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

(11) EP 1 838 209 B1

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:
25.11.2009 Bulletin 2009/48

(21) Application number: **05798909.7**

(22) Date of filing: **19.09.2005**

(51) Int Cl.:
A61B 5/00 *(2006.01)*

(86) International application number:
PCT/US2005/033297

(87) International publication number:
WO 2006/034104 (30.03.2006 Gazette 2006/13)

(54) **SYSTEM AND METHOD FOR REPOSITIONING A DIAGNOSTIC TEST STRIP AFTER INOCULATION**

SYSTEM UND VERFAHREN ZUR REPOSITIONIERUNG EINES DIAGNOSTISCHEN TESTSTREIFENS NACH INOKULATION

SYSTEME ET PROCEDE DE REPOSITIONNEMENT D'UNE BANDE DE TEST DIAGNOSTIQUE APRES INOCULATION

(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: **20.09.2004 US 611466 P**

(43) Date of publication of application:
03.10.2007 Bulletin 2007/40

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EP 1 838 209 B1

Printed by Jouve, 75001 PARIS (FR)

Description

FIELD OF THE INVENTION

[0001] The present invention relates generally to diagnostic instruments and, more particularly, to a system and method for repositioning a diagnostic test strip after inoculation for use in determining the concentration of an analyte in a liquid sample.

BACKGROUND OF THE INVENTION

[0002] Test strips (e.g., biosensors) containing reagents are often used in assays for determining the analyte concentration in a fluid sample. The quantitative determination of analytes in body fluids is of great importance in the diagnoses and maintenance of certain physiological abnormalities. For example, lactate, cholesterol, and bilirubin should be monitored in certain individuals. In particular, determining glucose in body fluids is important to diabetic individuals who must frequently check the glucose level in their body fluids to regulate the glucose intake in their diets. Each test requires that a new test sensor be used and, thus, cost of the individual test sensors is important to the users.

[0003] The material costs for an individual test strip (and the packing costs associated therewith) increase as the size of the individual test strips increase. Therefore, to minimize the cost of the test sensors, it is desirable to make the test strips as small as possible. However, as the size of the test sensors decreases, generally the difficulty in handling and manipulating the strip by a user increases. Additionally, the risk of contaminating a readhead on a meter increases as the size of the test strip decreases.

[0004] Therefore, it would be desirable to have a system and method that uses a diagnostic test strip and addresses these issues.

[0005] US 2001/0027277 A1 discloses a disposable lancet combined with a reagent carrying strip carriying a reagent that indicates the concentration of a blood component in a blood sample placed in contact with the strip. The lancet has one end, which is sharpened for piercing the skin of a user and has the reagent carrying strip connected to the lancet. The strip is sheet-like and has a first side and a second side, which sides are both accessible for the user, such that the reagent carrying strip can be inserted into a blood glucose meter without having to disconnect the strip from the lancet. The disposable lancet combined with a reagent carrying strip is placed in a guided position in the housing with a spring in a compressed position. Releasing the spring by pressing a release button causes the spring carrying a hammer to move forward. When the hammer impacts the lancet this is also moved forward. The length of the spring is determined so that the tip of the lancet is outside the boundaries of the housing when the spring is released and gone beyond its normal position, but inside the boundaries of the housing when the spring exceeds to its normal position. In this way, the finger will be pierced when pressed against the housing upon firing the lancet. After the finger has been pierced a drop of blood can be placed onto the reagent carrying strip, which is then automatically guided into the combined skin pricker and glucose meter, where a sensor senses the change in the reagent. In order to place the reagent carrying strip in a readable position, the whole disposable lancet with reagent carrying strip can be automatically shifted to a readable position.

[0006] US 2002/0188224 A1 discloses a test media cassette for a bodily fluid testing device. The bodily fluid testing device includes a piercing device and a sensor enclosed in a housing. A cassette, which contains test media, is positioned proximal to the sensor so that the sensor is able to analyze a bodily fluid sample collected on the testing media. The cassette includes a supply portion from which unused media is supplied and a storage portion in which contaminated media is stored after exposure to the bodily fluid. The cassette is adapted to collect a series of bodily fluid samples without requiring disposal of the test media.

[0007] EP 1 369 083 B1 discloses a test strip container system. Comprising a plurality of test strips, each including at least one forward facing lancet, a container body defining a plurality of test strip receptacles, each receptacle providing an access aperture at one end and at least one sheath portion at another end extending from at least one ledge to provide clearance for said at least one lancet and a barrier portion for closing off at least some of said receptacles at said access apertures. In using the test strip, the meter is actuated so that the microneedle is inserted into a target area of skin. Typically, the skin-piercing element is inserted into the skin of a finger or forearm for about 1 to 60 seconds. Once the meter that senses the reaction zone or matrix area is completely filled with the sample of body fluid, the meter electronics or optics are activated to perform analysis of the extracted sample. At this point, the meter may be removed by the patient from the penetrations site or kept on the skin surface until the test results are shown on the display.

[0008] US 5,109,866 discloses an artificial pancreas which comprises a unit for automatic periodical withdrawal of blood samples from the body of the patient, a unit for measuring the glycemia of this sample, a unit for injecting insulin or glucose and a unit for calculating and data processing in order to determine an amount of insulin or glucose which is to be administered to the patient as a function of the glucose level measured by the measurement unit and to control consequently the injection unit. This artificial pancreas is **characterized in that** the measurement of the glycemia is effected by reading the color of a strip reacting to glycemia, the measurement unit comprising to this effect: a) a strip distribution station ; b) a station for depositing a blood droplet on the strip; c) a station for wiping the strip; d) a station for optical reading of the color taken by the strip; e) a station for

removing the strip; f) a transportation device for conveying the strips individually from station to station. The unit for calculation and data processing is advantageously connected to a display screen and to a printer.

[0009] DE 101 56 811 A1 discloses a test strip analysis apparatus comprising a housing, an insertion station for receiving a test strip to be inspected, an optical measuring unit for measuring the test strip, a transport device for transporting the test strip from said insertion station to the optical measuring unit within the reaction period required for the test strip, and an analyzing unit for evaluating the measurement of the strip.

SUMMERY OF THE INVENTION

[0010] A system for analyzing the concentration of an analyte in a fluid sample is disclosed according to one embodiment of the present invention. The system includes a test strip and a meter. The test strip is capable of being inoculated by the fluid sample. The test strip includes a test element, the test element contains at least one reagent adapted to cause a reaction when brought into contact with the analyte in the fluid sample. The meter includes a read-head, a repositioning device, and a display. The read-head is capable of producing a signal indicative of the reaction between the analyte and the at least one reagent. The display is capable of displaying the concentration of the analyte. The repositioning device includes a test-strip-seating device and is adapted to move the seated test strip by rotational movement of the repositioning device from a loading position in which a test element on the seated test strip extends outside the meter and in which the test strip is inoculated with the fluid sample to a testing position after inoculation of the test strip, the testing position positioning the test element on the seated test strip proximate to the read-head.

