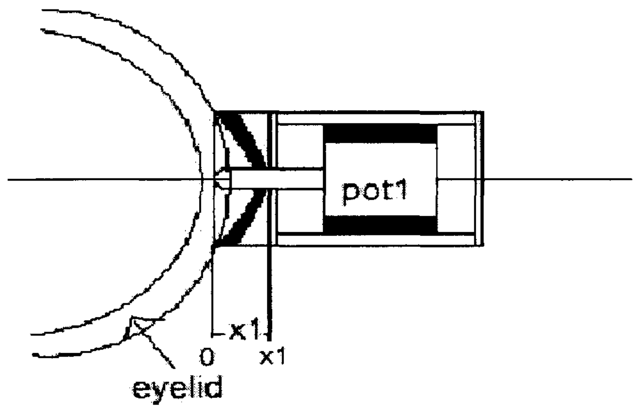


Figure 5.9: First Potentiometer (Pot 1)

Figure 5.10 shows the rear section with the second potentiometer in the larger telescoping piece. The maximum probe movement is x2.

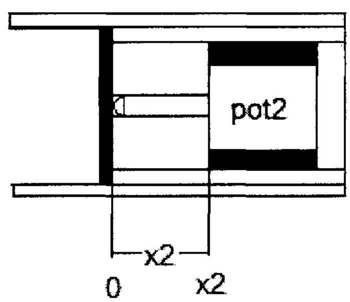


Figure 5.10: Second Potentiometer (Pot 2)

Figure 5.11 illustrates the tonometer's mathematical model. Fmax1 is the maximum force Pot 1 is capable of sensing and is greater or equal to F1, the force exerted by the eye on Pot 1:

$$Fmax1 >= F1 \qquad (4)$$

Fmax2 is the maximum force Pot 2 is capable of sensing and is equal to or greater than the total force on Pot 2:

$$Fmax2 >= Ftot2 \qquad (5)$$

$$Ftot2 = F1 + F2 \qquad (6)$$

The total force on Ftot2 is the addition of F1 and F2. F2 is the force exerted by the eyelid on the cup and is coupled to Pot 2 because the cup is attached to the front telescoping tubing and the tubing pushes on the probe of Pot 2. F1 is also measured by Pot 2 because Pot 1 is attached to the front casing which in turn exerts a force on probe of Pot 2.

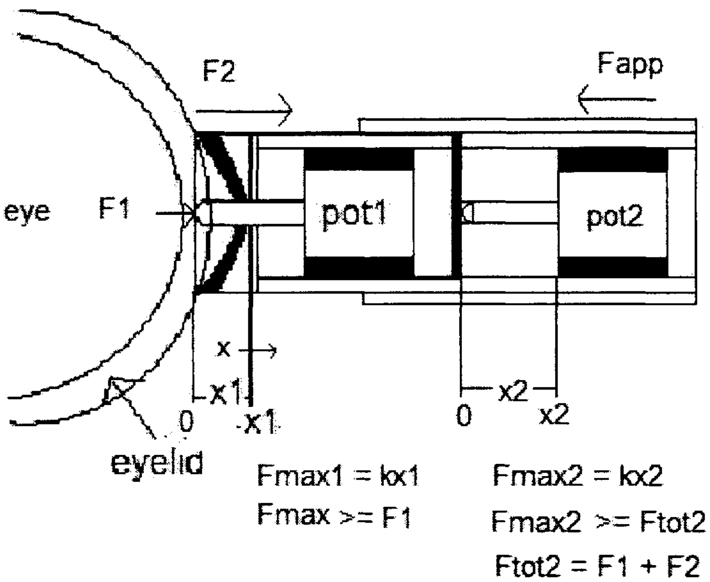


Figure 5.11: Mathematical Model of Tonometer

In the above tonometer design, several parameters can be set during the construction of the device: Fmax1, Fmax2, A1, and A2. The unknowns are F1 and F2, with F1 being the most important unknown needed to calculate IOP:

$$IOP = F1 / A1 \qquad (7)$$

5.3.3.2.b Reference Point

In order to compare IOP measurements, a constant reference point is needed. In the tonometer design, the reference is set as a predetermined force Fref. Fref is preset using two criteria: (1) the characteristics of the force-indentation curve in Figure 4.2; and (2) the calibration with the Goldmann applanation method.

When the patient holds onto the larger section of the telescoping tubing and presses the device, a force, Fapp, is applied onto the eyelid. To get a valid IOP measurement, Fapp must be large enough to flatten the eyelid and applanate the cornea; therefore, it must be equal to or greater than Ft as in Figure 4.2:

$$Fapp >= Ft \qquad (8)$$

Fapp is almost certainly different during each measurement because the patient is unlikely to press with the same force every time. Thus, Fref is essential to ensure measurement consistency and to account for the patient's specific eyelid characteristics.

From equation (6), Ftot has two components: F1 and F2. F1 is the force exerted by the eye on the instrument at the cornea applanation point and the force can be found using the Goldmann tonometer. During Goldman tonometry, the force applied, Fg, and the acquired IOP should be recorded. As the proposed device is pushed onto the eyelid during initial calibration, one wants F1 to equal Fg:

$$F1 = Fg \qquad (9)$$

Equivalently, one wants the IOP of the proposed tonometer to equal the IOP from the Goldmann tonometry. As soon as the IOP equals the Goldman IOP, Ftot on Pot 2 should be noted by the microprocessor. F2 can be found by Ftot – F1. F2, the force exerted by the eyelid on the cup, accounts for the individual's eyelid characteristics when the cornea is applanated, and becomes Fref:

$$Fref = F2 \qquad (10)$$

For the subsequent IOP measurements, the microprocessor constantly determines F2 from Ftot and F1, and uses Fref as the reference for determining the cornea applanation point. If Fapp is enough to trigger Fref, F1 is recorded, the IOP is shown on the display, and a beep is sounded to indicate the completion of the IOP measurement. If Fapp is not enough for Fref to occur, two beeps are sounded and a "RP" (repeat - press harder) message is displayed. Figure 5.12 illustrates the process for the initial Fref calibration:

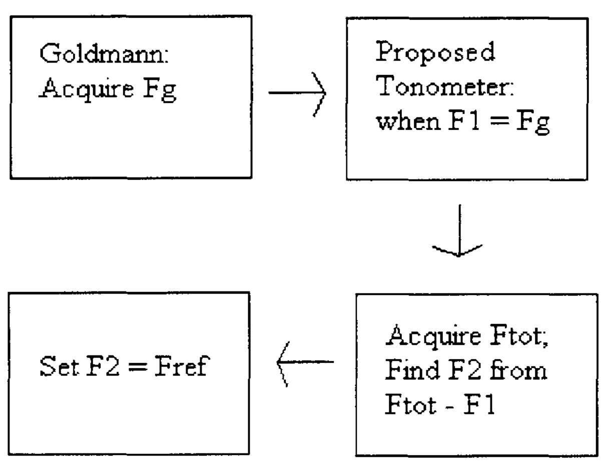


Figure 5.12: Setting Fref

Figure 5.13 shows the flow chart of the subsequent IOP measurement.

