(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 1 845 839 B1

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:
17.11.2010 Bulletin 2010/46

(21) Application number: **06719997.6**

(22) Date of filing: **31.01.2006**

(51) Int Cl.:
A61B 5/00 *(2006.01)* ***G01N 33/487*** *(2006.01)*
G01N 33/52 *(2006.01)*

(86) International application number:
PCT/US2006/003435

(87) International publication number:
WO 2006/083892 (10.08.2006 Gazette 2006/32)

(54) **FLUID SENSOR COMPRISING A FORMED PLASTIC BODY AND A REAGENT, AS WELL AS A SENSOR PACKAGE COMPRISING A PLURALITY OF SAID SENSORS.**

FLÜSSIGKEITSSENSOR MIT EINE AUSGEFORMTEN KUNSTSTOFFKÖRPER UND EINEM REAGENZ, SOWIE EIN SENSORPAKET, ENTHALTEND EINE VIELZAHL DIESER SENSOREN.

CAPTEUR DE FLUIDE COMPRENANT UN CORPS EN PLASTIQUE MOULE AINSI QU'UN ASSEMBLAGE CONTENANT UNE PLURALITE DESDITS CAPTEURS

(84) Designated Contracting States:
AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IS IT LI LT LU LV MC NL PL PT RO SE SI SK TR

(30) Priority: **01.02.2005 US 649046 P**

(43) Date of publication of application:
24.10.2007 Bulletin 2007/43

(60) Divisional application:
10175005.7

(73) Proprietor: **Bayer HealthCare LLC**
Tarrytown, NY 10591 (US)

(72) Inventors:
- **JUNG, Sung-Kwon**
  Granger, Indiana 46530 (US)
- **CHARLTON, Steven, C.**
  Osceola, Indiana 46561 (US)
- **GEORGE, Suny, J.**
  Granger, Indiana 46530 (US)
- **DOSMANN, Andrew, J.**
  Granger, Indiana 46530 (US)
- **MARFURT, Karen, L.**
  Edwardsburg, Michigan 49112 (US)

(74) Representative: **Burkert, Frank**
Bayer Schering Pharma Aktiengesellschaft
Law and Patents
Patents and Licensing
Building Q 18
51368 Leverkusen (DE)

(56) References cited:
EP-A- 0 990 706 **US-A- 5 223 219**
US-A- 5 854 074

EP 1 845 839 B1

Printed by Jouve, 75001 PARIS (FR)

Description

TECHNICAL FIELD

[0001] The present invention relates to a fluid monitoring system, and more particularly, to a new and improved sensor that is used in analyzing blood glucose or other analytes contained therein.

BACKGROUND

[0002] Those who have irregular blood glucose concentration levels are medically required to regularly self-monitor their blood glucose concentration level. An irregular blood glucose level can be brought on by a variety of reasons including an illness such as diabetes. An estimated 18 million people are afflicted with diabetes in the United States alone. A diabetic patient typically monitors his or her blood glucose concentration level to determine whether the level is too high or too low, and whether any corrective action, such as administering insulin or other medication, is necessary to bring the level back within a normal range. The failure to take corrective action can have serious implications. When blood glucose levels drop too low - a condition known as hypoglycemia - a person may become nervous, shaky, confused, have an impaired judgment, and eventually pass out. A person can also become very ill if their blood glucose level becomes too high - a condition known as hyperglycemia. Both hypoglycemia and hyperglycemia can potentially be life-threatening emergencies. As a result, a diabetic may require frequent sampling of his or her blood glucose - typically several times per day.

[0003] In one type of blood glucose testing system, sensors are used to test a sample of blood. Such a sensor may contain bio-sensing or reagent material that will react with blood glucose. The testing end of the sensor is adapted to be placed into the fluid being tested, for example, blood that has accumulated on a person's finger after the finger has been pricked. In one type of sensor, for example in U.S. Patent No. 5,100,620, issued March 31, 1992, and entitled Capillary Tube/Gap Reagent Format, the fluid is drawn into a capillary channel that extends in the sensor from the testing end to the reagent material by capillary action so that a sufficient amount of fluid to be tested is drawn into the sensor. For electrochemical sensors, the fluid then chemically reacts with the reagent material in the sensor. The chemical reaction results in an electrical signal indicative of the blood glucose level in the blood being tested, which is then supplied to contact areas located near the rear or contact end of the sensor. For optically read or photometric sensors, a reflectance reading can determine the color change indicative of the glucose concentration in the blood/reagent mixture.

[0004] US 5,223,219 discloses an analytical cartridge and system for detecting analytes in liquid samples. The cartridge has a rectangular shape and comprises a sample application site on a top surface and a reflectance reading site having a porous matrix impregnated with a glucose-responsive reagent either on the top or a bottom surface. The cartridge is basically flat and is typically operated in the horizontal orientation, although other orientations are permitted.

[0005] US 5,854,074 discloses a dispensing instrument for fluid monitoring sensors. Each of the sensor elements has a generally flat and rectangular shape and bears a top surface, a bottom surface and side walls interconnecting them, as well as a glucose-responsive reagent located on the first surface. A ledge in the form of a notch is also provided on the sensor.

[0006] EP 0 990 706 Al discloses a flat rectangular test strip for measuring glucose in a sample of whole blood, comprising a test site with a reagent comprising glucose dehydrogenase NAD, a NAD derivative, pyrrolo-quinoline quinone (PQQ) or a PQQ derivative, a tetrazolium dye precursor, a diaphorase enzyme or its analog, and a nitrite salt.

[0007] As with all medical diagnostic devices, contamination is of major concern. It is necessary to avoid contamination of both equipment and personnel by fluids, and to avoid contamination of a patient with fluids from others. For photometric blood glucose monitors in particular, a major concern is contamination of the read-head by blood. Blood on the optical read-head can give rise to erroneous measurements. To address this problem, current sensors have been designed so that they are inoculated with a patient's blood before the sensor is placed in the meter. While this configuration reduces the risk of contamination for the patient, the meter can still become contaminated with blood. In addition, this process is less convenient for the user.

[0008] To address the risk of meter contamination, some sensors have been designed to include a reactive membrane stretched across a through opening in a shaped sensor tip. While such sensors reduce the risk of meter contamination over conventional sensors, there still remains the risk that the read-head of the meter can become contaminated. The reactive membrane does not completely cover the through opening, allowing the possibility that blood may leak onto the meter or read-head either through the membrane or around the membrane/through opening juncture.

[0009] Manufacturing cost is another concern that exists with sensors that include a reactive membrane stretched across a through opening. Due to the large number of sensors a diabetic may use, even a minor reduction in the manufacturing cost of a sensor can result in substantial savings to the diabetic end user. Applying a separate membrane to a through opening involves extra manufacturing steps of handling a separate membrane and applying the membrane to the sensor base.

[0010] In addition to cost, reducing the sample volume is another concern that exists for current sensors. Current sensors require sample volumes anywhere from approximately 0.3 μL to 10.0 μL of blood. For example, in conventional capillary fill sensors, it is difficult to get a reasonable separation between the sample application point on the sensor and the read-head. To illustrate this, if the sensor protrudes 0.3 inches from the meter and the read-head is located 0.2 inches inside the meter case, then the capillary must be 0.5 inches long. Aside from resulting in a considerable waste of sample, this can also lead to a slow fill time and require larger punctures to extract the necessary quantity of blood.

[0011] Another challenge with current sensors is their packaging. Before use, the sensors need to be maintained at an appropriate humidity level so as to insure the integrity of the reagent materials in the sensor. Sensors can be packaged individually in tear-away packages so that they can be maintained at the proper humidity level. For instance, blister-type packaging methods have often been used. The packages can include desiccant material to maintain the proper humidity in the package. In order for a person to use an individual sensor for testing blood glucose, the package must be opened by tearing the seal. Alternatively, some packages require the user to exert force against one side of the package resulting in the sensor bursting or rupturing the foil on the opposite side. As can be appreciated, the opening of these packages can be difficult and may result in damage to the sensor. Moreover, once the package is opened the user needs to be sure that the sensor is not damaged or contaminated as it is being placed into the sensor holder and used to test the blood sample.

[0012] Other sensor packages, such as the one used in U.S. Patent No. 5,630,986, issued May 20, 1997, and entitled Dispensing Instrument for Fluid Monitoring Sensors, also maintain a low humidity environment, but they are not easy to manufacture. One reason is that the symmetry of the circular packaging array does not match the rectangular symmetry of standard sheet sensor printing processes, necessitating handling individual sensors during packaging. The meter is also mechanically complex because of the mechanism required to extract the sensor from the blister pack. In addition, the number of sensors is not visible at a glance.

