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(54) **NON-INVASIVE MEASUREMENT OF BLOOD GLUCOSE LEVEL**

NICHTINVASIVE MESSUNG DES BLUTGLUKOSESPIEGELS

TECHNIQUE NON INFRACTIVE DE MESURE DU TAUX DE GLYCEMIE

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(73) Proprietor: **Iris Medical Technologies International Ltd.**
Calgary,
Alberta T2W 5P6 (CA)

(72) Inventor: **SUBOTICS, Gyula**
H- Budapest (HU)

(74) Representative: **Grundmann, Dirk et al**
c/o Rieder & Partner,
Corneliusstrasse 45
42329 Wuppertal (DE)

(56) References cited:
GB-A- 990 222 US-A- 6 113 537

- **KURTENBACH A ET AL: "PRERETINOPIIC CHANGES IN THE COLOUR VISION OF JUVENILE DIABETICS" BRITISH JOURNAL OF OPHTHALMOLOGY, LONDON, GB, vol. 83, no. 1, January 1999 (1999-01), pages 43-46, XP001148306 ISSN: 0007-1161**
- **KURTENBACH A ET AL: "DEVELOPMENT OF BRIGHTNESS MATCHING AND COLOUR VISION DEFICITS IN JUVENILE DIABETICS" VISION RESEARCH, PERGAMON PRESS, OXFORD, GB, vol. 39, no. 6, March 1999 (1999-03), pages 1221-1229, XP001148167 ISSN: 0042-6989**

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Description

BACKGROUND OF THE INVENTION

5 FIELD OF THE INVENTION

[0001] The present invention relates to a non-invasive device for determining blood glucose levels through the measurement of colour perception.

10 DESCRIPTION OF THE PRIOR ART

[0002] Diabetes mellitus is a disease which afflicts millions of individuals throughout the world. It is a chronic metabolic disorder that is characterized by a high blood glucose concentration, otherwise known as hyperglycaemia. Elevated glucose levels are brought about by insulin deficiencies and/or insulin resistance. Hyperglycaemia occurs as a result of uncontrolled hepatic glucose output, in addition to a reduction of glucose uptake by skeletal muscle. If the threshold for renal glucose re-absorption is exceeded, a number of negative physiological outcomes can occur including, an increase in urine glucose levels and osmotic diuresis, a condition which leads to dehydration and excessive thirst. As the disease progresses, individuals afflicted with diabetes may experience damage to their kidneys, retina and peripheral nerves.

[0003] As a result of the potential negative effects of the disease, diabetes sufferers must take frequent measurements of their blood glucose levels, in order to monitor and control said glucose levels. Based on the results of these measurements, individuals can alter their food intake, physical activities, and insulin dosage, as a means of regulating blood glucose levels.

[0004] A number of methods and devices for measuring blood glucose levels are disclosed in the prior art. However, the majority of these means of blood glucose measurement are characterized by their invasiveness and their cost.

[0005] One such blood-glucose level measuring device, the D CONT Cabrio, requires an individual to perform the invasive step of pricking their finger in order to draw blood for testing. Puncturing of the finger can be quite painful and can result in significant discomfort for the individual. After blood has been drawn, a drop of blood from the finger is applied to a test strip, which is then inserted into an electronic glucose measuring device. Upon insertion in the measuring device, a chemical reaction occurs between the blood and the test strip, which results in the test strip changing colour based on the level of glucose present in the blood. Colour changes are detected by the electronic glucose measuring device and results are displayed as numeric values representative of the level of blood glucose. In addition to the aforementioned discomfort caused by this method of testing, the test strips used in this methodology are not always available in a sufficient quantity, and the cost of purchasing such strips can represent a large financial burden on the individual. Further, the purchase cost of the actual measuring device is also quite high, therefore, patients of limited financial means may not be able to afford the device.

[0006] Non-invasive, blood glucose level testing devices have also been described in the prior art, but such devices are also characterized by specific deficiencies. For example, the Gluco-Watch is one such device designed to eliminate the need for invasive blood glucose testing. The Gluco-Watch is worn on the arm of a patient and is equipped with sensors that can measure blood glucose levels at intervals of 3 hours. Unfortunately, this device is also costly to the consumer.

US-A-6113537 discloses a blood glucose level testing device which provides a light pattern which varies in regard to parameters such as colour, spatial contrast etc. A person observes the light pattern and a subjective visual effect correlating with blood glucose level.

[0007] The present invention seeks to provide a device for testing blood glucose levels that overcomes the deficiencies in the prior art. Specifically, the present invention provides a non-invasive measurement device, at a reasonable cost to the consumer.

SUMMARY OF THE INVENTION

50 **[0008]** The present invention relates to a blood-glucose level measuring device as defined in claim 1. Preferred embodiments of the invention are defined in claims 2-10.

BRIEF DESCRIPTION OF THE DRAWINGS

55 **[0009]** These and other features of the preferred embodiments of the invention will become more apparent in the following detailed description in which reference is made to the appended drawings wherein:

[0010] Figure 1 diagrammatically shows the diffuse and parallel light beams reflected from two test cards located side by side and eyes.

- [0011] Figure 2 diagrammatically shows an embodiment of the blood glucose-level measuring device.
- [0012] Figure 3 diagrammatically shows an embodiment of the present invention comprising a revolving blood-glucose level indicator for accommodating several test cards, and further comprising a closing cover.
- [0013] Figure 4 diagrammatically shows a detailed schematic of the electric circuit utilized in the blood-glucose level measuring device.
- [0014] Figure 5 diagrammatically shows the device formed by the invention
- [0015] Figure 6 diagrammatically shows the device composed by the invention in the box
- [0016] Figure 7 diagrammatically shows the device in an adjustable form.
- [0017] Figure 8 diagrammatically shows a detailed side view of one side of the present invention
- [0018] Figure 9 diagrammatically shows a detailed side view of a second side of the present invention
- [0019] Figure 10 diagrammatically shows a detailed schematic of the present invention comprising a revolving blood-glucose level indicator for accommodating several test cards.
- [0020] Figure 11 diagrammatically shows an additional detailed schematic of the present invention comprising a revolving blood-glucose level indicator for accommodating several test cards.
- [0021] Figure 12 diagrammatically shows an additional detailed schematic of a preferred embodiment of the present invention.
- [0022] Figure 13 diagrammatically shows an additional detailed schematic of a preferred embodiment of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0023] In a preferred embodiment, the present invention provides a non-invasive blood glucose level testing device that measures the level of blood glucose, utilizing an optical based test.

[0024] The preferred device can be used by individuals suffering from diabetes, said individuals having to control their blood glucose level through regular injections of insulin. In addition, the preferred device can also be used for preventative purposes. The preferred blood-glucose level measuring device allows for detection of increased blood glucose levels before such levels exceed safe physiological limits.

[0025] In a preferred embodiment, the blood-glucose level testing device is based on the principle that fluctuations in blood-glucose levels can dramatically influence eyesight. For example, during fluctuations in blood-glucose levels, because of the fact that the retina is highly sensitive to said fluctuations, the perception of an observed image and its color may be altered. As such, an individual may be able to directly assess the extent of vision changes and estimate such changes quantitatively, using a preferred embodiment of the disclosed invention.

[0026] Experiments have shown that blood-glucose level is interconnected with color perception. People with different blood-glucose levels perceive the same color differently, and if the color perception of the two eyes is changed simultaneously, the current blood-glucose level can be determined from this difference using Table 1, which is based on experimental results.

Table 1:

The sign of the color by the color-scale 1	The sign of the color by the color-scale 1/A	Blood-glucose level (mmol/litre)
S 2040-Y90R	S-1080-R	3
S 2050-R	S-1080-R	5
S 2050-Y90R	S-1080-R	6
S 1070-R	S-1080-R	8
S 3050-R30B	S-1080-R	12

[0027] The larger the difference between the color perception of the eyes, the more precisely the blood-glucose level can be determined. Experiments also showed that while watching a shade of color through a low-diameter hole with one eye, the other eye perceives a different shade. This difference can be enhanced using a tube with an arbitrary bore as a small hole, and the other end, positioned away from the eye, of the tube the bore is reduced, for example to 0.5 mm.

[0028] The experiments performed demonstrated that, if the photo-receptors of the eye receive diffuse light reflected from a color object, the extent of modification in the color sensing, due to the change in the blood-glucose level, is magnified by collecting the diffuse light beam into a nearly parallel beam. By comparing the color effects caused by the diffuse light reflected from a color object, with those caused by the parallel beam on the photo receptors, as well as allocating the blood-glucose level value at the time of measurement to the color difference estimated quantitatively, and then repeating the measurements with different blood-glucose level values, the possibility of establishing a blood-glucose

level scale based on color sensing was obtained. The aforementioned scale can be used to determine blood-glucose levels without requiring any blood samples and is therefore non-invasive.

