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**(54) Integrated test strip container with retaining insert**

Integrierter Teststreifenbehälter mit Halteeinsatz

Réceptif de bandelette réactive intégrée avec insert de rétention

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(56) References cited:  
**WO-A1-2007/090662 WO-A2-02/078533**  
**WO-A2-03/082091 WO-A2-2008/101217**  
**US-A1- 2008 118 400**

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## Description

### Technical Field

**[0001]** Embodiments of the present invention relate generally to blood glucose meters, and particularly to blood glucose meters having a disposable and removable cartridge and to methods of manufacturing and utilization thereof.

### Background

**[0002]** The use of test strips in the determination of biological analyte concentration is of widespread importance, particularly to persons afflicted with type one diabetes. In regulating their disease, such diabetic patients may be required to perform an average of five to ten blood glucose tests per day via a process of self-monitoring to determine their blood glucose levels. As a result, diabetic patients expend a significant amount of time throughout their daily lives testing their blood glucose levels.

**[0003]** As the number of patients suffering from diabetes increases, the practice of self-monitoring blood glucose levels has become routine. The process of self-monitoring typically involves diabetic patients obtaining a test strip by removing it from a test strip container, applying a sample of blood thereto, inserting the test strip into a blood glucose meter, and obtaining results by measuring the concentration of analytes. When the test is completed, the test strip is removed from the meter and discarded.

**[0004]** Systems for monitoring blood glucose typically include a test strip container, a blood glucose meter, and a lancing pen with lancet; thus, the portability of current blood glucose monitoring systems is limited. Test strip containers commonly take the form of conventional vials wherein test strips recess below the vial opening and must be manually removed; these designs are often large in size and awkward in form, limiting portability. While some attempts have been made to incorporate test strips into a blood glucose meter, eliminating the need to carry a test strip vial, these designs carry with them a variety of disadvantages. Generally, the designs have been shown not to be robust in protecting the strips from the environment due to seal damage from repetitive use, i. e. multiple user closings and openings.

**[0005]** US2008/0118400 discloses an apparatus for dispensing test strips suitable for use in diagnostic testing systems. Thus, additional embodiments for blood glucose meters and methods of manufacturing and utilization thereof are desirable.

### Summary

**[0006]** In one embodiment, the present invention relates to a blood glucose meter providing easy access to a test strip provided therewith and for measuring a blood glucose level of a blood sample provided to the test strip,

comprising a disposable and removable cartridge having surfaces which define a resealable cavity containing the test strips and a housing accommodating a blood glucose measuring component and providing a receptacle. The disposable and removable cartridge has a retaining member which releasably retains the test strips in a stacked configuration. The housing accommodates a blood glucose measuring component which measures the blood glucose level of the blood sample when provided to the test strip which has been removed from among the test strips contained in the resealable cavity. The receptacle has surfaces which retain the disposable and removable cartridge with the housing.

**[0007]** In another embodiment, the present invention relates to a disposable and removable cartridge for providing easy access to test strips. The disposable and removable cartridge comprises a flexible body comprising a moisture barrier film, a rigid lid attached to the flexible body, and a retaining member provided within the resealable cavity. The flexible body has surfaces which define a resealable cavity containing the test strips, the rigid lid has surfaces which abut with the surfaces of the flexible body for enclosing the resealable cavity, and the retaining member releasably retains the test strips in a stacked configuration. The disposable and removable cartridge for providing easy access to test strips has an open configuration and a closed configuration. The open configuration comprises the rigid lid being moved relative to the flexible body, such that the test strips are accessible in the cavity. The closed configuration comprises the rigid lid abutting with the flexible body, such that the test strips are sealed within the cavity.

**[0008]** In still another embodiment, the present invention relates to a method of manufacturing a blood glucose meter for providing easy access to test strips and measuring blood glucose, comprising providing a disposable and removable cartridge having surfaces which define a resealable cavity containing test strips and providing a housing accommodating a blood glucose measuring component and providing a receptacle. The disposable and removable cartridge has a retaining member which releasably retains the test strips in a stacked configuration. The housing accommodates a blood glucose measuring component for measuring a blood glucose level of a blood sample. The receptacle is integral with the blood glucose measuring component, wherein the receptacle has surfaces which retain the disposable and removable cartridge with the housing.

**[0009]** The present disclosure also relates to a method of providing easy access to test strips and measuring blood glucose which comprises utilizing the test strip container according to the present invention.

**[0010]** The invention therefore provides a disposable and removable cartridge for providing easy access to test strips comprising:

a flexible body comprising a moisture barrier film and having surfaces which define a resealable cavity

containing the test strips;  
 a rigid lid attached to the flexible body and having surfaces which abut with the surfaces of the flexible body for enclosing the resealable cavity; and  
 a retaining member provided within the cavity and releasably retaining the test strips in a stacked configuration, wherein the disposable and removable cartridge has an open configuration and a closed configuration, in which:

the open configuration comprises the rigid lid being moved relative to the flexible body, such that the test strips are accessible in the cavity, and

the closed configuration comprises the rigid lid abutting with the flexible body, such that the test strips are sealed within in the cavity.

**[0011]** The invention also provides a disposable and removable cartridge wherein the retaining member is configured to releasably retain the test strips in an upright configuration.

**[0012]** The invention also provides a disposable and removable cartridge wherein the rigid lid is attached to the flexible body with a hinging mechanism.

**[0013]** The invention also provides a disposable and removable cartridge wherein the flexible body comprises a gusseted bag. Preferably, the gusseted bag has a front wall, a back wall, inward-folded, substantially V-shaped folds at opposing sidewalls, and a sealed base. Preferably, the base is heat sealed.