[0011] A meter for repositioning a test strip and determining the concentration of an analyte in a fluid sample is disclosed according to one embodiment of the present invention. The meter includes a read-head, a repositioning device and a display. The display is capable of displacing the concentration of the analyte. -The read-head is capable of producing a signal indicative of a reaction between the analyte and at least one reagent. The repositioning device includes a test-strip-seating device and is adapted to move the seated test strip by rotational movement of the repositioning device from a loading position in which a test element on the seated test strip extends outside the meter and in which the test strip is inoculated with the fluid sample to a testing position after inoculation of the test strip. The testing position positions a test element on the seated test strip proximate to the read-head. The meter is adapted to maneuver the seated test strip when the meter is manipulated.

[0012] A method for analyzing the concentration of an analyte in a fluid sample is disclosed according to one embodiment of the present invention. The method includes the act of providing a meter including a read-head and a repositioning device. The repositioning device including a seating device located thereon. The method further includes the act of providing a test strip having a test element and an end portion removed spatially from the test element. The end portion of the test strip is adapted to correspond to the seating device. The method further includes the act of seating the test strip onto the corresponding seating device in a loading position in which the test element extends outside the meter. The method further includes the act of inoculating the test element with the fluid sample. The fluid sample contains the analytes to be analyzed. The method further includes the act of repositioning the test strip by rotation of the repositioning device after inoculating the test element. The repositioning brings the test element proximate to the read-head via the repositioning device. The method further includes the act of determining the analyte concentration in the fluid sample.

[0013] 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 are apparent from the detailed description, figures, and claims set forth below.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] FIG. 1 is a top view of a meter and test strip according to one embodiment of the present invention.

[0015] FIG. 2 is a side view of the meter of FIG. 1 and a repositioning device.

[0016] FIG. 3 is a perspective view of a meter, repositioning device, and test strip according to one embodiment of the present invention.

[0017] FIG. 4 is a top view of a meter and test strip according to a further embodiment of the present invention.

[0018] FIG. 5 is a flowchart illustrating a method for determining the concentration of an analyte in a fluid sample according to one embodiment of the present invention.

DESCRIPTION OF ILLUSTRATED EMBODIMENTS

[0019] The present invention is directed to a meter that contains a repositioning device for seating, holding, and repositioning a test strip. The meter and test strip are used to determine concentrations of at least one analyte. Analytes that may be measured using the present invention include glucose, lipid profiles (e.g., cholesterol, triglycerides, LDL and HDL), microalbumin, hemoglobin A1C, fructose, lactate, or bilirubin. The present invention is not limited, however, to these specific analytes and it is contemplated that other analyte concentrations may be determined. The analytes may be in, for example, a whole blood sample, a blood serum sample, a blood plasma sample, other body fluids like ISF (interstitial fluid) and urine, or other (non-body) fluid samples.

[0020] Turning now to the drawings and initially to FIG.

1, a meter 10 is illustrated according to one embodiment of the present invention. The meter 10 includes a read-head 12, a repositioning device 14, and a display 16 located on a face 18 of the meter 10. The read-head 12 may be an optical read-head that can be used to determine the analyte content in a fluid sample according to one embodiment. Typically, an optical read-head includes, for example, a light-emitting diode (LED) and a phototransistor.

[0021] The repositioning device 14 of FIG. 1 is a wheel that is attached to the meter 10 with a pin 20. The repositioning device 14 contains a seating device for seating a corresponding test strip 22 on the repositioning device 14. According to one embodiment, the seating device is a pocket 30 that corresponds to an end portion 28 of the test strip 22, as described in greater detail below with respect to FIG. 2. The pocket 30 is adapted to allow a user to insert a test strip 22 therein.

[0022] The repositioning device 14 is designed to pivot about an axis when a test strip 22 has been seated thereon. The repositioning device 14 is adapted to rotate at least approximately 90°, according to one embodiment of the present invention. In one embodiment of the present invention, the repositioning device 14 is adapted to rotate at least a full 360° in both directions. In other embodiments, the repositioning device 14 is adapted to rotate at least approximately 45°. In yet other embodiments of the present invention, the repositioning device 14 is adapted to rotate between approximately 90° and 180°. Additionally, in other embodiments of the present invention, the repositioning device 14 is adapted to reposition a test strip by other means, and should not be limited to merely rotating the repositioning device 14.

[0023] The test strip 22 includes a test element 24 located on a face 26 of the test strip 22. According to one embodiment, the test strip 22 is fashioned from an optically clear material, such as, for example, optically clear polyethylene terephthalate (PET). The test element 24 contains at least one reagents for reacting with an analyte of interest in a fluid sample. It is contemplated that two or more reagents may be included in the test element. The specific reagents incorporated into the test element 24 is a function of the analyte of interest and the type of read-head 12 to be used for determining the concentration of the analyte. For embodiments where the read-head 12 is an optical read-head, the reagents produce a colorimetric reaction indicative of the analyte concentration in the fluid sample.

[0024] In one embodiment of the present invention, for example, the reaction area could contain reagents adapted to the determination of glucose, such as the enzyme glucose oxidase in combination with indicators such as tetramethylbenzidine or dianisidine or 4-aminoantipyrine plus p-hydroxybenzenesulfonate in the presence of peroxidase. In another embodiment of the present invention, the enzyme glucose dehydrogenase could be used in combination with tetrazolium indicators such as p-iodonitrotetrazolium violet (INT), nitroblue tetrazolium (NBT) or tetranitroblue tetrazolium (TNBT), for example.

[0025] In yet another embodiment of the present invention where the analyte is cholesterol, the reagent area contains the enzymes cholesterol ester hydrolase and cholesterol oxidase plus indicators such as tetramethylbenzidine or dianisidine or 4-aminoantipyrine plus p-hydroxybenzenesulfonate in the presence of peroxidase.

[0026] In another embodiment of the present invention where the analytes are tryglycerides, the enzymes lipase, glycerokinase, glycerolphosphate dehydrogenase and diaphorase in combination with tetrazolium indicators such as p-iodonitrotetrazolium violet (INT), nitroblue tetrazolium (NBT) or tetranitroblue tetrazolium (TNBT) will produce a color indicative of the tryglyceride levels. In yet another embodiment of the present invention, the enzymes lipase, glycerokinase, glycerol phosphate oxidase combined with indicators such as tetramethylbenzidine or dianisidine or 4-aminoantipyrine plus p-hydroxybenzenesulfonate in the presence of peroxidase will produce color in response to triglycerides.

[0027] According to another embodiment of the present invention, where the analyte is the enzyme amylase, the reagent area contains, for example, the enzyme alpha glucosidase and the chromogenic indicator 4,6-ethylidene (G7) nitrophenyl (G1)-(alpha)D-maltoheptoside. In another embodiment of the present invention, hemoglobin can be detected using, for example, potassium ferricyanide, potassium cyanide and sodium bicarbonate.

[0028] Upon applying the sample to the test element 24, the analyte reacts with the at least one reagent located on the test element 24. The reaction is indicative of the analyte concentration in the sample and is evaluated using the read-head 12.

[0029] The test element 24 is adapted to be placed into contact with the fluid sample (e.g., a whole blood sample) to be tested. The whole blood sample may be generated by a lancing device such as a lancet. The whole blood sample may be obtained by a lancet that may be separate from the meter or may be integrated within the meter. The lancing device may obtain blood by, for example, pricking a person's finger.

