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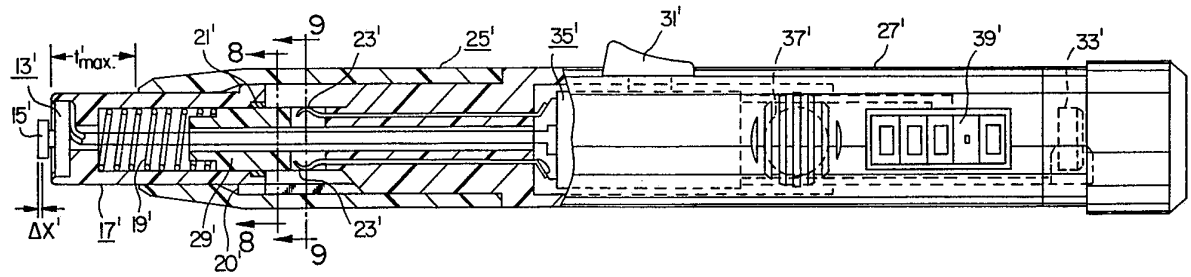
(54) Title: PORTABLE INTRAOCULAR PRESSURE MEASUREMENT METHOD AND APPARATUS



(57) Abstract

A device for continuously monitoring intraocular pressure includes a contact lens (11) having a pressure transducer (17), including at least one semiconductor strain gauge crystal (33) fixed to a membrane on lens (11), and fit with the sclera. A projection (27) for scleral indentation is positioned to transmit response to intraocular pressure to the crystal (33). A memory unit is mounted in the lens in non-scleral contact for recording measurements. A tonometer (11′) for monitoring intraocular pressure through the sclera has a frame forming a handle which includes a pressure transducer (13′) having sleeve (17′) mounting it on an axis along which a spring (19′) positions it in response to pressure applied byurging the probe against the sclera. The device (11′) includes a conductive ring (21′) on the sleeve (17′) and electrical contacts on the axis to complete a circuit to generate a signal when within a zone of measurement which has predetermined upper and lower limits of pressure.

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PORTABLE INTRAOCULAR PRESSURE MEASUREMENT METHOD AND APPARATUS

TECHNICAL FIELD

The present invention relates to a device for recording the intraocular pressure of a person or animal over a period of time. More particularly, the invention relates to a device which can be placed in the eye to continuously monitor and record intraocular pressure over an extended period of time such as 24 hours or more.

The present invention relates to a device for recording the intraocular pressure of a person or animal. More particularly, the invention relates to a hand held device which can be placed against the eye to record intraocular pressure of the patient without direct medical personnel supervision.

BACKGROUND ART

Three to four million persons in the United States suffer from glaucoma to some degree, although only about half of these persons are treated by routine administration of glaucoma medication. Glaucoma is recognized to be the leading cause of blindness in this country.

Typical treatment for glaucoma to reduce the excessive intraocular pressure involves the administration of drugs which operate on the intraocular pressure. These drugs do not have a long term straight line effect on intraocular pressure, however, an individual's treatments may be more or less effective at any particular period of time in the treatment cycle. For most glaucoma cases, intraocular pressure varies throughout the day, usually reaching its peak about 3:00 am. This diurnal cycle presents difficulties to the attending physician, who sees the patient at only one relatively short period of time. For this reason, it is difficult for the practitioner to accurately assess the effect of glaucoma medications.

At the present time, there is recognition that the cycle of intraocular pressure is diurnal and is subject to several variables. However, no acceptable means presently exists to continuously measure intraocular pressure.

One such means has been proposed in U.S. Patent No. 4,089,329, to Couvillon et al, in which a contact lens is used to maintain vision for the patient. The patent notes, however, that sensitivity of the cornea to the device presents a serious problem. To solve this problem, a miniature strain gauge pressure transducer is used, in the form of a noncompliant, planar diaphragm for applanating a small portion of the sclera. A hydrogel ring is placed within the conjunctival cul-de-sac of the eye in a concentric orientation with the cornea to permit vision during the process.

In the Couvillon et al device, separation of tissue supplies the necessary force to the transducer diaphragm to applanate the contacted portion of the sclera. The resultant stress, monitored as resistance variations, is sent to a transmitter via connecting wires. While the Couvillon et al patent does not say so explicitly, the wires appear to extend from the hydrogel ring to a transmitter which is external to the eye. Signals are sent to a receiver/transcriber for analysis and use in other ways.

The Couvillon et al device contemplates the use of a ring platform, made preferably from hydrogel. The ring must be sufficient to allow eye movement without serious contact with corneal tissue. Wire conductors convey the current from the strain gauges, and change in resistance is measured as change in voltage. As noted in the description of the "communicating means" described in the

Detailed Description of the Couvillon et al patent, the transmitter is fixed to the patient's glasses or person. Presumably, preventative methods are in place to prevent the patient from removing his or her glasses with the ring platform still in the eye and attached to the transmitter via the wire conductors.

The most economical method of measuring the intraocular pressure is for the patient to make the above-discussed measurements at home. At the present time, there is recognition that the cycle of intraocular pressure is diurnal and is subject to several variables. However, no acceptable means presently exists to measure intraocular pressure at home with any degree of safety. The primary difficulty is that all prior art tonometers are designed to measure intraocular pressure through corneal indentation or corneal applanation. This requires considerable skill and training along with anesthesia to the cornea.

Other methods such as air tonometry deflect the cornea with a burst of air. This method eliminates the need for anesthesia, but still requires considerable skill. The unit is quite costly and is not portable.

It is therefore an object of this invention to provide a portable tonometer which can be placed against the eye to record intraocular pressure by the patient without direct medical personnel supervision.

Another object of the present invention is to provide such a device which does not require anesthesia, and which is economical to manufacture and easy to use.

Yet another object of the present invention is to provide a device which can be used on the sclera of the eye to measure and record intraocular pressure and which has safety features to prevent too much pressure from being applied.

Other objects will appear hereinafter.