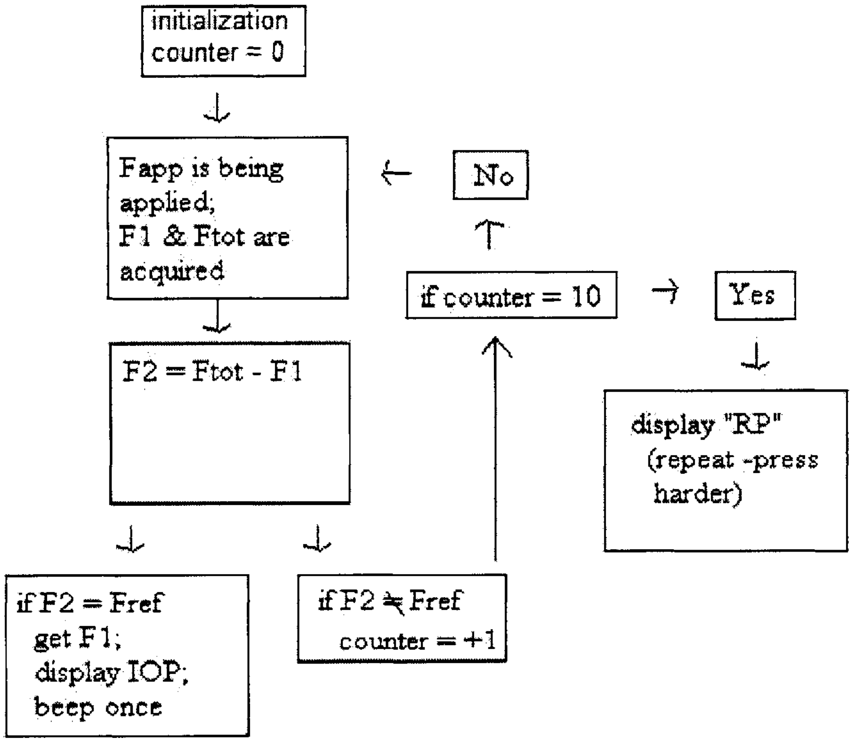


Figure 5.13: IOP Measurement

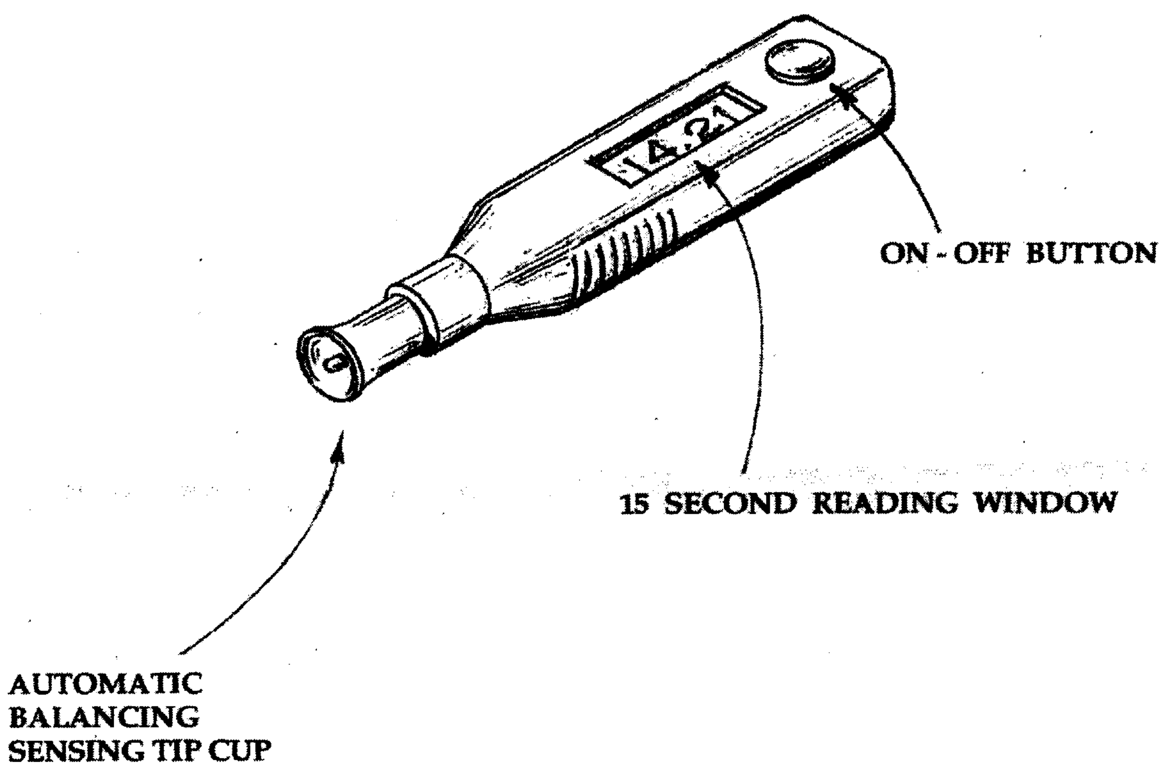
5.3.4 Challenges

The first prototype did not satisfy some of the design constraints. Though the construction cost was low, it lacked an LCD display, a buzzer system to aid in alignment, and a microprocessor.

5.4 Second Design and Prototype

The second design, as shown in Figure 5.14, addresses all of the design constraints.

OVER-THE-EYELID TONOMETER



OPERATION

First the on-off button is pressed, then the sensing tip cup is pressed over the eyelid and a beep alarm is heard. The sensor is then tilted until the sound stops indicating that the instrument is properly aligned. It is then pressed a little harder until a constant high pitch is heard. The instrument is then removed and the intraocular pressure will be shown at the reading window for 15 seconds and then go off by itself automatically to save battery life.

Figure 5.14: Second Tonometer Design – Dated March 25, 2005

5.4.1 Exterior

Parts of the second prototype exterior are shown in Figure 5.15. The back end of the tonometer is taken from the back end of a digital thermometer. The digital thermometer is used because it fulfills some of the design specifications: (1) the size is compact; (2) the LCD display is already installed; (3) the cost is low; and (4) the microprocessor is available. Figure 5.16 illustrates the original digital thermometer.

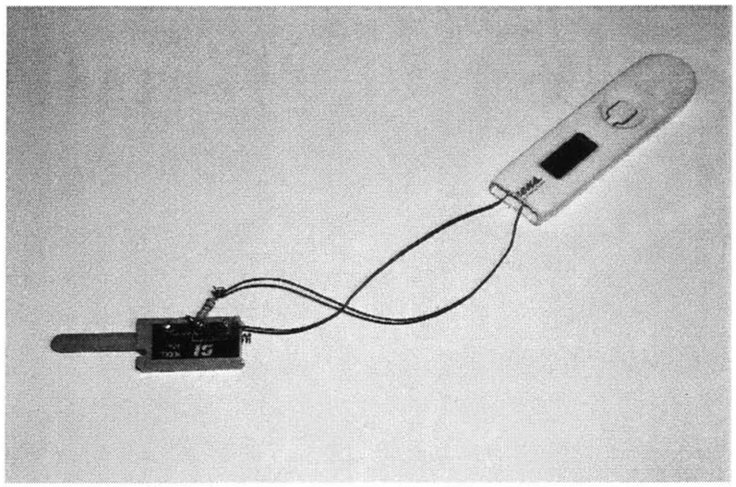


Figure 5.15: Parts of Second Prototype Exterior

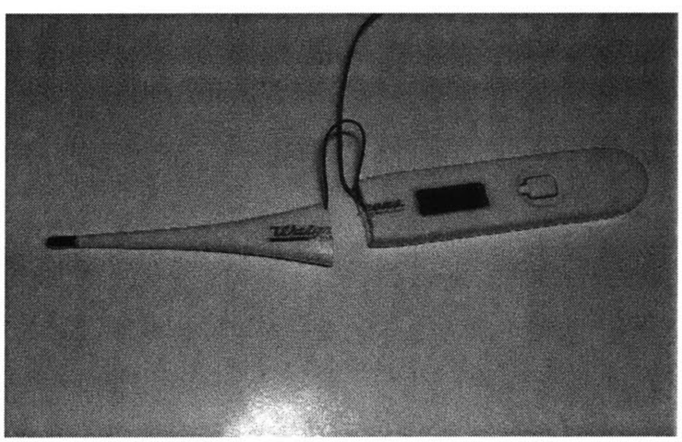


Figure 5.16: Digital Thermometer

The front end of the second prototype has not been built but the second design accounts for the first design's main deficiency: the tip has a buzzer system to help the patient align the device properly onto the eyelid to ensure the force is applied in the radial direction.

5.4.2 Interior

The interior of the second design is similar to the interior of the first design because the reference and IOP measurement potentiometers are needed. A microprocessor, a buzzer as shown in Figure 5.17, a battery for the buzzer as shown in Figure 5.18, and a LCD display are added.

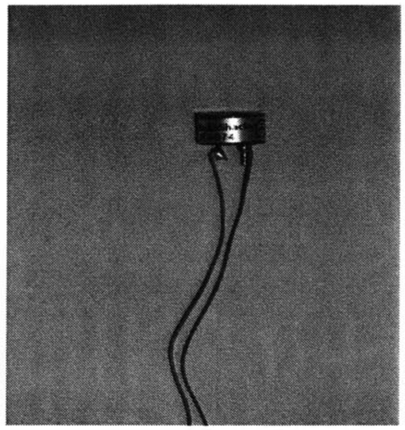


Figure 5.17: Buzzer

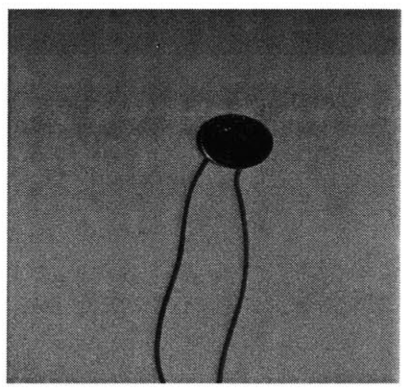


Figure 5.18: Battery

To display the IOP measurement on the LCD, the impedance of the linear potentiometer must be matched to the impedance of the digital thermometer's microprocessor. As shown in Figure 5.15, a 30kΩ resistor is added to the linear potentiometer. The value of the added resistor is determined by first treating the back end of the digital thermometer as a black box. It was found that the thermometer had an operating range from 30kΩ to 40kΩ. Since the linear potentiometer operated in the range from 0 to 10kΩ, an extra 30kΩ was added to change the operating range to 30kΩ to 40kΩ.

5.4.3 Improved Alignment System

The alignment system of the second design is improved by addressing the two sources of error as shown in Figure 5.19.

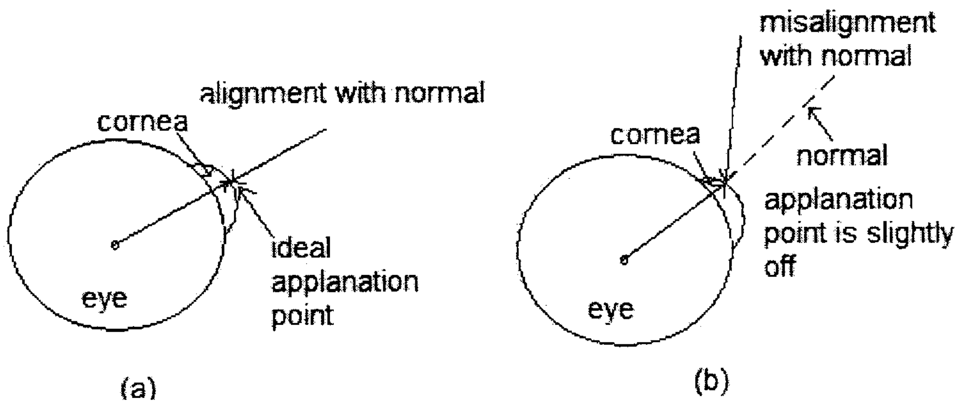


Figure 5.19: Two Sources of Error

Figure 5.19 (a) shows the ideal IOP measurement: (1) the applanation occurs at the most protruding point of the cornea; and (2) the tonometer's axis is collinear with the normal. Figure 5.19 (b) shows the two sources of error. First, the applanation does not occur at the most protruding point of the cornea. Second, the tonometer's axis is not collinear with the normal.

5.4.3.1 Consistent Applanation Point

To reduce the first source of error, a tripod system is proposed. As shown in Figure 5.20, the legs of the tripod are located on the forehead, the nasion, and the eyelid. The tripod enables a consistent applanation point because it provides more sensory motor feedback to the patient during the alignment process. Consistent applanation point is important because even if the ideal applanation point is not located, the consistent systematic error can be accounted by the initial calibration to the Goldmann tonometer.

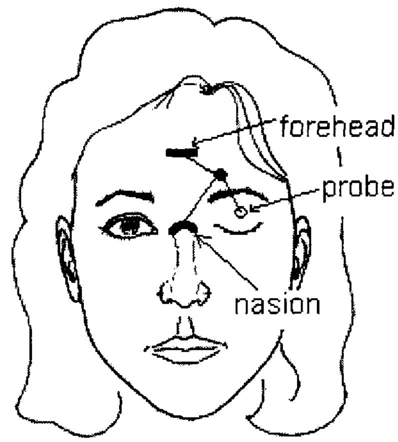


Figure 5.20: Tripod Location [25]

Figure 5.21 shows the enlargement of the tripod system. The tonometer is attached to a leg of the tripod through an adjustable end because it must align itself to the normal after the tripod is positioned on the consistent applanation point. Even after the normal alignment is accomplished, the tripod offers stability so the applied force is more likely to remain in the straight line during force application.