[0030] The test strips 22 may be provided with a capillary channel that extends from the front or testing end of the sensors to the reagent material disposed on the test element 24. When the testing end of the sensor is placed into fluid (e.g., blood that is accumulated on a person's finger after the finger has been pricked), a portion of the fluid is drawn into the capillary channel by capillary action. The fluid then chemically reacts with the reagent material in the sensor so that a color change occurs indicative of the analyte concentration in the blood being tested.

[0031] The display 16 may be a liquid crystal display or other suitable display for presenting information to a user. Some of the information that may be presented on the display 16 of the meter 10 include the following: an analyte mode indicator (to display the particular analyte

to be tested), a battery indication, a numerical display, a temperature indication, or various combinations thereof. The display 16 may also present a glucose trend for the week to a user or any other desired type of information. The display 16 is also used to present the analyte concentration to a user once a test has been performed.

[0032] The meter 10 of FIG. 1 also includes a button set 19 that comprises several individual buttons 19a,b,c that are depressed to operate the electronics of the meter 10. The button set 19 may be used, for example, to recall and have presented on the display 16 the results of prior testing procedures. The button set 19 may also be used to set and display date and time information, and to activate reminder alarms that remind the user to conduct, for example, a blood glucose test according to a predetermined schedule. The button set 19 may also be used to activate certain calibration procedures for the meter 10 and read-head 12.

[0033] The meter 10 may also contain an opening for a battery-tray assembly. The battery-tray assembly includes a battery-tray in which a battery is disposed. The battery-tray assembly may be inserted into the opening in a side of the meter 10, in one embodiment. When so inserted, the battery provides power for the electronics within the meter 10, including the circuitry on the circuit board assembly (not shown), the read-head 12, and the display 16.

[0034] The repositioning device 14-as illustrated in FIG. 1-is in its loading and inoculation position. An end portion 28 is illustrated after having been inserted into the pocket 30 (see also FIG. 2) of the repositioning device 14. Once the end portion 28 has been inserted into the pocket 30, a user can inoculate the test element 24 by applying a fluid to the test element 24. Once the test element 24 has been inoculated, the repositioning device 14 is rotated to position the test element 24 so that the sample can be analyzed by the read-head 12. This position, shown in shadow in FIG. 1, is the testing position, according to one embodiment.

[0035] The repositioning device 14 helps to protect the read-head 12 from being contaminated by providing a mechanism for the test element 24 to be inoculated away from the read-head 12 and then repositioned once the sample has been applied. This is a particularly helpful feature as the size of the test strip 22 and test element 24 decrease.

[0036] The repositioning device 14 and the meter 10 also allow a user to handle, manipulate, and inoculate the test strip 22 even when the size of the test strip 22 decreases. Once the test strip 22 has been inserted into the pocket 30, a user can manipulate the test strip 22 by handling the meter 10 itself, without handling the test strip 22 directly. Thus, the size of the test strip 22 does not effect a user's ability to manipulate the test strip 22.

[0037] It should be noted that the test strip 22 may be a top-load strip, a semi-capillary strip, a capillary strip, etc. The types of test strips are well-known within the art and need not be described in further detail to understand the present invention. However, the present invention allows the size of these common test strips to be reduced, without detracting from their intended functionality.

[0038] An example of a typically sized test strip is 0.8 x 5 cm, while an example of a test strip of decreased size, may be, for example, 0.4 x 4 cm. Another example of a test strip of decreased size, for example, is 0.2 x 3 cm. However, it is contemplated that other sized test strips may be used in to perform the present invention.

[0039] Referring again to FIG. 2, the pocket 30 is illustrated according to one embodiment. The pocket 30 is adapted to seat the end portion 28 of the corresponding test strip 22 when the end portion 28 of the test strip 22 has been inserted therein. The pocket is designed such that the test strip 22 remains seated even when the repositioning device 14 is moved from the loading and inoculation position to the testing position.

[0040] Referring now to FIG. 3, a repositioning device 32 is shown according to one embodiment of the present invention. The repositioning device 32 contains a post 34 adapted to seat the corresponding test strip 22 containing an aperture 36 through the end portion 28. In use, the post 34 is inserted through the aperture 36 in the end portion 28 of the test strip 22 while the repositioning device 14 is located in its loading and inoculation position.

[0041] Referring to FIG. 4, a repositioning device 33 is shown according to a further embodiment of the present invention. The repositioning device 33 is a wheel that is attached to meter 110 with, for example, the pin 20. The repositioning device 33 contains a seating device for seating a corresponding test strip 22 on the repositioning device, which is described in more detail above in connection with FIGS. 1 and 2. Unlike FIGS. 1 and 2, the repositioning device 33 is adapted to automatically move from the loading position to the test position after a test strip 22 is inserted therein. In one embodiment, the repositioning device 33 is adapted to automatically rotate.

[0042] To assist in detecting the insertion of a test strip 22, a detector 35 is located on the repositioning device 33 in this embodiment. It is contemplated that other mechanisms may be used to detect the insertion of a test strip 22. After the detector 35 detects the presence of a test strip 22, the repositioning device 33 automatically moves to the read-head 12. The repositioning device 33 may be automatically rotated in various degrees such as those described above in repositioning device 14.

[0043] Referring now to FIG. 5, one method for analyzing an analyte in a fluid sample is shown. A test strip 22 (FIG. 1) is inserted onto a corresponding seating device-such as, for example, a pocket 30 (FIG. 2)-by a user at step 40. The user then may maneuver the test strip 22 by manipulating the meter 10. The user manipulates the meter 10 to maneuver the test strip 22 to inoculate the test element 24 with a fluid sample at step 42. At step 44, the user then repositions the inoculated test strip 22-by, for example, rotating the repositioning device 14 (FIG. 1)-to align the test element 24 with the read-head 12.

The read-head 12 then analyzes the reaction between the analyte and the reactant and produces a signal that the meter 10 interprets to determine the concentration of the analyte at step 46. Finally, once the analyte concentration has been determined at step 46, the test strip 22 may be discarded at step 48.

[0044] While the invention is susceptible to various modifications and alternative forms, specific embodiments and methods thereof have been shown by way of example in the drawings and are described in detail herein. It should be understood, however, that it is not intended to limit the invention to the particular forms or methods disclosed, but, to 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 meter (10) for repositioning a test strip (22) and determining the concentration of an analyte in a fluid sample, the meter (22) comprising:

a display (16) capable of displaying the concentration of the analyte;
a read-head (12) capable of producing a signal indicative of a reaction between the analyte and at least one reagent; and
a repositioning device (14, 32, 33),
the repositioning device (14, 32, 33) includes a test-strip-seating device
characterized in that
the repositioning device (14, 32, 33) is adapted to move the seated test strip (22) by rotational movement of the repositioning device (14, 32, 33) from a loading position in which a test element (24) on the seated test strip (22) extends outside the meter for inoculation with the fluid sample to a testing position after inoculation of the test strip (22), the testing position positioning the test element (24) on the seated test strip (22) proximate to the read-head (12).

2. The meter (10) according to claim 1, wherein the repositioning device (14, 32, 33) is adapted to be moved by rotating the repositioning device (14, 32, 33) at least 90 degrees.