**[0014]** The invention also provides a disposable and removable cartridge wherein the disposable and removable cartridge further comprises a fastening mechanism for releasably fixing the disposable and removable cartridge in the closed configuration.

**[0015]** The invention also provides a disposable and removable cartridge wherein the retaining member comprises an elastic biasing member.

**[0016]** The invention also provides a disposable and removable cartridge wherein the flexible body comprises a rigid rim.

**[0017]** The invention also provides a disposable and removable cartridge wherein the disposable and removable cartridge comprises a seal provided between certain ones of the surfaces.

**[0018]** The invention further provides a blood glucose meter providing easy access to a test strip provided therewith and for measuring a blood glucose level of a blood sample provided to the test strip, said meter comprising:

a disposable and removable cartridge as described herein having surfaces which define a resealable cavity containing the test strips, wherein the disposable and removable cartridge has a retaining member which releasably retains the test strips in a stacked configuration; and  
 a housing accommodating a blood glucose measur-

ing component which measures the blood glucose level of the blood sample when provided to the test strip which has been removed from among the test strips contained in the resealable cavity, and providing a receptacle having surfaces which retain the disposable and removable cartridge with the housing.

**[0019]** Preferably, in the blood glucose meter of the invention, the disposable and removable cartridge is retained with the housing such that substantially all of the flexible body is disposed within the receptacle. Preferably, the disposable and removable cartridge is retained with the housing with a fastening device.

**[0020]** The invention further provides a method of manufacturing a blood glucose meter as described herein for providing easy access to test strips and measuring blood glucose, comprising:

providing a disposable and removable cartridge having surfaces which define a resealable cavity containing test strips, wherein the disposable and removable cartridge has a retaining member which releasably retains the test strips in a stacked configuration; and

providing a housing accommodating a blood glucose measuring component for measuring a blood glucose level of a blood sample and providing a receptacle having surfaces which retain the disposable and removable cartridge with the housing.

**[0021]** These and other features and advantages of these and other various embodiments according to the present invention will become more apparent in view of the drawings, detailed description, and claims provided that follow hereafter.

#### Brief Description of the Drawings

**[0022]** The following detailed description of the embodiments of the present invention can be best understood when read in conjunction with the following drawings, where like structure is indicated with like reference numerals, and in which:

FIG. 1 is a front perspective view of a blood glucose meter with a disposable and removable cartridge in a closed configuration according to an embodiment of the present invention;

FIG. 2 is a back perspective view of a blood glucose meter with a disposable and removable cartridge in an open configuration according to an embodiment of the present invention;

FIG. 3 is a front perspective view of a disposable and removable cartridge in an open configuration according to an embodiment of the present invention;

FIG. 4 is a front perspective view of a disposable and removable cartridge wherein the sealable base has been heat sealed according to an embodiment of the present invention;

FIG. 5a is a front perspective view which depicts loading test strips into an opening defined by a disposable and removable cartridge according to an embodiment of the present invention;

FIG. 5b is a front perspective view of the disposable and removable cartridge of FIG. 5a in the open configuration with test strips loaded therein;

FIG. 5c is a front perspective view of the disposable and removable cartridge of FIG. 5b wherein the sealable base has been heat sealed;

FIG. 6 is a side perspective view of a retaining member which releasably retains test strips in a stacked configuration according to an embodiment of the present invention; and

FIG. 7 is a back perspective view of a housing of a blood glucose meter according to an embodiment of the present invention.

**[0023]** Skilled artisans appreciate that elements in the figures are illustrated for simplicity and clarity and have not necessarily been drawn to scale. For example, the dimensions of some of the elements in the figures may be exaggerated relative to other elements, as well as conventional parts removed, to help to improve understanding of the various embodiments of the present invention.

#### Detailed Description

**[0024]** The following terms are used in the present application:

**[0025]** The term "stacked configuration" is used herein to refer to a configuration of the test strips wherein all of the test strips releasably retained by the retaining member overlap, such that they are arranged in a substantially upright pile, i.e. a deck of cards configuration.

**[0026]** In the context of a disposable and removable cartridge, the term "rigid lid" is used herein to refer to a lid that is configured to provide physical protection to test strips contained within a cavity of the disposable and removable cartridge.

**[0027]** The term "flexible body" is used herein to refer to a body that is configured to provide environmental protection to test strips contained within the cavity of the disposable and removable cartridge.

**[0028]** The term "gusseted bag" is used herein to refer to a bag-like material which has folds in the sidewalls.

**[0029]** Embodiments of the present invention relate to a disposable and removable cartridge comprising a flex-

ible body comprising a moisture barrier film and having surfaces which define a resealable cavity containing the test strips, a rigid lid attached to the flexible body and having surfaces which abut with the surfaces of the flexible body for enclosing the resealable cavity, and a retaining member provided within the resealable cavity and releasably retaining the test strips in a stacked configuration. The disposable and removable cartridge has an open configuration and a closed configuration.

**[0030]** Embodiments of the present invention also relate to a blood glucose meter providing easy access to a test strip provided therewith and for measuring a blood glucose level of a blood sample provided to the test strip. The blood glucose meter comprises a disposable and removable cartridge as described herein, having surfaces which define a resealable cavity containing the test strips, and a housing accommodating a blood glucose measuring component which measures the blood glucose level of the blood sample when provided to the test strip which has been removed from among the test strips contained in the resealable cavity, and providing a receptacle having surfaces which retain a disposable and removable cartridge with the housing. Embodiments of the present invention also relate to methods of manufacturing and to utilization thereof.

