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(54) **Test sensor and method for manufacturing the same**

Sensor und Verfahren zur Herstellung desselben

Senseur et son procédé de fabrication

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**EP-A- 1 203 823 US-A- 5 962 215**  
**US-A1- 2002 168 290**

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**Description****FIELD OF THE INVENTION**

[0001] The present invention relates generally to liquid sample monitoring devices and, more particularly, to the manufacture and design of a test sensor for use in determining the concentration of an analyte in a liquid sample.

**BACKGROUND OF THE INVENTION**

[0002] Test sensors are often used in assays for determining the concentration of an analyte in a liquid sample. A liquid sample is deposited in a reaction area of the test sensor that includes a reagent. The sample and the reagent mix producing a measurable reaction indicative the concentration of the analyte in the liquid sample. The reaction is measured with a test device that receives the test sensor.

[0003] Testing for the concentration of glucose in blood is a common use for test sensors. Those who have irregular blood-glucose concentration levels are often medically required to self-monitor their blood-glucose concentration level. Utilizing a testing device that implements a test sensor is one means that people use to monitor their blood-glucose concentration levels. Test sensors are also used be used for determining the concentration of or determining the presence of a various other analytes (*e.g.*, fructosamine, hemoglobin, cholesterol, glucose, alcohol, drugs, *etc.*) in a variety of body fluids (*e.g.*, blood, interstitial fluid, saliva, urine, *etc.*). Test sensors including appropriate reagents can be used in the harvesting of most any liquid sample for the determination of the concentration of an analyte in that sample.

[0004] The type of reagent implemented in the test sensor depends on the type of measuring used. For example, in a colorimetric assay, the color change of a reaction area containing a reagent following contact with the sample is measured to determine the concentration of the analyte of interest in the sample. The degree of color change is measured using an optical sensor(s) that converts the degree of color change to electrical signals that are evaluated with diagnostic equipment. For example, the optical device may measure the amount of light reflected from, or transmitted through, the reaction area. In other embodiments of the present invention, the amount of infrared light absorbed by the reaction of the analyte in the sample and the reagent is measured. Colorimetric testing is described in detail in U.S. Patent No. 5,723,284 entitled "Control Solution and Method for Testing the Performance of an Electrochemical Device for Determining the Concentration of an Analyte in Blood," which is incorporated herein by reference in its entirety. Colorimetric testing is also described in detail in U.S. Patent Nos. 6,181,417 B1 (entitled "Photometric Readhead with Light Shaping Plate"), 5,518,689 (entitled "Diffuse Light Reflectance Readhead"), and 5,611,999

(entitled "Diffuse Light Reflectance Readhead").

[0005] The reagent that is used in the test sensor is a chemical agent that is costly to produce. Thus, it is desirable to limit the amount of reagent used and to reduce any waste of the reagent. Current manufacturing processes waste the costly reagent by impregnating more test membrane material than necessary. The test sensors include a membrane that is impregnated with the reagent during manufacturing by dipping, which entails submerging a test membrane sheet in the reagent. Test sensor disks (*i.e.*, cut sections sized for inclusion in a test sensor) are cut from the impregnated membrane sheet which results in wasted portions of the reagent impregnated sheet. Further, picking and placing the reagent impregnated sensor disks into the test sensor introduces material handling issues due to the sensitivity of the reagent which impacts the complexity and cost of the test sensor manufacturing process.

[0006] US 2002/0168290 A1 discloses sample collection devices and a method of manufacturing the same. In one embodiment the test strip device is generally made up of at least the following components: a support element or substrate made of an inert material, a matrix area for receiving a sample, a reagent composition within matrix area that typically includes one or more members of an analyte oxidation signal producing system, an air venting port and a top transparent layer which covers at least the matrix area. In other embodiments, the top layer may be a membrane containing a reagent composition impregnated therein while the matrix area may or may not contain a reagent composition. The matrix area defines an inert area, preferably a recessed area, formed within a surface of the substrate wherein all four sides of matrix area are bordered by substrate. The matrix area provides an area for deposition of the sampled physiological fluid and for the various members of the signal producing system as well as for the light absorbing or chromogenic product produced by the signal producing system. For manufacturing of the device a webbing is formed of at least three layers of sheets, a metal substrate sheet, a membrane sheet and a double-sided adhesive layer there between. After fabrication of substrate a signal producing system is selected and deposited within the matrix area in the substrate. Such deposition may be accomplished with slot coating, needle coating or ink jet printing techniques.

[0007] US 5,962,215 discloses devices for utilizing dry chemistry dye indicator systems for body fluid analysis such as glucose level in whole blood having a porous membrane with a skin side which enables separation of whole blood and visually reading the indicator without removing the red blood cell portion of the blood from the membrane. The matrix has a skin side and a test side and is attached to a holder which contains an opening. The matrix is preferably an intrinsically hydrophilic material and is optionally impregnated or coated with separating reagents to facilitate and maximize blood separation. According to one embodiment a device member

contains a first opening and second opening with a restricted flow passageway communicating with the first opening and the second opening, whereby the fluid sample introduced into the first opening will flow by capillary action through the passageway to the second opening. The device further comprises a cover layer having an opening corresponding to the first opening. The device further comprises a transparent support member having an opening corresponding to the second opening which can optionally have a matrix member compressed into or pre-shaped to fit into the second opening. When the fluid reaches the second opening and flows into the matrix containing appropriate indicator reagents, the typical reaction will occur and the indication of the indicator can be observed or measured through the opening in the support member.

**[0008]** EP 1 203 823 A1 discloses a biosensor that comprises a substrate, a reagent positioned on the substrate, and a cover including a top side and a generally flat bottom side. The bottom side is coupled to the substrate to define a sealed portion and an unsealed portion. The unsealed portion cooperates with the substrate to define a chamber extending across the reagent. The reagent is positioned on the substrate.

**[0009]** US 6,206,841 B1 discloses an article capable of both collecting blood and detecting an analyte in that blood. The article, which contains an appropriate detection element for determining the amount of analyte in the blood, can be used in conjunction with a meter that measures the signal generated by the detection element of the article. In one embodiment, the article is a multiple-layer element comprising a layer capable of receiving blood and transporting blood received by means of chemical added wicking, a layer capable of the detecting the presence of analyte or measuring the amount of analyte in the blood, and a layer that can be placed in contact with a meter this meter-contactable layer overlying the blood-transporting layer.

### **SUMMARY OF THE INVENTION**

**[0010]** According to one embodiment of the present invention, an optical-based test sensor for use in the determination of an analyte in a liquid sample is disclosed. The test sensor includes a base, a polymer carrier, and a test membrane. The base has a capillary channel formed in a surface of the base that is adapted to move a liquid sample from an inlet to a reaction area formed in the base. The polymer carrier has a lower surface adhered to the surface of the base and is disposed over at least a portion of the capillary channel. The test membrane, which contains a reagent, is adhered to the lower surface of the polymer carrier and extends from the polymer carrier into the reaction area such that the test membrane is arranged to allow flow of the liquid sample across a bottom surface and an edge of the test membrane.

**[0011]** The above summary of the present invention is not intended to represent each embodiment, or every

aspect, of the present invention. Additional features and benefits of the present invention will become apparent from the detail description, figures, and claims set forth below.

### **Brief Description of the Drawings**

#### **[0012]**

FIG. 1 is a perspective view of a test sensor according to one embodiment of the present invention.

FIG. 2 is a perspective view of a system for manufacturing test membranes according to one embodiment of the present invention.

FIG. 3a is a perspective view of dipping system for applying a reagent to a test membrane according to one embodiment of the present invention.

FIG. 3b is a perspective view of pumping system for applying a reagent to a test membrane according to an alternative embodiment of the present invention.

FIG. 4 is a top perspective view of a substrate having a plurality of capillary channels formed therein according to one embodiment of the present invention.

FIG. 5 is a perspective view of a plurality of test membrane disks attached to a carrier and a substrate having a plurality of capillary channels formed therein according to one embodiment of the present invention.

FIG. 6 is a perspective view of a system for laminating the test membrane disks attached to a carrier to a substrate having a plurality of capillary channels formed therein according to one embodiment of the present invention.

FIG. 7 is a perspective view of a stamping system for cutting a test sensor from a sheet of test sensors according to one embodiment of the present invention.