[0013] For the foregoing reasons, there is a need for a blood glucose sensor that reduces the risk of contamination, the manufacturing cost, and the sample volume. Further, there is a need for a package for such a blood glucose sensor that maintains the sensors at the proper humidity, is simple to use, and has a visual display of the remaining sensors.

BRIEF SUMMARY

[0014] Accordingly, an object of the present invention is to provide a new and improved sensor used in testing blood glucose. In particular, objects of the present invention are to provide a new and improved blood glucose sensor made from a one-piece formed body with a reagent applied to the sensor, and which overcomes the problems or limitations discussed above.

[0015] In accordance with these and other objects of the present invention, the present invention is embodied in a fluid sensor that comprises a formed plastic body and a reagent. The body has a top face with an integral first surface. The body also has a bottom face opposed to the first surface and a sidewall that extends from the periphery of the top face past the bottom surface. The first surface is adapted to accept a fluid sample. The reagent is disposed on the integral first surface and causes a color change detectable on the bottom face when the reagent reacts with an analyte in the fluid sample.

[0016] In a second embodiment of the present invention, a fluid sensor comprises a formed porous plastic body, a surfactant, and a reagent. The body has a top face with an integral first surface, a bottom face with a second surface opposed to the first surface, and a sidewall adjacent to the top face extending past the bottom surface. The first surface is adapted to accept a fluid sample. The surfactant is disposed on the body. The reagent causes a color change detectable on the second surface when the reagent reacts with an analyte in the fluid sample.

[0017] According to a third aspect of the present invention, a method of making a fluid sensor includes the act of forming a plastic body. The plastic body has a top face with an integral first surface, a bottom face opposed to the first surface, and a sidewall extending from the periphery of the top face past the bottom surface. The first surface is adapted to accept a fluid sample. The method also includes the act of applying a reagent to the integral first surface. The reagent causes a color change detectable on the bottom face when the reagent reacts with an analyte in the fluid sample. The method also includes the act of applying a lid to a raised region on the top face.

BRIEF DESCRIPTION OF THE DRAWINGS

[0018] FIG. 1 is a perspective view of a blood glucose sensor constituting one embodiment of the present invention.

[0019] FIG. 2 is a partial cross-section view of the blood glucose sensor of FIG. 1.

[0020] FIG. 3 is a perspective view of a blood glucose sensor constituting a second embodiment of the present invention.

[0021] FIG. 4 is a partial cross-section view of the blood glucose sensor of FIG. 3.

[0022] FIG. 5 is a perspective view of a blood glucose sensor constituting a third embodiment of the present invention.

[0023] FIG. 6 is a cross-section view of the blood glucose sensor of FIG. 5.

[0024] FIG. 7 is a perspective view of a fourth embodiment of the present invention, illustrating a shoulder on the sidewall of the blood glucose sensor.

[0025] FIG. 8 is a cross-section view of the blood glucose sensor of FIG. 7.

[0026] FIG. 9 is an exploded perspective view of a blood glucose kit.

[0027] FIG. 10 is a top perspective view of a sensor package used with the blood glucose meter of FIG. 9.

[0028] FIG. 11 is a partial cross-section view of a read-head of a blood glucose meter inserted into the sensor of FIG. 7 contained within a sensor package.

[0029] FIG. 12 is a cross-section view of an array of the blood glucose sensors of FIG. 1, illustrating a sequence of steps in the typical construction of the sensors with integral spacers.

[0030] FIG. 13 is a cross-section view of an array of the blood glucose sensors in FIG. 3, illustrating a sequence of steps in the typical construction of the sensors with spacers made by printing.

DETAILED DESCRIPTION OF THE DRAWINGS

AND THE PRESENTLY PREFERRED EMBODIMENTS

[0031] Referring now more specifically to the drawings, therein is disclosed a fluid sensor generally designated by the reference numeral 10 and embodying the present invention. As illustrated in FIGS. 1-2, one embodiment of the sensor 10 includes a body 12, a reagent 30, and a lid 40.

[0032] The body 12 may be formed into a hollow frustum (such as a conical or pyramidal shape) shaped to mount on an optical read-head 510 of corresponding shape (FIGS. 9 and 11). The read-head 510 can host two light guides, one for alight source and another for reflected light. Body 12 may be formed from impermeable plastic such as polypropylene, polyethylene terephthalate, or other plastic, using techniques known in the art, such as film forming, injection molding, etc. The frustum shaped body 12 has only one open end, with integral sidewalls 14 that extend downward from the periphery of a top face 16. A bottom face 18 is located on the inside of body 12, opposite top face 16. Body 12 may be sized with an overall height of 0.2 inches, although other heights that are sufficient to avoid contamination of a glucose meter 502 by sample blood may also be used.

[0033] The engagement of body 12 with the read-head 510 can be facilitated by a first latch 24 located on the sidewall 14 of the sensor. The latch 24 may be formed using any technique known in the art and may comprise any number of shapes, such as indentations, holes, grooves, or embosses in the sidewall 14 of body 12.

[0034] The top face 16 has a raised region forming a spacer 22 that surrounds an integral first surface 20, which may be formed into a concave or recessed surface for ergonomic sample loading. In the embodiment shown in FIGS. 1-2, spacer 22 is depicted as an annulus, although other shapes may be used. Spacer 22 may be integrally formed with body 12. Alternately, spacer 22 may be formed as a separate molded spacer and attached to the top face 16 of body 12 through sonic welding, an adhesive, or other method of attachment.

[0035] Lid 40 is mounted to spacer 22 on the top face 16 of body 12, forming a capillary chamber 50. As best seen in FIG. 1, this arrangement has open sides formed by the gap between lid 40 and first surface 20 so as to provide access by a blood sample to the capillary chamber 50. Capillary chamber 50 allows for a controlled sample volume of blood to react with reagent 30. FIGS. 1 and 2 illustrate one embodiment where lid 40 is constructed of a rectangular strip of impermeable plastic, formed in a similar manner to body 12 described above. However, lid 40 is preferably colored to form an opaque barrier as described below. In addition, other shapes for lid 40, such as a circle, square, etc. may also be used. Similarly, spacer 22 may be formed such that it is only under the lid 40, and does not form a complete raised ring around top face 16 of body 12. Lid 40 may be attached to spacer 22 through sonic welding, an adhesive, or other attachment method.

[0036] Reagent 30 is applied to the first surface 20 such that when a droplet of blood is applied to first surface 20, the blood reacts with the reagent 30. Reagent 30 causes a color change that can be detected by read-head 510 from bottom face 18. As a result, top face 16 of body 12 is colored to allow sufficient light to be transmitted from first surface 20 to bottom face 18. For example, top face 16 may have a translucent or transparent coloring. To reduce manufacturing costs, reagent 30 may be applied directly to the plastic of body 12 through a coating, screen, or stencil-printing process. Alternatively, methods such as pipetting, pump deposition, or pin deposition can be used. If the reagent 30 is applied to the first surface 20 through pipetting or pump or pin deposition, improved results may be obtained if the reagent accepting surface has an area defined by a raised mesa. Reagent 30 may also be membrane-based, however, in another embodiment.

[0037] The reagent 30 may be made from any of a number of compositions that are capable of generating detectable specie that can be measured by a change in reflectance. One such reagent composition is a glucose dehydrogenase (GDH) - pyrroloquinoline quinone (PQQ) based system. Such a reagent system is described as follows:

1) glucose + GDH-PQQ (oxidized state) ——————> gluconolactone + GDH-PQQ (reduced state)

2) electron transferring mediator (oxidized state) + GDH-PQQ (reduced state) ——————> electron transferring mediator (reduced state) + GDH-PQQ (oxidized state)

3) electron transferring mediator (reduced state) + tetrazolium ——————> electron transferring mediator (oxidized state) + formazan

The intensity of the color of formazan, which is measured by a photometric sensor (not shown) in read-head 510, is a function of the concentration of glucose. Alternatively, a GDH and diaphorase based system can be used. Such a system is described as follows:

1) glucose + NAD^+ (nicotinamide adenine dinucleotide) $\xrightarrow{GDH}$ NADH + H^+ + gluconolactone

2) NADH + tetrazolium $\xrightarrow{Diaphorase}$ NAD^+ + formazan

The reagent 30 compositions can be deposited onto the first surface 20 of body 12 in a matrix, such as a titanium dioxide and polymer (e.g., polyacrylic) matrix, according to any of the methods described above.

[0038] In operation, the sensor 10 is mounted to read-head 510 on the blood glucose meter 502. Blood glucose meter 502 (seen in FIG. 9) takes an initial reflectance reading on sensor 10 prior to the application of a blood sample to the sensor 10. This initial reading serves to correct for variations in background color and sensor positioning. A user is then prompted to apply a blood sample to lid 40. The blood sample is drawn by capillary action into capillary chamber 50 to react with reagent 30. After a predetermined period of time, blood glucose meter 502 then takes another reflectance reading of sensor 10. This reflectance reading of reagent 30 on sensor 10 measures the color change of formazan or other detectable specie, which indicates the glucose concentration in the blood/reagent mixture.