**[0031]** As shown in FIGS. 1 and 2, in one embodiment, the blood glucose meter 10 of the present invention has a disposable and removable cartridge 30. The disposable and removable cartridge 30 has surfaces 32 which define a resealable cavity 34 containing test strips 36. The disposable and removable cartridge 30 provides physical and environmental protection to the test strips 36.

**[0032]** As shown in FIGS. 3 and 4, in one aspect of this embodiment, the disposable and removable cartridge 30 has a rigid lid 38 attached to a flexible body 40. In this aspect, the surfaces 32 are provided by the rigid lid 38 attached to the flexible body 40. In one particular aspect, the rigid lid 38 is configured to provide physical protection to the test strips 36 contained within the resealable cavity 34 of the disposable and removable cartridge 30. More particularly, the rigid lid 38 is configured to be resistant to bending and/or deformation, such that it protects the test strips 36 contained within the resealable cavity 34 from bending, tearing, and/or deforming. In this way, the rigid lid 38 preserves the physical structure of the test strips 36 such that the test strips 36 may be used by test strip users to accurately measure blood glucose levels.

**[0033]** In one particular aspect, the rigid lid 38 comprises plastics, polymers, rubbers, metals, composites and/or alloys. In a further aspect, the rigid lid 38 comprises polypropylene and/or polyethylene. In still a further aspect, the rigid lid 38 comprises polypropylene. However, the rigid lid 38 should not be limited to the materials disclosed herein, but may comprise any material capable of providing physical protection to the test strips 36 contained within the resealable cavity 34.

**[0034]** In another aspect of this embodiment, the disposable and removable cartridge 30 has a flexible body

40. The flexible body 40 is configured to provide environmental protection to the test strips 36 contained within the resealable cavity 34 of the disposable and removable cartridge 30. More particularly, the flexible body 40 is configured to provide a barrier against environmental contaminants such as moisture and/or particulates. In this way, the flexible body 40 substantially excludes environmental contaminants from contacting the test strips 36 contained within the resealable cavity 34, such that the test strips 36 may be used by test strip users to accurately measure blood glucose levels.

**[0035]** The flexible body 40 comprises a moisture barrier film. In one particular aspect, the flexible body comprises a thin material. In a further aspect, the flexible body 40 is configured such that it has a low permeability to moisture. In yet still a further aspect, the flexible body 40 comprises an aluminized foil layer. In one particular aspect, the aluminized foil layer provides a moisture barrier. In a further aspect, the flexible body 40 comprises a thermoplastic resin layer. In still a further aspect, the thermoplastic resin layer comprises polyethylene terephthalate ("PET"). In one particular aspect, the thermoplastic resin layer provides a hermetic seal. However, the flexible body 40 should not be limited to the configurations disclosed herein, however, but may comprise any configuration wherein the flexible body 40 protects test strips 36 from environmental contaminants by providing a barrier against environmental contaminants.

**[0036]** Referring to FIGS. 3, 4, 5a, 5b, and 5c, in one particular aspect, the flexible body 40 defines a gusseted bag. The gusseted bag comprises a front wall 41, a back wall 42, inward-folded, substantially V-shaped folds at opposing sidewalls 44 (same as the unshown sidewall) and a sealable base 46. In one aspect, the sealable base 46 extends around the bottom perimeter of the front and back walls, 41, 42, and the opposing sidewalls 44. In one aspect, the sealable base 46 defines an opening 48 such that the test strips 36 are loaded into the disposable and removable cartridge 30 through the opening 48 defined by the sealable base 46, as indicated in FIGS. 5a and 5b. In a further aspect, the sealable base 46 is heat sealed after loading the test strips 36 through the open sealable base 46, such that the opening 48 is enclosed, as indicated in FIG. 5c. In this aspect, the heat seal creates a hermetically resealable disposable and removable cartridge 30 (in the closed configuration), which provides environmental protection to the test strips 36 contained within the resealable cavity 34. In a further aspect, the heat seal creates a hermetically resealable disposable and removable cartridge 30, such that upon engaging the closed configuration after engaging the open configuration, the disposable and removable cartridge 30 is hermetically sealed.

**[0037]** The sealable base 46 may be heat sealed with a heat sealing device. The heat sealing device operates to fuse the sealable base 46 such that the resealable cavity 34 is enclosed upon the application of heat. Upon heat sealing, the sealable base 46 defines a heat seal

line 50. Suitable heat sealing devices include but are not limited to continuous heat sealers, impulse heat sealers, hot bar sealers, induction sealers, and/or ultrasonic welders. In one particular aspect, the heat sealing device is an ultrasonic welder, wherein a heat seal (i.e. heat weld) is created by the application of high-frequency ultrasonic acoustic vibrations. However, the heat sealing devices should not be limited to those disclosed herein, but may include any heat sealing device capable of fusing (i.e. welding) the sealable base 46 upon the application of heat.

**[0038]** Referring to FIGS. 3 and 4, in a further aspect, the rigid lid 38 is hingedly attached to the flexible body 40. In one aspect, the rigid lid 38 is hingedly attached to the flexible body 40 with a hinging mechanism 52. The hinging mechanism 52 may include a pin in hole mechanism or a living hinge mechanism. However, the hinging mechanism 52 should not be limited to those disclosed herein, but may include any hinging mechanism such that the rigid lid 38 may translate about its attachment to the flexible body 40. In an alternative aspect, the rigid lid 38 is attached to the flexible body 40 such that the rigid lid 38 releasably engages the flexible body 40. In this particular aspect, the rigid lid 38 may be wholly separated from the flexible body 40.