FIG. 8 is a side view of a cartridge having a reel of test membranes disposed therein according to an alternative embodiment of the present invention.

FIG. 9 is a side view of a dispensing cartridge having a reel of test membranes disposed therein and a collecting cartridge according to another alternative embodiment of the present invention.

**[0013]** While the invention is susceptible to various modifications and alternative forms, specific embodiments will be shown by way of example in the drawings and will be described in detail herein. It should be understood, however, that the invention is not intended to be limited to the particular forms disclosed. Rather, the invention is to cover all modifications, equivalents, and alternatives falling within the scope of the invention as defined by the appended claims.

### **Description of Illustrated Embodiments**

**[0014]** Turning now to the drawings and initially to FIG.

1, a test sensor 10 is shown according to one embodiment of the present invention. The test sensor 10 is used in the harvesting and analysis of a liquid sample for determining the presence or concentration of an analyte in the liquid sample. The test sensor 10 includes a test membrane disk 12 having a reagent 14 disposed therein. The test membrane disk 12 is adhered to the underside (as viewed in FIG. 1) of a carrier strip 16. The carrier strip 16 is laminated to a base 18 of the test sensor such that the test membrane disk 12 downwardly extends into a reaction area 21 of a capillary channel 20 formed in the base 18. The carrier strip 16 forms a lid over the capillary channel 20.

**[0015]** When conducting an assay, a liquid sample is harvested by positioning an inlet 22 of the capillary channel 20 adjacent the sample. The sample is moved, via capillary action, from the inlet 22 to the reaction area 21 where an analyte in the sample reacts with the reagent disposed in the test membrane 12. Optionally, the carrier 16 is positioned on the base 18 such that the upstream end of the capillary channel 20 remains uncovered to form a vent 23 to facilitate movement of the fluid sample in the capillary channel. Once the sample is moved into the reaction area, the analyte of interest (*e.g.*, glucose) reacts with the reagent 14 on the test membrane disk 12 and that reaction is measured with an optical device as previously described in the Background Section.

**[0016]** According to one embodiment of the present invention, the capillary channel 20 is sized to provide underfill protection so that a required volume of sample is delivered to the reaction area 21. Additionally the capillary channel 20 is widened to increase the lateral flow of the sample to the test membrane disk 12 by enlarging the surface area of the test membrane disk 12 periphery exposed to the sample flow in the capillary channel 20. The test sensor 10 base 18 is dimensioned to create a small gap between the side walls of the capillary channel 20 and the edges of the test membrane, the bottom wall of the capillary channel 20 and the bottom surface of the membrane, or both. These gaps provide a clearance to allow the flow of the sample across the bottom surface and edges of the test membrane disk 12, which decreases saturation time and uniformity of the assay. These gaps between the edge and bottom of the test membrane disk 12 and the capillary channel 20 can range between about 0.0005 inch (about 0.0127 mm) and about 0.001 inch (about 0.0254 mm). In other alternative embodiments, a wicking membrane or mesh is attached to the test membrane 12 to draw and diffuse the sample across the test membrane 12 to increase the flow of the sample across the test membrane disk 12.

**[0017]** According to one embodiment of the present invention, the test membranes 12 are made of a hydrophilic polyethersulfone material having pore sizes ranging from about 0.2 to about 8 micrometers. The Presense membrane and the Predator® membrane, both manufactured by Pall Specialty Materials of Port Washington, New York, are two examples of commer-

cially available test membranes that may be used in various embodiments of the present invention. Alternatively, the test membrane may be made of a nitrocellulose material. While the test membrane disks 12 shown in FIG. 1 are disk-shaped, the test membranes can be of any shape in alternative embodiments of the present invention.

**[0018]** The carrier 16 and the base 18 are both constructed of plastic. According to one embodiment of the present invention, the carrier 16 and the base 18 are constructed of plastic having a surface tension of less than about 45 milli-Newtons per meter such as polystyrene, polypropylene, polyethylene, polyethylene terephthalate, polycarbonate, and polyvinyl chloride, for example. The carrier 16 and base 18 are constructed of a somewhat hydrophobic material so as not to absorb the reagent 14 or the sample that moves through the capillary channel 20 formed in the base 18 according to one embodiment of the present invention. Further, these materials are not adversely affected by the liquid samples (*e.g.*, blood, urine, or saliva) to be tested. The carrier 16 is substantially optically transparent allowing the reaction between the analyte in the sample and the reagent to be optically measured through the carrier 16.

**[0019]** The dimensions of the test sensor 10 according to one embodiment of the present invention are as follows. The capillary channel 20 has a width ranging between about 1 mm and about 2 mm, with the reaction area 21 having a diameter of about 3-5 mm. The test membrane disk 12 has a diameter of about 2.5 to about 3.5 mm. In other embodiments, the test membrane disk 12 has a diameter of about 1 to about 2 mm, the reaction area 21 has a diameter of about 1.5 to about 2.5 mm, and the capillary channel 20 has a width of 0.75 to about 1 mm. The reaction area 21 has a depth of about 0.10 to about 0.20 mm, leaving clearance between the bottom surface of the reaction area 21 and the test membrane disk 12. This clearance increases fluid sample flow across the bottom surface of the test membrane disk 12.

**[0020]** Referring also to FIG. 2, a method of manufacturing the test sensor 10 according to one embodiment of the present invention will be described. The membrane material (*i.e.*, the material from which test membrane disks 12 are cut) and the carrier material (*i.e.*, the material from which the carrier 16 is cut) are stored on a first roll 24 and a second roll 26, respectively. An adhesive liner, for adhering the membrane material to the carrier material, is disposed on a third roll 28. The adhesive liner that adheres the test membrane disk 12 to the carrier 16 (formed from the carrier web 34) comprises a substantially optically clear adhesive for permitting the test membrane disk 12 to be read through the substantially optically clear carrier 16. A test membrane web 30 from the first roll 24, an adhesive liner web 32 from the third roll 28, and a carrier web 34 from the second roll 26 are fed between a cylindrical, rotating die 36 and counter pressure roller 38 that crush-cut the test membrane web 30 and the adhesive liner web 32 onto the carrier web 34.

The carrier web 34 is not cut resulting in a continuous membrane/carrier strip 40 having individual, cut test membrane disks 12 adhered thereto and spaced apart by a predetermined distance. The excess adhesive liner material and test membrane material 42 are lifted from the membrane/carrier strip 40 by a withdraw roller 44.

**[0021]** Turning now to FIG. 3a, the membrane/carrier strip 40 is dipped into a tank 50 containing a liquid reagent for impregnating the test membrane disks 12 with the reagent 14. As the membrane/carrier strip 40 is directed into the tank 50, via a plurality of rollers 51a-c, the test membrane disks 12 absorb the reagent 14. The carrier 34 does not absorb any of the reagent 14 due to its hydrophobic nature. Thus, only the test membrane disks 12 absorb the reagent 14.

**[0022]** Only the portions of the membrane material to be used (e.g., the test membrane disks 12) and not any excess membrane material absorb the costly reagent because the test membrane disks 12 have been cut to the appropriate size for insertion into a test sensor base 18 (FIG. 1) prior to being impregnated with the reagent. In addition to the size of the test membranes 12, further measures may be implemented for controlling the amount of reagent 14 absorbed by the test membrane disks 12 in alternative embodiments of the present invention. The speed at which the membrane/carrier strip 40 is advanced into the tank 50 of reagent 14 can be varied to control the amount of time each test membrane disk 12 spends dipped in the reagent 14. The degree of impregnation of each test membrane disk 12 is directly proportional to the amount of time that the test membrane disk 12 is dipped into the reagent 14. Additionally, apertures may be formed in the carrier web 34 so that the test membrane disks 12 absorb the reagent 14 from both sides. In such an embodiment, the time in which each test membrane disk 12 is dipped into the reagent 14 may be decreased because each test membrane disk 12 is absorbing reagent 14 from both sides which increases the test membrane disk's 12 rate of reagent 14 absorption.

**[0023]** Referring to FIG. 3b, an alternative embodiment for disposing the reagent 14 on the test membrane disks 12 is illustrated. The membrane/carrier strip 40 is moved past a nozzle 52, via a plurality of rollers 53, that is in fluid communication with a pump 54 for pumping the reagent 14 through the nozzle 52. The nozzle 52 directs the reagent 14 onto the test membrane disks 12. The pump 54 controls the amount of reagent 14 deposited on each test membrane disk 12.