[0039] Because the detectable specie generated from the analyte is measured by a change in reflectance, a significant fraction of light is transmitted through the reagent 30 where it can be lost or returned to the read-head 510 by scattering from the blood sample. The amount of light scattering depends on the sample volume and hematocrit, which may lead to inaccuracies in the reflectance measurement. Further, if the blood volume sample above the reagent 30 is not defined, the conversion reaction continues past the ideal test time. This leads to drifting of the result. Capillary chamber 50 is designed to serve as a reaction cell, providing a defined volume and surface on the side opposing the reagent 30. In addition, lid 40 preferably has an opaque coloration to provide a defined and consistent reflective background.

[0040] FIGS. 12 and 13 illustrate two construction methods for an array of sensors 10 with capillary chambers 50 as described above. In FIG. 12, the spacer 22 is integrally molded with the body 12. The reagent 30 is then applied to the first surface 20, in the area between spacer 22, as described above. The lid 40 is applied next. The surface of the lid 40 that faces the inside of the capillary chamber can be optimized for rapid filling and may also be a heat-activated adhesive, such as U53 water dispersible polyurethane available from Bayer Corporation of Elkhart, Indiana, United States of America. This lid formulation is known as ROA. The lid is temporarily mounted to a backing adhesive 41 and die-cut in this form, through the ROA but leaving the temporary backing 41 intact. This structure is aligned over the tips as shown and heated through the temporary backing 41 to adhere the ROA adhesive to the spacers 22 of the sensor 10. Finally the temporary backing 41 is removed leaving completed sensors 10.

[0041] FIG. 13 shows a variation of the construction method depicted in FIG. 12. Body 12 is molded without an integral spacer 22. The flat top of the body 12 is advantageously suited for screen or stencil-printing the spacer 22. Alternatively, spacer 22 may be made in a printing step. To avoid a heat sealing step when applying the lid 40, a hydrophilic pressure-sensitive adhesive may be used instead.

[0042] Another embodiment of a sensor 60 is illustrated in FIGS. 3 and 4. Sensor 60 includes body 12, reagent 30, and a sensor lid 45. Sensor lid 45 may be formed from impermeable plastic as a hollow frustum, similar to body 12, as described above. Sensor lid 45 may be attached to body through a second latch 48 located on a sidewall 49 of sensor lid 45. The second latch 48 may comprise any technique known in the art, such as indentations, holes, grooves, or embosses. Alternately, sensor lid 45 may be attached to body 12 through sonic welding, an adhesive, or another attachment method. Vent holes 46 are formed in sensor lid 45 to allow a blood sample to flow into capillary chamber 51 and air to flow out of chamber 51 formed by the sensor lid 45 and the body 12. Other aspects of the sensor 60 are similar to the sensor 10 shown in FIGS. 1 and 2 and described above.

[0043] Another embodiment of a sensor 70 is illustrated in FIGS. 5 and 6. Sensor 70 is made up of a body 112 and reagent 30, but does not include a lid or sensor lid (as those components are described in connection with the embodiments of FIGS. 1-4). Although a significant fraction of light may be lost and the blood volume sample above the reagent 30 may not be defined, blood glucose meter 502 may be adapted to correct for this by taking additional reflectance readings or with some other correction. Other aspects of sensor 70 are similar to the sensor 10 shown in FIGS. 1 and 2 and described above.

[0044] In another embodiment of the present invention, illustrated in FIGS. 7 and 8, the body 90 comprises a porous plastic. The porous plastic of body 90 may be formed similarly to the impermeable plastic of body 12, as described above in connection with the embodiments of FIGS. 1 and 2. The porous plastic is a sintered polymer such as polypropylene, polyvinylidene fluoride, polyethylenevinyl acetate, polystyreneacrylonitrite, polytetrafluoroethylene or related copolymers. The porous plastic may also be opaque, to reduce the amount of light transmitted through it and increase the amount of light reflected from the sample. The pore size may range from 5 to 100 microns, although other sizes may be used. The porous plastic is hydrophobic so that it resists sample flow unless first treated with a surfactant (not shown). Surfactant may be applied to a sample surface 94 on the outside tip surface 95 of the tip of body 90. Alternately, surfactant may be applied to the inside tip surface 96 of the body 90. To prevent uncontrolled sample flow within the body 90, however, only the reactive area is preferably treated with surfactant. Typical surfactants are derivatives of polyethylene glycol ester, polysorbate, or sorbitan ester.

[0045] Sample surface 94 accepts a sample, and can be formed into a concave surface for ergonomic sample loading. A sidewall 97 may extend around the periphery of sample surface 94. A reagent 30, as described above, is applied to the body 90 such that when a droplet of blood reacts with the reagent 30, a color change is caused that can be detected from the inside tip surface 96 of body 90. As illustrated in FIG. 8, the reagent 30 is affixed to the inside tip surface 96 of body 90, opposite sample surface 94. Alternately, the reagent 30 may be affixed to sample surface 94, with surfactant applied to the inside tip surface 96 of body 90. Other aspects of the sensor 90 are similar to the sensor 10 shown in FIGS. 1 and 2 and described above.

[0046] FIG. 9 illustrates a blood glucose sensor kit 500 comprising the blood glucose meter 502, a sensor package 550 containing the sensors 10 described above, an alignment guide 540, and an optional removable blood glucose meter cover 530. The blood glucose meter 502 comprises a housing 504, a display 506 for depicting the analyte concentration measured by the meter 502, an optical read-head 510 disposed on the housing 504, and a spring-loaded lancet mechanism 520. As described above, read-head 510 comprises a shape that corresponds to the shape of the sensor 10. An engagement mechanism, such as a push-button ejection mechanism, is located on read-head 510 to detachably engage sensor 10 through first latch 24.

[0047] As best seen in FIGS. 10-11, the sensor package 550 comprises a base portion 552, a desiccant material 557, and a protective sheet 558. Sensor cavities 554 are formed as depressions in the base portion 552, with each of the sensor cavities 554 adapted to house an individual sensor 10. As seen in FIG. 11, to prevent or inhibit movement of sensor 10 in the sensor cavity 554, the sensor cavity 554 has an inclined or sloped support wall to position the sensor 10 while it is disposed within the sensor cavity 554. Each of the sensor cavities 554 is in fluid communication with a desiccant cavity 556 formed by a small depression in the base portion 552. Desiccant material 557, such as a 6mg sphere of Grace 10A molecular sieve desiccant, is disposed in each of the desiccant cavities 556 to maintain an appropriate humidity level to preserve the reagent 30 on the sensor 10. The sensor cavities 554 and desiccant cavities 556 may be aligned in rectangular arrays, allowing for reduced manufacturing and packaging costs.

[0048] The protective sheet 558 is attached to base portion 552 such that it seals the individual sensor cavities 554 and desiccant cavities 556, providing a moisture barrier so that the desiccant material 557 can maintain the relative humidity within an optimal range. FIG. 11 illustrates a sensor package 550 design intended for aluminum foil as the protective sheet 558. The sensor cavity 554 is closed by heat-sealing an aluminum burst foil to the surface of the base foil. A typical configuration of this foil is a laminate consisting of a lacquer/8μ aluminium/10μ polypropylene heat-seal material, with an expected shelf life of one to two years for this configuration. One type of foil that can be used for the

protective sheet 558 is AL-191-01 foil distributed by Alusuisse Flexible Packaging, Inc. With a tip height of 0.247 inches and a seal width of 0.088 inches, the maximum elongation of the foil is estimated to be 36%.

[0049] A conductive calibration label 559 is also disposed on the sensor package 550. The conductive calibration label 559 can be located anywhere on sensor package 550 that space and size constraints allow, for example, on protective cover 558 or on base portion 552. The conductive calibration label 559 provides calibration and production information about the sensor package 550 that can be sensed by calibration circuitry in the blood glucose meter 502. Additional details regarding sensor package 550 are described in U.S. Patent No. 5,575,403, issued November 19, 1996, and entitled Dispensing Instrument For Fluid Monitoring Sensors, the contents of which are hereby incorporated by reference. One example of such a sensor pack is the Ascensia® AUTODISC™ with ten test strips also available from Bayer Corporation of Elkhart, Indiana, United States of America.