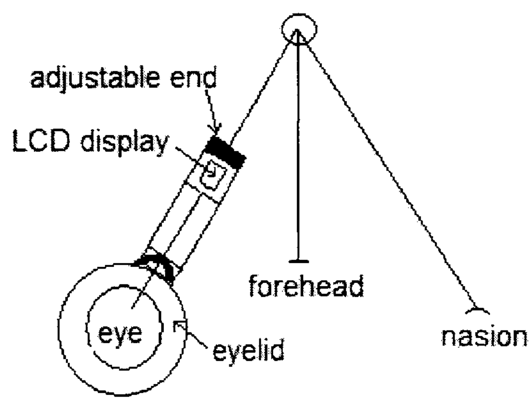


Figure 5.21: Tripod System

5.4.3.2 Redesigned Normal Alignment System

Though Section 5.2.3.1 suggested using three sensors on the cup rim to ensure the tonometer is collinear to the normal, this section proposes a simpler design for normal alignment. Figure 5.22 illustrates the sketch of the tonometer with the improved normal alignment system.

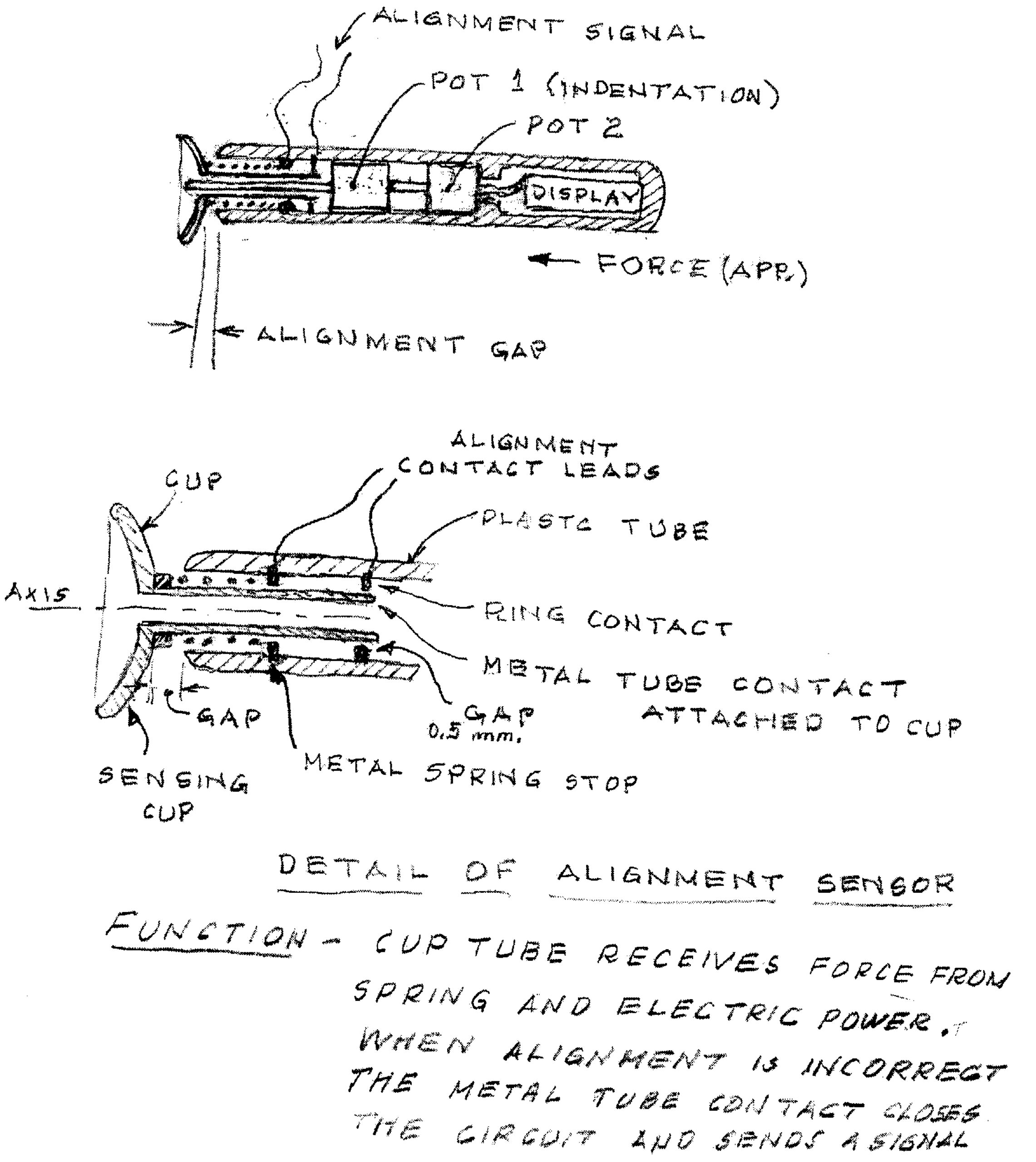
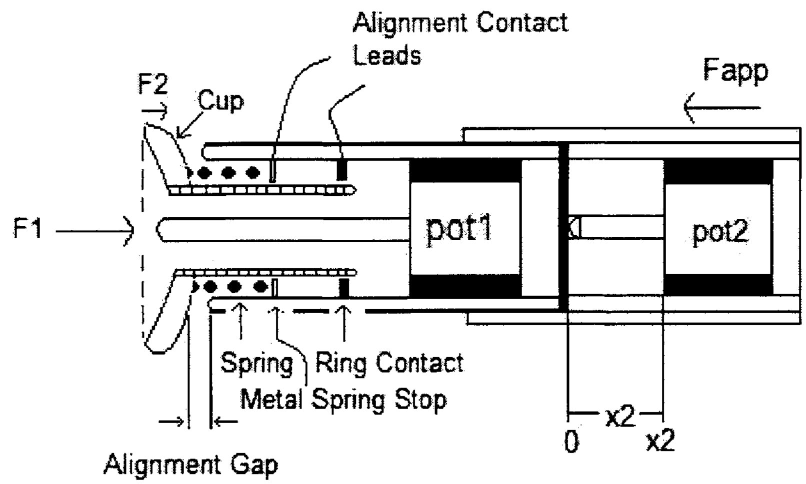


Figure 5.22: Redesigned Alignment System - Dated May 9, 2005

Figure 5.23 illustrates the mechanical details of the improved alignment system. The alignment system consists of a spring, shown as dots in the cross-sectional view, a metal spring stop, a ring contact, shown as solid rectangles, and alignment contact leads. The spring, which enables F2 to be transferred to Pot 2, is attached to the cup on one end and the metal spring stop on the other end. The mathematical model for this tonometer is the same as the model described in Section 5.3.3.2.a.



Fmax2 = kx2

Fmax2 >= Ftot2

Ftot2 = F1 + F2

Figure 5.23: Mechanical Details of Alignment System

The cup is connected to a metal tube. Between the metal tube and the ring contact is a small gap. If the metal tube touches the ring contact, the alignment contact leads close an electrical circuit and a beeping sound is produced to indicate the alignment is incorrect. Figure 5.24 illustrates how the system ensures normal alignment. In Figure 5.24 a, the probe is centered in the middle because the cup is balanced on the eyelid and the probe is collinear to the normal. In this case, the beeping sound is not heard because the metal tube is not touching the ring contact. In Figure 5.24 b and c, the metal tube touches the ring contact, signifying the probe is not perpendicular to the surface and a beeping sound is heard. In these cases, the patient must shift the tonometer until the beeping sound stops such that the probe is perpendicular to the eyelid. As a side note, if the force is applied horizontally, gravity would not cause the probe to sag and touch the ring contact because the user is applying a force on one end and the cup is touching the eyelid on the other end, which balances out the gravitational force.

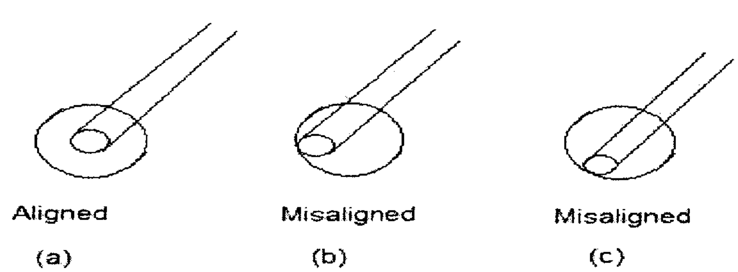


Figure 5.24: Probe Alignment

Chapter 6 Conclusion and Recommendation

The proposed through-the-eyelid tonometer offers many advantages over previous IOP measurement devices: (1) low cost; (2) compact size; (3) long-lasting (device automatically shuts off after measurement is taken to save battery life); (4) comfortable and simple self-tonometry system (includes a LCD display and a buzzer system to help with initial tonometer and eyelid alignment); and (5) calibration to the Goldmann tonometer to create a higher IOP measurement consistency. With the proposed tonometer, patients can take IOPs at different times throughout the day and average the IOPs to acquire a true IOP for better monitoring of glaucoma.

In the future, the second prototype should be completed and tested on human subjects.

Appendix A Expired Patents (1950 - 1979)

The table below lists expired patents from 1950 to 1979.

Patent Number	Inventor(s)	Name	Year	Month	Day
3,070,997	Papritz et al. (Goldmann)	Apparatus for Measuring The Intraocular or Tonometric Pressure of an Eye	1958	4	4
3,585,849	Grolman	Method and Apparatus for Measuring Intraocular Pressure	1971	6	22
3,597,964	Heine	Device for Testing by Applanation	1971	8	10
3,693,416	Dianetti	Applanation Tonometer Arrangement	1972	9	26
3,703,095	Holcomb et al.	Applanation Tonometer	1972	11	21
3,714,819	Webb	Applanation Tonometer Comprising Porous Air Bearing Support For Applanating Piston	1973	2	6
3,756,073	Lavallee et al.	Non-Contact Tonometer	1973	9	4
3,763,696	Krakau	Apparatus for Determining the Intraocular Pressure	1973	10	9
3,832,890	Grolman et al.	Non-Contact Tonometer Corneal Monitoring System	1974	9	3
3,832,891	Stuckey	Ocular Tension Measurement	1974	9	3
3,913,390	Piazza	Applanation Tonometer	1975	10	21
3,952,585	Perkins et al.	Applanation Tonometer	1976	4	27
3,977,237	Tesi	Tonometer	1976	8	31
4,089,329	Couvillon, Jr. et al.	Noninvasive, Continuous Intraocular Pressure Monitor	1978	5	16
4,172,447	Bencze et al.	Method and Apparatus for Investigation of Glaucoma in Eye Therapeutics	1979	10	3

Appendix B Summaries of Expired Patents (1950 - 1979)

Expired patents are summarized below. Novelty highlights the patent by describing the new tonometer arrangement, part, method, or reference point. Summary summarizes the patent. Published References cite important references. Occasionally, two patents share the Novelty, Summary, and Published References categories. This is intentional because the latter patent in the box is a continuation of the first patent.