[0029] Color objects, color test cards, colors projected on white cards, colors generated in electric way, colors generated by means of liquid crystals, can also be used for color sensing for the purpose of blood glucose level measurement.

[0030] In a preferred embodiment, as described further below, a blood-glucose level measuring device was produced that is enclosed in a box (19) that can be opened and closed. The device has a cover (39) provided with two openings (9,12) covered preferably with transparent material (e.g. glass, plastic) and is made preferably of dye-cast plastic, where, according to the invention, at least two test cards (1,2) are arranged at specified distances and specified positions within the box (19), and at least one illuminator (17) is built in the box preferably in front of a conical reflecting surface (18). In order to enable the diffuse beam that is generated by the illuminator, reflected from the inner surface of the closed box (19) to illuminate the two test cards (1,2) and reflected from one of the test cards (1) to fall on the sensing receptors of the eye (6), the box (19) is provided with an opening covered preferably with some transparent material, while in order to enable the part of diffuse beam (4) reflected from the other test card (2) made parallel preferably within 10 degrees to fall on the sensing receptors of the eye (5), the box is provided with a tubular prism (10) that is covered with a closing plate (7) with an opening (8) at the one end while having an opening (9) covered with some preferably transparent material at the other end.

[0031] Preferably, the test cards (1,2) paired appropriately, are fastened on the sides of a regular polygonal prism (21) that can be rotated within the blood-glucose level measuring device; a positioning spring holds the prism in its proper position and the blood glucose level value is indicated by the blood glucose indicator on the dial of the turn-knob.

[0032] It is preferred that the illuminator (17) of the blood-glucose level measuring device is actuated by a micro switch that is mounted between two springs fastened to the base plate of the box and fastened preferably to the upper spring when the turn knob is rotated.

[0033] Also in preferred embodiment, the illumination required for the blood-glucose level measuring device, is provided in the form of a glow lamp. The glow lamp is operated by a push-button switch or a rotating switch, and the illumination is active for a pre-determined time (e.g. 5 seconds) and, following this period, the illumination is disabled for a specified time (e.g. 4 seconds). When the device is ready to be switched on again, an indicator light is turned on. The device can be turned OFF and ON by a general switch.

[0034] In a preferred embodiment the blood-glucose level-measuring device is provided with a supply voltage indicator.

[0035] Referring now to figure 1 of the accompanying drawings, there is shown diffuse light beams 3 and parallel light beams 4 reflected from test cards 1 and 2, towards eyes 6,5. During experimentation it was determined that diffuse light beams 3 and parallel light beams 4, reflected from the test cards 1 and 2, respectively, were perceived as the same color in individuals with a 5 mmol/liter blood-glucose level. For example, the colour Ral 1004 golden yellow was perceived by both eye 6 exposed to the diffuse light beams 3, and eye 5 exposed to the parallel light beams. However, when an individual had a blood glucose level of 8 mmol/liter, Ral 1004 golden yellow was perceived to be golden yellow with diffuse light, while it is perceived to be of Ral 8008 olive brown colour with parallel light. As a result, if parallel light beams 4 reflected from a test card of RAL 1004 color arrive at eye 5, and diffuse light beams 3 reflected from a test card of RAL 8008 color arrives at eye 6, both of the test cards would be perceived to be a RAL 8008 olive-brown color.

[0036] Referring now to figure 2 of the accompanying drawings, there is shown a view of a preferred embodiment of the blood-glucose level measuring device in an open state. The inner space 16 of box 19, of a preferred blood-glucose level measuring device is illuminated by the illuminator 17. The illuminator 17 is surrounded by a conical light reflecting surface 18, which directs beams of light towards the, preferably, coloured test cards 1,2. The coloured test cards 1 and 2 reflect light through openings 12 and 9, which are covered with transparent material, to eyes 5 and 6. The beams of light 3 reflected from the test card 1 are diffuse, while the light beams 4 reflected from test card 2 are nearly parallel. In other words, the reflected light beams 4 are allowed to deviate by up to 5° from the vertical. The parallel light beams 4, arrive at eye 5 through the opening 8 of closing plate 7, which covers the end of the tubular prism 10, and through opening 9, which is covered with transparent material on the box 19. In order to enhance the purity of the appearing color, it is also necessary that inner surface 14 of the tubular prism 10 is comprised of a material with strong light absorbing properties. In addition, in a preferred embodiment, the light beams illuminating the test card 2 are shielded with a shielding 15 made of semi-transparent (ie. opaque) material. Such shielding is required if the test card 2 has a bright surface.

[0037] Because a distance (S) of the pupils of each individual varies, the position of the openings 12 and 9 can be adjusted by means of the oval shaped opening 11 on the box 19. In addition, sliding plate 13 can be displaced and fastened, in order to ensure that the diffuse and parallel light beams can be sensed by the 5, 6 eyes. The illuminator 17 operates only if the electronic unit activates the LED 20. When the device is ready to measure blood-glucose levels a green light on the LED 20 turns on. When the green light turns on, the 17 illuminator can be switched on and blood-glucose level measurement initiated.

[0038] It is preferred that the diameter D1, of the preferably circular opening arranged on the closing plate of the tubular prism built into the blood-glucose level measuring device, is of up to 2 mm, while the diameter D2 of the preferably circular opening covered with some transparent material, as well as the diameter D4 of the preferably circular opening

arranged on the slide plate, and covered with transparent material, are less than 10 mm each, and the diameter D3 of the tubular prism (10) is greater than or equal to the diameter D2.

5 [0039] Referring now to figure 3 of the accompanying drawings an additional embodiment of the preferred blood-glucose measuring device is provided. In this embodiment a preferred blood-glucose level measuring device is provided with a revolving blood-glucose level indicator and lockable cover plate 38. Several test cards 22, 22', can be fitted to a
10 decahedral regular prism 21, which can be rotated and is built into the lockable box 19. Paired test cards 22, 22' are fastened to the sides of the prism 21. It is preferred that the test cards not in use during the blood-glucose level measurement are covered by two cover plates 23, 24 in order to eliminate their disturbing effects. The regular prism 21 can be rotated using turn knob 25. The rim of the turn knob 25 is provided with a dial 26 suitable for indicating the blood-glucose level. The blood-glucose level is shown on the blood-glucose level indicator 27. Turning the regular prism 21 by a unit angle, its positioning is ensured by the positioning spring 28.

15 [0040] Spring 30, which is connected to and responsible for positioning the micro switch 29, is fastened to the bottom plate of lockable box 19 by fastening element 31. Between the two springs, the micro switch 29 is arranged and is fastened to the spring 30. The lockable box 19 is provided with dimming rims 32 arranged symmetrically. In order to ensure the comfortable use, the preferred embodiment has an indent 33 corresponding to the shape of a nose ridge. In order to ensure portable operation, the device is provided with rechargeable batteries 36 and 27, and a connector 47 for recharging. The readiness of the device to repeat the blood-glucose level measurement is indicated by the green light of the 20 LED. When the batteries 36 and 37 require recharging, a red light or voltage indicator 48 is switched on. The device can be switched off and on by using general switch 34. The repeated measurements can be initiated by means of touch-switch 35. The cover plate 38 is fastened to the box 19 by means of closing element 39, while it can be opened through opening hole 40. The undesired displacement of batteries is prevented fastening element 41.

20 [0041] Referring now to figure 4 of the accompanying drawings a preferred embodiment of the electric circuit of the preferred blood-glucose measuring device is provided. The internal illumination of the blood-glucose level-measuring device can be ensured for a specified time (e.g. 5 seconds) by means of the illuminator 17, said illuminator being activated
25 by touch-switch 29 and touch-switch 35, respectively. A further requirement for the evaluation of blood-glucose level measurement is that the re-activation of the device is prevented for a specified time (e.g. 5 seconds) following each measurement. When the preferred device is ready for operation, its status is indicated by the green light of LED 20. For the measurement of time, the monostable 42, 42 or in other words timing circuit (e.g. IC of type C556), is utilized. On activating the push-button 35 or the turn knob 29 switch, both monostables 42 and 43 receive a voltage pulse necessary
30 for tripping. The operating time of monostable 42 is approximately 5 seconds. The output from monostable 42 drives through the power amplifier 44 and 45 (T1 and T2 transistors in Darlington circuit) and the illuminator 17. The monostable 43 prevents the device from being re-started during the operation of the illuminator 17, and for 5 seconds following operation. As a result a time cycle of 10 seconds is controlled by the monostable 43, the output signal of which is fed back through the OR gate 46 to the starting input of the timing circuits 42 and 43.