**[0039]** As shown in FIGS. 2, 3, and 4, in one particular aspect of this embodiment, the disposable and removable cartridge 30 comprises an open configuration, wherein the rigid lid 38 is movable relative to the flexible body 40. In one aspect, the open configuration comprises the rigid lid 38 moving about its attachment to the flexible body 40 such that the test strips 36 are accessible in the resealable cavity 34. In this particular aspect, the rigid lid 38 is not wholly separated from the flexible body 40. In an alternative aspect, the open configuration comprises the rigid lid 38 being wholly separated from the flexible body 40 such that the test strips 36 are accessible in the resealable cavity 34.

**[0040]** As shown in FIG. 1, in another aspect, the disposable and removable cartridge 30 has a closed configuration. In one particular aspect, the closed configuration comprises the surfaces of the rigid lid 38 abutting with the surfaces of the flexible body 40, such that the test strips 36 are sealed within the resealable cavity 34. In this way, the closed configuration may be exploited to protect the test strips 36 within the resealable cavity 34 from moisture and other environmental contaminants when the test strips 36 are not required for testing.

**[0041]** In one particular aspect, the disposable and removable cartridge 30 comprises a fastening mechanism 54 such that the disposable and removable cartridge 30 may be releasably fixed in the closed configuration. In a further aspect, the fastening mechanism 54 is a latching mechanism comprising upper and lower releasably mating parts 56, 58, either mechanically or magnetically based. Alternatively, the fastening mechanism 54 may comprise a clamping mechanism or a snap-fit mechanism. In one particular aspect wherein the fastening

mechanism 54 is a snap-fit mechanism, the rigid lid 38 may further comprise a thumb tab.

**[0042]** As shown in FIGS. 2, 3, and 4, in another aspect, the disposable and removable cartridge 30 has a seal 60. The seal 60 provides a barrier against contaminants such as moisture and/or particulates. In this particular aspect, the seal 60 excludes contaminants in multiple capacities, i.e. the seal 60 excludes contaminants from the area in between the rigid lid 38 and the flexible body 40, and the seal 60 excludes contaminants from the area in between the disposable and removable cartridge 30 and the housing (not shown). In this way, the seal 60 protects the test strips 36 from contamination such that the test strips 36 may be used by test strip users to accurately measure blood glucose levels.

**[0043]** The seal 60 may be attached to and/or adhered to the disposable and removable cartridge 30. In one aspect, the seal 60 may be attached to and/or adhered to the rigid lid 38 of the disposable and removable cartridge 30. In a further aspect, the rigid lid 38 comprises an inner rim 62. In this particular aspect, the seal 60 is adhered to the inner rim 62. In another aspect, the seal 60 may be attached to and/or adhered to the flexible body 40 of the disposable and removable cartridge 30. In one particular aspect, the disposable and removable cartridge 30 has a rigid rim 64. In this particular aspect, the seal 60 may be attached to and/or adhered to the rigid rim 64 of the flexible body 40.

**[0044]** In one aspect of this embodiment, the rigid rim 64 is configured to increase the robustness of the seal. Additionally, the rigid rim 64 is configured to provide a robust surface wherein the disposable and removable cartridge 30 is retained with the housing 90. In one particular aspect, the rigid rim 64 comprises plastics, polymers, rubbers, metals, composites and/or alloys. In a further aspect, the rigid rim 64 comprises polypropylene and/or polyethylene. In still a further aspect, the rigid rim 64 comprises polypropylene. Generally, the rigid rim 64 comprises the same material as the rigid lid 38. The rigid rim 64 extends around the top, inner perimeter of the flexible body 40. In one particular aspect, the rigid lid 38 is hingedly attached to the rigid rim 64. In a further aspect, the rigid lid 38 is attached to the rigid rim 64 such that a seal is created via interference fit, i.e. a stopper in bottle-like configuration. In another aspect, the rigid rim 64 is overmolded with a thermoelastomer creating a seal, i.e. a gasket-like configuration. In an alternative embodiment, the rigid lid 38 may releasably engage the rigid rim 64.

**[0045]** The area wherein the seal 60 is attached to and/or adhered to the disposable and removable cartridge 30 is referred to as the seal line 66. In one particular aspect, the seal line 66 is reinforced to increase durability and to provide a more robust seal. The seal line 66 may be reinforced with plastics and/or polymers to increase the durability of the disposable and removable cartridge 30.

**[0046]** In one particular aspect, the rigid lid 38 is sub-

stantially ovular and the rigid rim 64 is substantially ovular in shape. However, the shape of the rigid lid 38 and the rigid rim 64 should not be limited to substantially ovular, but may comprise any shape such that the rigid lid 38 may abut with the rigid rim 64 to enclose the cavity, and such that the disposable and removable cartridge 30 may be retained with the housing (not shown).

**[0047]** As shown in FIGS. 5a, 5b, 5c, and 6, in yet another aspect of this embodiment, the disposable and removable cartridge 30 has a retaining member 70 which releasably retains the test strips 36 in a stacked configuration. The retaining member 70 may comprise an elastic biasing member, a molded frame, and/or retaining clip. In one particular aspect, the retaining member 70 comprises an elastic biasing member. In this particular aspect, the elastic biasing member releasably retains the test strips 36 via a biasing force which releasably clamps, squeezes or holds the test strips 36 together. Also in this particular aspect, the elastic biasing member releasably retains the test strips 36 such that upon removal of a test strip 36 by a test strip user, the elastic biasing member releasably clamps, squeezes or holds the remaining test strips 36 together. However, the retaining member 70 should not be limited to the configurations disclosed herein, but may include any retaining member 70 which releasably retains the test strips 36 in a stacked configuration. Moreover, in one particular aspect, the retaining member 70 may comprise a desiccant to absorb moisture.