**[0024]** Referring to FIG. 4, a polymer substrate 60 is provided from which the test sensor bodies 18 (FIG. 1) are formed. As discussed above, the bodies 18 are constructed of a polymer material so that the liquid sample to be analyzed is not absorbed by the test sensor base 18. A plurality of capillary channels 20, including the reaction areas 21, are formed in the polymer substrate 60. The capillary channels 20 are formed in the substrate 60 by any one of a variety of known manufacturing processes

including flat bed embossing or rotary embossing. The process of embossing the capillary channel 20 into the polymer substrate 60 is performed using a continuous web process, similar to the method described above for cutting the test membrane disks 12 from the web of membrane material 12 (FIG. 2). A long length of the substrate may be formed in a reel format or in a sheet format having a specific number (e.g., 5, 10 or 20) of capillary channels formed therein.

**[0025]** Referring to FIG. 5, the polymer substrate 60 having the capillary channels 20 formed therein is attached to the membrane/carrier strip 40 comprising the carrier 16 and the plurality of test membrane disks 12 disposed thereon. The membrane/carrier strip 40 is disposed on the polymer substrate 60 such that the test membrane disks 12 extends into the reaction areas 21 of the capillary channels 20 formed in the polymer substrate 60. The membrane/carrier strip 40 is laminated to the substrate 60 using an adhesive. According to alternative embodiments of the present invention, the adhesive may be applied to the polymer substrate 60 prior to or subsequent to forming the capillary channels 20 in the substrate 60. According to one embodiment of the present invention, the adhesive used to laminate the membrane/carrier strip 40 to the polymer substrate is heat and pressure sensitive. An example of an adhesive for use with the present invention is described in U.S. Patents Nos. 5,759,364 and 5,798,031, each of which is incorporated herein by reference in its entirety.

**[0026]** Referring to FIG. 6, a continuous process for laminating the membrane/carrier strip 40 to the polymer substrate 60 is illustrated according to one embodiment of the present invention. The substrate 60 and the membrane/carrier strip 40 are fed between a pair of rollers 70, 72 for continuously laminating the substrate 60 and the membrane/carrier strip 40 together. For example, according to one embodiment of the present invention, the capillary channels 20 are formed in a length of substrate 60 that is fed between rollers 70, 72 along with the membrane/carrier strip 40, wherein the membrane/carrier strip 40 is fed directly from the dipping process illustrated in FIG. 2 for forming a continuous length 76 of test sensors 10. Alternatively, non-continuous sheets of test sensors 10 (e.g., 5, 10, or 15 test sensors) such as shown in FIG. 5, are laminated to a substrate 60 having the same number of capillary channels 20 formed therein.

**[0027]** Referring to FIG. 7, individual test sensors 10 are cut from a length 80 a plurality of test sensors 10. According to the illustrated embodiment, the test sensors 10 are cut from the length 80 of test sensors 10 using a stamping process. The length 80 is fed into a stamping die 82 which contains a die to cut out the individual test sensors 10. After stamping, the individual test sensors are packaged. In an alternative embodiment, the test sensors 10 are cut from the length 80 of test sensors 10 using a blade, rather than a stamping die.

**[0028]** As indicated in the discussion above, the manufacturing steps described in connection with FIGS. 2-7

may be part of a continuous manufacturing process wherein the stages are disposed along an manufacturing line. For example, the membrane/carrier strip 40 formed as described in connection with FIG. 2 may be fed directly into the reagent tank 50 discussed in connection with FIG. 3a, or past the nozzle as described in connection with FIG. 3b. Alternatively, the various manufacturing stages of FIGS. 2-7 may be implemented in a non-continuous processes. For example, a reel of the membrane/carrier strip 40 may be formed (FIG. 2) and then that reel is later fed into the reagent tank 50 discussed in connection with FIG. 3a.

**[0029]** According to an alternative embodiment of the present invention, the reagent is applied to the test membrane disks 12 of the test sensors 10 by pumping the reagent 14 onto the test membrane disks 12. In such an embodiment, the test membranes disks 12 are die-cut onto the polymer carriers 14 as described above in connection with FIG. 2. However, instead of dipping the carrier/membrane strip 40 into the reagent tank 50 as described in connection with FIG. 3a, the carrier/membrane strip 40 is advanced past a reagent pump 54 as illustrated in FIG. 3b for depositing a predetermined amount of reagent 14 onto each of the test membrane disks 12. This method is also advantageous because the amount of reagent 14 deposited onto each the test membrane 12 is controlled by the pump. In another embodiment of the present invention, the reagent is deposited or "ink-jetted" onto the test membranes by use of a plurality of piezoelectric controlled nozzles as are commonly used for depositing ink on paper in ink jet printers.

**[0030]** While the test sensor 10 has been described thus far as having a two piece construction (*i.e.*, a base 18 and a carrier 16) with the a capillary channel 20 formed in the base, the test sensor can be have a three piece construction with the capillary channel cut in a middle piece in alternative embodiments of the present invention. For example, a flat base, a generally U-shaped middle layer, and a flat lid are adhered together. The side walls of the capillary channel are formed by the interior of the U-shaped middle layer. A test membrane disk, which is attached to the lid as described in connection with FIG. 1, is positioned within the closed end of the U-shaped middle layer and the open end of the U-shaped middle layer forms the inlet of the capillary channel.

**[0031]** Referring to FIG. 8, in another embodiment of the present invention, a reel 90 of the membrane/carrier strip 40 formed as described in connection with FIG. 2 is disposed with a dispensing cartridge 92 for dispensing test membrane disks 94 impregnated with a reagent attached to a carrier 96 one at a time. According to one embodiment of the present invention, the cartridge 92 includes a cutting means (*e.g.*, a sharp or serrated edge) for cutting the carrier 96 for dispensing one test membrane disk 94 at a time. Alternatively, the carrier 96 is perforated between test membrane disks 94 during manufacturing to facilitate the tearing off of a single test membrane disk 94 from the reel 90. The individually dispensed

test membrane disks 94 can be used with a top-fill device for determining the concentration of an analyte in a liquid sample according to an alternative embodiment of the present invention.

**[0032]** Referring to FIG. 9, in another embodiment of the present invention, a reel 100 of the membrane/carrier strip 40 formed as described in connection with FIG. 2 is disposed with a dispensing cartridge 102 for dispensing test membrane disks 104 impregnated with a reagent attached to a carrier 106 one at a time, similar to that described in connection with FIG. 8. A collecting cartridge 110 collects the used test membrane disks 104. According to one embodiment, the dispensing and collecting cartridges 102 and 110 are implemented in a top-fill blood monitoring device wherein, for a example, a user places a blood sample (or other body fluid sample) on a test membrane disk 104 dispensed from the dispensing cartridge 102. The top-fill device includes a light source 114 for illuminating the test membrane disk having a sample deposited thereon and a light detector 116 for measuring light reflected from the reaction of the analyte in the body fluid and the reagent on the test membrane disk 12 as is known in the art for determining the concentration of the analyte in the body fluid.

**[0033]** While the invention is susceptible to various modifications and alternative forms, specific embodiments thereof have been shown by way of example in the drawings and herein described in detail. It should be understood, however, that it is not intended to limit the invention to the particular forms disclosed, but on the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the scope of the invention as defined by the appended claims.

## Claims

1. A method for manufacturing a test sensor (10) for use in the determination of an analyte in a liquid sample, the method comprising:

providing a substantially hydrophobic polymer carrier (16) having a first surface;  
 adhering a test membrane (12) to the first surface of the polymer carrier (16), the test membrane (12) adapted to absorb a reagent (14);  
 impregnating the test membrane (12) with a reagent (14);  
 providing a base (18) having a capillary channel (20) formed therein; and  
 adhering the first surface of the carrier (16) to the base (18),

### characterized in that

the test membrane (12) extends into the capillary channel (20) formed in base (18) such that the test membrane (12) is arranged to allow flow of the liquid sample across a bottom surface and an edge of the test membrane (12).

2. The method of claim 1 wherein the reagent (14) is adapted to produce a colorimetric reaction indicative of the concentration of the analyte in the sample.