35 [0042] To the other input of the OR gate 46, push button 34 and the turn knob switch 29 are connected in parallel. As a result of the operation of the 46 OR gate, the timer circuit 42 is allowed to be re-started only if a 10-second operation of the 43 timer circuit is completed, and either the push-button 35 or the turn knob switch 29 is operated. The possibility of re-starting the device is indicated by the LED 20, connected to the output of the timer circuit 43, that operates for 10 seconds, and following the expiry of the 10-second period, it activates the LED 20. Once the conditions of re-starting
40 are fulfilled, the LED 20 is switched off.

[0043] The preferred blood-glucose level measuring device can be produced at low cost and is extremely simple to use. Further, no additional materials and supplies are required for operation of the device after its initial purchase.

45 [0044] Figure 5 and 6 show the preferred device has a color-scale (1, 1/A) and in front of that a looking appliance (5) formed to eyehole (4) which covers the eye (3). The (1) color-scale is composed to have a view of it with naked eye. The tube joins to the opening of looking appliance, the inside bore of its open end is 0.5 mm.

[0045] By the one device of the invention there are two color-scales (1, 1/A) side by side and they can rotate with the adjusting knob (16). There are 11 bulbs in front of the color-scales (1, 1/A) and 10 energy source, for example penlight battery, is intended for them. The color-scales can use as artificial light for example LED.

50 [0046] In figure 7 the set with 12 set bolts by invention is formed from the tiltable left (13) and right part (14) which can move around the rotation axis (15). We can adjust the distance between the eye (3) of patient (2) and the color-scales (1, 1/A) with rotating of the 12 set bolts. We can adjust the eyehole (6) to the patient's (2) eye (3) with moving of the tiltable left (13) and right part (14) which are been able to rotate around the rotation axis (15).

55 [0047] In what follows we describe with more details the mechanism of the invention according to the preferred device. The patient (2) moves the set of invention (4) in front of his eye (3) by the eyehole (6). The two eyes see clearly the color-scale 1. The eye of patient which is looking through the opening and the tube perceives the color-scale 1/A. The cause of the tube (7) the eye 3 perceives the same color in a different way as the eye 2 does. Than the patient is moving the color-scale I in front of the eye 2 until he will see the same dye perceived by his other eye (3).. In that time we read the sign of this dye from the color-scale 1/A named 'NCS Index, edition 2' and we compare it to a list made during the

practical measures and find the assigned current blood-glucose level.

[0048] Figures 8 to 13 describe the invention in further detail from a variety of perspectives.

[0049] Although the invention has been described with reference to certain specific embodiments, various modifications thereof will be apparent to those skilled in the art without departing from the scope of the invention as outlined in the claims appended hereto.

Claims

- 10 1. Blood-glucose level measuring device comprising a box (19) that can be opened and closed, respectively, that has a cover provided with opening a first and a second, (9, 12) each preferably covered with transparent material and made preferably of dye-cast plastic, **characterized by that** at least two test cards (1,2) are arranged at specified distances and specified positions within the box (19), and at least one illuminator (17) is built in the box, preferably in front of a conical reflecting surface (18), in order to enable a diffuse beam that is generated by the illuminator and/or reflected from an inner surface of the closed box (19) to illuminate the two test cards (1, 2) and reflected from one of the test cards (1) to fall on through the first of the two the sensing receptors of an eye (6) through the first of the two openings (12), while in order to enable a part of the diffuse beam (4) reflected from the other test card (2) to be made parallel, preferably within 10°, and to fall on the sensing receptors of an other eye (5), the box is provided with a tubular prism (10) that is covered with a closing plate (7) with an opening (8) at the one end the second opening (9) at the other end.
- 15 2. Blood-glucose level measuring device as in claim 1, **characterized by that** the test cards (1, 2, 22, 22') paired appropriately are fastened on the sides of a regular polygonal prism (21) that can be rotated within the blood-glucose level measuring device; a positioning spring (28) holds the prism in its proper position and the blood glucose level value is indicated by the blood glucose indicator (27) on the dial (26) of the turn-knob (25).
- 20 3. Blood glucose level measuring device as in claim 1, **characterized by that** the test strips out of use during the blood-glucose level measurement are covered by two cover plates (23, 24) in order to eliminate their disturbing effects.
- 25 4. Blood glucose level measuring device as in claim 1, **characterized by that**, during the use of the blood-glucose level measuring device, the pupil distance of eyes can be adjusted by means of a sliding plate (13).
- 30 5. Blood glucose level measuring device as in claim 1, **characterized by that** the illuminator (17) of the blood-glucose level measuring device is actuated by a micro switch (29) that is mounted between two springs (28, 30) fastened to the base plate of the box (19) and fastened preferably to the upper spring (30) when the turn knob (25) is rotated.
- 35 6. Blood glucose level measuring device as in claim 1, **characterized by that** that the diameter D1 of the preferably circular opening (8) arranged on the closing plate (7) of the tubular prism (10) is of up to 2 mm, while the diameter D2 of the preferably circular second opening (9) covered with some transparent material as well as the diameter D4 of the preferably circular first opening (12) arranged on a slide plate (13) and covered with some transparent material are less than 10 mm each, and the diameter D3 of the tubular prism (10) is greater than or equal to the diameter D2.
- 40 7. Blood glucose level measuring device as in claim 1, **characterized by that** the distances between the opening (9,12) covered with transparent material and the test card (1,2) are equal, that is $L_2 = L_3$ and preferably, $L_2 < 200$ mm and $L_3 < 200$ mm and the length of the tubular prism (10) is preferably larger than 10 mm.
- 45 8. Blood glucose level measuring device as in claim 1, **characterized by that** the internal illumination is ensured by a glow lamp (42) under the effect of operating a push-button switch (43) or a rotating switch (44) and the illumination is active for a pre-determined time and, following this period, the illumination is disabled for a specified time; the readiness of the device to be switched on again is indicated by and indicator lamp (45); furthermore, the switching the device OFF and ON will be ensured by a general switch (52).
- 50 9. Blood glucose level measuring device as in claim 1, **characterized by that** it is provided with a voltage indicator (53).
- 55 10. Blood glucose level measuring device as in claim 1, **characterized by that** it is provided with a connector (51) for recharging the battery.