DISCLOSURE OF INVENTION

It has now been discovered that the above and other objects of the present invention may be accomplished in the following manner. Specifically, the present invention provides a device for continuously monitoring the intraocular pressure in an eye.

The device includes a scleral contact lens having a pressure transducer thereon for measuring intraocular pressure and sized to fit within the sclera of an eye for positioning said pressure transducer in fixed contact with said sclera during movement of said eye. The transducer includes projection means for scleral indentation, as the projection operates in response to the actual intraocular pressure. In a preferred embodiment, the pressure transducer includes at least one semiconductor strain gauge crystal adapted to generate an electrical resistance which is responsive to intraocular pressure.

Also included are battery powered memory means mounted in said lens in non-scleral contact for recording measurements of pressure by said transducer over a predetermined period of time. Naturally, the data which is stored in the memory means is used to evaluate the changes, if any, of pressure in the eye for various reasons. Output means such as a central processing unit or computer is used for this evaluation. The device itself has connecting means for providing access to said measurements upon removal of said lens from the eye.

Data can be displayed in graphic form, on screen, or on paper, depending on the needs of the practitioner.

The device of this invention is self-contained and can be worn by a patient with minimal or no discomfort. The battery powered memory means, in the form of an integrated circuit chip, supplies a small current to the crystal, so that the resistance through said crystal is representative of the intraocular pressure. The crystal is fixed to a flexible membrane forming mounting means on said contact lens.

In the best mode for carrying out the invention, the scleral contact lens is designed to locate the transducer in the superior temporal quadrant of the eye in the superior cul-de-sac. Other locations are also contemplated.

It has now been discovered that the above and other objects of the present invention may be accomplished in the following manner. Specifically, the present invention provides a device for an individual monitoring the intraocular pressure in an eye without anesthesia and with complete safety.

The device of this invention comprises a hand held portable tonometer device for monitoring the intraocular pressure in an eye through the sclera. The device is supported on a tubular frame which forms the handle and which has an axis along which the device operates. The handle supports and contains a pressure transducer for generating intraocular pressure measurements. It is

mounted on the axis with a sliding transducer mounting sleeve. The transducer includes a scleral projection for scleral indentation, which is positioned to transmit response to intraocular pressure to provide an input to the transducer.

The transducer sleeve includes an annular conductive ring mounted on the inside of the mounting sleeve. The ring is aligned to complete a circuit upon meeting contact points on the shaft on which the sleeve slides. Also provided is a spring for positioning the transducer along the axis to permit movement along the shaft in response to pressure applied when the scleral projection is urged against the sclera.

The device has a safety feature utilizing the contact element which defines a position of the transducer along the axis to define a zone of measurement which has predetermined upper and lower limits of pressure. The device provides a signal means for providing a first audio signal when the device is operational and a second audio signal when the transducer is in the predetermined zone. The electrical contacts are positioned at a predetermined position on the shaft to engage with the conductive ring to complete an electrical circuit to generate a signal. An output means is also mounted in the frame for displaying relevant measurements of pressure by the transducer, preferably only in the zone of measurement.

BRIEF DESCRIPTION OF THE DRAWINGS

For a more complete understanding of the invention, reference is hereby made to the drawings, in which:

Fig. 1 is a schematic view of a device according to the present invention, shown in place on a human eye;

Fig. 2 is an enlarged view of the device shown in Fig. 1, removed from the eye;

Fig. 3 is an enlarged sectional plan view taken along line 3,3 of Fig. 1;

Fig. 4 is a greatly enlarged sectioned view taken along the line 4,4 of Fig. 2, showing details of the transducer portion of the device of this invention, with a small portion of the mounting flange shown in dot and dash outline;

Fig. 5 is a sectional plan view taken along line 5,5 of Fig. 4, showing additional details of the transducer assembly;

Fig. 6 is an enlarged schematic view, shown in perspective, of a device according to the present invention;

Fig. 7 is an enlarged, side elevational view taken along the line 7,7 in Fig. 6, showing a portion broken away and in section;

Fig. 8 is an enlarged transverse sectional view taken on the line 8,8 of Fig. 7;

Fig. 9 is an enlarged transverse sectional view taken on the line 9,9 of Fig. 7;

Fig. 10 is a greatly enlarged fragmentary sectional plan view showing the device of the present invention in position for use with the left eye, shown in the active or signal sending mode; and

Figs. 11A, 11B and 11C are schematic sequential views showing the use of the invention.

BEST MODE FOR CARRYING OUT THE INVENTION

As shown in Fig. 1, the device of this invention is placed in a patient's eye in order to measure and record intraocular pressure over a period of time. The device of the present invention includes a large scleral contact lens made of silicone or polymethylmethacrylate, for example. The contact lens 11 is shown in Fig. 1 in place in a patient's eye, and is comfortable and easy to wear without significant discomfort for the patient. The lens is soft, and ring shaped 13, and approximately 18 mm in diameter, with a 13.5 mm opening 15 in the center.

The lens 11 permits movement of the eye while maintaining the operable components in a fixed position. As will be apparent herein, movement of the lens 11 with respect to the eye could give the feeling of scratching or other discomfort due to the presence of a pressure transducer in contact with the sclera of the eye.

The lens 11 is shown in Fig. 2, and includes a ring 13 which has an outer circumferential end 15 which prevents contact of the lens 11 with the cornea and allows for complete vision without obstruction. The open center 15 of the lens 11 allows normal visual activities and also permits normal adsorption of medications during the time the lens 11 is in use. The system is non-invasive and can be comfortably worn by the patient. No restrictions are placed on the patent when the device of this invention is in use.

Forming part of the lens 11 is a pressure transducer 17 which is located for contact with the sclera. This transducer 17 monitors the intraocular pressure continuously or at regular intervals of time, depending upon the needs of the practitioner.