[0050] Alternatively, sensor package 550 may use a protective sheet 558 made from a thermoformed plastic barrier material. With a thermoformed plastic barrier material, a much greater degree of elongation or stretch is possible. This allows for a more compact package while also accommodating a taller sensor (approximately 0.2" tall). Formable packaging material is available from Klockner-Pentaplast, for example Pentapharm ACLAR PA 300/2. The product, containing ACLAR Ultrx3000, has a Moisture Vapor Transfer Rate (MVTR) of 0.005g/100sq in/day at 38°C and 90% Relative Humidity. With a 6mg desiccant bead having 15% of available moisture capacity, the expected lifetime of the sensor package 550 is about 45 days.

[0051] Referring to FIG. 9, alignment guide 540 is used because the sensors 10 are invisible behind the burst toil of the protective sheet 558. Alignment guide 540 serves to align the read-head 510 with the sensor 10. As shown in FIG. 11, the read-head has two levels of taper, with a step between the two sections. The smaller diameter section 512 of the read-head engages directly with the sensor 10. The larger diameter section 514 is sized to interact with the holes 542 in alignment guide 540 to correctly position the read-head 510 over the sensor 10. A step between the two sections of the read-head 510, with the diameter at the top of the step being slightly larger than the diameter at the base of the sensor, serves to prevent or inhibit the sensor from being caught on the alignment guide as the read-head and attached sensor are withdrawn from the sensor package.

[0052] Removable meter cover 530 detachably mounts to blood glucose meter 502, covering the read-head 510 and lancet mechanism 520. The removable meter cover 530 also has a recess adapted to contain the sensor package 550 and alignment guide 540.

[0053] To operate a typical blood glucose meter kit 500, the sensor package 550 is stored in the removable meter cover 530 of the blood glucose meter 502 underneath the alignment guide 540 with the calibration label 559 exposed at one end. The sensor package 550 is keyed to ensure the correct orientation within the removable meter cover. Before use, the removable meter cover 530 is removed and the read-head 510 is pushed down through the alignment guide 540 into the sensor package 550 beneath to engage and pick up a sensor 10. The lancet mechanism 520 on the meter 502 is then used to draw a blood droplet that is subsequently applied to the integral first surface 20 of the sensor 10 to start the measurement sequence. After the sequence is completed, the blood glucose measurement is displayed on the meter display 506, the sensor 10 is ejected, and the cover 530 is replaced. With the number of remaining sensors 10 being visible at a glance, an empty sensor package 550 can be easily replaced by raising the alignment guide 540 and removing it from the removable meter cover 530.

[0054] While the invention has been described with reference to details of the illustrated embodiments, these details are not intended to limit the scope of the invention as defined in the appended claims. For example, the sensor may be used for testing fluids other than blood glucose. In fact, the sensor can be used in connection with the analysis of any type of chemical fluid that can be analyzed by means of a reagent material. In addition, the sensors may use sizes, shapes, angles, etc. different than those described above. Further, porous or impermeable plastic body designs may be used with any of the sensor shapes described in FIGS. 1-8. A sensor lid or lid may also be used with porous designs. Moreover, except as noted above, the coloration of the sensor body may be altered such that it is transparent, translucent, or opaque. It is therefore intended to include within the invention all such variations and modifications that fall within the scope of the appended claims.

Claims

1. A fluid sensor (10) comprising:

a formed plastic body (12) having a top face (16) with an integral first surface (20), a bottom face (18) opposed to said first surface (20), and a sidewall (14) extending from the periphery of said top face (16), said first surface (20) being adapted to accept a fluid sample; and

a reagent (30), being disposed on said integral first surface (20) and adapted to cause a color change detectable on said bottom face (18) when said reagent (30) reacts with an analyte in said fluid sample,

characterized in that
said sidewall (14) is extending past said bottom face (18).

2. The sensor (10) of claim 1, wherein said formed plastic body (12) is a hollow frustum.

3. The sensor (10) of claim 1, wherein said formed plastic body (12) is a hollow frustum with a larger open end and a smaller closed end.

4. The sensor (10) of one of the claims 1 to 3, wherein said sidewall (14) has at least one latch (24).

5. The sensor (10) of claim 4, wherein said at least one latch (24) is an indentation, hole, groove, or emboss.

6. The sensor (10) of one of the claims 1 to 5, wherein said sidewall (14) forms a shoulder.

7. The sensor (10) of one of the claims 1 to 6, wherein said color change is measured by a change in reflectance on said bottom face (18).

8. The sensor (10) of claim 7, wherein said reagent (30) is a glucose dehydrogenase and pyrroloquinoline quinone-based system.

9. The sensor (10) of claim 8, wherein said reagent (30) further comprises an electron transferring mediator, tetrazolium, and formazan.

10. The sensor (10) of claim 7, wherein said reagent (30) is a glucose dehydrogenase and diaphorase-based system.

11. The sensor (10) of claim 10, wherein said reagent (30) further comprises nicotinamide adenine dinucleotide, tetrazolium, and formazan.

12. The sensor (10) of claim 7, wherein said reagent (30) is a titanium dioxide and polymer matrix.

13. The sensor (10) of claim 9, wherein said reagent (30) is a titanium dioxide and polymer matrix.

14. The sensor (10) of one of the claims 3 to 13, wherein said frustum has a circular or rectangular cross-section.

15. The sensor (10) of one of the claims 1 to 14, wherein said top face (16) has a raised region substantially surrounding said integral first surface (20).

16. The sensor (10) of claim 15, further comprising a lid (40) attached to said raised region.

17. The sensor (10) of claim 16, wherein said lid (40) is a rectangular plastic strip, said lid (40) being attached to said raised region forming a plurality of vent openings (46).

18. The sensor (10) of claim 16, wherein said lid (40) is attached to said raised region and forms a capillary chamber (51).

19. The sensor (10) of claim 16, wherein said lid (40) is a hollow plastic frustum, having a large open end and a smaller closed end, said smaller closed end having a first surface (20) with a plurality of vent holes (46).

20. The sensor (10) of one of the claims 1 to 19, wherein said top face (16) is transparent.

21. The sensor (10) of one of the claims 16 to 19, wherein said top face (16) is transparent or translucent, and said lid (40) is opaque.

22. The sensor (10) of claim 1, wherein said formed plastic body (12) is porous, and further comprises a surfactant applied to said first surface (20).

23. The sensor (10) of claim 22, wherein said porous plastic body (12) is opaque.

24. The sensor (10) of claim 22 or 23, wherein said formed plastic body (12) has a pore size from about 5 microns to

about 100 microns.

25. The sensor (10) of one of the claims 1 to 24, wherein said first surface (20) is concave.

26. A fluid sensor (10) comprising:

a formed porous plastic body (12) having a top face (16) with an integral first surface (20), a bottom face (18) with a second surface opposed to said first surface (20), and a sidewall (14) adjacent to said top face (16), wherein said first surface (20) is adapted to accept a fluid sample;
a surfactant disposed on said body (12); and
a reagent (30) adapted to cause a color change detectable on said second surface when said reagent (30) reacts with an analyte in said fluid sample,
characterized in that
said sidewall (14) is extending past said bottom face (18).

27. The sensor (10) of claim 26, wherein said reagent (30) is disposed on said second surface and said surfactant is applied to said first surface (20).

28. The sensor (10) of claim 26, wherein said reagent (30) is disposed on said first surface (20) and said surfactant is applied to said second surface.

29. The sensor (10) of one of the claims 26 to 28, wherein said porous plastic body (12) is opaque.

30. The sensor (10) of one of the claims 26 to 29, wherein said formed plastic body (12) has a pore size of from about 5 microns to about 100 microns.

31. The sensor (10) of one of the claims 26 to 30, wherein said top face (16) has a raised region substantially surrounding said integral first surface (20).

32. The sensor (10) of claim 31, further comprising a lid (40) attached to said raised region.

33. The sensor (10) of one of the claims 26 to 32, wherein said color change is measured by a change in reflectance on said bottom face (18).

34. The sensor (10) of claim 33, wherein said reagent (30) is a glucose dehydrogenase and pyrroloquinoline quinone-based system.

35. The sensor (10) of claim 34, wherein said reagent (30) further comprises an electron transferring mediator, tetrazolium, and formazan.

36. The sensor (10) of claim 33, wherein said reagent (30) is a glucose dehydrogenase and diaphorase-based system.

37. The sensor (10) of claim 36, wherein said reagent (30) further comprises nicotinamide adenine dinucleotide, tetrazolium, and formazan.

38. The sensor (10) of claim 35, wherein said reagent (30) is a titanium dioxide and polymer matrix.

39. The sensor (10) of claim 37, wherein said reagent (30) is a titanium dioxide and polymer matrix.

40. A method of making a fluid sensor (10) comprising the acts of:

a) forming a plastic body (12) having a top face (16) with an integral first surface 20), a bottom face (18) opposed to said first surface (20), and a sidewall (14) extending from the periphery of said top face (16), wherein said first surface (20) is adapted to accept a fluid sample;
b) applying a reagent (30) to said integral first surface (20), said reagent (20) being adapted to cause a color change detectable on said bottom face (18) when said reagent (30) reacts with an analyte in said fluid sample; and
c) applying a lid (40) to a raised region on said top face (16),

characterized in that
said sidewall (14) is extending past said bottom face (18).