Patentansprüche

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1. Blutglukosespiegelmessvorrichtung, umfassend ein Gehäuse (19), das geöffnet und geschlossen werden kann, das eine Hülle aufweist, die mit einer ersten und einer zweiten Öffnung, von der jede vorzugsweise mit transparentem Material abgedeckt ist, versehen ist und vorzugsweise aus Druckgusskunststoff hergestellt ist, **dadurch gekennzeichnet, dass** zumindest zwei Testkarten (1, 2) innerhalb des Gehäuses (19) in spezifizierten Abständen und spezifizierten Positionen angeordnet sind und dass zumindest eine Beleuchtungseinrichtung (17) in das Gehäuse eingebaut ist, vorzugsweise vor eine konische Reflektionsoberfläche (18), um es einem diffusen Strahl, der mittels der Beleuchtungseinrichtung erzeugt und/oder von einer inneren Oberfläche des geschlossenen Gehäuses (19) reflektiert wird, zu ermöglichen, die zwei Testkarten (1, 2) zu beleuchten und, reflektiert von einer der Testkarten (1), auf die Tastrezeptoren eines Auges (6) durch die erste der zwei Öffnungen (12) zu fallen, während um einem Teil des diffusen Strahls (4), der von der anderen Testkarte (2) reflektiert wird, zu ermöglichen, parallel gerichtet zu werden, vorzugsweise innerhalb von 10° , und auf die Tastrezeptoren eines anderen Auges (5) zu fallen, das Gehäuse mit einem Röhrenprisma (10) versehen ist, das abgedeckt ist mit einer Verschlussplatte (7) mit einer Öffnung (8) an dem einen Ende, während es die zweite Öffnung (9) an dem anderen Ende aufweist.
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2. Blutglukosespiegelmessvorrichtung gemäß Anspruch 1, **dadurch gekennzeichnet, dass** die geeignet gepaarten Testkarten (1, 2, 22, 22') an den Seiten eines regelmäßigen polygonalen Prismas (21) befestigt sind, dass innerhalb der Blutglukosespiegelmessvorrichtung gedreht werden kann, wobei eine Positionierfeder (28) das Prisma in seiner richtigen Position hält und der Blutglukosespiegelwert mittels des Blutglukoseindikators (27) auf der Skalenscheibe (26) des Drehknopfes (25) angezeigt wird.
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3. Blutglukosespiegelmessvorrichtung gemäß Anspruch 1, **dadurch gekennzeichnet, dass** die nicht im Gebrauch befindlichen Teststreifen während der Blutglukosespiegelmessung mittels zwei Abdeckplatten (22, 24) abgedeckt sind, um deren Störeffekte zu eliminieren.
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4. Blutglukosespiegelmessvorrichtung gemäß Anspruch 1, **dadurch gekennzeichnet, dass** während des Gebrauchs der Blutglukosespiegelmessvorrichtung der Pupillenabstand der Augen mittels einer Gleitplatte (13) eingestellt werden kann.
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5. Blutglukosespiegelmessvorrichtung gemäß Anspruch 1, **dadurch gekennzeichnet, dass** die Beleuchtungseinrichtung (17) der Blutglukosespiegelmessvorrichtung mittels eines Mikroschalters (29) betätigt wird, der zwischen zwei Federn (28, 30) montiert ist, die an der Basisplatte des Gehäuses (19) befestigt sind, und der vorzugsweise an der oberen Feder (30) befestigt ist, wenn der Drehknopf (25) gedreht wird.
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6. Blutglukosespiegelmessvorrichtung gemäß Anspruch 1, **dadurch gekennzeichnet, dass** der Durchmesser D1 der vorzugsweise runden Öffnung (8), die an der Verschlussplatte (7) des Röhrenprismas (10) vorgesehen ist, bis zu 2 mm beträgt, während der Durchmesser D2 der vorzugsweise runden zweiten Öffnung (9), die mit einem transparenten Material abgedeckt ist, wie auch der Durchmesser D4 der vorzugsweise runden ersten Öffnung (12), die auf einer Gleitplatte (13) vorgesehen und mit transparentem Material abgedeckt ist, jeweils weniger als 10 mm beträgt und wobei der Durchmesser D3 des Röhrenprismas (10) größer als oder gleich zu dem Durchmesser D2 ist.
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7. Blutglukosespiegelmessvorrichtung gemäß Anspruch 1, **dadurch gekennzeichnet, dass** die Abstände zwischen der mit transparentem Material abgedeckten Öffnung (9, 12) und der Testkarte (1, 2) gleich sind, das heißt $L_2 = L_3$, und vorzugsweise $L_2 < 200$ mm und $L_3 < 200$ mm, und dass die Länge des Röhrenprismas (10) vorzugsweise größer als 10 mm ist.
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8. Blutglukosespiegelmessvorrichtung gemäß Anspruch 1, **dadurch gekennzeichnet, dass** die innere Beleuchtung mittels einer Glühlampe (42) als Folge der Betätigung eines Druckknopfschalters (43) oder eines Drehschalters (44) gewährleistet wird und dass die Beleuchtung für eine vorbestimmte Zeit aktiv ist und dieser Periode folgend die Beleuchtung für eine spezifische Zeit gesperrt wird; wobei die Bereitschaft der Vorrichtung, wieder eingeschaltet zu werden, mittels einer Indikatorlampe (45) angezeigt wird; und dass weiterhin das Schalten der Vorrichtung AUS und EIN mittels eines Hauptschalters (52) gewährleistet wird.
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9. Blutglukosespiegelmessvorrichtung gemäß Anspruch 1, **dadurch gekennzeichnet, dass** sie mit einem Spannungsanzeiger (53) versehen ist.
10. Blutglukosespiegelmessvorrichtung gemäß Anspruch 1, **dadurch gekennzeichnet, dass** sie mit einem Anschluss

(51) zur Wiederaufladung der Batterie versehen ist.

Revendications

- 5
1. Dispositif de mesure du niveau de glucose dans le sang comprenant une boîte (19) qui peut être ouverte et fermée, respectivement, comprenant un couvercle, muni d'une première et d'une deuxième ouvertures (9, 12), chacune de préférence couverte par du matériau transparent et formée de préférence de matière plastique coulée sous pression, **caractérisé en ce qu'**au moins deux cartes de test (1, 2) sont agencées à des distances spécifiées et à des positions spécifiées, à l'intérieur de la boîte (19), et un moins un élément d'éclairage (17) est installé dans la boîte, de préférence à l'avant d'une surface conique (18) réfléchissante, afin de permettre à un rayon diffus, généré par l'élément d'éclairage et/ou réfléchi par la surface intérieure de la boîte (19) fermée, d'éclairer les deux cartes de test (1, 2) et d'être réfléchi par l'une des cartes de test (1), pour tomber sur les récepteurs de détection d'un oeil (6), en passant par la première des deux ouvertures (12), tandis que, pour permettre à une partie du rayon diffus (4), réfléchi par l'autre carte de test (2), d'être rendue parallèle, de préférence dans une plage de 10°, et de tomber sur les récepteurs de détection d'un autre oeil (5), la boîte est munie d'un prisme (10) tubulaire, couvert par une plaque de fermeture (7), avec une ouverture (8) à une extrémité et avec la deuxième ouverture (9) à l'autre extrémité.
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2. Dispositif de mesure du niveau de glucose dans le sang selon la revendication 1, **caractérisé en ce que** les cartes de test (1, 2, 22, 22'), appariées de manière appropriée, sont fixées sur les côtés d'un prisme (21) polygonal régulier, pouvant être tourné dans le dispositif de mesure du niveau de glucose dans le sang ; un ressort de positionnement (28) maintient le prisme à sa position correcte, et la valeur du niveau de glucose dans le sang est indiquée par l'indicateur de glucose dans le sang (27), sur le cadran (26) du bouton tournant (25).
- 20
3. Dispositif de mesure du niveau de glucose dans le sang selon la revendication 1, **caractérisé en ce que** les bandes de test, hors d'utilisation pendant la mesure du niveau de glucose dans le sang, sont couvertes par deux plaques de couverture (23, 24), afin d'éliminer leurs effets perturbateurs.
- 25
4. Dispositif de mesure du niveau de glucose dans le sang selon la revendication 1, **caractérisé en ce que**, pendant l'utilisation du dispositif de mesure du niveau de glucose dans le sang, la distance de pupille des yeux peut être ajustée au moyen d'une plaque coulissante (13).
- 30
5. Dispositif de mesure du niveau de glucose dans le sang selon la revendication 1, **caractérisé en ce que** l'élément d'éclairage (17) du dispositif de mesure du niveau de glucose dans le sang est actionné par un micro-interrupteur (29), monté entre deux ressorts (28, 30) fixés à la plaque de base de la boîte (19) et fixé de préférence au ressort supérieur (30), lorsque le bouton tournant (25) est tourné.
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6. Dispositif de mesure du niveau de glucose dans le sang selon la revendication 1, **caractérisé en ce que** le diamètre D1 de l'ouverture (8), de préférence circulaire, agencée sur la plaque de fermeture (7) du prisme tubulaire (10) est d'une valeur allant jusqu'à 2 mm, tandis que le diamètre D2 de la deuxième ouverture (9), de préférence circulaire, couverte par un certain matériau transparent, ainsi que le diamètre D4 de la première ouverture (12), de préférence circulaire, agencée sur une plaque coulissante (13) et couverte par un certain matériau transparent, sont chacun inférieurs à 10 mm, et le diamètre D3 du prisme tubulaire (10) est supérieur ou égal au diamètre D2.
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7. Dispositif de mesure du niveau de glucose dans le sang selon la revendication 1, **caractérisé en ce que** les distances entre l'ouverture (9, 12), couverte par du matériau transparent, et la carte de test (1, 2) sont identiques, c'est-à-dire $L_2=L_3$ et, de préférence, $L_2<200$ mm et $L_3<200$ mm, et la longueur du prisme tubulaire (10) est de préférence supérieure à 10 mm.
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8. Dispositif de mesure du niveau de glucose dans le sang selon la revendication 1, **caractérisé en ce que** l'éclairage interne est assuré par une lampe à incandescence (42), sous l'effet de l'actionnement d'un interrupteur à bouton poussoir (43) ou d'un interrupteur rotatif (44), et l'éclairage est actif pour une période de temps prédéterminée et, à la suite de cette période de temps, l'éclairage est désactivé pour une période de temps spécifiée ; la disponibilité du dispositif à être commuté en service de nouveau est indiquée par une lampe indicatrice (45) ; en outre la commutation EN SERVICE et HORS SERVICE du dispositif va être assurée par un commutateur général (52).
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9. Dispositif de mesure du niveau de glucose dans le sang selon la revendication 1, **caractérisé en ce qu'**il est muni d'un indicateur de tension (53).
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10. Dispositif de mesure du niveau de glucose dans le sang selon la revendication 1, **caractérisé en ce qu'il est muni d'un connecteur (51) pour recharger la batterie.**