B.1 Applanation Tonometry

Patent Number	Inventor(s)	Name	Novelty	Summary	Published References
3,070,997	Papritz et al. (Goldmann)	Apparatus for Measuring the Intraocular or Tonometric Pressure of an Eye	Predetermined area (diameter ranges from 2.7 to 4mm); adjustable force	IOP is determined from the force applied against the eyeball and the size of a flattened area of the cornea. The amount of force applied against the eyeball is adjusted to a value so that the flattened area reaches a predetermined constant size for each measurement. The adjusted force and the predetermined area are used to calculate the IOP. The predetermined constant area with diameter = 3.06 mm is chosen because the influences of the opposing forces on the eye (rigidity of the cornea and eye's wetting fluid) are eliminated.	
3,597,964	Heine	Device for Testing by Applanation	Determined weight (constant force)	A precisely determined weight provides a constant force which falls vertically downward along a central axis to applanate the cornea. The diameter of the flattened area is determined and is compared to the diameter which produces a normal IOP.	
3,693,416	Dianetti	Applanation Tonometer Arrangement	Biprism location: entrance pupil of optical system	Biprism is positioned so slight misalignment of the apparatus relative to the eye would not affect IOP.	
3,703,095	Holcomb et al.	Applanation Tonometer	Electric applanation tonometer (strain gage)	Pressure is taken when desired applanation triggers an electronic switch: electrical resistance changes as single electrode disc electrically and mechanically contacts the	

				eye.	
3,714,819	Webb	Applanation Tonometer Comprising Porous Air Bearing Support For Applanating Piston	Gas drives a piston attached to a sensing tip with hollow interior center to applanate the eye	Measured pressure in the hollow interior center is related to actual IOP by a constant of proportionality which is a function of the dimension of the pressure sensing head.	US 3,099,262 (pneumatic sensing tip)
3,763,696	Krakau	Apparatus for Determining the Intraocular Pressure	Probe contacting the eye vibrates at constant amplitude and frequency; pendulum arm provides static pressure between probe and eye	A loudspeaker with frequency oscillations at 20 Hz provides the mechanical oscillations. Reactional pressure exerted by the eye against the oscillations is determined by a pressure sensitive device (piezo-electric crystal) connected between the generator and the probe. Electrical outputs are sent to amplifiers and filters to generate a final output signal on a dial of an instrument.	
3,832,891	Stuckey	Ocular Tension Measurement	Applanating surface made of transparent material with same refractive index as tear fluid	Total internal reflection would not occur over the area of applanation when the material is the same as tear film. The applanating end would stop being a mirror and the applanted area can viewed at an angle incident to plane of applanation. The end may also be marked to define the "normal" diameter of the applanation area.	US 3,597,964 (Heine)
3,913,390	Piazza	Applanation Tonometer	Applanating surface made with fiber optic material	Reference markings and applanating surface are positioned without optical distortion to provide clear view of the cornea.	US 3,597,964 (Heine)
3,952,585	Perkins et al.	Applanation Tonometer	Portable version of Goldmann tonometer; springs apply adjustable forces	The applanating force forms an approximately linear relationship to the movement of the main spring. IOP is determined from the predetermined applanation area and the force.	
3,977,237	Tesi	Tonometer	Precise weight piston made with transparent material	Flattens a cornea area with a constant force and determines whether the flattened area is greater or less than a predetermined "normal" area.	US 3,597,964 (Heine)

B.2 Non-Contact Tonometry

Patent Number	Inventor	Name	Novelty	Summary	Published References
3,585,849	Grolman	Method and Apparatus for Measuring Intraocular Pressure	Photo-detection system, pneumatic system	An air pulse is directed at the cornea to deform its convexity to a slight concavity. During the process, the amount of light reflected off the cornea is detected and is plotted as a function of time. A maximum occurs when the cornea is applanated. The relationship between the reflected light and time is calibrated as a measure of IOP.	
3,832,890		Non-Contact Tonometer Corneal Monitoring System	Pneumatic alignment and corneal monitoring system are on same axis	Pneumatic alignment and corneal monitoring systems are located along the same axis normal.	
3,756,073	Lavallee et al.	Non-Contact Tonometer	Pneumatic alignment corneal monitoring systems aligned relative to cornea; air discharge only when systems aligned	The pneumatic and corneal monitoring systems are aligned relative to the cornea such that a target image reflected from the cornea is placed on an aiming reticule and on a photocell. Air pulse will discharge only when systems are aligned.	
4,172,447	Bencze et al.	Method and Apparatus for Investigation of Glaucoma in Eye Therapeutics	Sampling IOP at different pulsation points	IOP is measured at systolic and diastolic moments during a pulse. The samples are compared to give an indication of the dynamic eye performance caused by the dynamic air puff pressure.	

B.3 Others

Patent Number	Inventor	Name	Novelty	Summary	Published References
4,089,329	Couvillon, Jr. et al.	Noninvasive, Continuous Intraocular Pressure Monitor	Planar-faced pressure transducer with strain gage elements is fixed in a protruding section of a compliant hydrogel ring placed on the sclera	Strain gage elements sense the variations in resistance caused by the applied stress to the transducer diaphragm. These resistances are converted to IOP measurements and recorded as IOP as a function of the time-of-day.	

Appendix C Patents (1980 - 2005)

The table below lists patents from 1980 to 2005.

Patent Number	Inventor(s)	Name	Year	Month	Day
4,523,597	Sawa et al.	Apparatus and Method For Measuring the Intraocular Pressure of An Eyeball and Auxiliary Device for Using Therewith	1985	6	18
4,621,644	Eilers	Automatic Applanation Tonometer	1986	11	11
4,624,235	Krabacher et al.	Force-Triggered Applanation Tonometer	1986	11	25
4,628,938	Lee	Continuous Applanation Tonometer	1986	12	16
4,705,045	Nishimura	Non-Contact Tonometer	1987	11	10
4,724,843	Fisher	Tonometer	1988	2	16
4,735,209	Foody	Sterilizable Applanation Tonometer	1988	4	5
4,747,296	Feldon et al.	Electronic Tonometer with Baseline Nulling System	1988	5	31
4,759,370	Kozin et al.	Ophthalmotonometer	1988	7	26
4,766,904	Kozin et al.	Applanation Tonometer	1988	8	30
4,860,755	Erath	Differential Pressure Applanation Tonometer	1989	8	29
4,922,913	Waters, Jr. et al.	Intraocular Pressure Sensor	1990	5	8
4,928,697	Hsu	Non-Contact High Frequency Tonometer	1990	5	29
4,947,849	Takahashi et al.	Non-Contact Type Tonometer	1990	8	14
4,951,671	Coan	Tonometry Apparatus	1990	8	28
4,987,899	Brown	Applanation Tonometer	1991	1	29
5,002,056	Takahashi et al.	Non-Contact Type Tonometer	1991	3	26
5,012,812	Stockwell	Applanation Tonometers	1991	5	7
5,031,623	Kohayakawa et al.	Non-Contact Tonometer	1991	7	16
5,042,484	Hideshima	Air Puff Type Tonometer	1991	8	27
5,048,526	Tomoda	Gas Jet Shooting Device for Use with a Non-Contact Tonometer	1991	9	17
5,070,875	Falck et al.	Applanation Tonometer Using Light Reflection to Determine Applanation Area Size	1991	12	10
5,076,274	Matsumoto	Non-Contact Tonometer	1991	12	31
5,107,851	Yano	Non-Contact Tonometer	1992	4	28

5,131,739	Katsuragi	Ophthalmological Instrument For Cornea Curvature and Pressure Measurement	1992	7	21
5,148,807	Hsu	Non-Contact Tonometer	1992	9	22
5,165,408	Tomoda	Gas Jet Shooting Device for Use with a Non-Contact Tonometer	1992	11	24
5,165,409	Coan	Tonometry Apparatus	1992	11	24
5,174,292	Kusar	Hand Held Intraocular Pressure Recording System	1992	12	29
5,176,139	Fedorov et al.	Method for Estimation of Intraocular Pressure using Free-Falling Ball	1993	1	5
5,179,953	Kusar	Portable Diurnal Intraocular Pressure Recording System	1993	1	19
5,190,042	Hock	Apparatus and Determining Intraocular Pressure	1993	3	2
5,197,473	Fedorov et al.	Ocular Tonometer For Estimation of Intraocular Pressure Using Free-Falling Ball	1993	3	30
5,203,331	Draeger	Applanation Tonometer	1993	4	20
5,349,955	Suzuki	Tonometer	1994	9	27
5,355,884	Bennett	Applanation Tonometer For Measuring Intraocular Pressure	1994	10	18
5,375,595	Sinha et al.	Apparatus and Method For Non-Contact, Acoustic Resonance Determination of Intraocular Pressure	1994	12	27
5,396,888	Massie et al.	Non-Contact Tonometer and Method using Ultrasonic Beam	1995	3	14
5,474,066	Grolman	Non-Contact Tonometer	1995	12	12
5,546,941	Zeimer et al.	Patient Operated Tonometers	1996	8	20
5,634,463	Hayafuji	NonContact Type Tonometer	1997	6	3
5,636,635	Massie et al.	Non-Contact Tonometer	1997	6	10
5,638,149	Machemer et al.	Motorized Applanation Tonometer	1997	6	10
5,671,737	Harosi	Self-Operable Tonometer For Measuring Intraocular Pressure Of a Patient's Eye	1997	9	30
5,727,551	Takagi	Non-Contact Tonometer	1998	3	17
5,735,275	Ballou et al.	Tonometer Utilizing Hydraulic Pressure	1998	4	7
5,754,273	Luce	Non-Contact Tonometer Having Off-Axis Fluid Pulse System	1998	5	19
5,779,633	Luce	Tonometer Air Pulse Generator	1998	7	14
5,830,139	Abreu	Tonometer System For Measuring Intraocular Pressure By Applanation And/Or Indentation	1998	11	3
5,833,606	Haraguchi	NonContact Tonometer For Measuring Intraocular Pressure	1998	11	10
5,836,873	Fresco	Tonometer	1998	11	17
5,865,742	Massie	Non-Contact Tonometer	1999	2	2
5,946,073	Miwa	Non-Contact Type Tonometer	1999	8	31
5,954,645	Luce	Applanation Detection System For A Non-Contact Tonometer	1999	9	21
5,964,704	Hayafuji	Intraocular Pressure Measuring Apparatus	1999	10	12