The pressure transducer 17 is mounted on a flange of the ring 13 with an 8 mm projection, preferably extending into the superior temporal quadrant of the eye. Both right and left hand models will be needed, along with two overall sizes to fit normal and large eyes. The inferior margin of the contact lens 11 is truncated or flattened in order to position the transducer 17 in the inferior cul-de-sac. This alignment prevents rotation and keeps the transducer 17 in the desired location. Transducer 17 is powered by electrical current from battery 19 which is also mounted on the lens 11. The sclera is readily exposed to indention by the transducer at this location, as the tissues are relatively thin in this area and there are no extraocular muscles to interfere with indention. The area is also broad, allowing for some normal positional changes.

Battery 19 is operably connected to the transducer 17 in order to power the pressure measuring component of the device. Memory chip 21 is also connected to battery 19 and to transducer 17 to receive and store data taken during operation of the device. Chip 21 is of conventional design.

The device of this invention is shown in enlarged detail in Fig. 3, which has been magnified approximately 6 times the size of a normal eye. The ring 13 rests comfortably on the sclera 23 of the eye and permits the transducer 17 to measure the intraocular pressure at 25.

The sclera 23 of the eye is indented by pressing the apex of a mushroom shaped projection 27 into the appropriate region 29 of sclera 23. Projection 27 moves in response to pressure and changes in pressure in the intraocular region 25 to provide the needed data. Electrical power for the transducer 17 and for transmission of data is accomplished via small electrically conductive insulated wires 31. All electrical and electronic components are inbeded in a water proof shroud.

As shown in Fig. 4 and Fig. 5, the projection 27 of about 3.5 mm in size is operably connected to a semiconductor strain gauge crystal 33, such as those used in automatic blood pressure devices. In one embodiment, a 1 x 2.5 mm crystal 33 with a nominal resistance of 1125 ohms was attached to a flexible membrane 35 by means of epoxy 39. Thin leads 37 were attached to both ends of crystal 33.

As current flows through the crystal 33, the memory chip 21 records the resistance in the crystal 33. As pressure changes in the intraocular region 25, the projection 27 reacts to this change in pressure to increase or decrease the bending moment on crystal 33,

thus changing the resistance of the crystal 33.

Once the lens 11 has been placed in the eye, a period of stabilization is needed. It has been noted that there will be a temporary rise in intraocular pressure as the device is applied to the globe by decreasing the volume of fluid within the globe. This will cause an initial increase in the intraocular pressure. Depending upon the outflow resistance of that particular patient, this excess fluid will be forced out of the eye through the trabecular network and the pressure within the eye will stabilize. This is reached when the pre-application and post-application intraocular pressure are the same. Experience suggests that this takes about 5 minutes to be achieved.

As the pressure within the eye changes, scleral indention will be greater or less. The distance between the base of the transducer 17 and the face of the mushroom shaped projection 27 which is attached to the crystal 33 via membrane 35 will respond and be greater or less. This is measured as described above by recording the change in resistance in the crystal 33.

The stored data can then be withdrawn from memory chip 21 and processed with computer technology to convert resistance values into pressure. Since the initial pressure can also be measured independently at the time when the lens 11 is inserted into the eye and when it is removed, such as by applanation tonometric measurements. Also, while the patient is still with the practitioner,

additional applanation measurements can be made to verify stabilization of the intraocular pressure. The patient is now free to continue with normal activity for the period of time of testing. Typically, 24 hours is sufficient to obtain adequate data.

In order to demonstrate the operability and effectiveness of the device of the present invention, a series of tests were made in a laboratory setting. Intraocular pressure in an animal cadaver eye was varied over a range of pressure from about 10 mm Hg. up to about 55 mm Hg. by varying the height of a bottle containing fluid and connected to the eye. The results of the tests demonstrated that linear and repeatable data was attainable using the device of this invention. In actual practice, a printout of the data recording the intraocular pressure in the eye can be correlated with the times when medication is administered, to evaluate the effectiveness of the prescribed treatment program. The printout would also provide a permanent assurance of the safety of any external pressure applied to the eye.

The advantage of the present invention is most importantly that it can be used with minimum skill and training. It is totally self contained and portable and no anesthesia is needed for virtually all patients. This device, shown generally at 11' in the drawings, is the first such device which is capable of being applied to the sclera and which measures the intraocular pressure accurately and in a reproducible manner via scleral

indentation.

The hand held tonometer 11' includes a transducer 13' and probe 15' mounted in the tonometer frame. Transducer 13' is mounted in a sliding transducer mounting sleeve 17' which fits inside the tonometer along its central axis. Sleeve 17' includes an inwardly facing annular conductive (or metal) ring 21' which is aligned to make electrical contact with a plurality of at least two switch contact points 23'. Spring 19' positions the sleeve 17' (and thus the transducer 13' and probe 15') along this same axis.

Transducer 13' is discussed above and is of the type disclosed in my co-pending application entitled **PORTABLE, DIURNAL INTRAOCULAR PRESSURE RECORDING SYSTEM,** filed August 27, 1991 and having Serial No. 07/750,528, the disclosure of which is incorporated herein by reference.

The outer housing 25' is formed with an outer barrel sleeve 27' which functions as a handle. Also contained inside the housing 25', is a truncated cylindrical shaft 29'. Sleeve 17' slides on shaft 29' freely and is held in position by spring 19' urging the probe 15' in the anterior direction. Sleeve 17' includes a flange 18' which engages limit stop 20' to keep the device assembled.

Figs. 8 and 9 show the use of a key 22' which is integral with housing 25' to prevent rotation of sleeve 17' and thus prevent breakage of leads to transducer 13'.

The housing portion 25' also includes a switch 31' which operates as an off/on switch. The device 11' includes its own power supply, such as battery 33'. Battery 33' powers an ohm meter and computer chip unit 35' which functions as will be described. A first signal is produced by speaker 37' when the device 11' is ready for operation and will produce a second signal, such as a plurality of repeated sounds or beeps under certain conditions of use.