3. The meter (10) according to claim 1, wherein the repositioning device (14, 32, 33) is adapted to be moved by rotating the repositioning device (14, 32, 33) at least 45 degrees.

4. The meter (10) according to claim 1, wherein the repositioning device (14, 32, 33) is adapted to be moved by rotating the repositioning device (14, 32, 33) between at least 45 degrees and 180 degrees.

5. The meter (10) according to claim 1, wherein the repositioning device (14, 32, 33) is adapted to be moved by rotating the repositioning device (14, 32, 33) at least a full 360 degrees.

6. The meter (10) according to one of the claims 2 to 5, wherein the test-strip-seating device is a pocket (30) extending into the repositioning device(14, 32, 33), the pocket (30) being adapted to allow an end portion (28) of the test strip (22) to be inserted.

7. The meter (10) according to one of the claims 2 to 5, wherein the test-strip-seating device is a post (34) extending from an outer surface of the repositioning device (14, 32, 33), the post (34) being adapted to be inserted through an aperture (36) in the end portion (28) of the test strip (22).

8. The meter (22) according to one of the claims 1 to 7, wherein the read-head (12) is an optical read-head and the signal produced is indicative of a calorimetric reaction between the analyte and the at least one reagent.

9. The meter (10) according to one of the claims 1 to 8, wherein the repositioning device (14, 32, 33) further includes a detector (35), the detector (35) adapted to assist in determining the presence of the test strip (22), the repositioning device (14, 32, 33) being adapted to automatically move the test strip (22) from the loading position to the testing position.

10. The meter (10) according to one of the claims 1 to 8, wherein the repositioning device (14, 32, 33) is adapted to automatically move the test strip (22) from the loading position to the testing position.

11. The meter (10) according to one of the claims 1 to 10, wherein the analyte is glucose.

12. The meter (10) according to claim 11, wherein the fluid sample is a blood sample.

13. The meter (10) according one of the claims 1 to 12, wherein the repositioning device (14, 32, 33) includes a pocket (30) being adapted to seat the test strip (22) therein, the pocket (30) being further adapted to allow the test strip (22) to remain seated as the repositioning device (14, 32, 33) moves from the loading position to the testing position.

14. The meter (10) according to one of the claims 1 to 12, wherein the repositioning device (14, 32, 33) includes a post (34) being adapted to seat the test strip (22) thereon, the post (34) being further adapted to allow the test strip (22) to remain seated as the repositioning device (14, 32, 33) pivots from the loading position to the testing position.

15. A system for analyzing the concentration of an analyte in a fluid sample, the system comprising:

a test strip (22) capable of being inoculated by the fluid sample, the test strip (22) including a test element (24), the test element (24) containing at least one reagent adapted to cause a reaction when brought into contact with the analyte in the fluid sample; and
a meter (10) according to one of the claims 1 to 14.

16. The system according to claim 15, wherein the test strip (22) includes an aperture (36) extending through an end portion (28) of the test strip (22), the end portion (28) being opposite the test element (24).

17. The system according to one of the claims 15 or 16, wherein the test strip (22) is a capillary test strip.

18. A method for analyzing the concentration of an analyte in a fluid sample, the method comprising the acts of:

providing a meter (10) including a read-head (12) and a repositioning device (14, 32, 33), the repositioning device (14, 32, 33) including a test-strip-seating device;
providing a test strip (22) having a test element (24) and an end portion (28) removed spatially from the test element (24), the end portion (28) of the test strip (22) being adapted to correspond to the test-strip-seating device;
placing the test strip (22) onto the corresponding test-strip-seating device in a loading position in which the test element (24) extends outside the meter (10); inoculating the test element (24) with the fluid sample, the fluid sample containing the analyte to be analyzed;
characterized in the further steps of
repositioning the seated test strip (22) after inoculating the test element (24) by rotating the repositioning device (14, 32, 33), the repositioning bringing the test element (24) proximate to the read-head (12); and
determining the analyte concentration in the fluid sample.

19. The method according to claim 18, wherein the repositioning of the test strip (22) is done automatically after the test strip (22) is placed.

20. The method according to claim 18, wherein the repositioning of the test strip (22) is done manually after the test strip (22) is placed.

21. The method according to one of the claims 18 to 20, wherein the repositioning device (14, 32, 33) is rotated 90 degrees.

22. The method according to one of the claims 18 to 20, wherein the repositioning device (14, 32, 33) is adapted to rotate at least a full 360 degrees.

23. The method according to one of the claims 18 to 22, wherein the test-strip-seating device is a pocket (30) extending into the repositioning device (14, 32, 33), the seating of the test strip (22) being so performed by inserting the end portion (28) of the test strip (22) into the pocket (30).

24. The method according to one of the claims 18 to 22, wherein the test-strip-seating device is a post (34) extending from a surface of the repositioning device (14, 32, 33), the seating of the test strip (22) being performed by inserting the post (34) through an aperture (36) in the end portion (28) of the test strip (22).

Patentansprüche

1. Messgerät (10) zur Repositionierung eines Teststreifens (22) und zur Bestimmung der Konzentration eines Analyts in einer Fluidprobe, wobei das Messgerät (22) Folgendes umfasst:

eine Anzeige (16), geeignet ist, die Konzentration des Analyts anzuzeigen;
einen Lesekopf (12), der geeignet ist, ein Signal zu erzeugen, das eine Reaktion zwischen dem Analyt und zumindest einem Reagens anzeigt; und
eine Repositionierungsvorrichtung (14, 32, 33), wobei die Repositionierungsvorrichtung (14, 32, 33) eine Teststreifenauflagevorrichtung umfasst, **dadurch gekennzeichnet, dass**
die Repositionierungsvorrichtung (14, 32, 33) ausgebildet ist, um den aufgelegten Teststreifen durch eine Drehbewegung der Repositionierungsvorrichtung (14, 32, 33) aus einer Ladeposition, in der sich ein Testelement (24) auf dem aufgelegten Teststreifen (22) außerhalb des Messgeräts erstreckt, um mit der Fluidprobe beimpft zu werden, nach dem Beimpfen des Teststreifens (22) in eine Testposition zu bewegen, wobei in der Testposition das Testelement (24) auf dem aufgelegten Teststreifen (22) unmittelbar im Bereich des Lesekopfs (12) angeordnet ist.

2. Messgerät (10) nach Anspruch 1, worin die Repositionierungsvorrichtung (14, 32, 33) ausgebildet ist, um durch das Drehen der Repositionierungsvorrichtung (14, 32, 33) um zumindest 90 Grad bewegt zu werden.

3. Messgerät (10) nach Anspruch 1, worin die Repositionierungsvorrichtung (14, 32, 33) ausgebildet ist, um durch das Drehen der Repositionierungsvorrichtung (14, 32, 33) um zumindest 45 Grad bewegt zu werden.

4. Messgerät (10) nach Anspruch 1, worin die Repositionierungsvorrichtung (14, 32, 33) ausgebildet ist, um durch das Drehen der Repositionierungsvorrichtung (14, 32, 33) um zwischen 45 Grad und 180 Grad bewegt zu werden.