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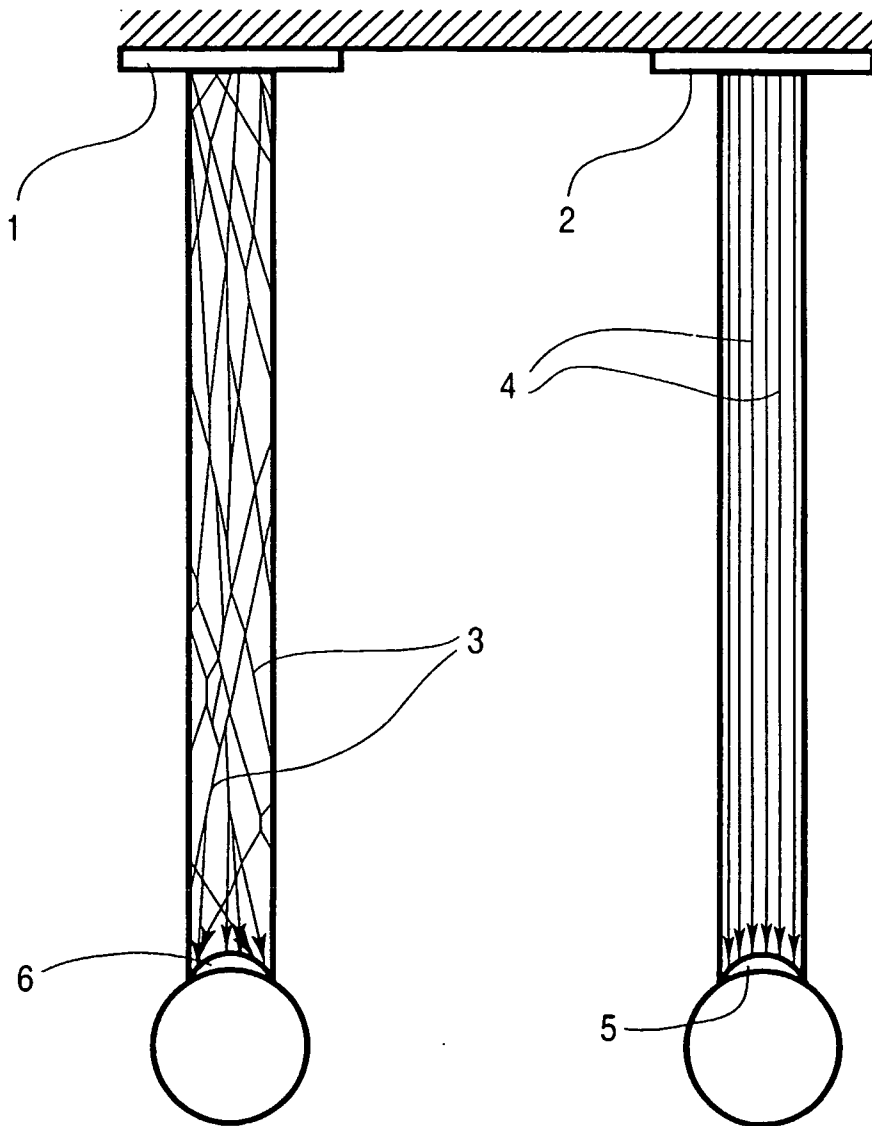
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Figure 1