Patentansprüche

1. Fluidsensor (10), umfassend:

   einen geformten Kunststoffkörper (12) mit einer oberen Fläche (16) mit einer integralen ersten Oberfläche (20), einer der ersten Oberfläche (20) gegenüberliegenden unteren Fläche (18) und einer Seitenwand (14), die sich von der Peripherie der oberen Fläche (16) erstreckt, wobei die erste Oberfläche (20) dazu ausgelegt ist, eine Fluidprobe aufzunehmen; und
   ein Reagens (30), das sich auf der integralen ersten Oberfläche (20) befindet und dazu ausgelegt ist, einen auf der unteren Fläche (18) erfassbaren Farbwechsel zu verursachen, wenn das Reagens (30) mit einem Analyten in der Fluidprobe reagiert,
   dadurch gekennzeichnet, dass
   sich die Seitenwand (14) an der unteren Fläche (18) vorbei erstreckt.

2. Sensor (10) nach Anspruch 1, wobei es sich bei dem geformten Kunststoffkörper (12) um einen hohlen Pyramidenstumpf handelt.

3. Sensor (10) nach Anspruch 1, wobei es sich bei dem geformten Kunststoffkörper (12) um einen hohlen Pyramidenstumpf mit einem größeren offenen Ende und einem kleineren geschlossenen Ende handelt.

4. Sensor (10) nach einem der Ansprüche 1 bis 3, wobei die Seitenwand (14) mindestens eine Verriegelung (24) aufweist.

5. Sensor (10) nach Anspruch 4, wobei es sich bei der mindestens einen Verriegelung (24) um eine Vertiefung, ein Loch, eine Nut oder eine Prägung handelt.

6. Sensor (10) nach einem der Ansprüche 1 bis 5, wobei die Seitenwand (14) einen Ansatz ausbildet.

7. Sensor (10) nach einem der Ansprüche 1 bis 6, wobei der Farbwechsel durch eine Änderung des Reflexionsgrads an der unteren Fläche (18) gemessen wird.

8. Sensor (10) nach Anspruch 7, wobei das Reagens (30) ein System auf Basis von Glucosedehydrogenase und Pyrrolochinolinchinon ist.

9. Sensor (10) nach Anspruch 8, wobei das Reagens (30) ferner einen Elektronenübertragungsvermittler, Tetrazolium und Formazan umfasst.

10. Sensor (10) nach Anspruch 7, wobei das Reagens (30) ein System auf Basis von Glucosedehydrogenase und Diaphorase ist.

11. Sensor (10) nach Anspruch 10, wobei das Reagens (30) ferner Nikotinamidadenindinukleotid, Tetrazolium und Formazan umfasst.

12. Sensor (10) nach Anspruch 7, wobei das Reagens (30) eine Titandioxid- und Polymermatrix ist.

13. Sensor (10) nach Anspruch 9, wobei das Reagens (30) eine Titandioxid- und Polymermatrix ist.

14. Sensor (10) nach einem der Ansprüche 3 bis 13, wobei der Pyramidenstumpf einen kreisförmigen oder rechteckigen Querschnitt aufweist.

15. Sensor (10) nach einem der Ansprüche 1 bis 14, wobei die obere Fläche (16) einen erhabenen Bereich aufweist, der die integrale erste Oberfläche (20) im Wesentlichen umgibt.

16. Sensor (10) nach Anspruch 15, ferner umfassend einen Deckel (40), der an dem erhabenen Bereich angebracht ist.

17. Sensor (10) nach Anspruch 16, wobei der Deckel (40) ein rechteckiger Kunststoffstreifen ist, wobei bei der Anbringung des Deckels (40) an dem erhabenen Bereich mehrere Lüftungsöffnungen (46) ausgebildet werden.

18. Sensor (10) nach Anspruch 16, wobei der Deckel (40) an dem erhabenen Bereich angebracht ist und eine Kapillarkammer (51) ausbildet.

19. Sensor (10) nach Anspruch 16, wobei der Deckel (40) ein hohler Kunststoffpyramidenstumpf ist, der ein großes offenes Ende und ein kleineres geschlossenes Ende aufweist, wobei das kleinere geschlossene Ende eine erste Oberfläche (20) mit mehreren Lüftungslöchern (46) aufweist.

20. Sensor (10) nach einem der Ansprüche 1 bis 19, wobei die obere Fläche (16) transparent ist.

21. Sensor (10) nach einem der Ansprüche 16 bis 19, wobei die obere Fläche (16) transparent oder durchscheinend und der Deckel (40) opak ist.

22. Sensor (10) nach Anspruch 1, wobei der geformte Kunststoffkörper (12) porös ist und ferner ein Tensid, das auf die erste Oberfläche (20) aufgebracht ist, umfasst.

23. Sensor (10) nach Anspruch 22, wobei der poröse Kunststoffkörper (12) opak ist.

24. Sensor (10) nach Anspruch 22 oder 23, wobei der geformte Kunststoffkörper (12) eine Porengröße von ungefähr 5 Mikrometer bis ungefähr 100 Mikrometer aufweist.

25. Sensor (10) nach einem der Ansprüche 1 bis 24, wobei die erste Oberfläche (20) konkav ist.

26. Fluidsensor (10), umfassend:

einen geformten porösen Kunststoffkörper (12) mit einer oberen Fläche (16) mit einer integralen ersten Oberfläche (20), einer unteren Fläche (18) mit einer der ersten Oberfläche (20) gegenüberliegenden zweiten Oberfläche und einer Seitenwand (14) neben der oberen Fläche (16), wobei die erste Oberfläche (20) dazu ausgelegt ist, eine Fluidprobe aufzunehmen;
ein Tensid, das sich auf dem Körper (12) befindet; und
ein Reagens (30), das dazu ausgelegt ist, einen auf der zweiten Oberfläche erfassbaren Farbwechsel zu verursachen, wenn das Reagens (30) mit einem Analyten in der Fluidprobe reagiert,
dadurch gekennzeichnet, dass
sich die Seitenwand (14) an der unteren Fläche (18) vorbei erstreckt.

27. Sensor (10) nach Anspruch 26, wobei sich das Reagens (30) auf der zweiten Oberfläche befindet und das Tensid auf der ersten Oberfläche (20) aufgebracht ist.

28. Sensor (10) nach Anspruch 26, wobei sich das Reagens (30) auf der ersten Oberfläche (20) befindet und das Tensid auf der zweiten Oberfläche aufgebracht ist.

29. Sensor (10) nach einem der Ansprüche 26 bis 28, wobei der poröse Kunststoffkörper (12) opak ist.

30. Sensor (10) nach einem der Ansprüche 26 bis 29, wobei der geformte Kunststoffkörper (12) eine Porengröße von ungefähr 5 Mikrometer bis ungefähr 100 Mikrometer aufweist.

31. Sensor (10) nach einem der Ansprüche 26 bis 30, wobei die obere Fläche (16) einen erhabenen Bereich aufweist, der die integrale erste Oberfläche (20) im Wesentlichen umgibt.

32. Sensor (10) nach Anspruch 31, ferner umfassend einen Deckel (40), der an dem erhabenen Bereich angebracht ist.

33. Sensor (10) nach einem der Ansprüche 26 bis 32, wobei der Farbwechsel durch eine Änderung des Reflexionsgrads an der unteren Fläche (18) gemessen wird.

34. Sensor (10) nach Anspruch 33, wobei das Reagens (30) ein System auf Basis von Glucosedehydrogenase und Pyrrolochinolinchinon ist.

35. Sensor (10) nach Anspruch 34, wobei das Reagens (30) ferner einen Elektronenübertragungsvermittler, Tetrazolium und Formazan umfasst.

36. Sensor (10) nach Anspruch 33, wobei das Reagens (30) ein System auf Basis von Glucosedehydrogenase und Diaphorase ist.

37. Sensor (10) nach Anspruch 36, wobei das Reagens (30) ferner Nikotinamidadenindinukleotid, Tetrazolium und Formazan umfasst.