3. The method of claim 1 or 2 wherein adhering comprises:

disposing a length of an adhesive liner (32) on a length of the polymer carrier (34);  
 disposing a length of test membrane material (30) on the length of adhesive liner (32);  
 crush-cutting a plurality of individual test membrane sections from the length of the test membrane material (30);  
 adhering the plurality of individual test membrane sections to the polymer carrier (34); and  
 removing the excess membrane material (30) and adhesive liner (32).

4. The method of one of the claims 1 to 3 further comprising forming one or more apertures in the polymer carrier (34).

5. An optical-based test sensor (10) for use in the determination of an analyte in a liquid sample, the test sensor (10) comprising:

a base (18) having a capillary channel (20) formed in a surface of the base (18), the capillary channel (20) adapted to move a liquid sample from an inlet (22) to a reaction area (21) formed in the base (18);  
 a polymer carrier (16) having a lower surface adhered to the surface of the base (18), the polymer carrier (16) being disposed over at least a portion of the capillary channel (20); and  
 a test membrane (12) adhered to the lower surface of the polymer carrier (16), the test membrane (12) containing a reagent (14),  
**characterized in that** the test membrane (12) extends from the polymer carrier (16) into the reaction area (21) such that the test membrane (12) is arranged to allow the flow of the liquid sample across a bottom surface and an edge of the test membrane (12).

6. The test sensor (10) of claim 5 wherein the reagent (14) is adapted to produce a colorimetric reaction indicative of the concentration of the analyte in the sample.

7. The test sensor (10) of claim 5 or 6 wherein the carrier (16) is constructed of a substantially hydrophobic material.

8. The test sensor (10) of one of the claims 5 to 7 wherein the capillary channel (20) has an inlet end and an opposite end, the opposite end being uncovered by

the carrier (16).

### Patentansprüche

1. Verfahren zur Herstellung eines Testensors (10) zur Verwendung zur Bestimmung eines Analyts in einer flüssigen Probe, wobei das Verfahren Folgendes umfasst:

das Bereitstellen eines im Wesentlichen hydrophoben Polymerträgers (16) mit einer ersten Oberfläche;  
 das Anhaften einer Testmembran (12) an die erste Oberfläche des Polymerträgers (16), wobei die Testmembran (12) geeignet ist, um ein Reagens (14) zu absorbieren;  
 das Imprägnieren der Testmembran (12) mit einem Reagens (14);  
 das Bereitstellen einer Basis (18) mit einem darin ausgebildeten Kapillarkanal (20); und  
 das Anhaften der ersten Oberfläche des Trägers (16) an die Basis (18),

### dadurch gekennzeichnet, dass

sich die Testmembran (12) in den in der Basis (18) ausgebildeten Kapillarkanal (20) so erstreckt, dass die Testmembran (12) angeordnet ist, um zu ermöglichen, dass die flüssige Probe über eine untere Oberfläche und einen Rand der Testmembran (12) strömt.

2. Verfahren nach Anspruch 1, worin das Reagens (14) geeignet ist, um eine kolorimetrische Reaktion hervorzurufen, die die Konzentration des Analyts in der Probe anzeigt.

3. Verfahren nach Anspruch 1 oder 2, worin das Anhaften Folgendes umfasst:

das Aufbringen einer Länge einer Haftlage (32) auf einer Länge des Polymerträgers (34);  
 das Aufbringen einer Länge des Testmembranmaterials (30) auf die Länge der Haftlage (32);  
 das Quetschschneiden einer Vielzahl einzelner Testmembranabschnitte von der Länge des Testmembranmaterials (30);  
 das Anhaften der Vielzahl einzelner Testmembranabschnitte an den Polymerträger (34) und  
 das Entfernen von überschüssigem Membranmaterial (30) und überschüssiger Haftlage (32).

4. Verfahren nach den Ansprüchen 1 bis 3, das ferner das Ausbilden einer oder mehrerer Öffnungen in dem Polymerträger (34) umfasst.

5. Testsensor (10) auf optischer Basis zur Verwendung

zur Bestimmung eines Analyts in einer flüssigen Probe, wobei der Testsensor (10) Folgendes umfasst:

eine Basis (18) mit einem in einer Oberfläche der Basis (18) ausgebildeten Kapillarkanal (20), wobei der Kapillarkanal (20) geeignet ist, um eine flüssige Probe von einem Einlass (22) zu einem in der Basis (18) ausgebildeten Reaktionsbereich (21) zu transportieren; einen Polymerträger (16) mit einer unteren Oberfläche, die an der Oberfläche der Basis (18) anhaftet, wobei der Polymerträger (16) zumindest über einem Abschnitt des Kapillarkanals (20) angeordnet ist, und eine Testmembran (12), die an der unteren Oberfläche des Polymerträgers (16) anhaftet, wobei die Testmembran (12) ein Reagens (14) enthält,

**dadurch gekennzeichnet, dass** sich die Testmembran (12) von dem Polymerträger (16) so in den Reaktionsbereich (21) erstreckt, dass die Testmembran (12) angeordnet ist, um zu ermöglichen, dass die flüssige Probe über eine untere Oberfläche und einen Rand der Testmembran (12) strömt.

6. Testsensor (10) nach Anspruch 5, worin das Reagens (14) geeignet ist, um eine kolorimetrische Reaktion hervorzurufen, die die Konzentration des Analyts in der Probe anzeigt.
7. Testsensor (10) nach Anspruch 5 oder 6, worin der Träger (16) aus einem im Wesentlichen hydrophoben Material besteht.
8. Testsensor (10) nach einem der Ansprüche 5 bis 7, worin der Kapillarkanal (10) ein Einlassende und ein entgegengesetztes Ende aufweist, wobei das entgegengesetzte Ende nicht durch den Träger (16) bedeckt ist.

## Revendications

1. Procédé pour fabriquer un détecteur d'essai (10) destiné à être utilisé dans la détermination d'un analyte dans un échantillon liquide, le procédé comprenant :

la fourniture d'un support polymère (16) sensiblement hydrophobe ayant une première surface ;  
l'adhésion d'une membrane d'essai (12) à la première surface du support polymère (16), la membrane d'essai (12) conçue pour absorber un réactif (14) ;  
l'imprégnation de la membrane d'essai (12) avec un réactif (14) ;

la fourniture d'une base (18) ayant un canal capillaire (20) formé dans celle-ci ; et l'adhésion de la première surface du support (16) à la base (18),

### caractérisé en ce que

la membrane d'essai (12) s'étend dans le canal capillaire (20) formé dans la base (18) de telle sorte que la membrane d'essai (12) est agencée pour permettre l'écoulement de l'échantillon liquide sur une surface inférieure et un bord de la membrane d'essai (12).

2. Procédé selon la revendication 1 où le réactif (14) est adapté pour produire une réaction colorimétrique indiquant la concentration de l'analyte dans l'échantillon.
3. Procédé selon la revendication 1 ou 2 où l'adhésion comprend :

la disposition d'une longueur d'une doublure adhésive (32) sur une longueur du support polymère (34) ;

la disposition d'une longueur d'un matériau de membrane d'essai (30) sur la longueur de la doublure adhésive (32) ;

le découpage par écrasement d'une pluralité de sections de membrane d'essai individuelles dans la longueur du matériau de membrane d'essai (30) ;

l'adhésion de la pluralité de sections de membrane d'essai individuelles au support polymère (34) ; et

le retrait du matériau de membrane (30) et de la doublure adhésive (32) en excès.

4. Procédé selon l'une des revendications 1 à 3 comprenant en outre la formation d'une ou plusieurs ouvertures dans le support polymère (34).
5. Détecteur d'essai (10) à base optique destiné à être utilisé dans la détermination d'un analyte dans un échantillon liquide, le détecteur d'essai (10) comprenant :

une base (18) ayant un canal capillaire (20) formé dans une surface de la base (18), le canal capillaire (20) adapté pour déplacer un échantillon liquide depuis une entrée (22) jusqu'à une zone de réaction (21) formée dans la base (18) ; un support polymère (16) ayant une surface inférieure adhérent à la surface de la base (18), le support polymère (16) étant disposé sur au moins une partie du canal capillaire (20) ; et une membrane d'essai (12) adhérent à la surface inférieure du support polymère (16), la membrane d'essai (12) contenant un réactif (14),

**caractérisé en ce que** la membrane d'essai (12) s'étend depuis le support polymère (16) dans une zone de réaction (21) de telle sorte que la membrane d'essai (12) est agencée pour permettre l'écoulement de l'échantillon liquide sur une surface inférieure et un bord de la membrane d'essai (12).