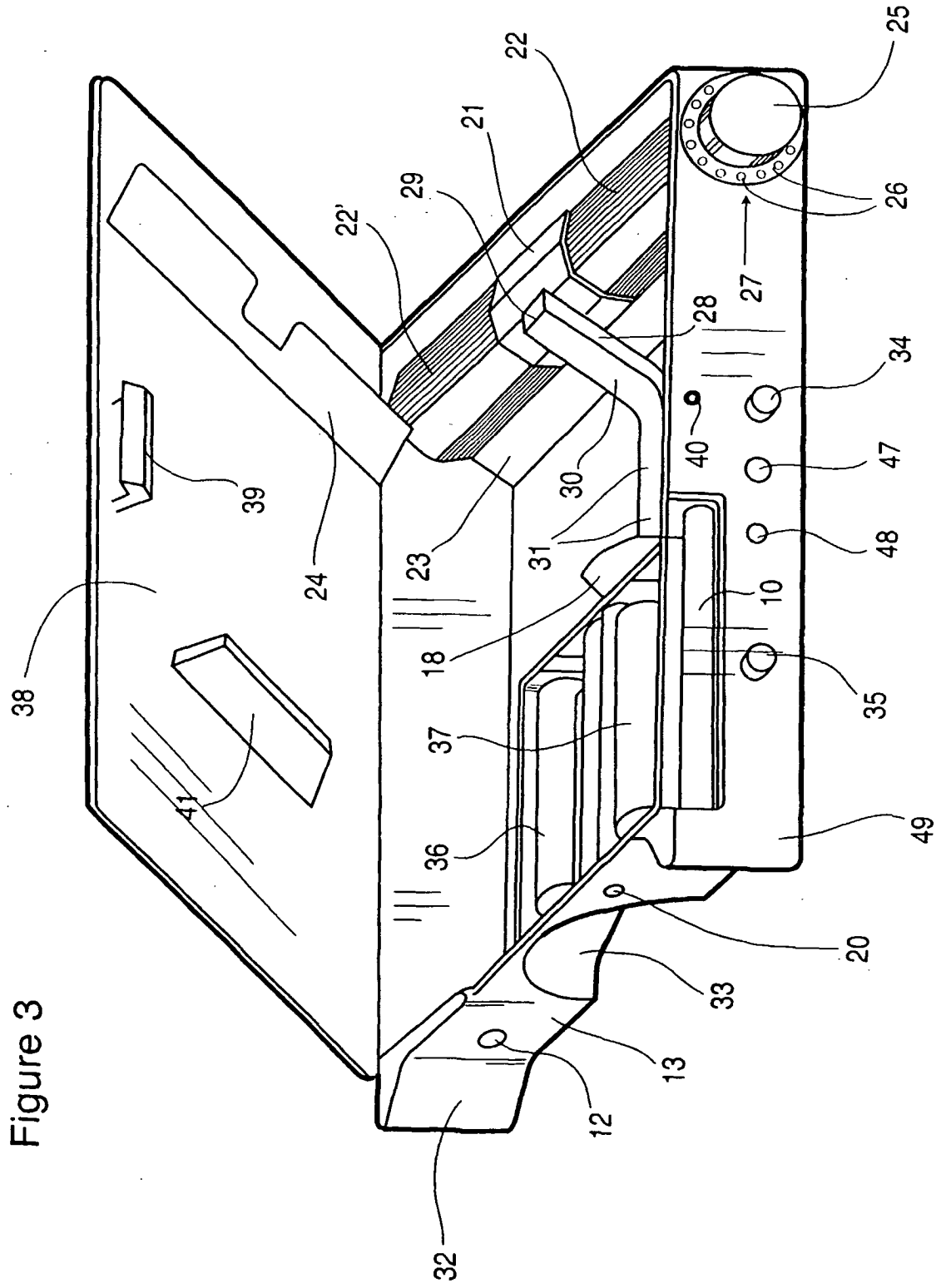


Figure 3

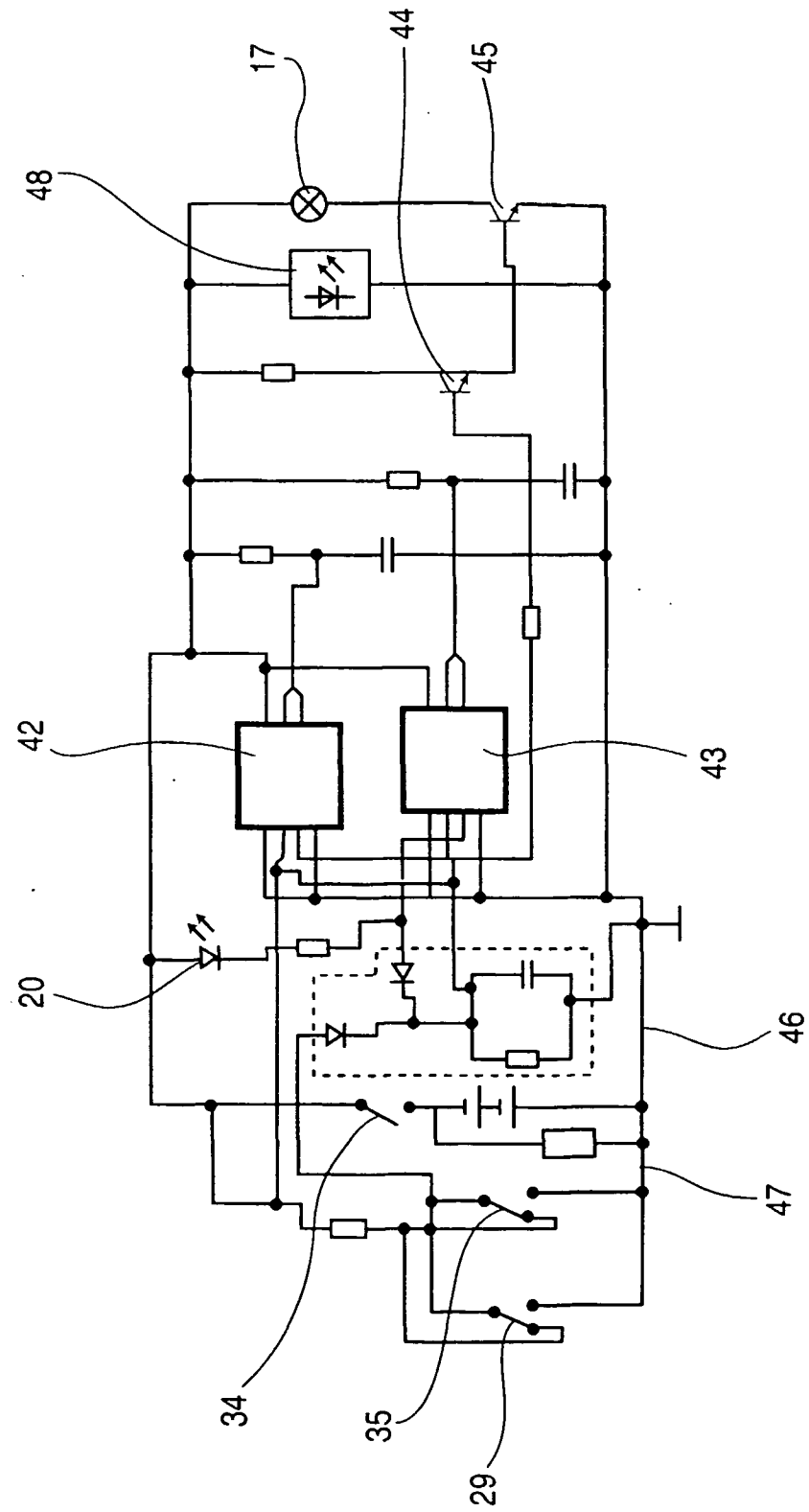


Figure 4

Figure 5

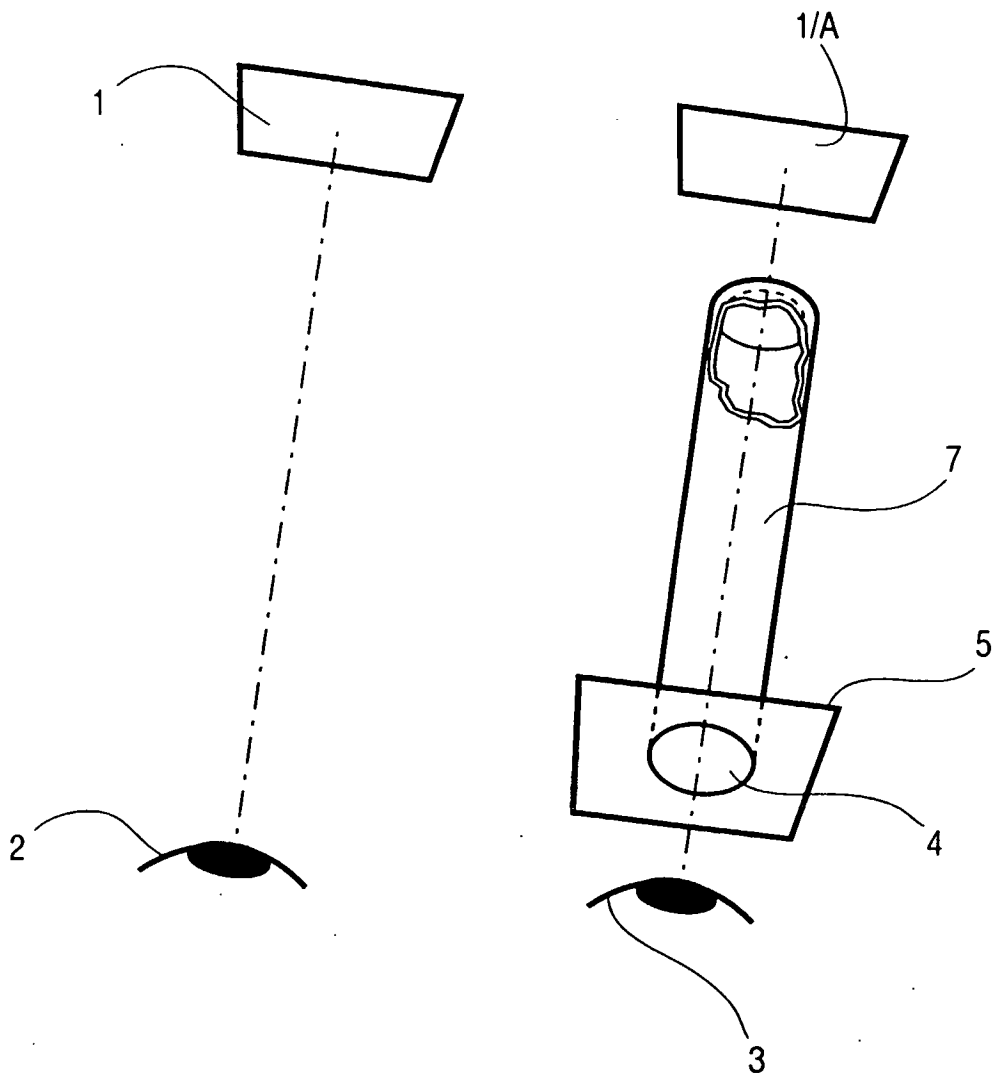
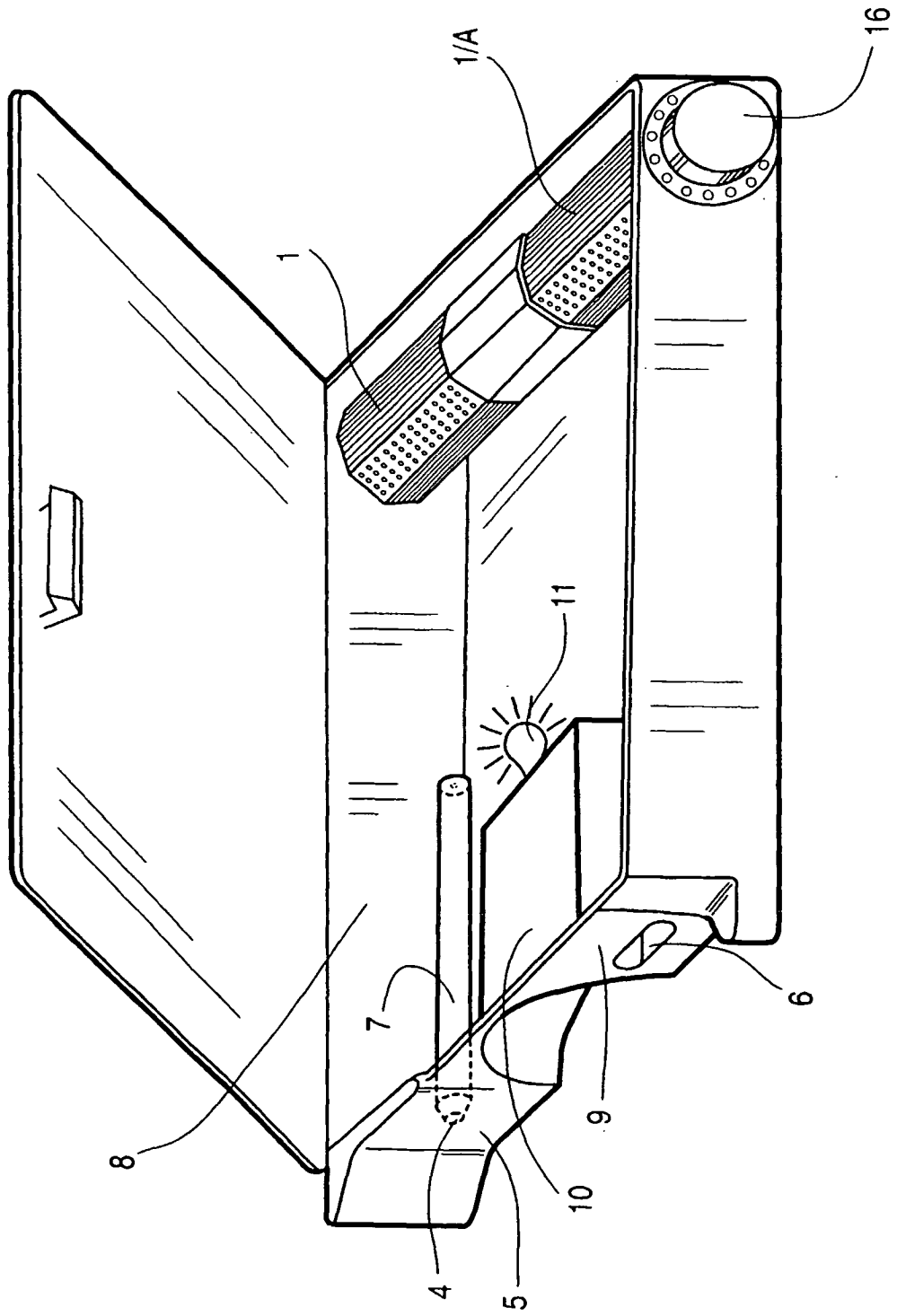