38. Sensor (10) nach Anspruch 35, wobei das Reagens (30) eine Titandioxid- und Polymermatrix ist.

39. Sensor (10) nach Anspruch 37, wobei das Reagens (30) eine Titandioxid- und Polymermatrix ist.

40. Verfahren zum Herstellen eines Fluidsensors (10), umfassend die folgenden Handlungen:

a) Formen eines Kunststoffkörpers (12) mit einer oberen Fläche (16) mit einer integralen ersten Oberfläche (20), einer der ersten Oberfläche (20) gegenüberliegenden unteren Fläche (18) und einer Seitenwand (14), die sich von der Peripherie der oberen Fläche (16) erstreckt, wobei die erste Oberfläche (20) dazu ausgelegt wird, eine Fluidprobe aufzunehmen;
b) Auftragen eines Reagens (30) auf der integralen ersten Oberfläche (20), wobei das Reagens (30) dazu ausgelegt ist, einen auf der unteren Fläche (18) erfassbaren Farbwechsel zu verursachen, wenn das Reagens (30) mit einem Analyten in der Fluidprobe reagiert; und
c) Auflegen eines Deckels (40) auf einen erhabenen Bereich auf der oberen Fläche (16),

dadurch gekennzeichnet, dass
sich die Seitenwand (14) an der unteren Fläche (18) vorbei erstreckt.

Revendications

1. Détecteur (10) de fluide comprenant :

- un corps (12) moulé en plastique qui présente une face supérieure (16) comprenant une première surface (20) d'un seul tenant, une face inférieure (18) opposée à ladite première surface (20) et une paroi latérale (14) qui déborde de la périphérie de ladite face supérieure (16), ladite première surface étant adaptée pour (20) recevoir un échantillon de fluide, et
- un réactif (30) placé sur ladite première surface (20) d'un seul tenant et adapté pour induire un changement de couleur détectable sur ladite face inférieure (18) lorsque ledit réactif (30) réagit avec un analyte présent dans ledit échantillon de fluide, **caractérisé en ce que**

ladite paroi latérale (14) déborde au-delà de ladite face inférieure (18).

2. Détecteur (10) selon la revendication 1, dans lequel ledit corps (12) moulé en plastique est un tronc de cône creux.

3. Détecteur (10) selon la revendication 1, dans lequel ledit corps (12) moulé en plastique est un tronc de cône creux qui présente une extrémité ouverte plus grande et une extrémité fermée plus petite.

4. Détecteur (10), selon l'une quelconque des revendications 1 à 3, dans lequel ladite paroi latérale (14) présente au moins un cliquet (24).

5. Détecteur (10) selon la revendication 4, dans lequel ledit ou lesdits cliquets (24) sont des indentations, des trous, des rainures ou des bosses.

6. Détecteur (10) selon l'une quelconque des revendications 1 à 5, dans lequel ladite paroi latérale (14) forme un épaulement.

7. Détecteur (10) selon l'une quelconque des revendications 1 à 6, dans lequel ledit changement de couleur est mesuré par un changement de la réflectance sur ladite face inférieure (18).

8. Détecteur (10) selon la revendication 7, dans lequel ledit réactif (30) est un système à base de glucose déshydrogénase et de pyrroloquinoléine quinone.

9. Détecteur (10) selon la revendication 8, dans lequel ledit réactif (30) contient de plus un médiateur transférant des électrons, du tétrazolium et du formazan.

10. Détecteur (10) selon la revendication 7, dans lequel ledit réactif (30) est un système à base de glucose déshydrogénase et de diaphorase.

11. Détecteur (10) selon la revendication 10, dans lequel ledit réactif (30) contient de plus un dinucléotide d'adénine nicotinamide, du tétrazolium et du formazan.

12. Détecteur (10) selon la revendication 7, dans lequel ledit réactif (30) est une matrice de polymère et de dioxyde de titane.

13. Détecteur (10) selon la revendication 9, dans lequel ledit réactif (30) est une matrice de polymère et de dioxyde de titane.

14. Détecteur (10) selon l'une quelconque des revendications 3 à 13, dans lequel ledit tronc de cône présente une section transversale circulaire ou rectangulaire.

15. Détecteur (10) selon l'une quelconque des revendications 1 à 14, dans lequel ladite face supérieure (16) présente une partie surélevée entourant essentiellement ladite première surface (20) d'un seul tenant.

16. Détecteur (10) selon la revendication 15, comprenant de plus un couvercle (40) relié à ladite partie surélevée.

17. Détecteur (10) selon la revendication 16, dans lequel ledit couvercle (40) est une bande rectangulaire en plastique, ledit couvercle (40) étant relié à ladite partie surélevée qui forme plusieurs orifices d'échappement (46).

18. Détecteur (10) selon la revendication 16, dans lequel ledit couvercle (40) est attaché à ladite partie surélevée et forme une chambre capillaire (51).

19. Détecteur (10) selon la revendication 16, dans lequel ledit couvercle (40) est un tronc de cône creux en plastique qui présente une grande extrémité ouverte et une extrémité fermée plus petite, ladite extrémité plus petite fermée présentant une première surface (20) qui présente plusieurs orifices d'échappement (46).

20. Détecteur (10) selon l'une quelconque des revendications 1 à 19, dans lequel ladite face supérieure (16) est transparente.

21. Détecteur (10) selon l'une quelconque des revendications 16 à 19, dans lequel ladite face supérieure (16) est transparente ou translucide et ledit couvercle (40) est opaque.

22. Détecteur (10) selon la revendication 1, dans lequel ledit corps (12) moulé en plastique est poreux et contient de plus un agent tensioactif appliqué sur ladite première surface (20).

23. Détecteur (10) selon la revendication 22, dans lequel ledit corps (12) en plastique poreux est opaque.

24. Détecteur (10) selon les revendications 22 ou 23, dans lequel ledit corps (12) moulé en plastique présente des pores dont la taille est comprise entre environ 5 micromètres et environ 100 micromètres.

25. Détecteur (10) selon l'une quelconque des revendications 1 à 24, dans lequel ladite première surface (20) est concave.

26. Détecteur de fluide (10) comprenant :

- un corps (12) moulé en plastique poreux qui présente une face supérieure (16) comprenant une première surface (20) d'un seul tenant, une face inférieure (18) présentant une deuxième surface opposée à ladite première surface (20) et une paroi latérale (14) adjacente à ladite face supérieure (16), ladite première surface

(20) étant conçue pour recevoir un échantillon de fluide,
- un agent tensioactif disposé sur ledit corps (12) et
- un réactif (30) conçu pour induire un changement de couleur détectable sur ladite deuxième surface lorsque ledit réactif (30) réagit avec un analyte présent dans ledit échantillon de fluide,

caractérisé en ce que
ladite paroi latérale (14) déborde au-delà de ladite face inférieure (18).

27. Détecteur (10) selon la revendication 26, dans lequel ledit réactif (30) est placé sur ladite deuxième surface et ledit agent tensioactif est appliqué sur ladite première surface (20).

28. Détecteur (10) selon la revendication 26, dans lequel ledit réactif (30) est placé sur ladite première surface (20) et ledit agent tensioactif est appliqué sur ladite deuxième surface.

29. Détecteur (10) selon l'une quelconque des revendications 26 à 28, dans lequel ledit corps (12) en plastique poreux est opaque.

30. Détecteur (10) selon l'une quelconque des revendications 26 à 29, dans lequel ledit corps (12) moulé en plastique présente des pores dont la taille est comprise entre environ 5 micromètres et environ 100 micromètres.

31. Détecteur (10) selon l'une quelconque des revendications 26 à 30, dans lequel ladite face supérieure (16) présente une partie surélevée qui entoure essentiellement ladite première surface (20) d'un seul tenant.

32. Détecteur (10) selon la revendication 31, comprenant de plus un couvercle (40) relié à ladite partie surélevée.

33. Détecteur (10) selon l'une quelconque des revendications 26 à 32, dans lequel ledit changement de couleur est mesuré par un changement de la réflectance sur ladite face inférieure (18).

34. Détecteur (10) selon la revendication 33, dans lequel ledit réactif (30) est un système à base de glucose déshydrogénase et de pyrroloquinoléine quinone.

35. Détecteur (10) selon la revendication 34, dans lequel ledit réactif (30) contient de plus un médiateur transférant les électrons, du tétrazolium et du formazan.

36. Détecteur (10) selon la revendication 33, dans lequel ledit réactif (30) est un système à base de glucose déshydrogénase et de diaphorase.

37. Détecteur (10) selon la revendication 36, dans lequel ledit réactif (30) contient de plus du nicotinamide adénine dinucléotide, du tétrazolium et du formazan.

38. Détecteur (10) selon la revendication 35, dans lequel ledit réactif (30) est une matrice de polymère et de dioxyde de titane.

39. Détecteur (10) selon la revendication 37, dans lequel ledit réactif (30) est une matrice de polymère et de dioxyde de titane.