6,030,343	Chechersky et al.	Single Beam Tone Burst Ultrasonic Non-Contact Tonometer and Method of Measuring Intraocular Pressure	2000	2	29
6,053,867	Iijima	NonContact Tonometer For Measuring Intraocular Pressure	2000	4	25
6,083,160	Lipman	Applanation Tonometry Apparatus	2000	7	4
6,083,161	O'Donnell, Jr.	Apparatus and Method for Improved Intraocular Pressure Determination	2000	7	4
6,093,147	Kontiola	Apparatus for Measuring Intraocular Pressure	2000	7	25
6,113,542	Hyman et al.	Diagnostic Apparatus and Method To Provide Effective Intraocular Pressure Based on Measured Thickness of the Cornea	2000	9	5
6,159,148	Luce	Non-Contact Tonometer Having Non-Linear Pressure Ramp	2000	12	21
6,193,656	Jeffries et al.	Intraocular Pressure Monitoring/Measuring Apparatus and Method	2001	2	27
6,579,235	Abita et al.	Method for Monitoring Intraocular Pressure Using a Passive Intraocular Pressure Sensor and Patient Worn Monitoring Recorder	2003	6	17
6,251,071 B1	Fresco et al.	Tonometer	2001	6	26
6,361,495 B1	Grolman	Hand-Held Non-Contact Tonometer	2002	3	26
6,413,214 B1	Yang	Applanating Tonometers	2002	7	2
6,419,631 B1	Luce	Non-Contact Tonometry Method	2002	7	16
6,447,449 B1	Fleischman et al.	System for Measuring Intraocular Pressure of an Eye and a MEM Sensor for Use Therewith	2002	9	10
6,524,243 B1	Fresco	Tonometer Incorporating An Electrical Measurement Device	2003	2	25
6,570,235 B1	Abita et al.	Method for Monitoring Intraocular Pressure Using A Passive Intraocular Pressure Sensor and Patient Worn Monitoring Recorder	2003	6	17
6,595,920 B2	Walton	Non-Contact Instrument For Measurement of Internal Optical Pressure	2003	7	22
6,616,609 B2	Siskowskiet al.	Method for Optimizing Piston Diameter in a Non-Contact Tonometer, and Non-Contact Tonometer Having Fluid Pump Designed by Said Method	2003	9	9
6,623,429 B2	Percival et al.	Hand-Held Non-Contact Tonometer	2003	9	23
6,706,001 B2	Fresco	Dual Tonometer Pressure Measurement Device	2004	3	16
6,712,764 B2	Jeffries et al.	Intraocular Pressure Monitoring/Measuring Apparatus and Method	2004	3	30
6,726,625 B2	Luce	Non-Contact Tonometer Having Improved Air Pump	2004	4	27
6,736,778 B2	Falck, Jr. et al.	Replaceable Prism for Applanation Tonometer	2004	5	18
6,746,400 B2	Rathjen	Devices and Methods for Determining the Inner Pressure of An Eye	2004	6	8
6,749,568 B2	Fleischman et al.	Intraocular Pressure Measurement System Including a Sensor Mounted in a Contact Lens	2004	6	15
6,776,756 B2	Feldon et al.	Applanation Tonometer	2004	8	17

Appendix D Summaries of Patents (1980 - 2005)

Patents are summarized below. Novelty highlights the patent by describing a new tonometer arrangement, part, method, or reference point. Summary summarizes the patent. Published References cite other important references. Occasionally, the Novelty, Summary, and Published References categories are shared by more than one patent. This is intentional because the latter patent(s)/patent application(s) in the box is/are a continuation of the first patent.

D.1 Applanation Tonometry

Patent Number	Inventor(s)	Name	Novelty	Summary	Published References
4,523,597	Sawa et al.	Apparatus and Method For Measuring the Intraocular Pressure of An Eyeball and Auxiliary Device for Using Therewith	Better control of cornea flattening process with the use of a rotating stepping motor; less fluorescein is used; ability to measure IOP changes due to beating of the heart	First, a stepping motor is constructed to more accurately control the amount of cornea flattening. Second, the tonometer is capable of measuring changes in IOP due to the beating of the heart: maximum and minimum IOPs are recorded and then averaged. Finally, the amount of fluorescein used on the cornea is minimized. Even if the fluorescein ring is not circular, IOP can be measured with high accuracy with the improved tonometer.	US 3,070,997 (Papritz et. al)
4,621,644 4,624,235	Eilers Krabacher et al.	Automatic Applanation Tonometer Force-Triggered Applanation Tonometer	Footplate with measurable force	The applied force and the applanated area are constantly sensed until the applanated area equals the predetermined applanation area. The force urging the footplate is processed and IOP is determined.	US 3,070,997 (Papritz et. al)
4,628,938	Lee	Continuous Applanation Tonometer	Continuous IOP monitoring using contact lens with inflatable applanating chamber; pump moves noncompressible fluid	A thin, ultraflexible membrane on the concave surface of the contact lens is capable of being inflated with a noncompressible fluid to indent a predetermined area of the eye. The fluid pressure in the chamber used to indent the predetermined area is directly proportional to the IOP. During the	

			from reservoir to chamber	applanation process, the contact lens remains adherent to the eye; if the lens become detached from the ocular surface, the area of the eye being applanated would be variable and the measured IOP would be inaccurate. Various factors such as the surface tension between the contact lens and the surface of the eye, and the base curve of the contact lens, are also accounted during IOP calculation.	
4,735,209	Foody	Sterilizable Applanation Tonometer	Pivotable housing for sterilization	Sterilizes corneal contact surface of tonometer after each use.	
4,747,296	Feldon et al.	Electronic Tonometer with Baseline Nulling System	LCD readout display; reference baseline signal is created by equalizing differential inputs of amplifying stages (gain of zero, and carrier signal removed)	A pressure sensitive element produces a voltage proportional to IOP. An electrical waveform is produced by bringing the transducer in contact with the cornea. The waveform is converted to a digital signal and processed by a microprocessor. The microprocessor processes the differential levels of the signals and uses criteria such as slope and configuration of the waveform for accepting a reading as valid and the average IOP and IOP reliability estimates are displayed. A reference baseline is created by equalizing differential inputs on the amplifying stages, resulting in a gain of zero and removing any carrier signal.	
4,759,370	Kozin et al.	Ophthalmotonometer	Frequency-output transducer of linear motions; a reference-frequency generator; a frequency comparator	Frequency comparator compares frequencies from linear motions transducer with reference frequency to calculate IOP. IOP is related to the length of the plunger displacement.	
4,766,904	Kozin et al.	Applanation Tonometer	Rod with contact disk is arranged coaxially with main sleeve	The main sleeve has an inside diameter equal to a preset value of the applanation circle diameter and is arranged coaxially with a rod carrying the cornea contact disk at the terminal end. The rod traverses along the rod axis. When the contact disk becomes coplanar with the main sleeve, a contact triggers the recording of the force at the applanating moment.	
4,860,755	Erath	Differential Pressure	Inner and outer probes	Due to the shape of the eye, the inner probe	"Fast,

		Applanation Tonometer	are arranged coaxially; IOP is determined by the difference in longitudinal forces applied by the eye to the inner and outer probes	contacts the eye first and the outer probe follows. To flatten the cornea, a greater force will be exerted by the eye's hydrostatic pressure on the inner probe than on the outer probe. As the device is moved into full contact with the eye, the pressure difference between the inner and outer probes rises until outer probe contacts the eye, after which the pressure difference will plateau. The difference in force or pressure is sensed and IOP is determined.	Automatic Ocular Pressure Measurement Based on an Exact Theory," IRE Transactions on Medical Electronics, MacKay & Marg, Apr. 1960, pp. 61-67
4,951,671	Coan	Tonometry Apparatus	Air chamber with deformable wall portion is inflated as the contact surface applanates the eye	The back of the contact surface is attached to the air chamber. As the air chamber is inflated with air, the contact surface presses against the eye until a predetermined area is applanated and the air chamber pressure is recorded. IOP is calculated from the air chamber pressure and the predetermined area.	
4,987,899	Brown	Applanation Tonometer	Measures IOP in one step by using second unused optical axis of the bimicroscope	Arrangement using mirrors and/or prisms allows the display of IOP along the normally unused optical viewing axis of the bimicroscope. As a result, both the compressed corneal surface and IOP can be viewed simultaneously.	US 3,070,997 (Papritz)
5,012,812	Stockwell	Applanation Tonometers	Springs are arranged to prevent coils from binding to each other	Tonometer is redesigned to prevent errors in estimating the force. Two spiral springs are arranged in series between the knob and the arm via an intermediate spindle to provide a low-rate spring arrangement while eliminating coil bindings on each other.	US 3,952,585 (Perkins)
5,070,875	Falck et al.	Applanation Tonometer Using Light Reflection to Determine Applanation Area Size	Applanating surface of a prism; Snell's Law of refraction is used	Snell's Law of refraction is used to determine the size of an applanated area on the cornea. The tonometer divides the light incident on an applanating prism surface: a portion of the light transmits through the prism surface in the applanated area and another portion of the light	US 3,070,997 (Papritz)

				reflects around the applanated area. Both portions vary with the size of the applanated area and the tonometer detects one portion to determine the size of the applanated area. IOP can be determined from the difference in force required to change the applanation from the reference size to the applanted size. Springs are used to determine force.	
5,165,409	Coan	Tonometry Apparatus	Magnets used for preventing probe's rearward movement	A probe is capable of moving forward and backward. It moves forward to progressively deform the eye until a predetermined applanation area is reached. The rearward movement is prevented by magnetic repulsion as magnets are placed at the rear end of the probe and in the housing. Applied force is measured at the predetermined applanation area.	
5,190,042	Hock	Differential Pressure Applanation Tonometer	Prism is pressed against the eye as force and the corresponding applanated area are measured	As a measurement prism is continuously pressed against the eye by a spring-pretensioned motion, a plurality of force and the corresponding applanted area are acquired. The values are plotted in a curve so IOP can be determined differentially from the measured values.	
5,203,331	Draeger	Applanation Tonometer	Means for self tonometry with forehead support to stabilize the tonometer	Unit automatically measures applanation area and force as a linear motor displaces a probe towards the eye	
5,355,884	Bennett	Applanation Tonometer For Measuring Intraocular Pressure	Two different ways are proposed to ensure predetermined applanation area is reached before force is taken with force sensor	To ensure the reference probe-corneal surface contact is attained, two tonometry arrangements are offered. In the first embodiment, a signal originating from a light source is reflected from the corneal surface through the probe to a photosensor. The reflected light increases with increasing probe-corneal surface contact. In the second embodiment, an electronic signal from the probe-corneal surface contact is measured by a voltmeter and is inversely proportional to the probe-corneal contact.	US 3,070,997 (Papritz)
5,546,941	Zeimer et al.	Patient Operated Tonometers	A stepper motor and a bellows control the probe	To minimize the applied force on the eye, a stepper motor accurately drives the bellows, which	US 5,203,331 (Draeger)