Figure 6



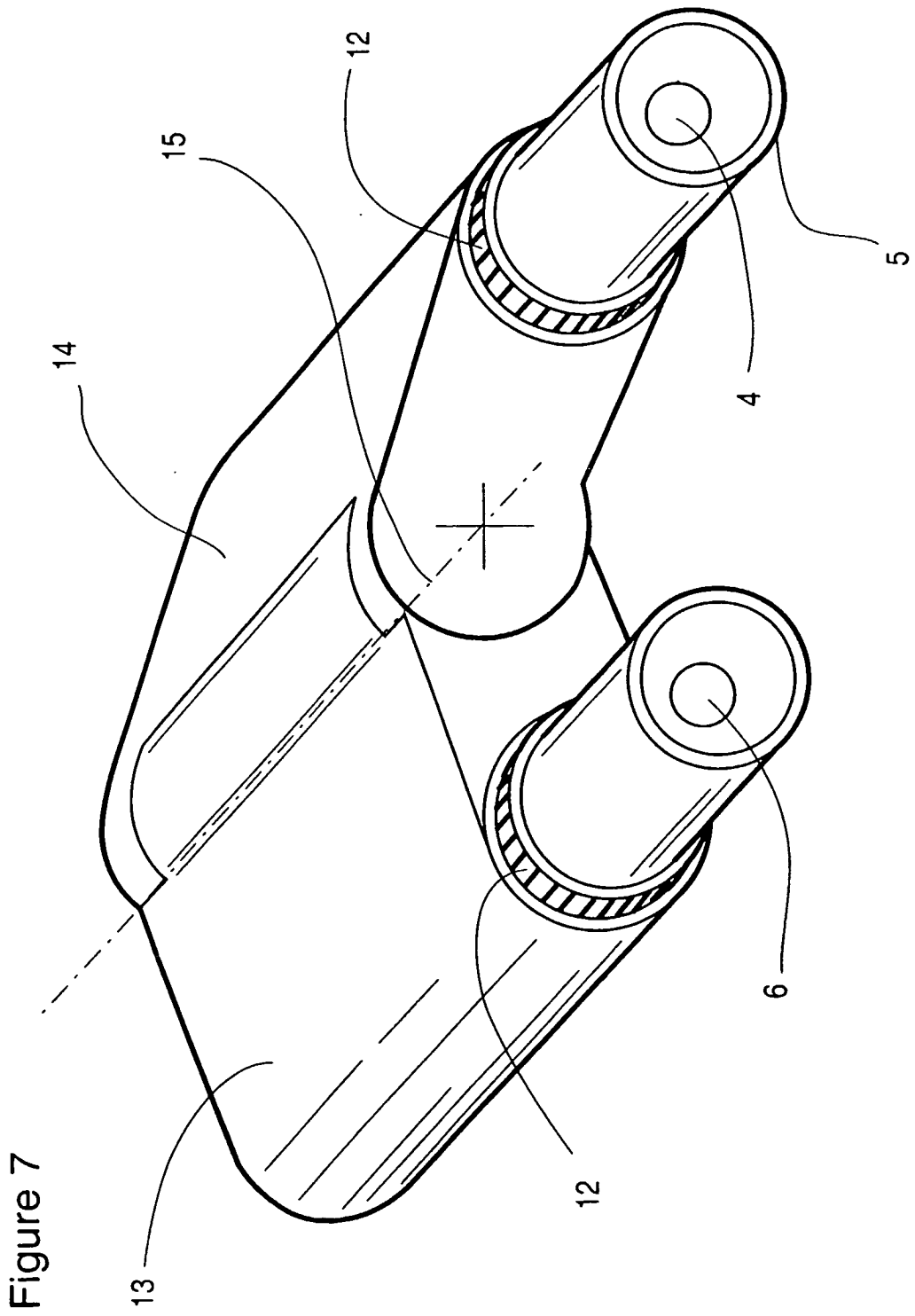


Figure 8

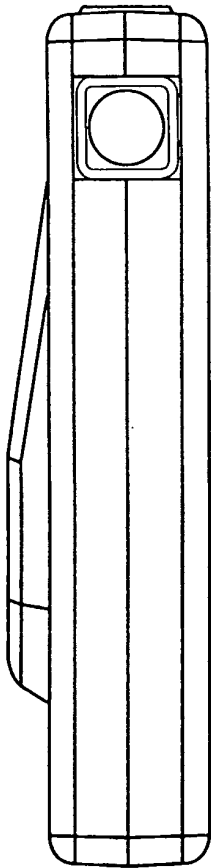
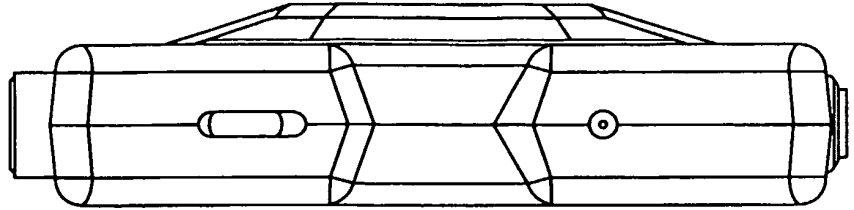