40. Procédé de fabrication d'un détecteur (10) de fluide, comprenant les actions qui consistent à :

a) mouler un corps (12) en plastique qui présente une face supérieure (16) comprenant une première surface (20) d'un seul tenant, une face inférieure (18) opposée à ladite première surface (20) et une paroi latérale (14) qui déborde de la périphérie de ladite face supérieure (16), ladite première surface (20) étant conçue pour recevoir un échantillon de fluide,
b) appliquer un réactif (30) sur ladite première surface (20) d'un seul tenant, ledit réactif (30) étant conçu pour induire un changement de couleur détectable sur ladite face inférieure (18) lorsque ledit réactif (30) réagit avec un analyte présent dans ledit échantillon de fluide et
c) placer un couvercle (40) sur une partie surélevée située sur ladite face supérieure (16), **caractérisé en ce que**

ladite paroi latérale (14) déborde au-delà de ladite face inférieure (18).

FIG. 1

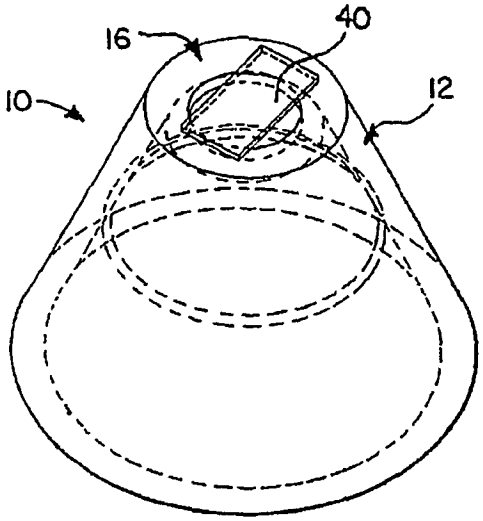


FIG. 2

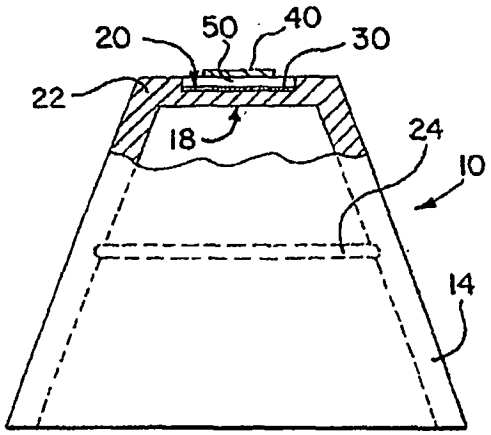


FIG. 3

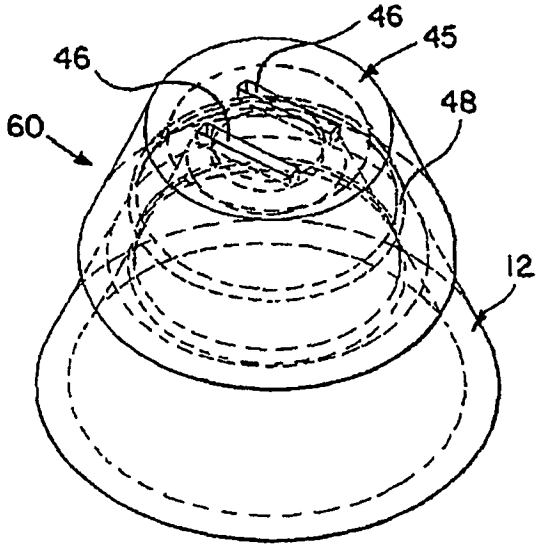


FIG. 4

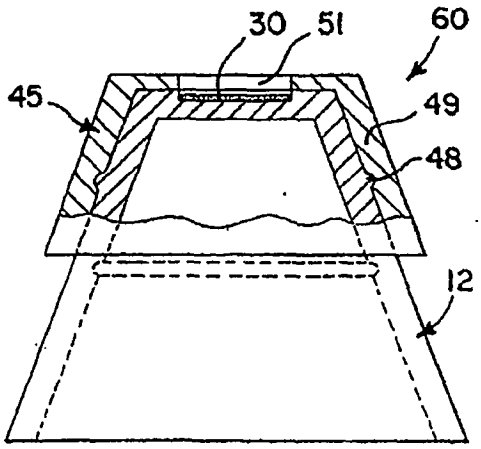


FIG.5

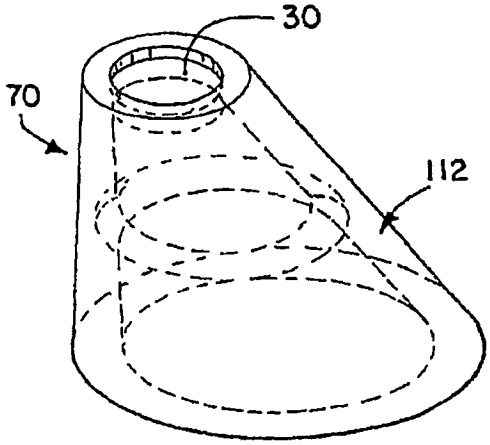


FIG.6

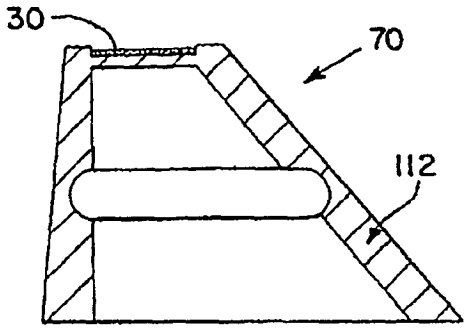


FIG.7

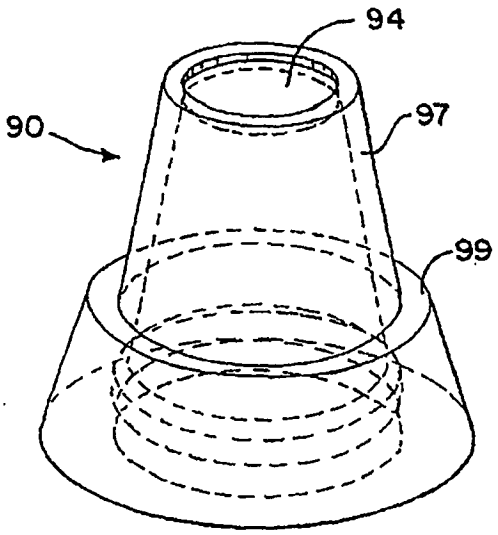
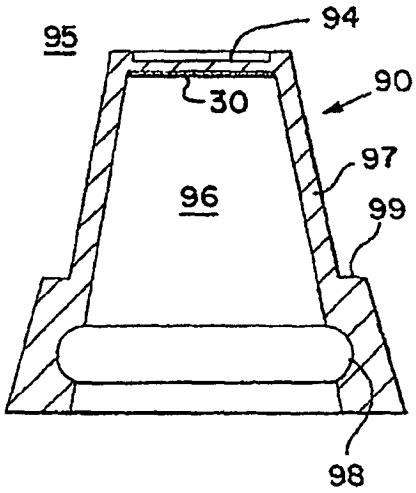