5. Messgerät (10) nach Anspruch 1, worin die Repositionierungsvorrichtung (14, 32, 33) ausgebildet ist, um durch das Drehen der Repositionierungsvorrichtung (14, 32, 33) um zumindest volle 360 Grad bewegt zu werden.

6. Messgerät (10) nach einem der Ansprüche 2 bis 5, worin die Teststreifenauflagevorrichtung eine Tasche (30) ist, die sich in die Repositionierungsvorrichtung (14, 32, 33) erstreckt, wobei die Tasche (30) ausgebildet ist, um das Einführen eines Endabschnitts (28) des Teststreifens (22) zu ermöglichen.

7. Messgerät (10) nach einem der Ansprüche 2 bis 5, worin die Teststreifenauflagevorrichtung ein Stift (34) ist, der sich von einer Außenoberfläche der Repositionierungsvorrichtung (14, 32, 33) weg erstreckt, wobei der Stift (34) ausgebildet ist, um durch eine Öffnung (36) in dem Endabschnitt (28) des Teststreifens (22) eingeführt zu werden.

8. Messgerät (10) nach einem der Ansprüche 1 bis 7, worin der Lesekopf (12) ein optischer Lesekopf ist und das erzeugte Signal eine kalorimetrische Reaktion zwischen dem Analyt und dem zumindest einen Reagens anzeigt.

9. Messgerät (10) nach einem der Ansprüche 1 bis 8, worin die Repositionierungsvorrichtung (14, 32, 33) ferner einen Detektor (35) umfasst, wobei der Detektor (35) ausgebildet ist, um festzustellen, ob der Teststreifen (22) vorliegt, wobei die Repositionierungsvorrichtung (14, 32, 33) ausgebildet ist, um den Teststreifen (22) automatisch aus der Ladeposition in die Testposition zu bewegen.

10. Messgerät (10) nach einem der Ansprüche 1 bis 8, worin die Repositionierungsvorrichtung (14, 32, 33) ausgebildet ist, um den Teststreifen (22) automatisch von der Ladeposition in die Testposition zu bewegen.

11. Messgerät (10) nach einem der Ansprüche 1 bis 10, worin der Analyt Glucose ist.

12. Messgerät (10) nach Anspruch 11, worin die Fluidprobe eine Blutprobe ist.

13. Messgerät (10) nach einem der Ansprüche 1 bis 12, worin die Repositionierungsvorrichtung (14, 32, 33) eine Tasche (30) umfasst, die ausgebildet ist, um den Teststreifen (22) darin aufzunehmen, wobei die Tasche (30) ferner ausgebildet ist, um zu ermöglichen, dass der Teststreifen (22) weiter darin aufgenommen bleibt, wenn sich die Repositionierungsvorrichtung (14, 32, 33) von der Ladeposition in die Testposition bewegt.

14. Messgerät (10) nach einem der Ansprüche 1 bis 12, worin die Repositionierungsvorrichtung (14, 32, 33) einen Stift (34) umfasst, der ausgebildet ist, um den Teststreifen (22) darauf aufzunehmen, wobei der Stift (34) ferner ausgebildet ist, um zu ermöglichen, dass der Teststreifen (22) weiter darauf aufgenommen bleibt, wenn die Repositionierungsvorrichtung (14, 32, 33) von der Ladeposition in die Testposition schwenkt.

15. System zur Analyse der Konzentration eines Analyts in einer Fluidprobe, wobei das System Folgendes umfasst:

einen Teststreifen (22), der geeignet ist, mit der Fluidprobe beimpft zu werden, wobei der Teststreifen (22) ein Testelement (24) umfasst, wobei das Testelement (24) zumindest ein Reagens umfasst, das geeignet ist, eine Reaktion hervorzurufen, wenn es mit dem Analyt in der Fluidprobe in Kontakt gebracht wird; und
ein Messgerät (10) nach einem der Ansprüche 1 bis 14.

16. System nach Anspruch 15, worin der Teststreifen (22) eine Öffnung (36) umfasst, die sich durch einen Endabschnitt (28) des Teststreifens (22) erstreckt, wobei der Endabschnitt (28) dem Testelement (24) gegenüberliegt.

17. System nach einem der Ansprüche 15 oder 16, worin der Teststreifen (22) ein Kapillarteststreifen ist.

18. Verfahren zur Analyse der Konzentration eines Analyts in einer Fluidprobe, wobei das Verfahren folgende Schritte umfasst:

das Bereitstellen eines Messgeräts (10), das einen Lesekopf (12) und eine Repositionierungsvorrichtung (14, 32, 33) umfasst, wobei die Repositionierungsvorrichtung (14, 32, 33) eine Teststreifenauflagevorrichtung umfasst;
das Bereitstellen eines Teststreifens (22) mit einem Testelement (24) und einem Endabschnitt (28), der räumlich von dem Testelement entfernt ist, wobei der Endabschnitt (28) des Teststrei-

fens (22) angepasst ist, um zu der Teststreifenauflagevorrichtung zu passen;
das Platzieren des Teststreifens (22) auf der entsprechenden Teststreifenauflagevorrichtung in einer Ladeposition, in der sich das Testelement (24) außerhalb des Messgeräts (10) erstreckt;
das Beimpfen des Testelements (24) mit der Fluidprobe, wobei die Fluidprobe den zu analysierenden Analyt enthält;

wobei das Verfahren durch folgende weitere Schritte **gekennzeichnet** ist:

das Repositionieren des platzierten Teststreifens (22) nach dem Beimpfen des Testelements (24) durch das Drehen der Repositionierungsvorrichtung (14, 32, 33), wobei das Repositionieren das Testelement (24) in eine Position im Bereich des Lesekopfs (12) bringt; und
das Bestimmen der Analytkonzentration in der Fluidprobe.

19. Verfahren nach Anspruch 18, worin das Repositionieren des Teststreifens (22) nach dem Platzieren des Teststreifens (22) im Wesentlichen automatisch erfolgt.

20. Verfahren nach Anspruch 18, worin das Repositionieren des Teststreifens (22) nach dem Platzieren des Teststreifens (22) manuell erfolgt.

21. Verfahren nach einem der Ansprüche 18 bis 20, worin die Repositionierungsvorrichtung (14, 32, 33) um 90 Grad gedreht wird.

22. Verfahren nach einem der Ansprüche 18 bis 20, worin die Repositionierungsvorrichtung (14, 32, 33) ausgebildet ist, um um zumindest volle 360 Grad gedreht zu werden.

23. Verfahren nach einem der Ansprüche 18 bis 22, worin die Teststreifenauflagevorrichtung eine Tasche (30) ist, die sich in die Repositionierungsvorrichtung (14, 32, 33) erstreckt, wobei das Platzieren des Teststreifens (22) durch das Einführen des Endabschnitts (28) des Teststreifens (22) in die Tasche (30) erfolgt.

24. Verfahren nach einem der Ansprüche 18 bis 22, worin die Teststreifenauflagevorrichtung ein Stift (34) ist, der sich von einer Oberfläche der Repositionierungsvorrichtung (14, 32, 33) erstreckt, wobei das Platzieren des Teststreifens (22) durch das Einführen des Stifts (34) durch eine Öffnung (36) in dem Endabschnitt (28) des Teststreifens (22) erfolgt.