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6. Détecteur d'essai (10) selon la revendication 5 où le réactif (14) est adapté pour produire une réaction colorimétrique indiquant la concentration de l'analyse dans l'échantillon. 10
7. Détecteur d'essai (10) selon la revendication 5 ou 6 où le support (16) est construit en un matériau sensiblement hydrophobe. 15
8. Détecteur d'essai (10) selon l'une des revendications 5 à 7 où le canal capillaire (20) a une extrémité d'entrée et une extrémité opposée, l'extrémité opposée n'étant pas recouverte par le support (16). 20

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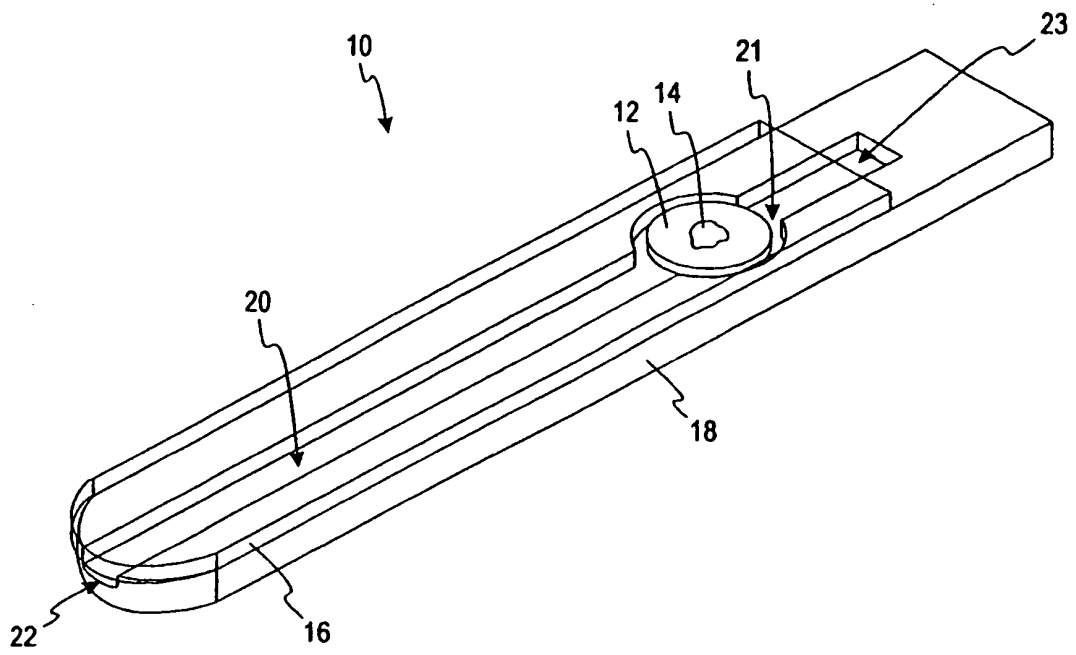
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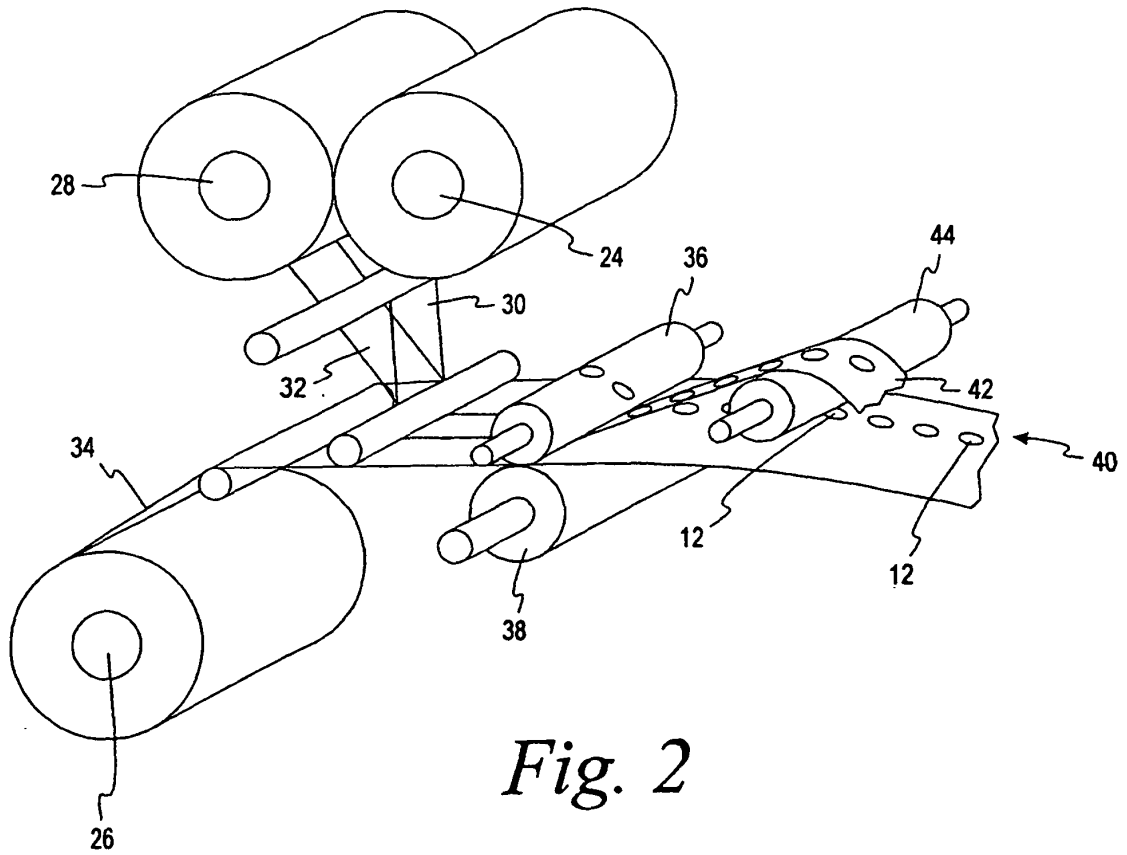
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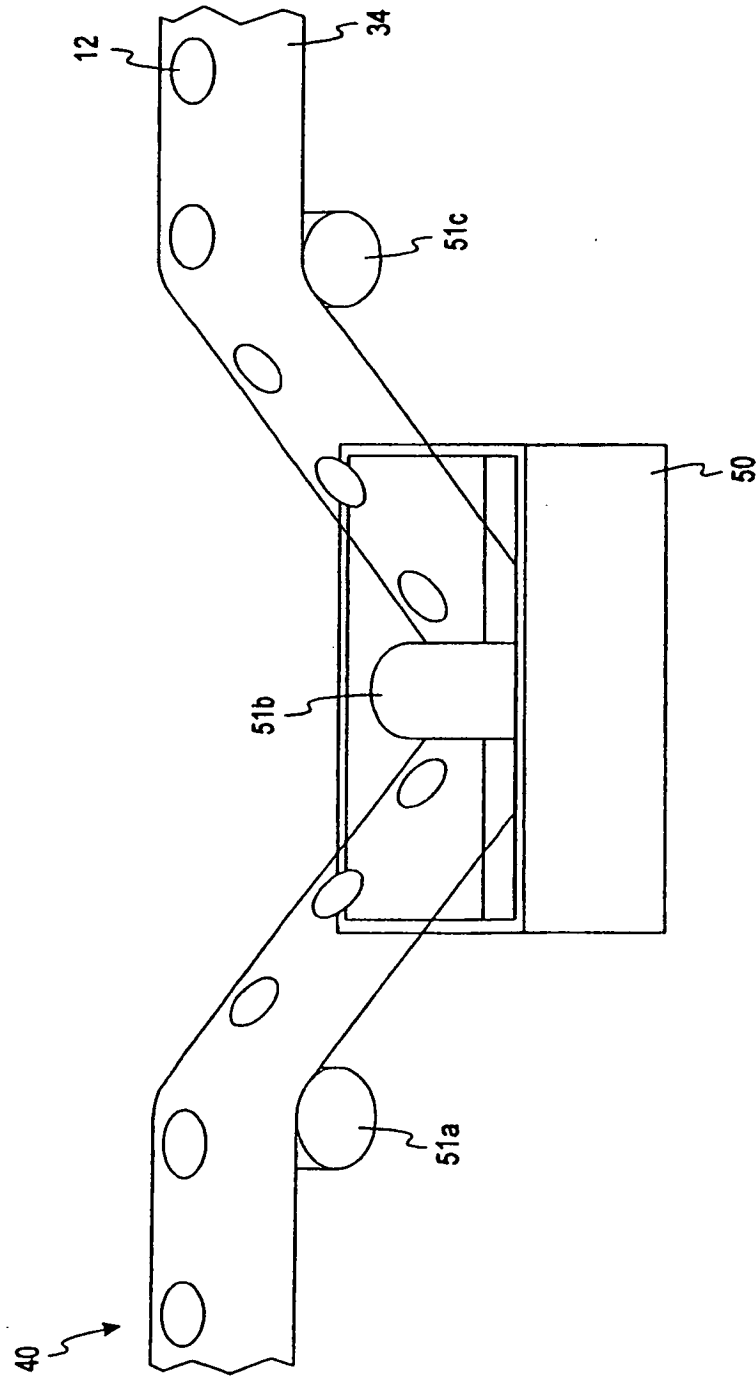
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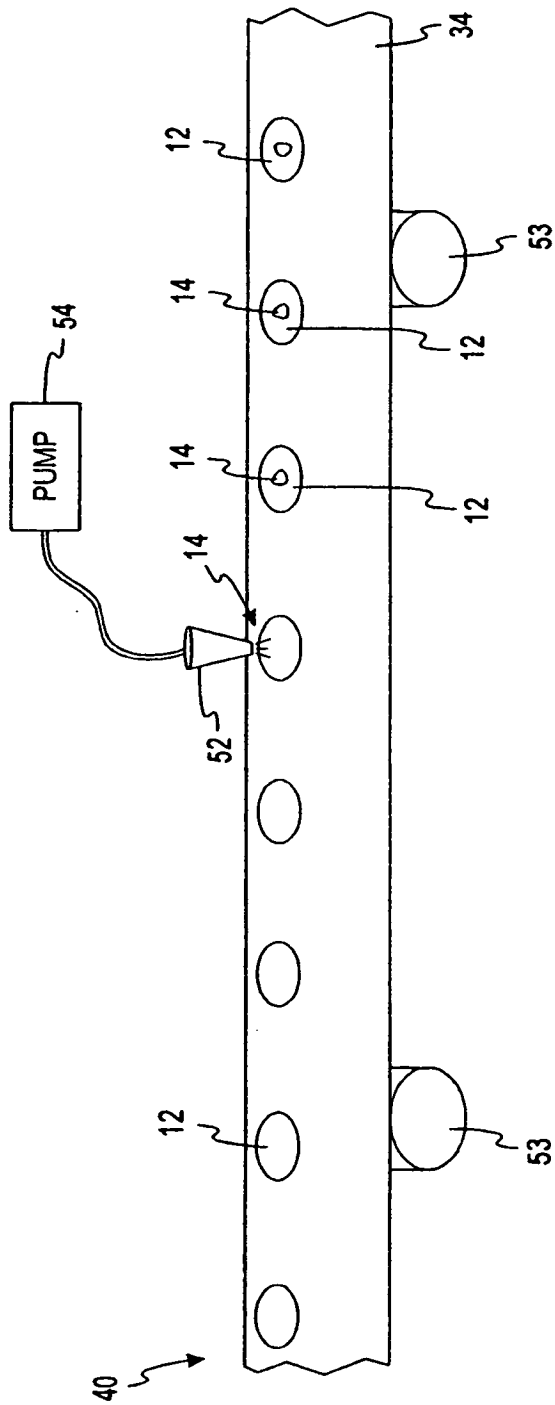
*Fig. 1*