			movement towards the eye; a laser improves centering of the eye and detects predetermined applanation; an occluder blocks the eye not being tested; a safety detection device terminates operation if probe fails to move in the barrel	pressurizes the barrel, to propel the probe towards the eye. In the beginning, the air pressure behind probe is high to overcome the static inertia of the probe. Once the probe moves, the pressure behind the probe is reduced so the probe is not accelerated. When the probe contacts the eye, the air pressure behind the probe is elevated rapidly so the applanation occurs before the patient withdraws his/her head from probe. The laser centers the patient's eye and detects whether the predetermined area is reached. A safety detection device terminates operation if the probe fails to move along the barrel after a certain amount of pressure built up.	
5,638,149	Machemer et al.	Motorized Applanation Tonometer	Improvement on conventional tonometer motor	The unit is mounted in operative relationship to a conventional tonometer adjustment wheel to improve adjustment ease during IOP measurement.	
5,671,737	Harosi	Self-Operable Tonometer For Measuring Intraocular Pressure Of a Patient's Eye	Video camera detects applanated area; force transducer measures force; IOP is determined from a plurality of force and applanated area data	Force is measured with a force transducer which includes a variable capacitor. Applanated area is detected optically with a video camera which senses light reflected from the cornea through a window in the probe, and provides signals indicating the applanated area to a central processing unit (CPU). CPU receives at least two samples for the force and the area of applanation data and determines IOP by performing image analysis on data from the video camera and linear regression analysis on force and area measurements.	
5,830,139	Abreu	Tonometer System For Measuring Intraocular Pressure By Applanation And/Or Indentation	Determines IOP by applanation and by indentation method	The tonometer is arranged to calculate IOP in two ways: applanation and indentation. By applanation: the amount of force is detected when the predetermined applanation is achieved. By indentation: the indenting distance, which is inversely proportional to IOP, is acquired when the predetermined force is applied to the eye.	
6,083,160	Lipman	Applanation Tonometry Apparatus	Light conducting pressure applicator assembly;	The probe has a light conducting contact face and an imaging transducer at the opposite end. The	

			imaging transducer to indicate when the predetermined area is reached	transducer receives an optical image of subject's cornea and converts optical image to electrical signals to indicate when the predetermined area is applanated.	
6,113,542	Hyman et al.	Diagnostic Apparatus and Method To Provide Effective Intraocular Pressure Based on Measured Thickness of the Cornea	Pachymetric probe measures corneal thickness	As the applanation probe touches the eye, the pachymeter generates a signal indicative of the central corneal thickness. Calculated IOP automatically corrects for corneal thickness variations.	"Applanation Tonometry and Central Corneal Thickness", Ehlers et al., *Acta Ophthalmologica* 53: 34-43 (1975)
6,413,214 B1	Yang	Applanating Tonometers	Light-transmitting contact face for applanated area measurement; dynamic forces are compensated during force measurement process	The applanating element has a light transmitting contact face for projecting a light beam on the cornea and for passing reflected light. The reflected light is used to calculate the applanated area. Force is detected by a force transducer. Progressive measurements of the force and reflected measurement are analyzed accordingly to compensate for dynamic force components that may appear in the measurement of the force on the applanating element. IOP is determined by the predetermined applanating area and the applied force.	
6,447,449 B1 6,749,568 B2 2002/0177768 A1	Fleischman et al.	System for Measuring Intraocular Pressure of an Eye and a MEM Sensor for Use Therewith Intraocular Pressure Measurement System Including a Sensor Mounted in a Contact Lens Apparatus and Method for Measuring Intraocular	A contact lens includes an outer non-compliant region and inner compliant region fabricated as an impedance element that varies in impedance as the inner compliant region changes shape.	An applanator applies an external force to the outer region until the sensor engages the surface portion of the eye causing the compliant region to change shape and vary in impedance. The impedance region is energized and the representative pressure is determined every time the element is energized. IOP is derived from a series of representative pressure measurements.	

2002/0193674 A1		Pressure Measurement System Including a Sensor Mounted in a Contact Lens		Sensor further comprises a conductive region electrically coupled to the impedance element of the compliant region and responsive to external signal for energizing the impedance element.	
6,736,778 B2 2001/0002430 A1	Falck, Jr. et al.	Replaceable Prism for Applanation Tonometer Method of Operating Tonometer	Replaceable prism for contacting cornea has emitter and detector ports	Emitter and detector ports are arranged opposite each other on opposite sides of a longitudinal axis, with ports aimed at 45 degrees to longitudinal axis. The portion of the light internally reflected from the applanation surface area provides a signal indicating the size of the applanated area.	
6,776,756 B2	Feldon et al.	Applanation Tonometer	Optics array to obtain eye image; a force transducer to measure force	A force transducer measures force applied during applanation while an image sensor uses optic arrays to obtain data image of the eye. IOP is calculated by using one or more pairs of measured force and applanated area. Geometric properties of eye such as the diameter, and the major and minor axes of cornea, are also accounted in the calculation.	

D.2 Non-Contact Tonometry

D.2.1 Air Puff

Patent Number	Inventor(s)	Name	Novelty	Summary	Published References
4,705,045	Nishimura	Non-Contact Tonometer	Alignment system with projection optical system and an alignment verification optical system	The alignment optical system comprises a projection optical system and an alignment verification optical system. The projection optical system projects a pair of target rays for alignment verification towards the cornea. The alignment verification optical system guides the reflections of the target rays to the objective lens. When an optical axis of the projection optical system is made coincident with the focal point of the cornea and the reflected target images are formed by the objective lens, alignment verification is effected based on duplication of the pair of target images.	
4,724,843	Fisher	Tonometer	Hand-held system; amount of cornea applanation is determined by image contrast	The amount of cornea applanation is detected using image contrast (difference in light level), not the total amount of collected light.	
4,947,849 5,002,056	Takahashi et al.	Non-Contact Type Tonometer Non-Contact Type Tonometer	Optical detection system using rotary solenoid, a cylinder, and a rotary solenoid driving circuit	An optical system detects the amount of cornea applanation while the air flow pressure is continuously sensed. As the cornea transfigures, a function curve is obtained to correlate the flow pressure and the amount of cornea applanation to deduce IOP.	
5,031,623	Kohayakawa et al.	Non-Contact Tonometer	Plural sensor elements to detect cornea deformation even when eye alignment is off	Even if the eye alignment is inaccurate, the tonometer can detect off-central axis light reflected from the cornea using the plural sensor elements and can compensate for misalignment to calculate IOP when the cornea is deformed by a predetermined amount.	
5,042,484	Hideshima	Air Puff Type Tonometer	Measures IOP irrespective of cornea	IOP is measured irrespective of cornea irregularity and differences in reflectance. The tonometer includes a	

			irregularity and differences in reflectance	device for setting the comparison reference value based on the quantity of light received by the alignment sensor rather than the presumed constant maximum or minimum reflectance.	
5,048,526 5,165,408	Tomoda	Gas Jet Shooting Device for Use with a Non-Contact Tonometer Gas Jet Shooting Device for Use with a Non-Contact Tonometer	Filter added to tonometer	Air sent out of the tonometer is filtered so cornea is applanated by clean, dust-free air	
5,076,274	Matsumoto	Non-Contact Tonometer	Detecting system detects speed of cornea deformation	The tonometer deforms the cornea to a predetermined amount. A detecting system detects the speed of cornea deformation and a calculating system uses the information to calculate IOP.	
5,107,851	Yano	Non-Contact Tonometer	Two air pressure ranges for high and low IOP measurements	The tonometer is designed not to supply excess air to the cornea. Thus, the device is capable of selecting a first air pressuring range for measurement of low IOP and a second pressuring range with a higher degree of air pressurization for measurement of a high IOP.	
5,131,739	Katsuragi	Ophthalmological Instrument For Cornea Curvature and Pressure Measurement	Tonometer and keratonmeter in one	The device measures radius of curvature and IOP simultaneously because both measurements require alignment.	
5,474,066	Grolman	Non-Contact Tonometer	Corneal thickness is measured before IOP is taken	Light source is pulsed just prior to IOP to illuminate a central corneal section to measure corneal thickness. IOP is compensated if corneal thickness deviates from norm.	
5,634,463	Hayafuji	NonContact Type Tonometer	Measures IOP much higher than normal; circuit controls air discharge	The tonometer is capable of measuring IOP much higher than normal. A circuit determines the moment for stopping the air discharge according to the discharge pressure detected by the pressure detecting means.	
5,727,551	Takagi	Non-Contact Tonometer	Measures IOP on the basis of the maximum	The tonometer determines IOP through the maximum value of a correlation function curve between a standard	

			value of a correlation curve	light value and a light changing value, instead of detecting a peak of a light changing curve.	
5,754,273	Luce	Non-Contact Tonometer Having Off-Axis Fluid Pulse System	Fluid axis forms a non-zero angle with the eye's fixation axis	The tonometer uses an alignment system where the gaze of the eye is fixed in the direction of the fixation axis and a fluid axis forms a non-zero angle with the fixation axis. This arrangement avoids (1) the need to relocate a patient's upper eyelid in situations where the patient's natural eyelid position interferes with the fluid pulse directed along coincident fluid and fixation axis, and (2) the need to applanate a surgically altered central region of the cornea in patients who have undergone photo-refractive keratotomy.	
5,779,633	Luce	Tonometer Air Pulse Generator	Uses a bi-directional linear motor to reduce unnecessary air pulse	The tonometer reduces unnecessary air pulse energy delivered to an eye by using a bi-directional linear motor. After receiving an applanation signal, the motor controller reverses current flow in coil of motor to reverse the electromagnetic force to stop generation of air pulse.	
5,833,606	Haraguchi	NonContact Tonometer For Measuring Intraocular Pressure	Plurality of energy storing mechanisms	The tonometer is capable of measuring IOP soon after a preceding measurement through the use of a plurality of energy storing mechanisms.	
5,946,073 2002/0103427 A1	Miwa	Non-Contact Type Tonometer Non-Contact Type Tonometer	Associates different IOP measurements to different phase points in pulsation	The tonometer has three parts: (1) IOP measurement; (2) pulsation measurement; and (3) measurement timing determination. IOP measurement detects the deformed state of the cornea and determines IOP; pulsation measurement detects the patient's pulsation; the measurement timing determination decides measurement timing based on the detected pulsation to obtain a predetermined number of IOPs in synchronization with different phase points in the pulsation.	
5,954,645	Luce	Applanation Detection System For A Non-Contact Tonometer	Non-telecentric applanation detection system uses a plurality of photosensitive detector array	The system uses a plurality of photosensitive detector array which enables the relaxation of the instrument alignment requirements. The detector array generates different signal curves for light energy received at different locations on the array as a function of time.	