Revendications

1. Dispositif de mesure (10) pour repositionner une bande de test (22) et déterminer la concentration d'un analyte dans un échantillon fluide, le dispositif de mesure (22) comprenant :

un dispositif d'affichage (16) susceptible d'afficher la concentration de l'analyte ;
une tête de lecture (12) susceptible de produire un signal indicatif d'une réaction entre l'analyte et au moins un réactif ; et
un dispositif de repositionnement (14, 32, 33),
le dispositif de repositionnement (14, 32, 33) comprenant un dispositif de logement de bande de test,
caractérisé en ce que :

le dispositif de repositionnement (14, 32, 33) est adapté pour déplacer la bande de test logée (22) par un mouvement de rotation du dispositif de repositionnement (14, 32, 33) d'une position de chargement dans laquelle un élément de test (24) sur la bande de test logée (22) s'étend à l'extérieur du dispositif de mesure pour une inoculation avec l'échantillon fluide à une position de test après l'inoculation de la bande de test (22), la position de test positionnant l'élément de test (24) sur la bande de test logée (22) à proximité de la tête de lecture (12).

2. Dispositif de mesure (10) selon la revendication 1, dans lequel le dispositif de repositionnement (14, 32, 33) est adapté pour être déplacé en faisant tourner le dispositif de repositionnement (14, 32, 33) d'au moins 90 degrés.

3. Dispositif de mesure (10) selon la revendication 1, dans lequel le dispositif de repositionnement (14, 32, 33) est adapté pour être déplacé en faisant tourner le dispositif de repositionnement (14, 32, 33) d'au moins 45 degrés.

4. Dispositif de mesure (10) selon la revendication 1, dans lequel le dispositif de repositionnement (14, 32, 33) est adapté pour être déplacé en faisant tourner le dispositif de repositionnement (14, 32, 33) entre au moins 45 degrés et 180 degrés.

5. Dispositif de mesure (10) selon la revendication 1, dans lequel le dispositif de repositionnement (14, 32, 33) est adapté pour être déplacé en faisant tourner le dispositif de repositionnement (14, 32, 33) d'au moins 360 degrés complets.

6. Dispositif de mesure (10) selon l'une des revendications 2 à 5, dans lequel le dispositif de logement de

bande de test est une poche (30) s'étendant dans le dispositif de repositionnement (14, 32, 33), la poche (30) étant adaptée pour permettre à une partie d'extrémité (28) de la bande de test (22) d'être insérée.

7. Dispositif de mesure (10) selon l'une des revendications 2 à 5, dans lequel le dispositif de logement de bande de test est un montant (34) s'étendant à partir d'une surface extérieure du dispositif de repositionnement (14, 32, 33), le montant (34) étant adapté pour être inséré à travers une ouverture (36) dans la partie d'extrémité (28) de la bande de test (22).

8. Dispositif de mesure (22) selon l'une des revendications 1 à 7, dans lequel la tête de lecture (12) est une tête de lecture optique et le signal produit est indicatif d'une réaction calorimétrique entre l'analyte et le réactif au nombre d'au moins un.

9. Dispositif de mesure (10) selon l'une des revendications 1 à 8, dans lequel le dispositif de repositionnement (14, 32, 33) comprend de plus un détecteur (35), le détecteur (35) étant adapté pour aider à déterminer la présence de la bande de test (22), le dispositif de repositionnement (14, 32, 33) étant adapté pour déplacer automatiquement la bande de test (22) de la position de chargement à la position de test.

10. Dispositif de mesure (10) selon l'une des revendications 1 à 8, dans lequel le dispositif de repositionnement (14, 32, 33) est adapté pour déplacer automatiquement la bande de test (22) de la position de chargement à la position de test.

11. Dispositif de mesure (10) selon l'une des revendications 1 à 10, dans lequel l'analyte est du glucose.

12. Dispositif de mesure (10) selon la revendication 11, dans lequel l'échantillon fluide est un échantillon sanguin.

13. Dispositif de mesure (10) selon l'une des revendications 1 à 12, dans lequel le dispositif de repositionnement (14, 32, 33) comprend une poche (30) qui est adaptée pour loger la bande de test (22) à l'intérieur de celle-ci, la poche (30) étant de plus adaptée pour permettre à la bande de test (22) de rester logée lorsque le dispositif de repositionnement (14, 32, 33) se déplace de la position de chargement à la position de test.

14. Dispositif de mesure (10) selon l'une des revendications 1 à 12, dans lequel le dispositif de repositionnement (14, 32, 33) comprend un montant (34) qui est adapté pour loger la bande de test (22) sur celui-ci, le montant (34) étant de plus adapté pour permettre à la bande de test (22) de rester logée lorsque le dispositif de repositionnement (14, 32, 33) pivote de la position de chargement à la position de test.

15. Système pour analyser la concentration d'un analyte dans un échantillon fluide, le système comprenant :

une bande de test (22) susceptible d'être inoculée par l'échantillon fluide, la bande de test (22) comprenant un élément de test (24), l'élément de test (24) contenant au moins un réactif adapté pour provoquer une réaction lorsqu'il est amené en contact avec l'analyte dans l'échantillon fluide ; et
un dispositif de mesure (10) selon l'une des revendications 1 à 14.

16. Système selon la revendication 15, dans lequel la bande de test (22) comprend une ouverture (36) s'étendant à travers une partie d'extrémité (28) de la bande de test (22), la partie d'extrémité (28) étant opposée à l'élément de test (24).

17. Système selon l'une des revendications 15 ou 16, dans lequel la bande de test (22) est une bande de test capillaire.

18. Procédé pour analyser la concentration d'un analyte dans un échantillon fluide, le procédé comprenant les actions consistant à :

disposer un dispositif de mesure (10) comprenant une tête de lecture (12) et un dispositif de repositionnement (14, 32, 33), le dispositif de repositionnement (14, 32, 33) comprenant un dispositif de logement de bande de test ;
disposer une bande de test (22) comportant un élément de test (24) et une partie d'extrémité (28) éloignée spatialement de l'élément de test (24), la partie d'extrémité (28) de la bande de test (22) étant adaptée pour correspondre au dispositif de logement de bande de test ;
disposer la bande de test (22) sur le dispositif de logement de bande de test correspondant dans une position de chargement dans laquelle l'élément de test (24) s'étend à l'extérieur du dispositif de mesure (10) ;
inoculer l'élément de test (24) avec l'échantillon fluide, l'échantillon fluide contenant l'analyte devant être analysé ;
caractérisé par les étapes additionnelles consistant à :

repositionner la bande de test logée (22) après l'inoculation de l'élément de test (24) en faisant tourner le dispositif de repositionnement (14, 32, 33), le repositionnement amenant l'élément de test (24) à proximité de la tête de lecture (12) ; et

déterminer la concentration d'analyte dans l'échantillon fluide.

19. Procédé selon la revendication 18, dans lequel le repositionnement de la bande de test (22) est effectué automatiquement après que la bande de test (22) ait été disposée.

20. Procédé selon la revendication 18, dans lequel le repositionnement de la bande de test (22) est effectué manuellement après que la bande de test (22) ait été disposée.