This second signal is produced when the ring 21' completes a circuit by being in contact with contact points 23' indicating that the pressure which is forcing the probe against the transducer 13' is that needed to produce useful measurements of intraocular pressure. The probe 15' also forces transducer 13' to compress spring 19' and urge the sleeve 17' along shaft 29' and so that contact between ring 21' and contact points 23' is made.

The housing 25' also encloses a LED readout device 39', of conventional design. LED readout device 39' displays the pressure being measured by the transducer 15' after it has been converted from resistance in ohms into pressure, such as in millimeters of mercury (mm Hg.). It is preferred to limit the display of pressure by LED readout device 39' only when electrical contact between ring 21' and contact points 23' is being made. This provides a zone of measurement which has predetermined upper and lower limits of pressure on the spring 19', so that no data is provided at other

locations of the sleeve 17' on shaft 29'.

Turning now to Fig. 10, the operation of the present invention can be seen. The prove 15' indents the sclera 41' as force is applied by the user by pushing the probe 15' against the eye at the appropriate place, away from the cornea. There is substantially no feeling of pressure and pain is not present at all. Probe 15' is rounded, causing a comfortable and non-abrasive contact with the conjunctiva and sclera. Applanation consists of a very small indentation, less than a millimeter in length, and does not cause any permanent change to the sclera.

The intraocular pressure P' resists the intrusion and a force is thus directed to the transducer 13'. Transducer 13' includes a simple ohm meter and some circuitry to recognize that ring 21' and contact points 23' have completed a circuit.

Application of a consistent and reproducible pressure to the eye is of critical importance and can be done here for the first time. In order to be consistent and reproducible, it is necessary to press the transducer 13' against the eye with the same force each time. It has been observed herein that excess pressure will cause a false elevation of the intraocular pressure, while a lesser pressure will not indent the sclera enough to give reproducible flexion to the ceramic crystal forming the transducer 13'. Either condition will, at best, result in inconsistence in the intraocular pressure readings and

is to be avoided.

The probe 15' is about 3.5 mm in size and is operably connected to a semiconductor strain gauge crystal in transducer 13', such as those used in automatic blood pressure devices. In one embodiment, a 1 x 2.5 mm crystal with a nominal resistance of 1125 ohms was attached to a flexible membrane by means of epoxy and thin leads were attached to both ends of the crystal. As current flows through the crystal, and as pressure changes in the intraocular region of the eye, the projection probe 15' reacts to this change in pressure to increase or decrease the bending moment on crystal, thus changing the resistance of the crystal. The ohm meter registers this change and transmits the reading to the LED readout 39'.

An important part of the present invention is the use of sound or audio signals to assist in the operation of the device and maintain the safety feature, particularly when the patient is using the device alone. A small sound device or speaker 37' which has two purposes in the best mode for carrying out the invention. Upon turning the device 11' on, a brief time is needed for the system to warm up. Once the transducer 13' has stabilized, a single tone will be sent by speaker 37' to alert the user that the system is ready to use. Then, as the transducer probe 15' is pressed against the sclera of the eye, a double tone will sound from speaker 37' at that point in the pressure induced movement of sleeve

17' on shaft 29' when ring 21' and contact points 23' are in contact with one another.

This double tone indicates to the user that a valid measurement has been made because the transducer 13' has been subjected to the correct pressure to place the device 11' in the zone of measurement.

Figs. 11A, 11B and 11C illustrate the operation of this important safety feature in schematic form. In Fig. 11A, probe 15' is pressing against the sclera and the pressure in the eye is resisting with a force equal to F1'. In this case, F1' is less than the pressure P' for which the device 11' has been calibrated and for which the contact points 23' will meet ring 21'. No data is transmitted to the LED readout 39'. As noted above, a lesser pressure will not indent the sclera enough to give reproducible flexion to the ceramic crystal forming the transducer 13'.

In Fig. 11B, probe 15' is also pressing against the sclera and the pressure in the eye is resisting with a force equal to F2'. In this case, F2' is the same as the pressure P' for which the device 11' has been calibrated and for which the contact points 23' will meet ring 21'. Data is transmitted to the LED readout 39' as previously described, as the double tone indicates a successful measurement in the appropriate measurement zone.

In Fig. 11C, probe 15' is pressing against the sclera and the pressure in the eye is resisting with a force equal to F3'. F3' is greater than the pressure P'

for which the device 11' has been calibrated and for which the contact points 23' will meet ring 21'. As can be seen, ring 21' is beyond contact points 23' and again no data is transmitted to the LED readout 39'. This eliminates the concern that excess pressure will cause a false elevation of the intraocular pressure. When this condition occurs, the double beep tone stops, warning that excessive pressure may be being applied.

With the device 11' of the present invention, it is possible for the first time to measure the intraocular pressure without invasion of the cornea and without anesthetics. It is easy for a patient to be trained to take readings alone and without assistance, yet obtain consistent readings that are of significant value in evaluating treatments and in screening for eye problems such as Glaucoma screening.

While particular embodiments of the present invention have been illustrated and described, it is not intended to limit the invention, except as defined by the claims.

CLAIMS

What is claimed is:

1. A device for continuously monitoring the intraocular pressure in an eye, comprising:

a scleral contact lens having a pressure transducer thereon for measuring intraocular pressure and sized to fit within the sclera of an eye and position said pressure transducer in fixed contact with said sclera to indent said sclera in the superior temporal quadrant of the eye in the superior cul-de-sac during movement of said eye, said pressure transducer including at least one semiconductor strain gauge crystal adapted to vary its electrical resistance in response to intraocular pressure and projection means for positive scleral indentation, said projection means being positioned to transmit a response to intraocular pressure to said crystal;

battery powered memory means mounted in said lens in non-scleral contact for recording measurements of the resistance through said crystal; and

output means for providing access to said measurements upon removal of said lens from the eye.

2. The device of claim 1, wherein said battery powered memory means includes means for measuring the resistance through said crystal, and said crystal being fixed to a

flexible membrane forming mounting means on said contact lens.