**[0048]** As shown in FIGS. 1, 2, and 7, in yet another aspect of this embodiment, the blood glucose meter 10 comprises a housing 90 accommodating a blood glucose measuring component 92 for measuring a blood glucose level of a blood sample. In one particular aspect, the blood glucose measuring component 92 comprises a test strip port 95. The test strip port 95 may be sized to receive a test strip 36 for testing a blood sample. An example of a suitable blood glucose measuring component 92 includes the blood glucose measuring device described in U.S. Patent Application Serial No. 12/486,805.

Examples of test strips 36 suitable for use with the blood glucose measuring device 92 include those described in U.S. Patent Nos. 6,193,873; 6,475,372; 6,716,577; 6,620,310; and 6,558,528.

**[0049]** The blood glucose measuring component 92 may be accommodated by the housing 90 such that it is attachable to the housing 90 or integral with the housing 90. In one aspect, the blood glucose measuring component 92 is attachable to the housing 90 via a snap-fit mechanism, an interference fit mechanism, or a latching mechanism (not shown). In a further aspect, the latching mechanism may comprise a latch and hook. In an alternative aspect, the blood glucose measuring component 92 is integral with the housing 90 such that it is co-molded with the housing 90.

**[0050]** Still referring to FIGS. 1, 2, and 7, in yet another aspect of this embodiment, the housing 90 provides a receptacle 94 having surfaces 96 and a disposable and

removable cartridge-engaging rim 98 which retain the disposable and removable cartridge 30 with the housing 90. In one particular aspect, the disposable and removable cartridge 30 is retained with the housing such that substantially all of the flexible body 40 is disposed within the receptacle 94. In this particular aspect, the rigid lid 38 is exposed to the ambient environment.

**[0051]** In a further aspect, the disposable and removable cartridge 30 is retained with the housing 90 with a fastening device 100. The fastening device 100 may comprise a snap-fit mechanism, an interference fit mechanism, or a latching mechanism. In one particular aspect, the fastening device 100 is a snap-fit mechanism, wherein the rigid rim 64 of the flexible body 40 snaps onto the disposable and removable cartridge-engaging rim 98, such that the disposable and removable cartridge 30 is releasably retained with the housing 90. Alternatively, the fastening device 100 may retain the disposable and removable cartridge 30 with the housing with latches and hooks, detents and ribs, and/or magnets. However, the fastening device 100 should not be limited to the mechanisms disclosed herein, but may comprise any mechanism capable of releasably retaining the disposable and removable cartridge 30 with the housing 90.

**[0052]** In another embodiment, a method of providing easy access to test strips 36 and measuring blood glucose which comprises utilizing a blood glucose meter 10 according to the present invention is also disclosed.

**[0053]** In still another embodiment, the present invention relates to a method of manufacturing a blood glucose meter 10 for providing easy access to test strips 36 and measuring blood glucose. The method comprises providing a disposable and removable cartridge 30 and providing a housing 90. The disposable and removable cartridge 30 has surfaces 32 which define a resealable cavity 34 containing test strips 36 wherein the disposable and removable cartridge 30 has a retaining member 70 which releasably retains the test strips 36 in a stacked configuration. The housing 90 accommodates a blood glucose measuring component 92 for measuring a blood glucose level of a blood sample and provides a receptacle 94 having surfaces 96 which retain the disposable and removable cartridge 30 with the housing 90.

**[0054]** For the purposes of describing and defining the present invention it is noted that the terms "about" and "substantially" are utilized herein to represent the inherent degree of uncertainty that may be attributed to any quantitative comparison, value, measurement, or other representation. The terms "about" and "substantially" are also utilized herein to represent the degree by which a quantitative representation may vary from a stated reference without resulting in a change in the basic function of the subject matter at issue.

**[0055]** Further provided are the following aspects of the present disclosure:

1. A blood glucose meter providing easy access to a test strip provided therewith and for measuring a

blood glucose level of a blood sample provided to the test strip, said meter comprising:

a disposable and removable cartridge as described herein having surfaces which define a resealable cavity containing the test strips, wherein the disposable and removable cartridge has a retaining member which releasably retains the test strips in a stacked configuration; and a housing accommodating a blood glucose measuring component which measures the blood glucose level of the blood sample when provided to the test strip which has been removed from among the test strips contained in the resealable cavity, and providing a receptacle having surfaces which retain the disposable and removable cartridge with the housing.

2. The blood glucose meter of aspect 1, wherein the surfaces which define the resealable cavity are provided by a rigid lid attached to a flexible body of the disposable and removable cartridge.

3. The blood glucose meter of aspect 2, wherein the flexible body comprises a rigid rim.

4. The blood glucose meter of aspect 2, wherein the flexible body comprises a moisture barrier film.

5. The blood glucose meter of aspect 2, wherein the flexible body comprises a gusseted bag.

6. The blood glucose meter of aspect 5, wherein the gusseted bag is heat sealed at a base thereof.

7. The blood glucose meter of aspect 2, wherein the rigid lid is movable relative to the flexible body to provide an open configuration such that the test strips are accessible in the resealable cavity.

8. The blood glucose meter of aspect 2, wherein the rigid lid abuts with the flexible body to provide a closed configuration, such that the test strips are sealed within the resealable cavity.

9. The blood glucose meter of aspect 1, wherein the disposable and removable cartridge comprises a seal provided between certain ones of the surfaces.