21. Procédé selon l'une des revendications 18 à 20, dans lequel le dispositif de repositionnement (14, 32, 33) est tourné de 90 degrés.

22. Procédé selon l'une des revendications 18 à 20, dans lequel le dispositif de repositionnement (14, 32, 33) est adapté pour tourner d'au moins 360 degrés complets.

23. Procédé selon l'une des revendications 18 à 22, dans lequel le dispositif de logement de bande de test est une poche (30) s'étendant dans le dispositif de repositionnement (14, 32, 33), le logement de la bande de test (22) étant effectué par insertion de la partie d'extrémité (28) de la bande de test (22) dans la poche (30).

24. Procédé selon l'une des revendications 18 à 22, dans lequel le dispositif de logement de bande de test est un montant (34) s'étendant à partir d'une surface du dispositif de repositionnement (14, 32, 33), le logement de la bande de test (22) étant effectué par insertion du montant (34) à travers une ouverture (36) dans la partie d'extrémité (28) de la bande de test (22).

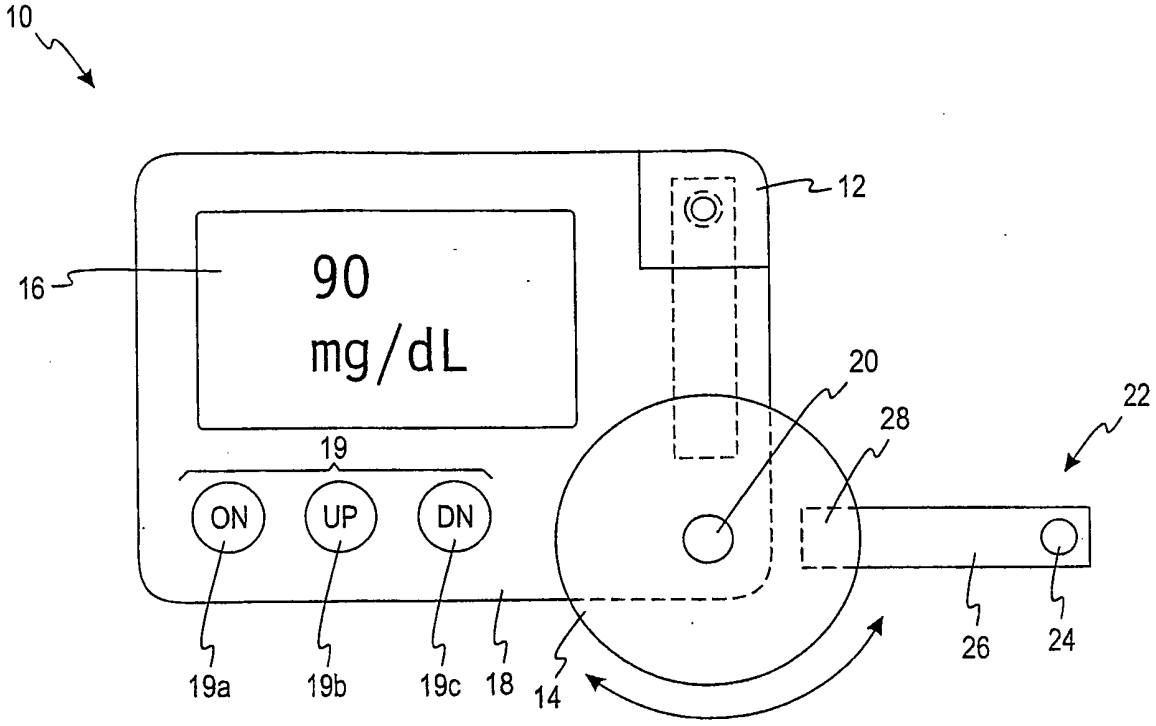

Fig. 1

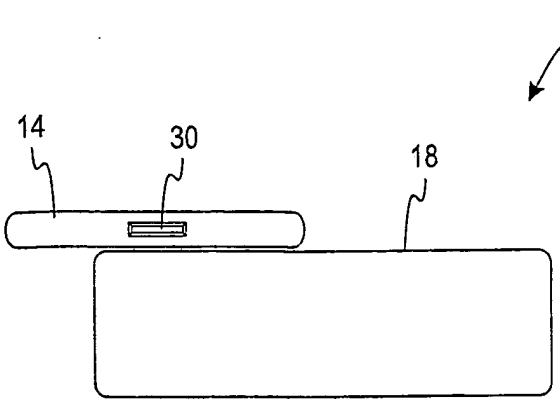
10
14
30
18

Fig. 2

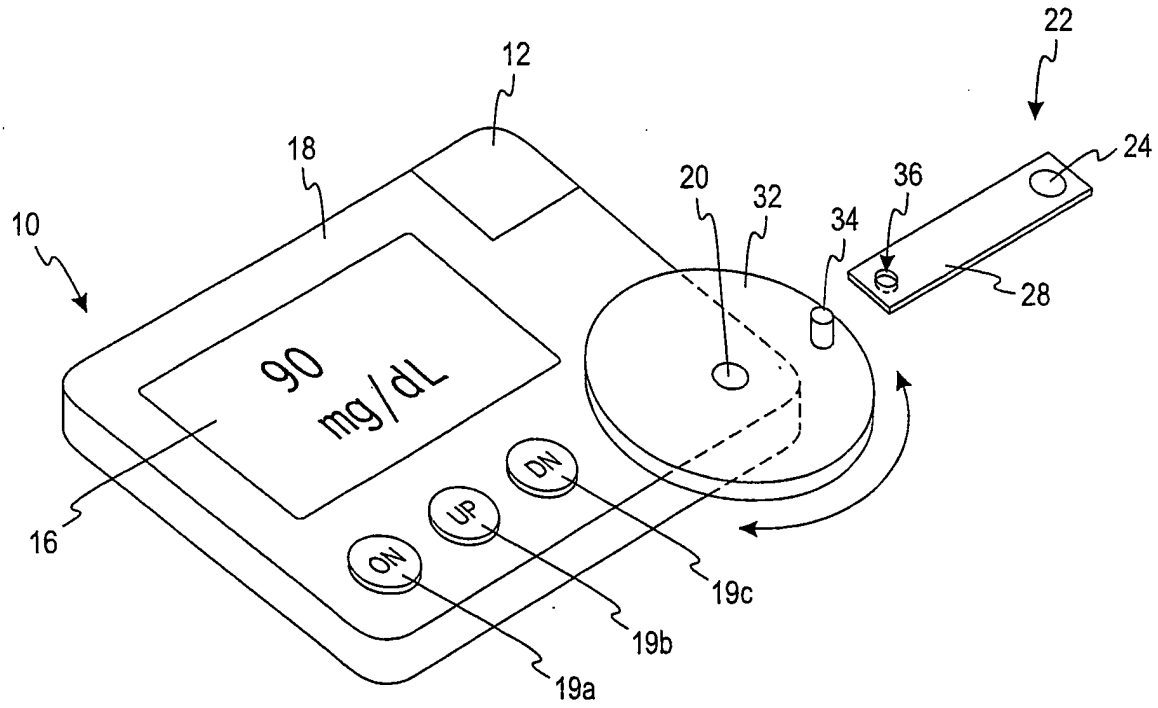
22
12
18
24
20
32
36
34
10
28
90
mg/dL
16
DN
UP
ON
19c
19b
19a