3. A method for continuously monitoring the intraocular pressure in an eye, comprising:

placing a scleral contact lens having a pressure transducer thereon for measuring intraocular pressure within the sclera of an eye in fixed contact to indent said sclera in the superior temporal quadrant of the eye in the superior cul-de-sac during movement of said eye, said pressure transducer including at least one semiconductor strain gauge crystal adapted to vary its electrical resistance in response to intraocular pressure and projection means for positive scleral indentation, said projection means being positioned to transmit a response to intraocular pressure to said crystal;

recording measurements of the resistance through said crystal using a battery powered memory means mounted in said lens in non-scleral contact; and

providing access to said measurements upon removal of said lens from the eye.

4. The method of claim 3, wherein said battery powered memory means measures the resistance through said crystal, said crystal being fixed to a flexible membrane mounting said crystal on said contact lens.

5. A hand held portable tonometer device for

monitoring the intraocular pressure in an eye through the sclera, comprising:

a tubular frame having an axis and forming a handle, said handle including pressure transducer means for generating intraocular pressure measurements, said transducer means including scleral probe means for scleral indentation;

biasing means for positioning said transducer means along said axis and for permitting movement thereof along said axis in response to pressure applied by urging said scleral probe means against the sclera;

contact means at a location along said axis for defining a zone of measurement within which said transducer means must be located to enable measurement of pressure, said zone having limits which correspond to predetermined upper and lower limits of measurable intraocular pressure and for providing a signal when said transducer means is in said zone; and

output means mounted in said frame for displaying measurements of pressure by said transducer means in said zone of measurement upon receipt of said signal.

6. The device of claim 5, wherein said device further includes audio signal means for generating a first audio signal when said device is operational and a second audio signal forming said signal when said transducer means is in said zone.

7. The device of claim 5, wherein said transducer means includes at least one semiconductor strain gauge crystal adapted to generate an electrical resistance which is responsive to intraocular pressure.

8. The device of claim 7, wherein said transducer means includes means for measuring the resistance through said crystal.

9. The device of claim 5, wherein said transducer means includes a sliding transducer mounting sleeve for mounting said transducer means in said handle along said axis and having conductive means, said contact means including electrical contact positioned at a predetermined position on said axis for engagement with said conductive means to complete an electrical circuit to generate said signal.

10. The device of claim 9, wherein said conductive means comprises an annular conductive ring mounted on said mounting sleeve.

11. A hand held portable tonometer device for monitoring the intraocular pressure in an eye through the sclera, comprising:

a tubular frame having an axis and forming a handle, said handle including pressure transducer means for generating intraocular pressure measurements and

having a sliding transducer mounting sleeve for mounting said transducer means on said axis, said transducer means including scleral probe means for scleral indentation, said transducer means including conductive means comprising an annular conductive ring mounted on said mounting sleeve;

biasing means for positioning said transducer means along said axis and for permitting movement thereof along said axis in response to pressure applied by urging said scleral probe means against the sclera;

contact means at a location along said axis for defining a zone of measurement within which said transducer means must be located to enable measurement of pressure, said zone having limits which correspond to predetermined upper and lower limits of measurable intraocular pressure and including signal means for providing a first audio signal when said device is operational and a second audio signal when said transducer means is in said zone, said contact means including electrical contacts positioned at a predetermined position on said axis for engagement with said ring to complete an electrical circuit to generate said second signal; and

output means mounted in said frame for displaying measurements of pressure by said transducer in said zone of measurement upon receipt of said second signal.

12. The device of claim 11, wherein said pressure

transducer means includes at least one semiconductor strain gauge crystal adapted to generate an electrical resistance which is responsive to intraocular pressure.

13. A method of monitoring the intraocular pressure in an eye through the sclera, comprising the steps of:

contacting the eye by scleral indentation with a scleral projection means mounted on a pressure transducer means for generating intraocular pressure measurements, said transducer means being positioned to transmit a response to intraocular pressure when said transducer means is located in a zone of measurement defined along an axis of a frame that supports said transducer means, said zone having limits which correspond to predetermined upper and lower limits of measurable intraocular pressure;

positioning said transducer means along said axis and permitting movement thereof along said axis in response to pressure applied by urging said scleral projection means against the sclera; and

displaying the results of measurements in said zone.

14. The method of claim 13, which further includes the steps of providing a first audio signal when said device is operational and a second audio signal when said transducer means is in said zone.