10. The blood glucose meter of aspect 2, wherein the disposable and removable cartridge is retained with the housing such that substantially all of the flexible body is disposed within the receptacle.

11. The blood glucose meter of aspect 1, wherein the disposable and removable cartridge is retained with the housing with a fastening device.

12. The blood glucose meter of aspect 1, wherein the retaining member comprises an elastic biasing member.

13. A method of providing easy access to test strips and measuring blood glucose which comprises utilizing the blood glucose meter of aspect 1.

14. A disposable and removable cartridge for providing easy access to test strips comprising:

a flexible body having surfaces which define a resealable cavity containing the test strips; a rigid lid attached to the flexible body and having surfaces which abut with the surfaces of the flexible body for enclosing the resealable cavity; and a retaining member provided within the cavity and releasably retaining the test strips in a stacked configuration, wherein the disposable and removable cartridge has an open configuration and a closed configuration, in which:

the open configuration comprises the rigid lid being moved relative to the flexible body, such that the test strips are accessible in the cavity, and

the closed configuration comprises the rigid lid abutting with the flexible body, such that the test strips are sealed within in the cavity.

15. The disposable and removable cartridge of aspect 14, wherein the rigid lid is attached to the flexible body with a hinging mechanism.

16. The disposable and removable cartridge of aspect 14, wherein the flexible body comprises a gusseted bag having a front wall, a back wall, inward-folded, substantially V-shaped folds at opposing sidewalls, and a sealed base.

17. The disposable and removable cartridge of aspect 16, wherein the base is heat sealed.

18. The disposable and removable cartridge of aspect 14, further comprising a fastening mechanism to releasably fix the disposable and removable cartridge in the closed configuration.

19. The disposable and removable cartridge of aspect 14, wherein the retaining member comprises an elastic biasing member.

20. A method of manufacturing a blood glucose meter for providing easy access to test strips and measuring blood glucose comprising, comprising:

providing a disposable and removable cartridge having surfaces which define a resealable cavity

containing test strips, wherein the disposable and removable cartridge has a retaining member which releasably retains the test strips in a stacked configuration; and

providing a housing accommodating a blood glucose measuring component for measuring a blood glucose level of a blood sample and providing a receptacle having surfaces which retain the disposable and removable cartridge with the housing.

## Claims

1. A disposable and removable cartridge (30) for providing easy access to test strips (36) comprising:

a flexible body (40) comprising a moisture barrier film and having surfaces (32) which define a resealable cavity (34) containing the test strips (36);

a rigid lid (38) attached to the flexible body (40) and having surfaces which abut with the surfaces of the flexible body (40) for enclosing the resealable cavity (34); and

a retaining member (70) provided within the cavity (34) and releasably retaining the test strips (36) in a stacked configuration, wherein the disposable and removable cartridge (30) has an open configuration and a closed configuration, in which:

the open configuration comprises the rigid lid (38) being moved relative to the flexible body (40), such that the test strips (36) are accessible in the cavity (34), and

the closed configuration comprises the rigid lid (38) abutting with the flexible body (40), such that the test strips (36) are sealed within in the cavity (34).

2. The disposable and removable cartridge (30) of claim 1, wherein the retaining member (70) is configured to releasably retain the test strips (36) in an upright configuration.

3. The disposable and removable cartridge (30) of claim 1, wherein the rigid lid (38) is attached to the flexible body (40) with a hinging mechanism (52).

4. The disposable and removable cartridge (30) of claim 1, wherein the flexible body (40) comprises a gusseted bag.

5. The disposable and removable cartridge (30) of claim 4, wherein the gusseted bag has a front wall (41), a back wall (42), inward-folded, substantially V-shaped folds at opposing sidewalls (44), and a

sealed base (46).

6. The disposable and removable cartridge (30) of claim 4, wherein the base (46) is heat sealed.
7. The disposable and removable cartridge (30) of claim 1, further comprising a fastening mechanism (54) for releasably fixing the disposable and removable cartridge (30) in the closed configuration.
8. The disposable and removable cartridge (30) of claim 1, wherein the retaining member (70) comprises an elastic biasing member.
9. The disposable and removable cartridge (30) of claim 1, wherein the flexible body (40) comprises a rigid rim (64).
10. The disposable and removable cartridge (30) of claim 1, wherein the disposable and removable cartridge (30) comprises a seal (60) provided between certain ones of the surfaces.
11. A blood glucose meter (10) providing easy access to a test strip (36) provided therewith and for measuring a blood glucose level of a blood sample provided to the test strip (36), said meter comprising:
- a disposable and removable cartridge (30) according to any of claims 1 to 10, having surfaces (32) which define a resealable cavity (34) containing the test strips (36), wherein the disposable and removable cartridge (30) has a retaining member (70) which releasably retains the test strips (70) in a stacked configuration; and a housing (90) accommodating a blood glucose measuring component (92) which measures the blood glucose level of the blood sample when provided to the test strip (36) which has been removed from among the test strips (36) contained in the resealable cavity (34), and providing a receptacle (94) having surfaces (96) which retain the disposable and removable cartridge (30) with the housing (90).
12. The blood glucose meter of claim 11, wherein the disposable and removable cartridge (30) is retained with the housing (90) such that substantially all of the flexible body (40) is disposed within the receptacle (94).
13. The blood glucose meter of claim 11, wherein the disposable and removable cartridge (30) is retained with the housing (90) with a fastening device (100).
14. A method of manufacturing a blood glucose meter (10) according to claim 11 for providing easy access to test strips (36) and measuring blood glucose, com-

prising:

providing a disposable and removable cartridge (30) having surfaces (32) which define a resealable cavity (34) containing test strips (36), wherein the disposable and removable cartridge (30) has a retaining member (70) which releasably retains the test strips (36) in a stacked configuration; and providing a housing (40) accommodating a blood glucose measuring component for measuring a blood glucose level of a blood sample and providing a receptacle (94) having surfaces (96) which retain the disposable and removable cartridge (30) with the housing (90).