				The signal curves are evaluated to determine an optimal signal curve to indicate the moment of applanation.	
5,964,704	Hayafuji	Intraocular Pressure Measuring Apparatus	Shortens IOP measurement time	The tonometer shortens an IOP measurement time by decreasing the charge time of the condenser. (The condenser connects to the solenoid which activates the piston to cause a nozzle to spray air out of the tonometer.)	
6,053,867	Iijima	NonContact Tonometer For Measuring Intraocular Pressure	XY-alignment detecting circuit; corneal thickness adjustment	The tonometer sends an air puff only after the XY-alignment detecting circuit declares the measuring unit is in a predetermined range narrower than and in an allowable alignment range when the alignment of the IOP unit is readjusted after the thickness of a specific corneal section is measured.	
6,159,148	Luce	Non-Contact Tonometer Having Non-Linear Pressure Ramp	Reduces energy used for corneal deformation	Impulse energy delivered to the eye is reduced by providing a linearly increasing current source for driving the piston mechanism to create a non-linearly increasing relationship between pressure and time.	
6,361,495 B1	Grolman	Hand-Held Non-Contact Tonometer	3D alignment; color diodes indicates IOP measurement range	A 3D alignment system is used to align the eye to the system. Color diodes are used to indicate the IOP result: safe, borderline, or elevated pressure.	
6,419,631 B1	Luce	Non-Contact Tonometry Method	Measures the plenum pressure when the cornea is applanated and when the cornea returns to convexity	A fluid pulse is directed at the cornea to cause reversible deformation of the cornea from convexity to concavity, and back through convexity. Throughout the process, the plenum pressure of the pump mechanism generating the pulse is measured. These values are recorded as function of time and regressions are performed to generate IOP without the corneal effect.	
6,595,920 B2	Walton	Non-Contact Instrument For Measurement of Internal Optical Pressure	Interferometer is included in a tonometer	The tonometer directs a beam of light along the path to the cornea by incorporating an interferometer.	US 5,963,568 (Paoli)
6,616,609 B2	Siskowski et al.	Method for Optimizing Piston Diameter in a Non-Contact Tonometer, and Non-Contact Tonometer	Piston diameter is selected based on target applanation constraints	Piston diameter is selected based on stroke length limitations and target applanation pressure requirements after a fluid pump system is numerically simulated through its compression strokes by a software program.	

		Having Fluid Pump Designed by Said Method			
6,623,429 B2	Percival et al.	Hand-Held Non-Contact Tonometer	Hand held; 3D alignment system; infrared data association transceiver for wireless uploading of measurement data to a remote computer	A hand held tonometer uses a 3D alignment system to guide the operator in positioning the eye relative to the system. Wireless data uploading to a remote computer is done through an infrared data association transceiver.	
6,726,625 B2	Luce	Non-Contact Tonometer Having Improved Air Pump	Improved fluid pump system	The alignment is improved by decoupling the piston from the driven member to eliminate the need for critical alignment between the driven member and piston.	

D.2.2 High Frequency Light/Sound Waves

Patent Number	Inventor(s)	Name	Novelty	Summary	Published References
4,928,697	Hsu	Non-Contact High Frequency Tonometer	Head rest for stabilization; reflected high frequency waves are amplitude modulated; collector collects less beams when IOP is high	Low frequency sound waves (10 -500 Hz) are sent to perturb a given corneal area and high frequency sound waves (10KHz to 1MHz) are directed toward the perturbed corneal area. The curvature of the cornea is dependent on IOP. When IOP is high, the cornea bulges more. Therefore, the incident high frequency waves are more diverged as they are reflected towards the receiver, and the collector collects less of the beams. The reflected waves are amplitude modulated as the surface is perturbed by low frequency waves and the output signals are directly related to IOP.	
5,148,807		Non-Contact Tonometer	High frequency sound or light waves	Uses techniques of frequency/phase modulation to determine IOP	

5,375,595	Sinha et al.	Apparatus and Method For Non-Contact, Acoustic Resonance Determination of Intraocular Pressure	Ultrasound with different frequencies is swept onto the eye; a fiber-optic reflection vibration sensor detects resonant vibrations	Resonant frequency of the eye is dependent on IOP; changes in IOP can be determined after a reference pressure is established. An ultrasonic transducer sweeps a range of audio frequencies in which human eyes can resonate onto the eye. A fiber-optic reflection vibration sensor detects the resonant vibrations of eye to determine IOP.	
5,396,888 5,636,635 5,865,742	Massie et al.	Non-Contact Tonometer and Method using Ultrasonic Beam Non-Contact Tonometer Non-Contact Tonometer	Ultrasonic and optical system	An ultrasonic transducer directs an ultrasonic beam to the eye and the force generated by the acoustic pressure applanates the eye. The amount of acoustic pressure and eye distortion are detected by an ultrasonic or optical means to determine IOP.	
6,030,343	Chechersky et al.	Single Beam Tone Burst Ultrasonic Non-Contact Tonometer and Method of Measuring Intraocular Pressure	Single ultrasonic beam deforms eye	An ultrasonic transducer emits a single ultrasonic beam of appropriate frequency and power to deform the eye. IOP is calculated based on the phase shift between the incident and reflected beam.	
6,083,161 2004/0044278 A1	O'Donnell, Jr.	Apparatus and Method for Improved Intraocular Pressure Determination Apparatus and Method for More Accurate Intraocular Pressure Determination	Pachymeter and tonometer in one	Applanation is done with an ultrasonic transducer which measures the corneal thickness simultaneously as the applanation. A microprocessor converts the applanation pressure and adjusts the IOP measurement based on the corneal thickness.	

D.3 Through-the-Eyelid Tonometry

Patent Number	Inventor(s)	Name	Novelty	Summary	Published References
5,176,139 5,197,473	Fedorov et al.	Method for Estimation of Intraocular Pressure using Free-Falling Ball Ocular Tonometer For Estimation of Intraocular Pressure Using Free-Falling Ball	Balls inside a tubular housing are dropped onto the eyelid	A ball falls freely onto an eyelid-covered cornea and the kinetic energy of ball becomes a force causing a deformation of the cornea. IOP is determined by the amount of the ball rebound.	
5,349,955	Suzuki	Tonometer	Change in slope from deformation of eyelid to deformation of eyeball in load vs displacement time graph; 20 ms is predicted to be the time needed to deform the eyelid	The amount of pressure applied on the eyeball via the eyelid is detected by a load sensor. Pressure is exerted when a pressure rod is moved at a constant velocity against the eyelid. To prevent movement of the eyeball while IOP is measured, a cylinder immobilizes the subject's eye in a longitudinal direction by pressing against the peripheral portion of the eye via the eyelid while a fixation lamp is used to fix the other eye to the front. A calculating means measures the IOP on the basis of changes over time in the load as detected by the load sensor. The initial 20ms is used to deform the eyelid. After that, the load deforms the eyeball. Because the resiliency of the eyelid is less than the eyeball, if the detected load is graphed versus displacement time, the plotted line corresponding to the eyelid deformation would have a smaller slope. Thereafter, the gradient would change and the line would be a function of IOP. Furthermore, the gradient relating to the IOP would be larger if IOP is elevated and smaller if IOP is less than normal.	
5,735,275	Ballou et al.	Tonometer Utilizing Hydraulic Pressure	Amount of fluid in reservoir determines IOP	Fluid in a reservoir serves as a force to applanate the eye/eyelid. The level of fluid is proportional to IOP. The predetermined applanated area is the area of the	

				contact face of the plunger.	
5,836,873 6,251,071 B1	Fresco	Tonometer Tonometer	Transparent, tubular body with a plunger inside; coil spring acts between the body and the plunger	The plunger plunges the closed eyelid until a pressure phosphene is seen by the patient. The applied pressure, which corresponds to IOP, is indicated on a marker on the body.	US 5,176,139 Federov
6,524,243 B1	Fresco	Tonometer Incorporating An Electrical Measurement Device	Electrical measuring apparatus detecting mechanical displacement; reference is pressure phosphene	Electrical measuring apparatus detects the mechanical displacement of a plunger. When a pressure phosphene is seen by the patient, the amount of mechanical displacement is seen on a LCD display.	
6,706,001 B2	Fresco	Dual Tonometer Pressure Measurement Device	Reference pressure is constantly applied to the first location on the eyelid; a second applanation pressure is applied and increased at another location until the first location detects an increase in pressure	Applanation pressure is applied to a plurality of locations on the eyelid and a hands free holder is adapted to secure the tonometer device on the eye. Initially, two plungers are brought into contact with the eyelid at different locations. A reference pressure is set by applying a constant known pressure on the first plunger. The applanation pressure on the second plunger is then increased until an increase in the reference pressure is detected. The IOP is determined by the pressure differential between the reference pressure and the second pressure when it is terminated.	US 3,287,957 Martens US 4,886,066 Ingalz et al. US 5,174,292 Kusar
6,093,147	Kontiola	Apparatus for Measuring Intraocular Pressure	A propulsion device propels the probe towards the eye or the eyelid	The probe is propelled at a constant velocity towards the eye. When the probe hits the eye, the motion of the probe changes. A device measures the probe's changing velocity and uses the data to derive IOP. The time from the probe's contact to the separation of the eye is longer for the low IOP than the high IOP. The change in velocity is more substantial for the high IOP than the low IOP.	