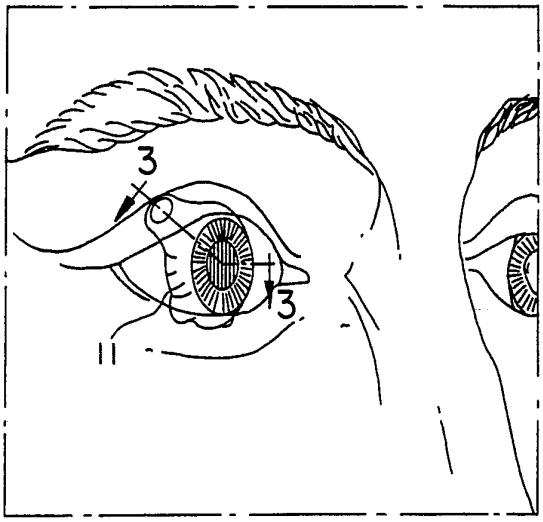

FIG. 1

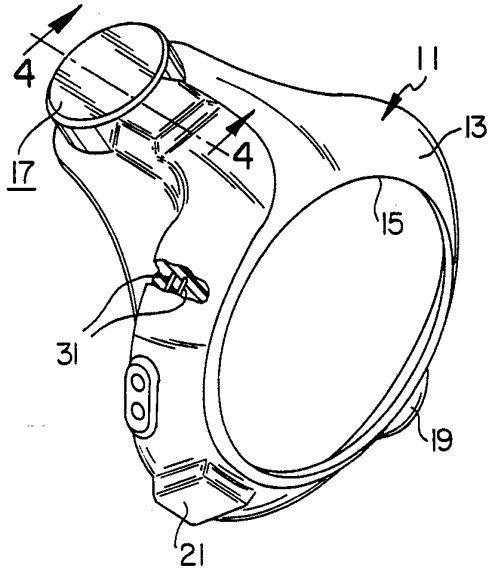

FIG. 2

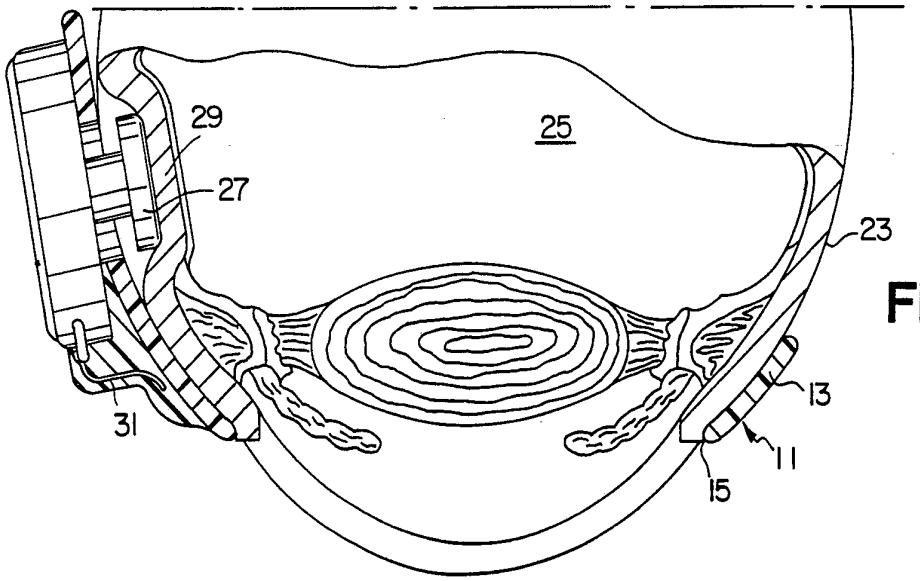

FIG. 3

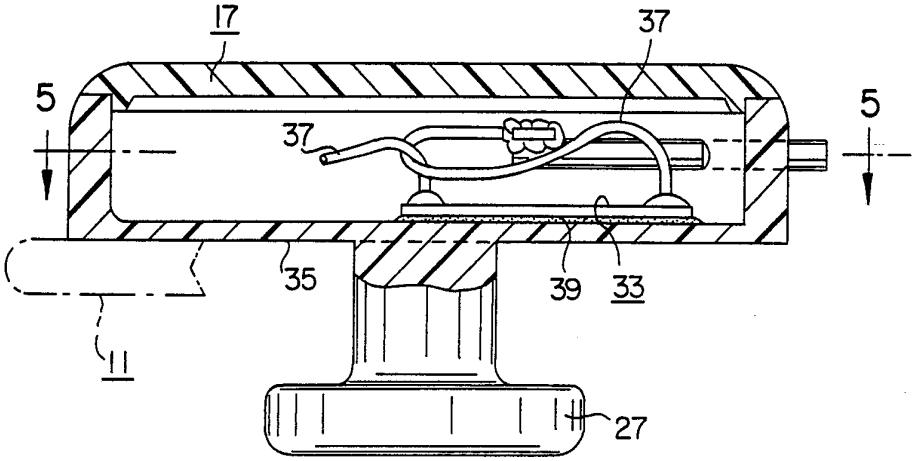

FIG.4

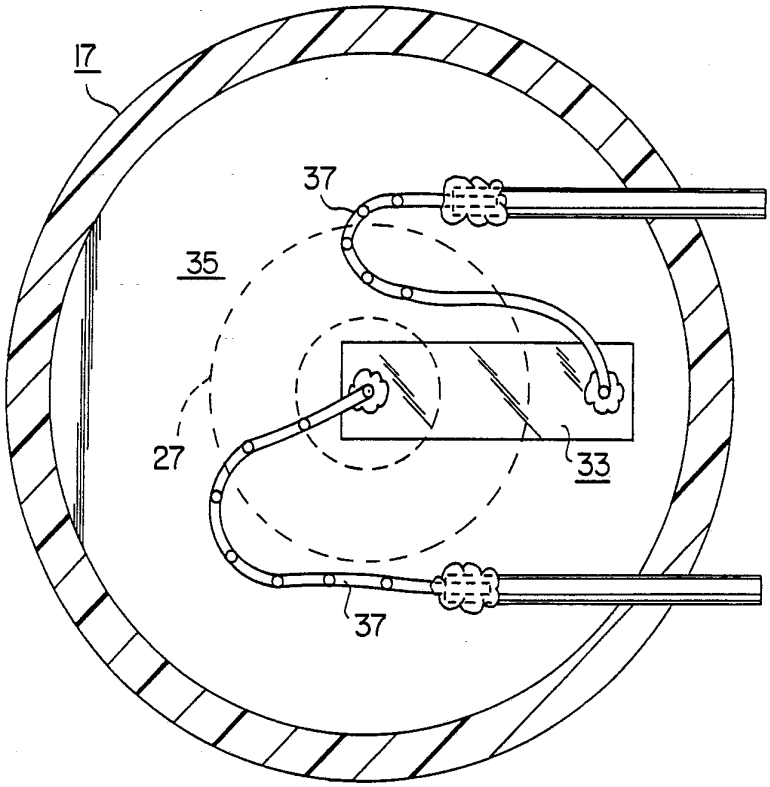

FIG.5

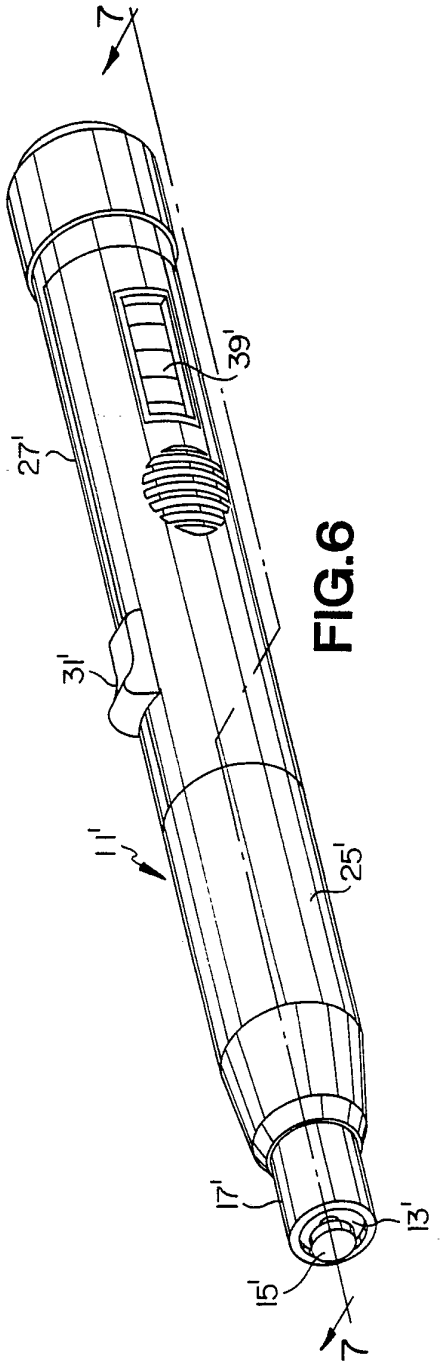

FIG.6

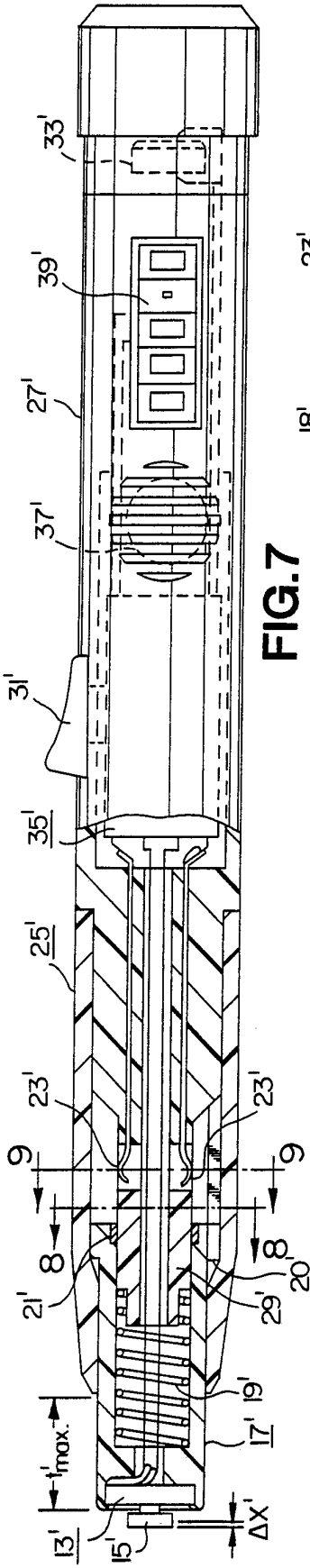

FIG.7

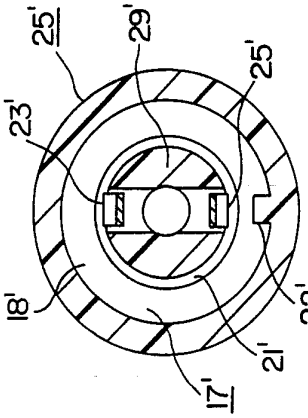

FIG.9

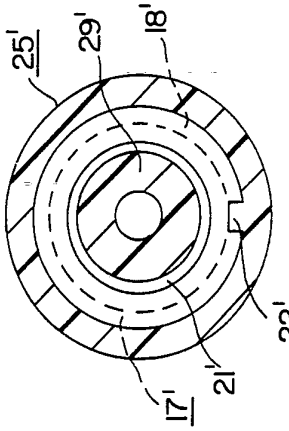

FIG.8

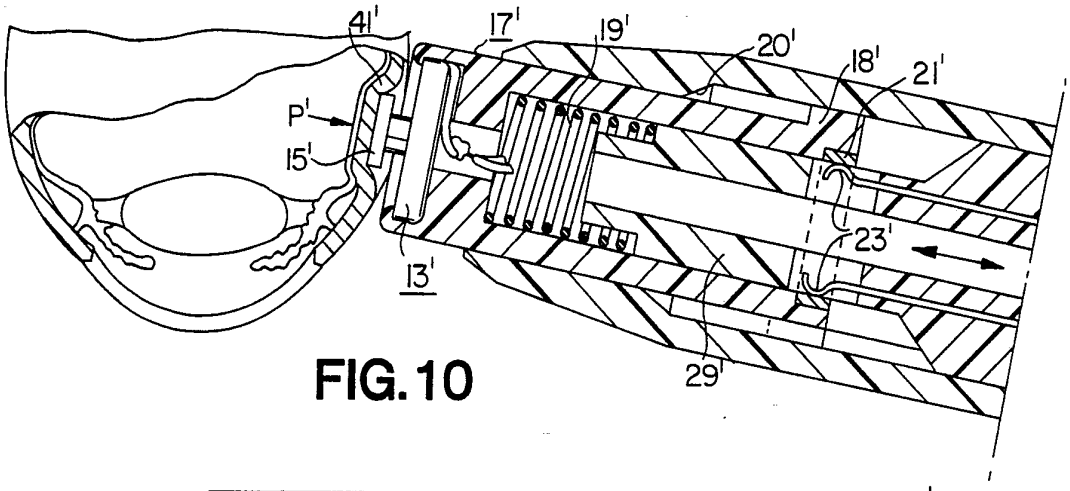

FIG. 10

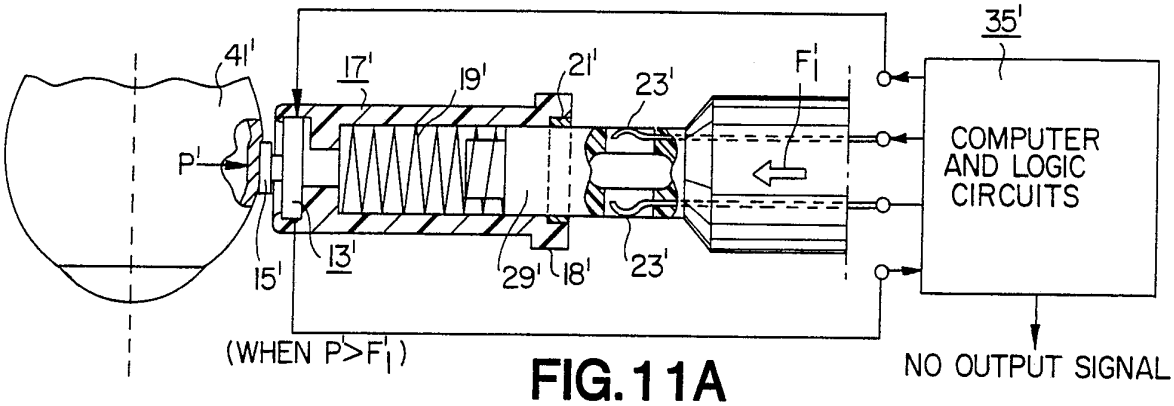

FIG. 11A

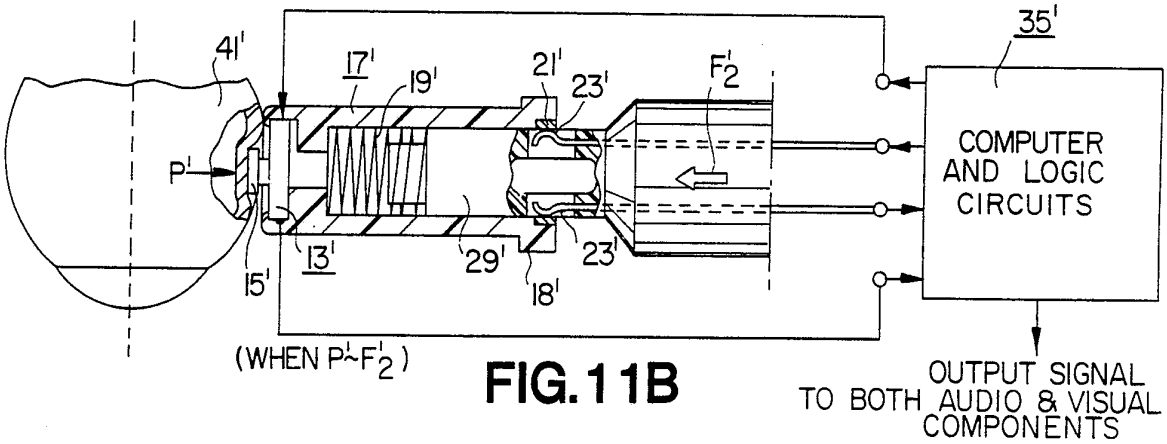

FIG. 11B

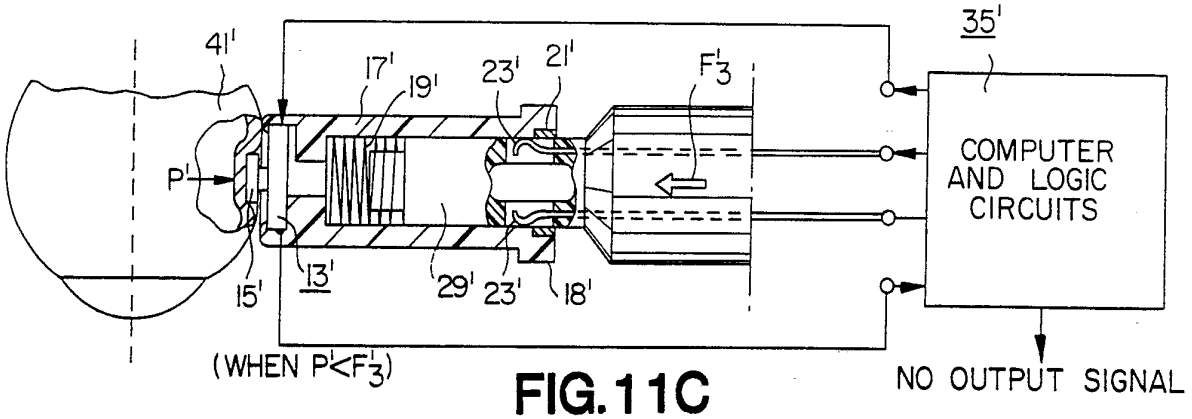

FIG. 11C

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US92/07084

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61B 3/16
US CL :128/645
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/645, 646, 650, 651, 652

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

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

none

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 4,922,913 **(WATERS, JR. ET AL.)** 08 May 1990, see entire document.	1-14
A	US, A, 3,564,907 **(HOLCOMB ET AL.)** 23 February 1971, see entire document.	5-14
A	US, A, 4,951,671 **(COAN)** 28 August 1990, see entire document.	5-14

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

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

Date of the actual completion of the international search
08 OCTOBER 1992

Date of mailing of the international search report
30 NOV 1992

Name and mailing address of the ISA/
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. NOT APPLICABLE

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Telephone No. (703) 308-2907

Form PCT/ISA/210 (second sheet)(July 1992)*

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US92/07084

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Group I, claims 1-4, drawn to a method and apparatus for intraocular pressure measurement, classified in Class 128, Subclass 645.

Group II, claims 5-14, drawn to a method and apparatus for intraocular pressure measurement, classified in Class 128, Subclass 645.

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims. (Telephone Practice)

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any addtional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention frist mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☒ No protest accompanied the payment of additional search fees.