### Patentansprüche

1. Herausnehmbare Einwegpatrone (30) zum Bereitstellen eines einfachen Zugangs zu Teststreifen (36), umfassend:

einen flexiblen Körper (40), umfassend einen Feuchtigkeitssperrfilm und mit Oberflächen (32), die einen die Teststreifen (36) enthaltenden wiederversiegelbaren Hohlraum (34) definieren,

einen starren Deckel (38), der an dem flexiblen Körper (40) angebracht ist und Oberflächen aufweist, die an den Oberflächen des flexiblen Körpers (40) zum Einschließen des wiederversiegelbaren Hohlraums (34) anliegen; und ein Halteelement (70), das in dem Hohlraum (34) bereitgestellt ist und die Teststreifen (36) lösbar in einer gestapelten Konfiguration hält, wobei die herausnehmbare Einwegpatrone (30) eine offene Konfiguration und eine geschlossene Konfiguration aufweist, in denen:

die offene Konfiguration den starren Deckel (38) umfasst, der relativ zu dem flexiblen Körper (40) bewegt wird, sodass die Teststreifen (36) in dem Hohlraum (34) zugänglich sind, und die geschlossene Konfiguration den starren Deckel (38) umfasst, der an dem flexiblen Körper (40) anliegt, sodass die Teststreifen (36) in dem Hohlraum (34) versiegelt sind.

2. Herausnehmbare Einwegpatrone (30) nach Anspruch 1, wobei das Halteelement (70) konfiguriert ist, die Teststreifen (36) lösbar in einer aufrechten Konfiguration zu halten.
3. Herausnehmbare Einwegpatrone (30) nach Anspruch 1, wobei der starre Deckel (38) an dem flexiblen Körper (40) mit einem Gelenkmechanismus

(52) angebracht ist.

4. Herausnehmbare Einwegpatrone (30) nach Anspruch 1, wobei der flexible Körper (40) einen Seitenfaltenbeutel umfasst. 5
5. Herausnehmbare Einwegpatrone (30) nach Anspruch 4, wobei der Seitenfaltenbeutel eine vordere Wand (41), eine hintere Wand (42), nach innen gefaltete, im Wesentlichen V-förmige Falten an gegenüberliegenden Seitenwänden (44) und eine versiegelte Basis (46) aufweist. 10
6. Herausnehmbare Einwegpatrone (30) nach Anspruch 4, wobei die Basis (46) heißgesiegelt ist. 15
7. Herausnehmbare Einwegpatrone (30) nach Anspruch 1, ferner umfassend einen Befestigungsmechanismus (54) zum lösbaren Fixieren der herausnehmbaren Einwegpatrone (30) in der geschlossenen Konfiguration. 20
8. Herausnehmbare Einwegpatrone (30) nach Anspruch 1, wobei das Halteelement (70) ein elastisches Vorspannelement umfasst. 25
9. Herausnehmbare Einwegpatrone (30) nach Anspruch 1, wobei der flexible Körper (40) einen starren Rand (64) umfasst. 30
10. Herausnehmbare Einwegpatrone (30) nach Anspruch 1, wobei die herausnehmbare Einwegpatrone (30) eine Dichtung (60) umfasst, die zwischen bestimmten der Oberflächen bereitgestellt ist. 35
11. Blutzuckermessgerät (10), das einfachen Zugang zu einem damit bereitgestellten Teststreifen (36) bereitstellt, und zum Messen eines Blutzuckerspiegels einer Blutprobe, die dem Teststreifen (36) bereitgestellt ist, wobei das Messgerät Folgendes umfasst: 40
  - eine herausnehmbare Einwegpatrone (30) nach einem der Ansprüche 1 bis 10, die Oberflächen (32) aufweist, die einen die Teststreifen (36) enthaltenden wiederversiegelbaren Hohlraum (34) definieren, wobei die herausnehmbare Einwegpatrone (30) ein Halteelement (70) aufweist, das die Teststreifen (70) lösbar in einer gestapelten Konfiguration hält; und 45
  - ein Gehäuse (90), das eine Blutzuckermesskomponente (92) beherbergt, die den Blutzuckerspiegel der Blutprobe misst, wenn diese dem Teststreifen (36) bereitgestellt ist, der aus den in dem wiederversiegelbaren Hohlraum (34) enthaltenen Teststreifen (36) herausgenommen wurde, und einen Behälter (94) mit Oberflächen (96) bereitstellt, die die herausnehmbare Einwegpatrone (30) mit dem Gehä-

se (90) halten.

12. Blutzuckermessgerät nach Anspruch 11, wobei die herausnehmbare Einwegpatrone (30) mit dem Gehäuse (90) gehalten wird, sodass im Wesentlichen der gesamte flexible Körper (40) in dem Behälter (94) angeordnet ist.
13. Blutzuckermessgerät nach Anspruch 11, wobei die herausnehmbare Einwegpatrone (30) mit dem Gehäuse (90) mit einer Befestigungsvorrichtung (100) gehalten wird.
14. Verfahren zum Herstellen eines Blutzuckermessgeräts (10) nach Anspruch 11 zum Bereitstellen eines einfachen Zugangs zu Teststreifen (36) und Messen des Blutzuckers, umfassend:

Bereitstellen einer herausnehmbaren Einwegpatrone (30) mit Oberflächen (32), die einen Teststreifen (36) enthaltenden wiederversiegelbaren Hohlraum (34) definieren, wobei die herausnehmbare Einwegpatrone (30) ein Halteelement (70) aufweist, das die Teststreifen (36) lösbar in einer gestapelten Konfiguration hält; und Bereitstellen eines Gehäuses (90), das eine Blutzuckermesskomponente zum Messen eines Blutzuckerspiegels einer Blutprobe beherbergt und einen Behälter (94) mit Oberflächen (96) bereitstellt, die die herausnehmbare Einwegpatrone (30) mit dem Gehäuse (90) halten.