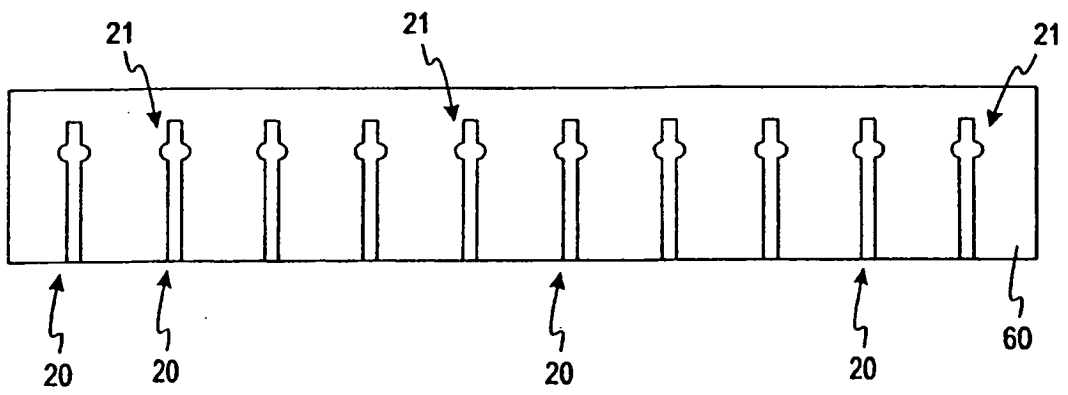
*Fig. 2*



*Fig. 3a*



*Fig. 3b*



*Fig. 4*

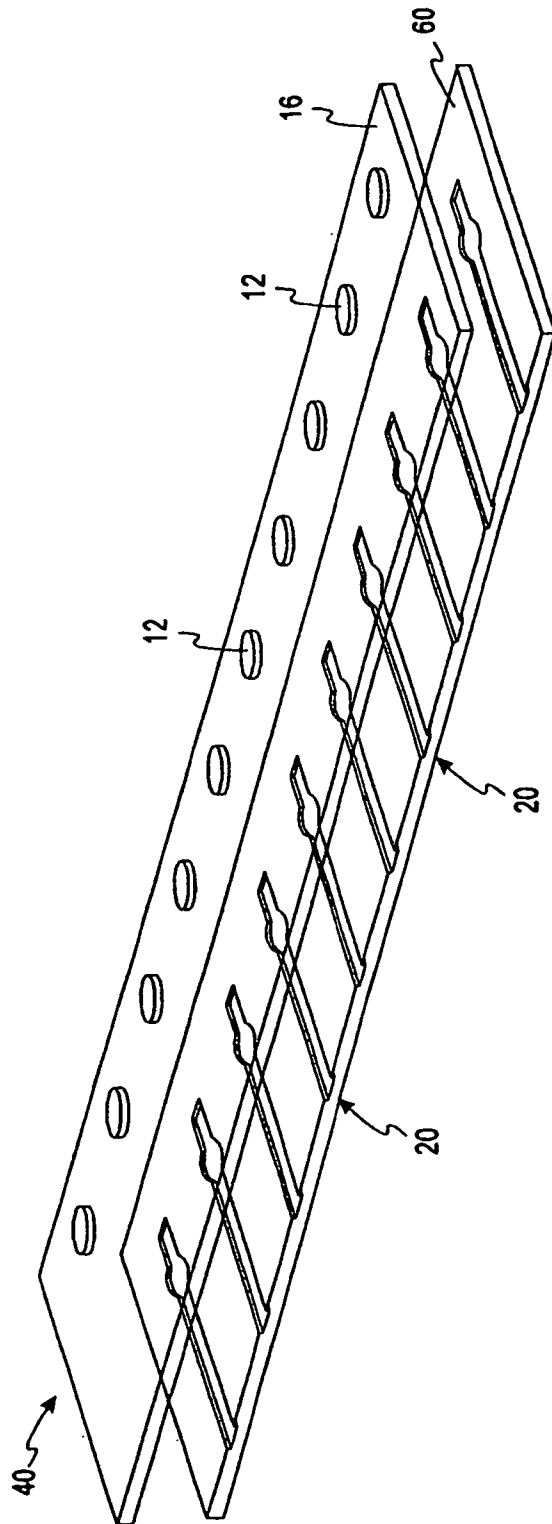


Fig. 5

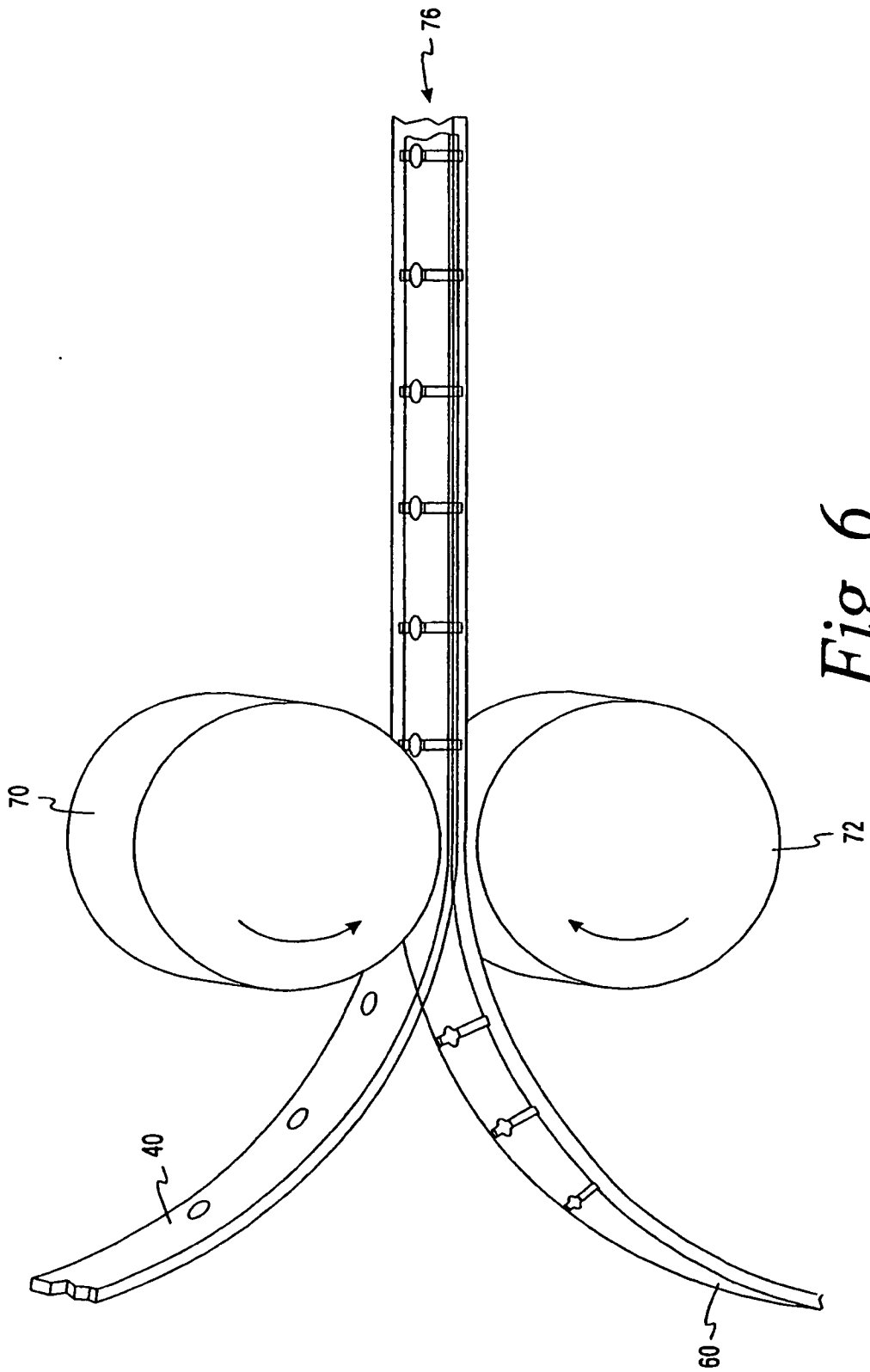


Fig. 6

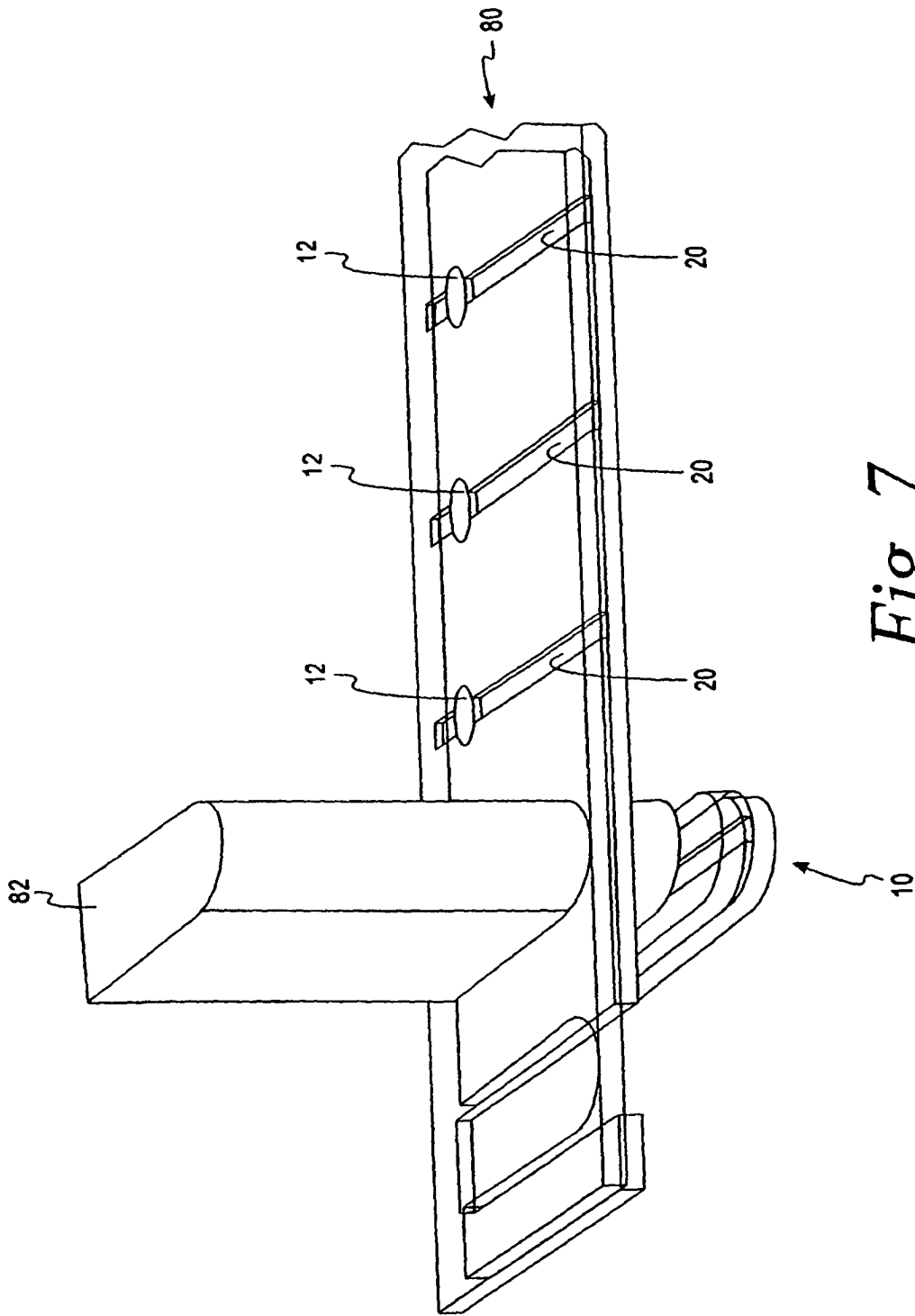
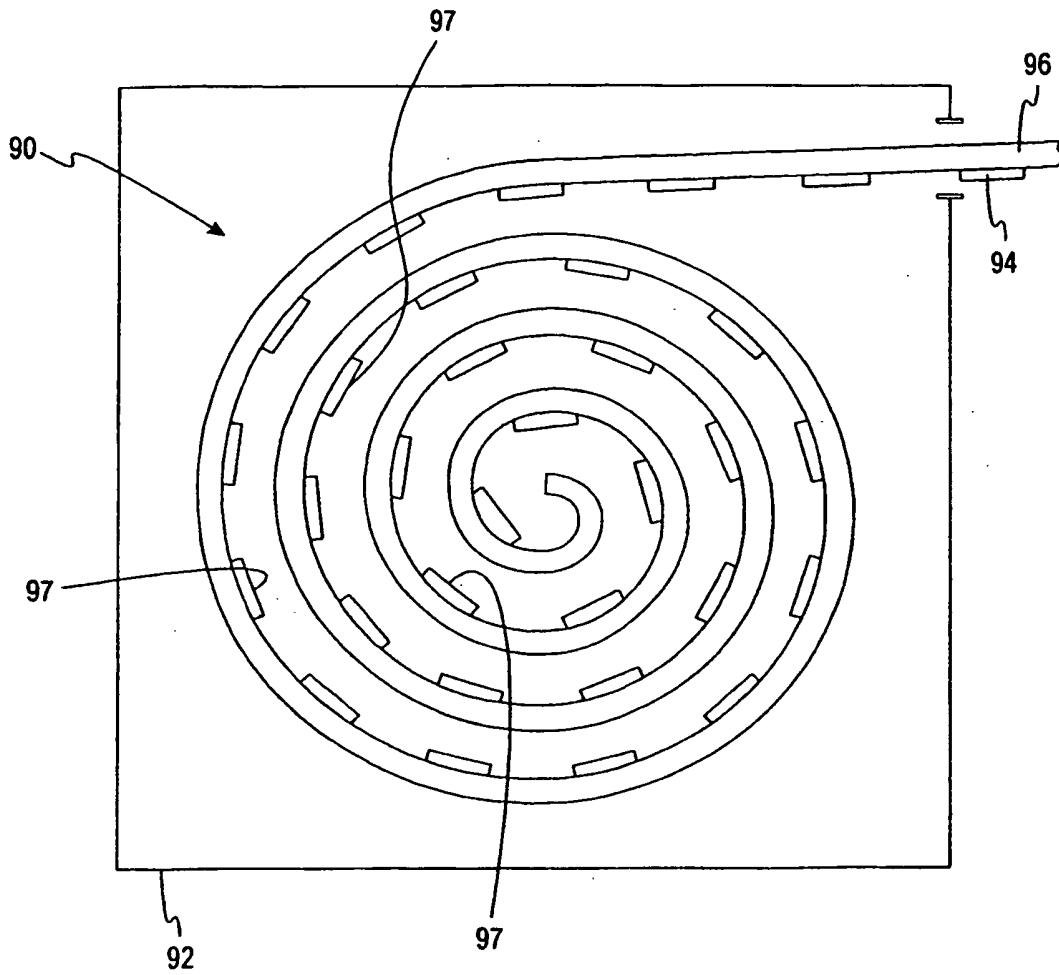
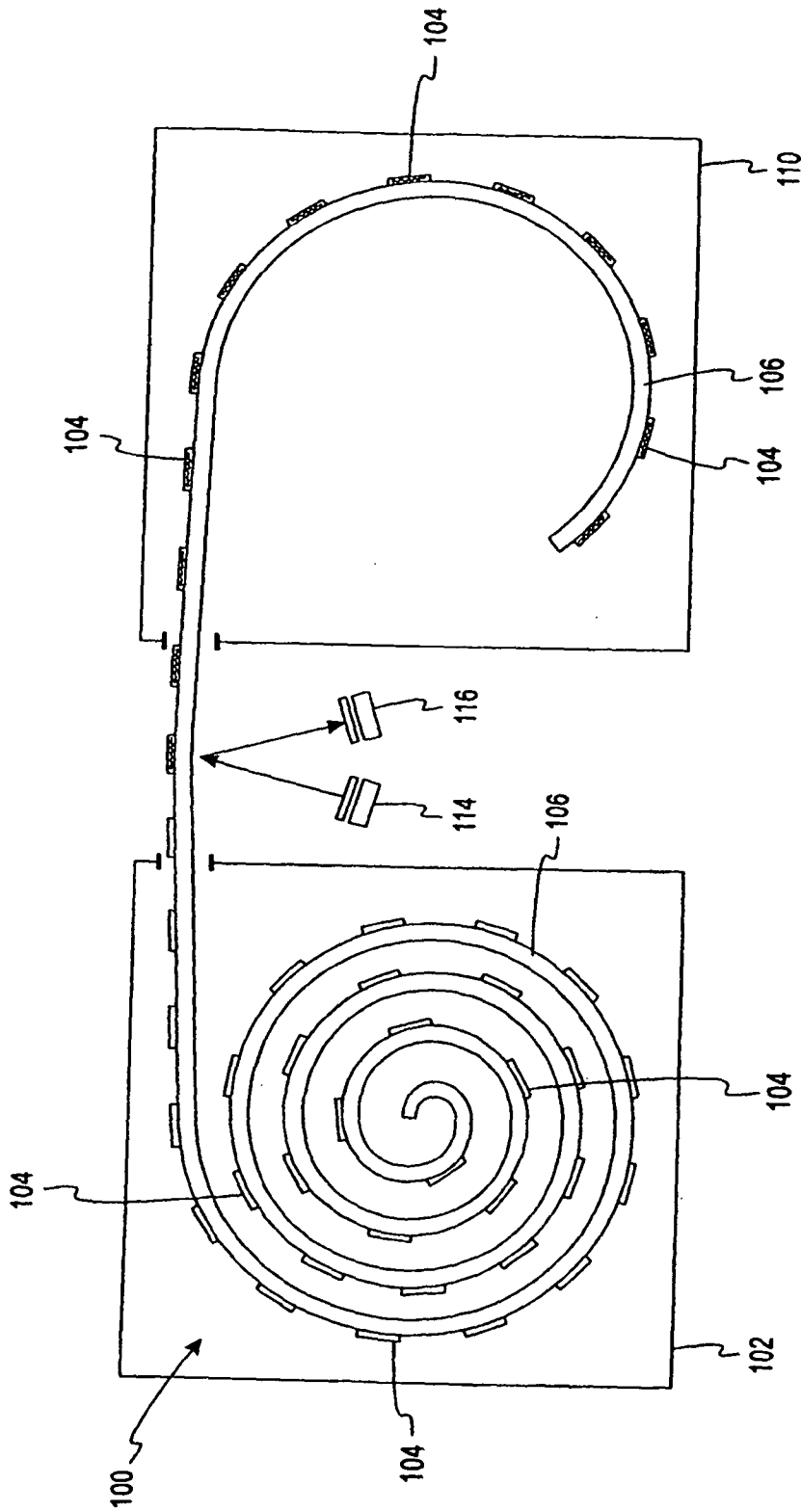


Fig. 7



*Fig. 8*



*Fig. 9*