FIG.8



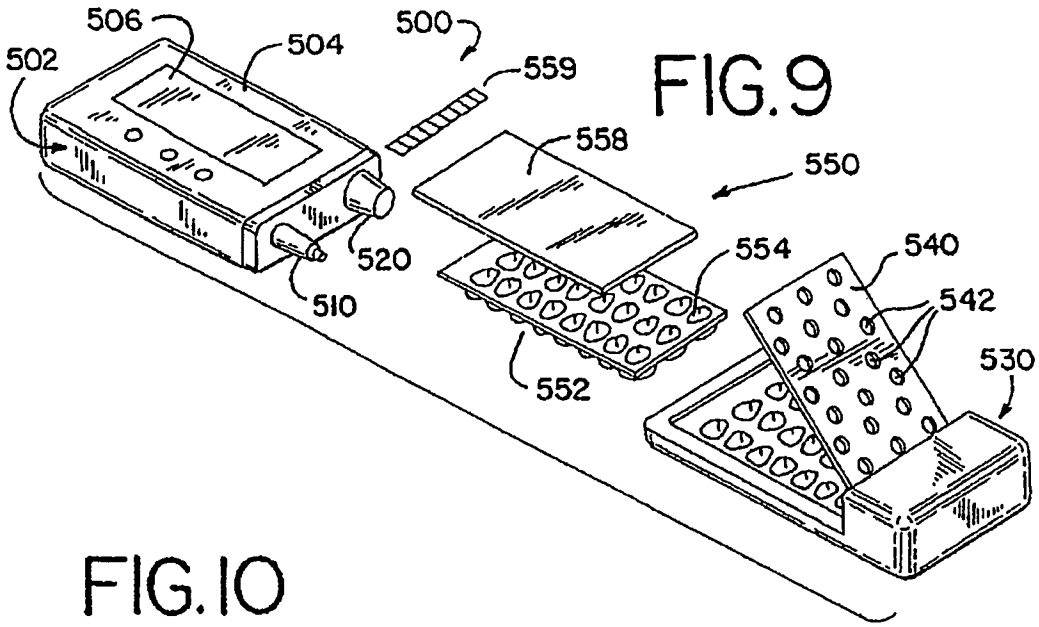


FIG.9

FIG.10

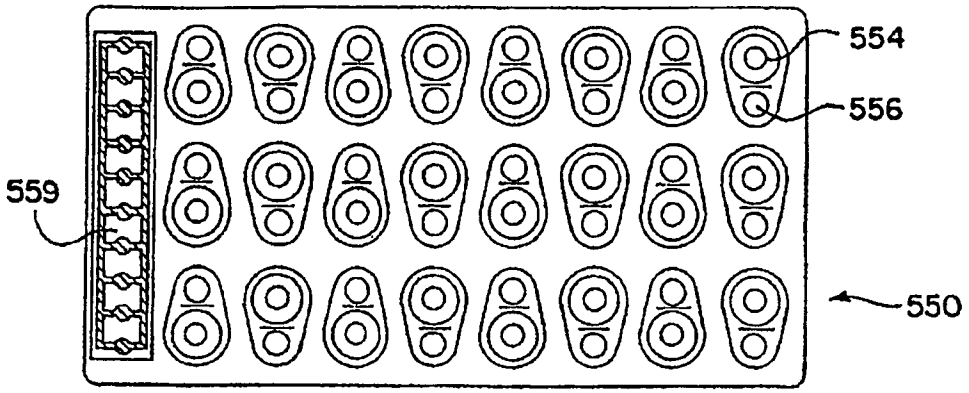


FIG.11

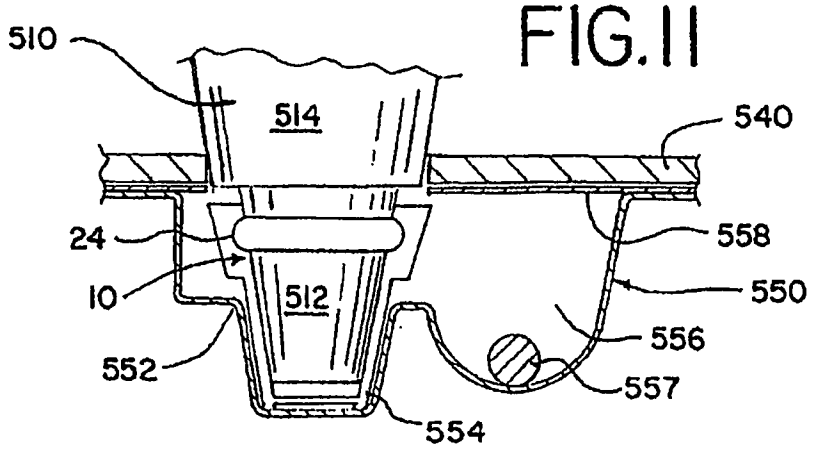


FIG. 12

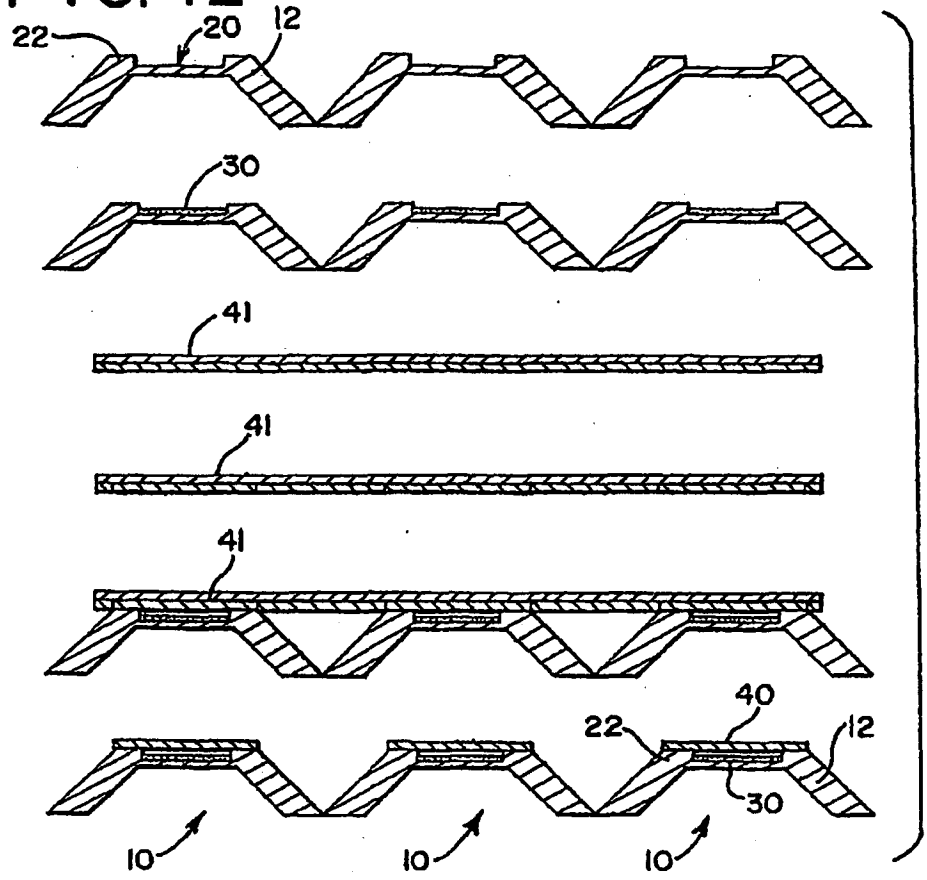
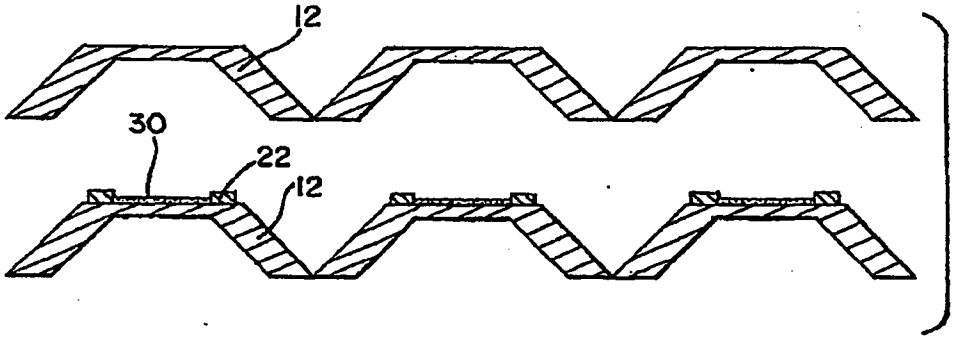


FIG. 13



REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

Patent documents cited in the description

- US 5100620 A **[0003]**
- US 5223219 A **[0004]**
- US 5854074 A **[0005]**
- EP 0990706 A1 **[0006]**
- US 5630986 A **[0012]**
- US 5575403 A **[0049]**

专利名称(译)	流体传感器包括成形的塑料体和试剂，以及包括多个所述传感器的传感器组件。		
公开(公告)号	EP1845839B1	公开(公告)日	2010-11-17
申请号	EP2006719997	申请日	2006-01-31
[标]申请(专利权)人(译)	拜尔健康护理有限责任公司		
申请(专利权)人(译)	拜耳医药保健有限责任公司		
当前申请(专利权)人(译)	拜耳医药保健有限责任公司		
[标]发明人	JUNG SUNG KWON CHARLTON STEVEN C GEORGE SUNY J DOSMANN ANDREW J MARFURT KAREN L		
发明人	JUNG, SUNG-KWON CHARLTON, STEVEN, C. GEORGE, SUNY, J. DOSMANN, ANDREW, J. MARFURT, KAREN, L.		
IPC分类号	A61B5/00 G01N33/487 G01N33/52		
CPC分类号	G01N33/66 A61B5/1411 A61B5/14532 A61B5/1455 A61B5/150022 A61B5/150213 A61B5/150274 A61B5/150343 A61B5/150358 A61B5/157 A61B2562/242 G01N21/78 G01N33/521 G01N33/528		
代理机构(译)	BURKERT，FRANK		
优先权	60/649046 2005-02-01 US		
其他公开文献	EP1845839A2		
外部链接	Espacenet		

摘要(译)

流体传感器包括成形的塑料体和试剂。主体的顶面具有整体的第一表面。主体还具有与第一表面相对的底面和从顶面的周边延伸的侧壁。第一表面适于接受流体样品。试剂设置在整体的第一表面上，并且当试剂与流体样品中的分析物反应时，引起底面上可检测的颜色变化。