Figure 9

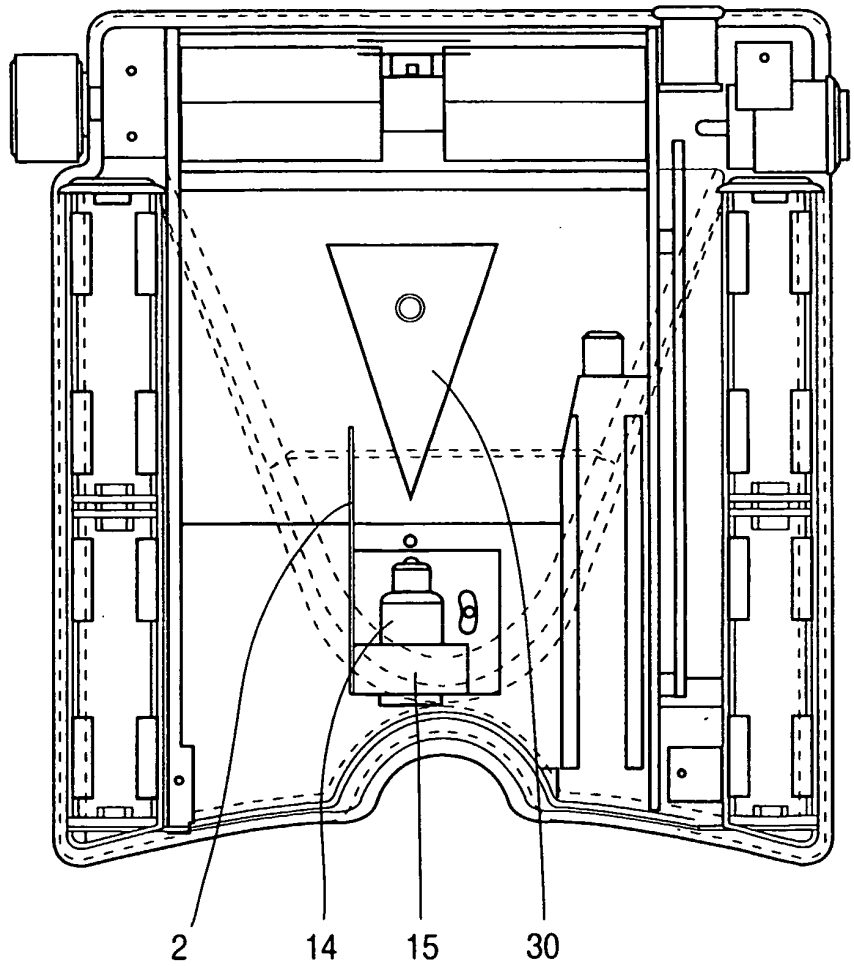


Figure 10

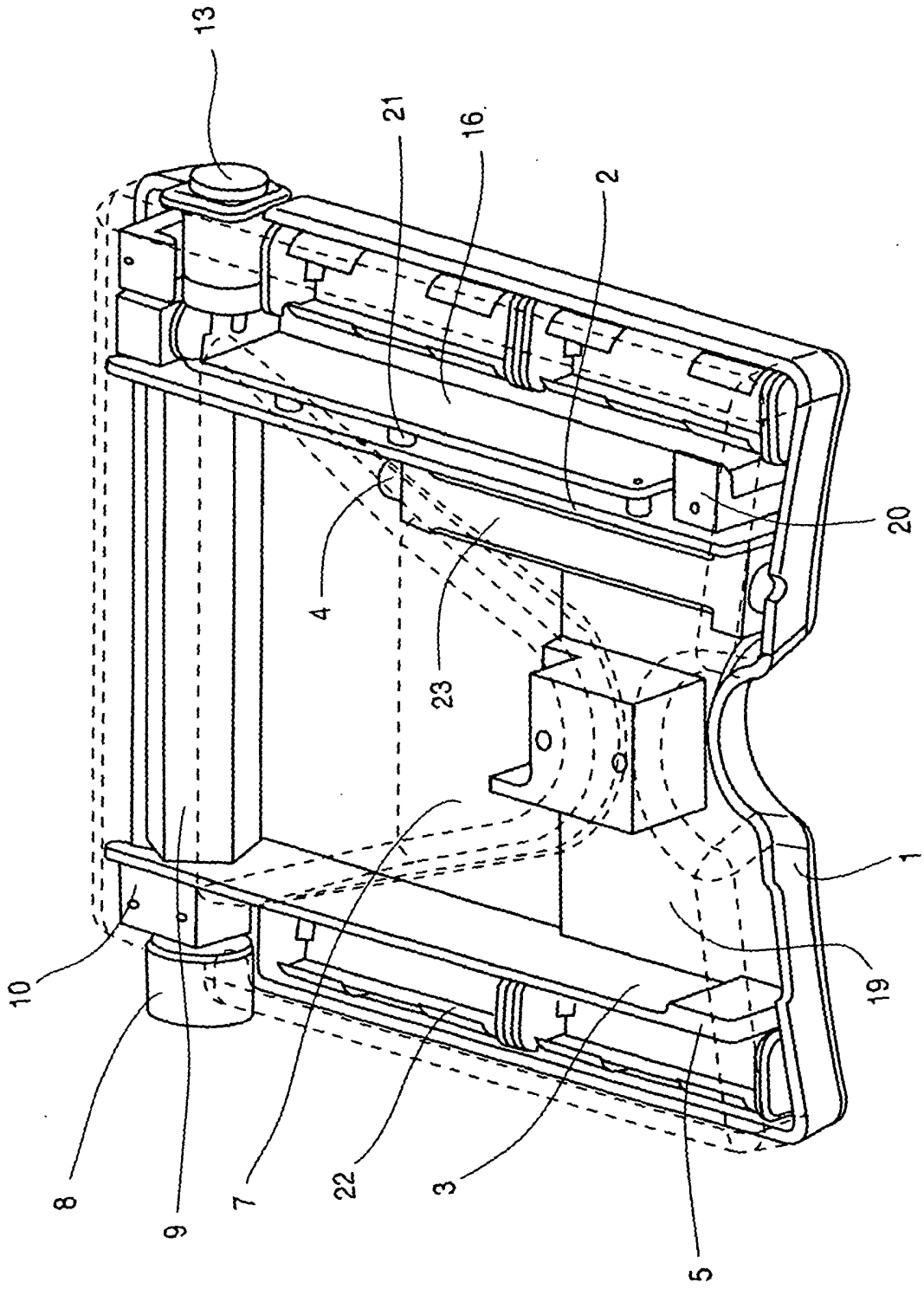


Figure 11

Figure 12

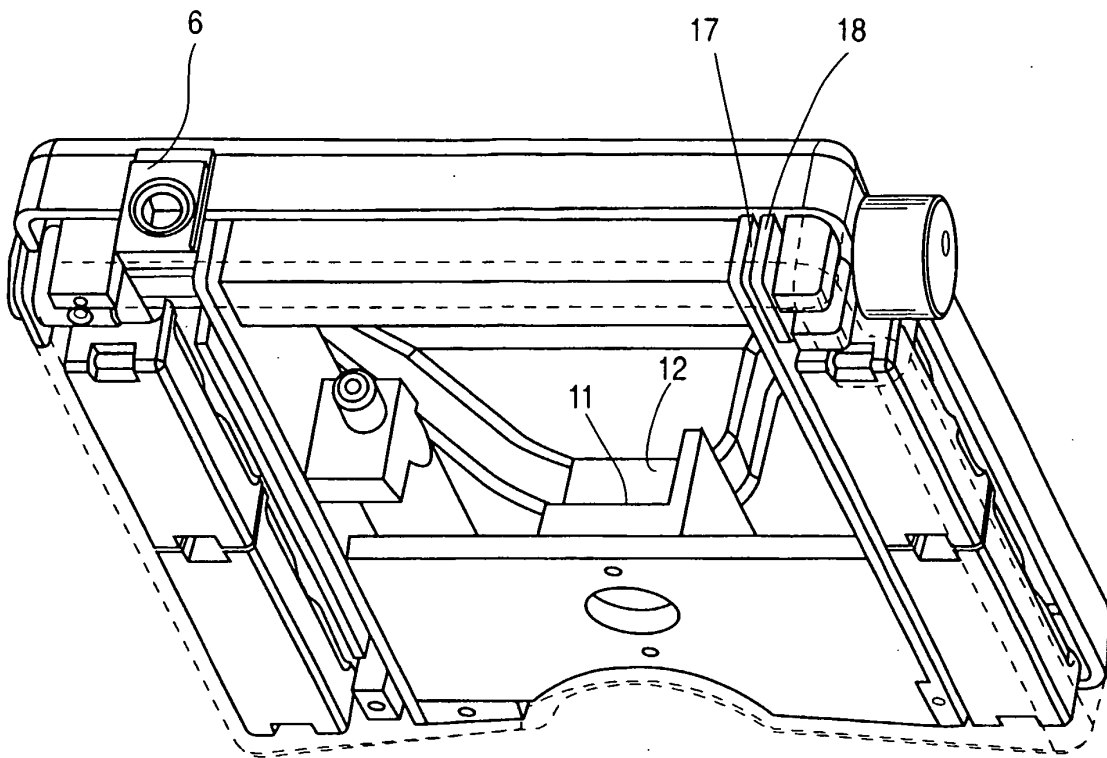
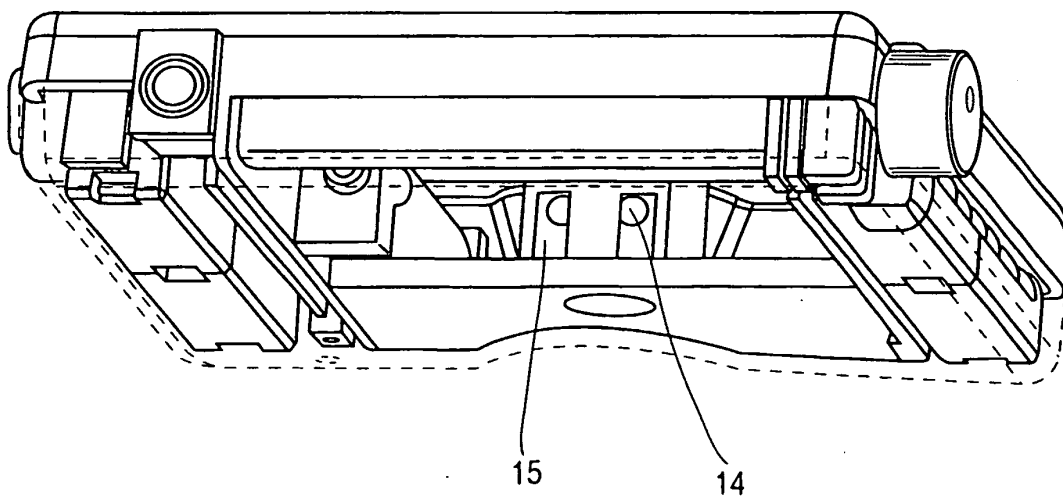


Figure 13



REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- US 6113537 A [0006]

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申请(专利权)人(译)	IRIS医疗技术INTERNATIONAL LTD.		
当前申请(专利权)人(译)	IRIS医疗技术INTERNATIONAL LTD.		
[标]发明人	SUBOTICS GYULA		
发明人	SUBOTICS, GYULA		
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优先权	2001004610 2001-10-31 HU		
其他公开文献	EP1441637A1		
外部链接	Espacenet		

摘要(译)

用于无创测量血糖水平的方法包括监测个体对颜色变化的感知以及其与血糖水平的相关性。

Figure 1