**REFERENCES CITED IN THE DESCRIPTION**

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专利名称(译)	测试传感器及其制造方法		
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申请(专利权)人(译)	拜耳医药保健, LLC		
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	KURIGER REX J		
发明人	KURIGER, REX J.		
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CPC分类号	G01N33/525 A61B5/14532 A61B5/1455 B01L3/5027 B01L3/502707 G01N21/78 G01N27/3272 Y10T156/1052 Y10T156/1054		
优先权	60/473703 2003-05-29 US		
其他公开文献	EP1482299A1		
外部链接	<a href="#">Espacenet</a>		

摘要(译)

根据本发明的一个实施例，公开了一种用于确定液体样本中的分析物的基于光学的测试传感器。测试传感器包括基座，聚合物载体和测试膜。基部具有形成在基部表面中的毛细管通道，其适于将液体样品从入口移动到形成在基部中的反应区域。聚合物载体具有粘附到基底表面的下表面，并设置在毛细管通道的至少一部分上。含有试剂的测试膜粘附在聚合物载体的下表面上，并从聚合物载体延伸到反应区域。

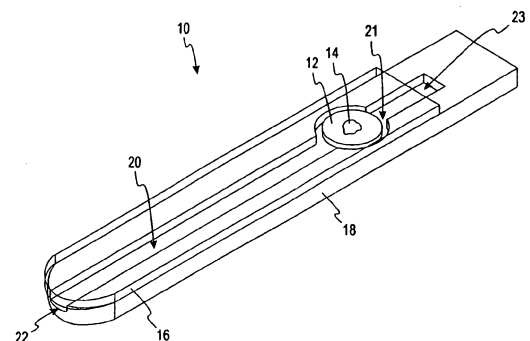


Fig. 1