Fig. 3

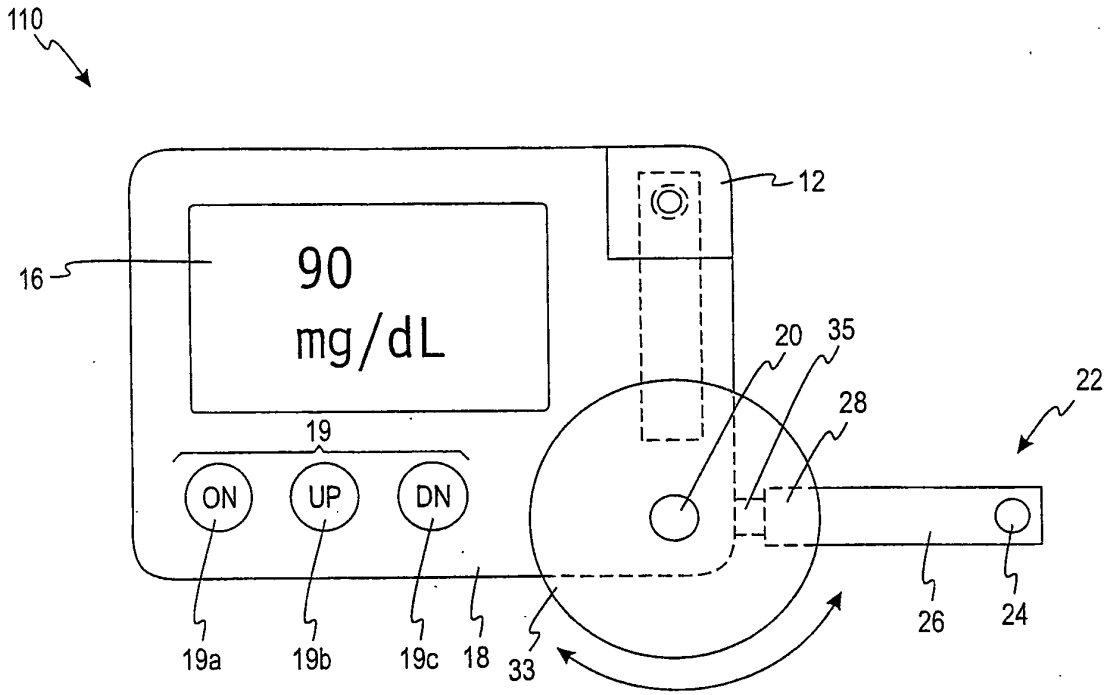

Fig. 4

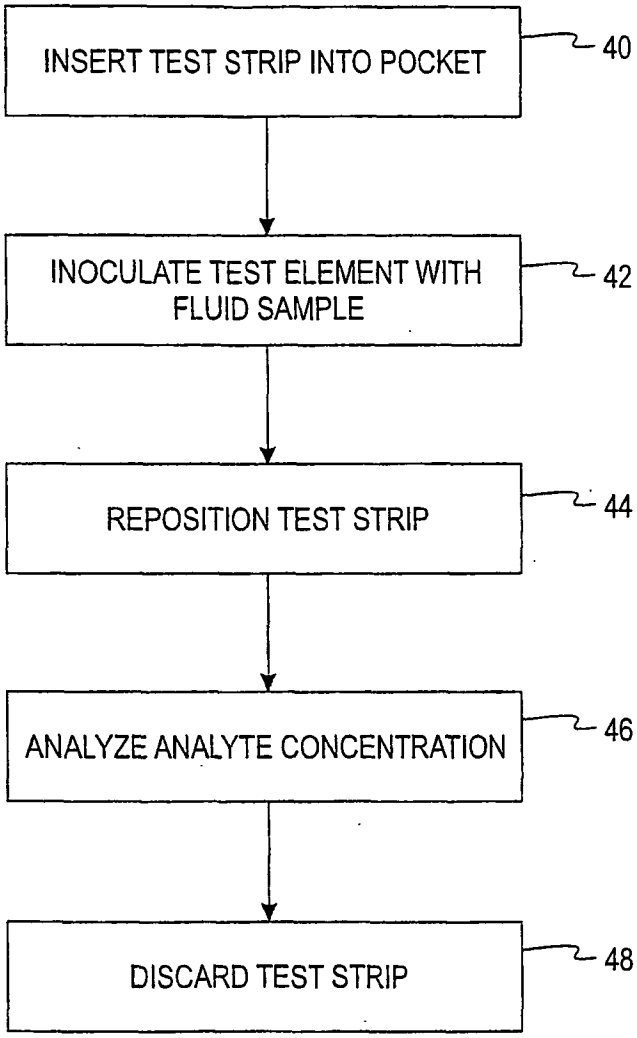
INSERT TEST STRIP INTO POCKET
40
INOCULATE TEST ELEMENT WITH FLUID SAMPLE
42
REPOSITION TEST STRIP
44
ANALYZE ANALYTE CONCENTRATION
46
DISCARD TEST STRIP
48

Fig. 5

REFERENCES CITED IN THE DESCRIPTION

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专利名称(译)	用于在接种后重新定位诊断测试条的系统和方法		
公开(公告)号	EP1838209B1	公开(公告)日	2009-11-25
申请号	EP2005798909	申请日	2005-09-19
[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，LLC		
当前申请(专利权)人(译)	拜耳医药保健，LLC		
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发明人	JUNG, SUNG-KWON CHARLTON, STEVEN, C.		
IPC分类号	A61B5/00		
CPC分类号	A61B5/14532 A61B2562/0295 Y10T436/11 Y10T436/110833		
代理机构(译)	BURKERT，FRANK		
优先权	60/611466 2004-09-20 US		
其他公开文献	EP1838209A1		
外部链接	Espacenet		

摘要(译)

用于分析流体样品中分析物浓度的系统包括测试条（22）和仪表（10）。测试条能够被流体样品接种。测试条包括测试元件（24），其包含至少一种适于在与分析物接触时引起反应的试剂。仪表包括读头（12），重新定位装置（14）和显示器（16）。读头能够产生指示分析物和至少一种试剂之间反应的信号。显示器能够显示分析物浓度。重新定位装置适于将测试条从装载位置移动到测试位置。测试位置将测试元件定位在读头附近。

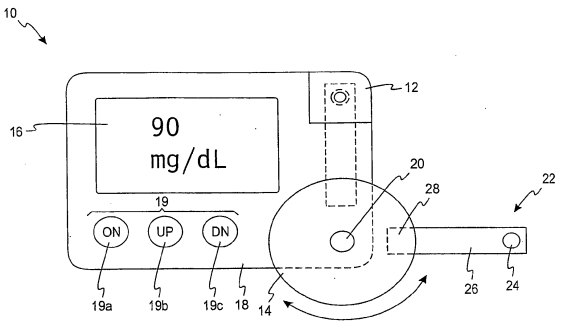

Fig. 1