D.4 Others

Patent Number	Inventor	Name	Novelty	Summary	Published References
6,193,656	Jeffries et al.	Intraocular Pressure Monitoring/Measuring Apparatus and Method	Polysilicon Resonant Transducer is attached to the iris or the lens	A miniature pressure sensor (preferably a Polysilicon Resonant Transducer) is attached to the iris or the lens of the eye for IOP detection.	
6,712,764 B2		Intraocular Pressure Monitoring/Measuring Apparatus and Method		An IOP measuring device is placed in the sclera or the cornea. An external device displays the internal IOP to the user.	
2003/0078487 A1		Ocular Pressure Measuring Device	A pressure measuring device is placed in the sclera or the cornea; external wireless system used for communication with the internal device		
6,570,235 B1	Abita et al.	Method for Monitoring Intraocular Pressure Using A Passive Intraocular Pressure Sensor and Patient Worn Monitoring Recorder	IOP sensor is placed in the eye; external instrument remotely energizes the sensor to allow the sensor to determine IOP	IOP sensor with a capacitive and an inductive component is placed in the eye. An external instrument remotely energizes the inner pressure sensor to determine IOP.	US 6,193,656 (Jeffries)
6,579,235		Method for Monitoring Intraocular Pressure Using A Passive Intraocular Pressure Sensor and Patient Worn Monitoring Recorder			
5,174,292	Kusar	Hand Held Intraocular Pressure Recording System	Sclera applanation; audio sounds are produced at different points	The device applanates the sclera to a predetermined amount and a pressure transducer measures IOP. An audio sound is heard when the transducer is first operational and another audio sound is produced when	US 4,951,671 (Coan)

				the transducer is in a predetermined measurement zone - the predetermined upper and lower limits of pressure.	
4,922,913	Waters, Jr. et al.	Intraocular Pressure Sensor	Piezo-resistance strain gauge is mounted in a curved semi-rigid holder like a contact lens for continuous IOP measurements	Deformation of the strain gauge cell due to the contact with the eyeball produces an output signal corresponding to IOP. Fine wires are led from the sensor out over the eyelid for connection to an external recording/monitoring device. IOP is continuously monitored.	
5,179,953	Kusar	Portable Diurnal Intraocular Pressure Recording System	Pressure transducer includes a strain gage fixed inside a sclera contact lens	Sclera contact lens is worn for continuous IOP measurements. Data is stored in an attached recording unit.	US 4,089,329 (Couvillon)
6,746,400 B2	Rathjen	Devices and Methods for Determining the Inner Pressure of An Eye	Multiple pressure sensors (MEM) in arrays are placed on the eye	The IOP is determined from the sum of the measured sensor pressure values and the number of pressure-sensing elements contributing to the sum. Pressure distribution profiles with spatial resolution and pressure distribution matrices are shown graphically.	US 6,447,449 (Fleishman et al.)

Appendix E Patent Applications (2001 - 2005)

The table below lists patent applications from 2001 to 2005.

Patent Application #	Inventors	Name	Year	Month	Day
2001/0002430 A1	Falck et al.	Method of Operating Tonometer	2001	5	31
2002/0103427 A1	Miwa et al.	Non-Contact Type Tonometer	2002	8	1
2002/0177768 A1	Fleischman et al.	Apparatus and Method for Measuring Intraocular Pressure	2002	11	28
2002/0193674 A1	Fleischman et al.	Measurement System Including a Sensor Mounted in a Contact Lens	2002	12	19
2003/0078487 A1	Jeffries et al.	Ocular Pressure Measuring Device	2003	4	24
2003/0097052 A1	Ahmed	Tonometer & Method of Use	2003	5	22
2003/0187343 A1	Cuzzani et al.	Force Feedback Tonometer	2003	10	2
2003/0225318 A1	Montegrande et al.	Intraocular Pressure Sensor	2003	12	4
2004/0002639 A1	Luce	Duel Mode Non-Contact Tonometer	2004	1	1
2004/0002640 A1	Luce	Method For Eliminating Error in Tonometric Measurements	2004	1	1
2004/0044278 A1	O'Donnell, Jr.	Apparatus and Method for More Accurate Intraocular Pressure Determination	2004	3	4
2004/0046936 A1	Iwanaga	NonContact Tonometer	2004	3	11
2004/0054277 A1	Uchida	NonContact Tonometer	2004	3	18
2004/0087849 A1	Masaki	Non-Contact Tonometer	2004	5	6
2004/0210123 A1	Davidson	Load Sensing Applanation Tonometer	2004	10	21
2004/0236204 A1	Feldon et al.	Tip Cover for Applanation Tonometer	2004	11	25
2004/0242986 A1	Matthews et al.	Hand Held Tonometer with Optical Arrangement for Indicating Critical Distance from an Eye	2004	12	2
2004/0249255 A1	Matthews et al.	Hand Held Tonometer Including Optical Proximity Indicator	2004	12	9
2004/0249256 A1	Matthews et al.	Hand Held Tonometer with Improved Viewing System	2004	12	9
2004/0267108 A1	Moore	Non-Invasive Electro-Mechanical Tonometer for Measurement of Intraocular Pressure	2004	12	30

Appendix F Summaries of Patent Applications (2001 - 2005)

Patent applications are summarized below. Novelty highlights the patent application by describing a new tonometer arrangement, part, method, or reference point. Summary summarizes the patent application. Published References cite important references. Occasionally, two patent applications share the Novelty, Summary, and Published References categories. This is intentional because the latter patent application in the box is a continuation of the first patent application.

F.1 Applanation Method

Patent Number	Inventor(s)	Name	Novelty	Summary	Published References
2004/0236204 A1	Feldon et al.	Tip Cover for Applanation Tonometer	Tip cover	Disposable tip cover is created to maintain a clean tip for the applanation tonometer	
2004/0210123 A1	Davidson	Load Sensing Applanation Tonometer	A force sensor attached to a conventional slit lamp senses applanation force on the cornea	The use of the force sensor to generate the force applied to applanate the cornea eliminates the need for complex mechanical calibrations of weights, springs, and bearings of previous Goldmann devices	

F.2 Non-Contact Tonometry (Air Puff)

Patent Number	Inventor(s)	Name	Novelty	Summary	Published References
2004/0002639 A1	Luce	Duel Mode Non-Contact Tonometer	Dual fluid-strength mode selection: (1) patient comfort - standard measurement,	The tonometer provides two measurement modes: standard and alternate. Standard mode stresses patient comfort by minimizing impulse energy of the air pulse: the solenoid drive current increases linearly with time until	

2004/0002640 A1		Method For Eliminating Error in Tonometric Measurements	(2) observation of corneal hysteresis associated with the dynamic measurement process - pressure-time characteristics of fluid pulse are varied	corneal applanation is detected. Alternate mode emphasizes on accounting for corneal rigidity by varying pressure-time characteristics of the pulse to look at corneal hysteresis (inward and outward process mode from convexity to concavity) associated with dynamic measurement process: the solenoid drive current decreases linearly with time at the same rate as it is increased.	
2004/0046936 A1	Iwanaga	NonContact Tonometer	Efficiently measures IOP n times	The tonometer measures IOP n times and compares each of the IOP measurement to a predetermined upper and lower limit. Remeasurements serve to confirm IOP values.	
2004/0054277 A1	Uchida	NonContact Tonometer	Imaging the cornea before IOP is measured	Anterior ocular segment is imaged before IOP is taken to ensure IOP measurement is properly performed. If an anomaly is found in the measurement, instrument displays the ocular segment prior to IOP measurement and illustrates the error so IOP can be retaken.	Japan 3,108,261
2004/0087849 A1	Masaki	Non-Contact Tonometer	Reference signal is adjusted depending on the reflectance of the cornea	Accurate IOP measurement is performed irrespective of the cornea reflectance. The reference signal is initially adjusted based on the reflectance of the cornea and is used to determine the reliability of the signal showing the amount of cornea deformation.	Japan 2002-310972
2004/0249255 A1 2004/0242986 A1	Matthews et al.	Hand Held Tonometer Including Optical Proximity Indicator Hand Held Tonometer with Optical Arrangement for Indicating Critical Distance from an Eye	Photoelectric sensors	The tonometer assists in eye alignment before an air puff is blown towards the cornea. The alignment uses a plurality of photoelectric sensors and detects light reflections from the cornea. Air is automatically blown when eye is centered.	UK 2,175,412 EP 0,289,545
2004/0249256 A1	Matthew et al.	Hand Held Tonometer with Improved Viewing System	Pechan-Schmidt prism	A tonometer with the eyepiece and the objective lens forming a simple telescope which can present an in-focus image of distant objects. The prism can invert images and can present to the user an image of the patient's eye which is correctly oriented.	

F.3 Through-the-Eyelid Tonometry

Patent Number	Inventor(s)	Name	Novelty	Summary	Published References
2003/0097052 A1	Ahmed	Tonometer & Method of Use	Tonometer has a bulbous-like end made of a flexible resilient material with hollow interior	The bulbous-like end is pressed against the eye through the eyelid. The higher the IOP, the more the hollow interior decreases in volume. A liquid moves along the probe as a result of the change and this movement is detected to determine whether IOP is within the safe range.	
2003/0187343 A1	Cuzzani et al.	Force Feedback Tonometer	Vibrational energy with constant amplitude and a range of frequencies is transmitted; static force is applied to ensure vibration in eyeball; derived IOP is calibrated with Goldmann. Vibrational impedance is characterized by the minimum point on the force vs. frequency graph and the maximum point on the phase vs. frequency graph; there is less phase lag in a high IOP than a low IOP; the frequencies at which the amplitude of the force reaches a minimum and at which the phase reaches a	A vibrator transmits vibrational energy into an eyeball through the eyelid and a force transducer coupled to the vibrator measures the force or phase response in the eyeball. Vibrational energy, which maybe derived from a solenoid, must be capable of producing a constant amplitude and a range of frequencies for inducing vibration in at least a portion of an underlying eyeball. In order to ensure the eyeball is vibrated and a vibrational response will be detected by the force transducer, a static force sensor can be applied to the eyelid. By using acoustic energy to obtain IOP, the volume of the eye does not change during measurement and the pressure is not affected. It is also predicted the response of the eyelid is not a substantial factor in determining the response of the eyeball beneath. The vibrational impedance of the eye is calculated from the force or phase response and IOP is calculated as a function of V (eye volume, which is dependent on axial length), E (elastic modulus of the eye, which is a function of the thickness and the water content of the cornea), and Ri (biomechanical rigidity of the eye, which can be derived from the vibrational response of the eye). The derived IOP is then compared to the IOP obtained using the Goldmann method. To ensure accurate IOP	

			maximum, increases with increased IOP.	measurements using vibrational impedances, at least one calibration factor is used to define the relationship between the two methods for the specific patient. Furthermore, additional eye properties, such as the axial length of the eye and the cornea thickness, may be gathered to normalize vibrational responses between different eyes.	
2004/0267108 A1	Moore	Non-Invasive Electro-Mechanical Tonometer for Measurement of Intraocular Pressure	A strain gage and a linear voltage differential transducer (LVDT) are mounted on a frame to measure force and distance respectively;	The tonometer processing unit operates to (1) time-synchronize signals received from the strain gage and the LVDT, and (2) identify a change in the relationship between synchronized force and distance measurements. Because the compliances of the eye and eyelid are different, a change in the force and distance relationship correlates with IOP and can be observed as an inflection in a force-distance graph.	

F.4 Others

Patent Number	Inventor(s)	Name	Novelty	Summary	Published References
2003/0225318 A1	Montegrande et al.	Intraocular Pressure Sensor	Implanted pressure sensor and transponder for measuring and transmitting IOP measurements	A pressure sensor and a transponder are implanted inside the eye. The pressure sensor consists of a sensor reed and a strain gage. The transponder has an antenna which is used to communicate IOP measurements to an external central monitoring station.	

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