#### Revendications

1. Cartouche jetable et amovible (30) destinée à permettre un accès facile à des bandelettes d'essai (36) comprenant :
  - un corps flexible (40) comprenant un film barrière à l'humidité et ayant des surfaces (32) qui définissent une cavité détachable (34) contenant les bandelettes d'essai (36) ;
  - un couvercle rigide (38) fixé au corps flexible (40) et ayant des surfaces qui butent contre les surfaces du corps flexible (40) pour renfermer la cavité détachable (34) ; et
  - un élément de retenue (70) prévu dans la cavité (34) et retenant de manière détachable les bandelettes d'essai (36) dans une configuration empilée, la cartouche jetable et amovible (30) présentant une configuration ouverte et une configuration fermée, dans lesquelles :
    - la configuration ouverte comprend le déplacement du couvercle rigide (38) par rapport au corps flexible (40), de sorte que les bandelettes d'essai (36) soient accessibles

- dans la cavité (34), et la configuration fermée comprend la butée du couvercle rigide (38) contre le corps flexible (40), de sorte que les bandelettes d'essai (36) scellées dans la cavité (34). 5
2. Cartouche jetable et amovible (30) de la revendication 1, dans laquelle l'élément de retenue (70) est conçu pour retenir de manière détachable les bandelettes d'essai (36) dans une configuration verticale. 10
3. Cartouche jetable et amovible (30) de la revendication 1, dans laquelle le couvercle rigide (38) est attaché au corps flexible (40) avec un mécanisme de charnière (52). 15
4. Cartouche jetable et amovible (30) de la revendication 1, dans laquelle le corps flexible (40) comprend un sac à soufflet. 20
5. Cartouche jetable et amovible (30) de la revendication 4, dans laquelle le sac à soufflet possède une paroi avant (41), une paroi arrière (42), des plis sensiblement en V repliés vers l'intérieur au niveau de parois latérales opposées (44) et une base scellée (46). 25
6. Cartouche jetable et amovible (30) de la revendication 4, dans laquelle la base (46) est thermo-scellée. 30
7. Cartouche jetable et amovible (30) de la revendication 1, comprenant en outre un mécanisme de fixation (54) destiné à fixer de manière détachable la cartouche jetable et amovible (30) dans la configuration fermée. 35
8. Cartouche jetable et amovible (30) de la revendication 1, dans laquelle l'élément de retenue (70) comprend un élément de sollicitation élastique. 40
9. Cartouche jetable et amovible (30) de la revendication 1, dans laquelle le corps flexible (40) comprend un rebord rigide (64). 45
10. Cartouche jetable et amovible (30) de la revendication 1, la cartouche jetable et amovible (30) comprenant un joint (60) prévu entre certaines des surfaces. 50
11. Indicateur de glycémie (10) permettant un accès facile à une bandelette d'essai (36) fournie avec celui-ci et destiné à mesurer une glycémie d'un échantillon sanguin fourni à la bandelette d'essai (36), ledit indicateur comprenant : 55
- une cartouche jetable et amovible (30) selon l'une quelconque des revendications 1 à 10, possédant des surfaces (32) qui définissent une cavité détachable (34) contenant les bandelettes d'essai (36), la cartouche jetable et amovible (30) comprenant un élément de retenue (70) qui retient de manière détachable les bandelettes d'essai (36) dans une configuration empilée ; et un logement (90) logeant un composant de mesure de glycémie (92) qui mesure la glycémie de l'échantillon sanguin lorsqu'il est fourni à la bandelette d'essai (36) qui a été retirée parmi les bandelettes d'essai (36) contenues dans la cavité détachable (34), et prévoyant un réceptacle (94) possédant des surfaces (96) qui retiennent la cartouche jetable et amovible (30) avec le logement (90).
12. Indicateur de glycémie de la revendication 11, dans lequel la cartouche jetable et amovible (30) est retenue avec le logement (90) de sorte que sensiblement la totalité du corps flexible (40) soit disposée dans le réceptacle (94).
13. Indicateur de glycémie de la revendication 11, dans lequel la cartouche jetable et amovible (30) est retenue avec le logement (90) avec un dispositif de fixation (100).
14. Procédé de fabrication d'un indicateur de glycémie (10) selon la revendication 11 destiné à permettre un accès facile à des bandelettes d'essai (36) et à mesurer la glycémie, comprenant :
- la fourniture d'une cartouche jetable et amovible (30) possédant des surfaces (32) qui définissent une cavité détachable (34) contenant les bandelettes d'essai (36), la cartouche jetable et amovible (30) comprenant un élément de retenue (70) qui retient de manière détachable les bandelettes d'essai (36) dans une configuration empilée ; et la fourniture d'un logement (40) logeant un composant de mesure de glycémie destiné à mesurer une glycémie d'un échantillon sanguin et prévoyant un réceptacle (94) possédant des surfaces (96) qui retiennent la cartouche jetable et amovible (30) avec le logement (90).

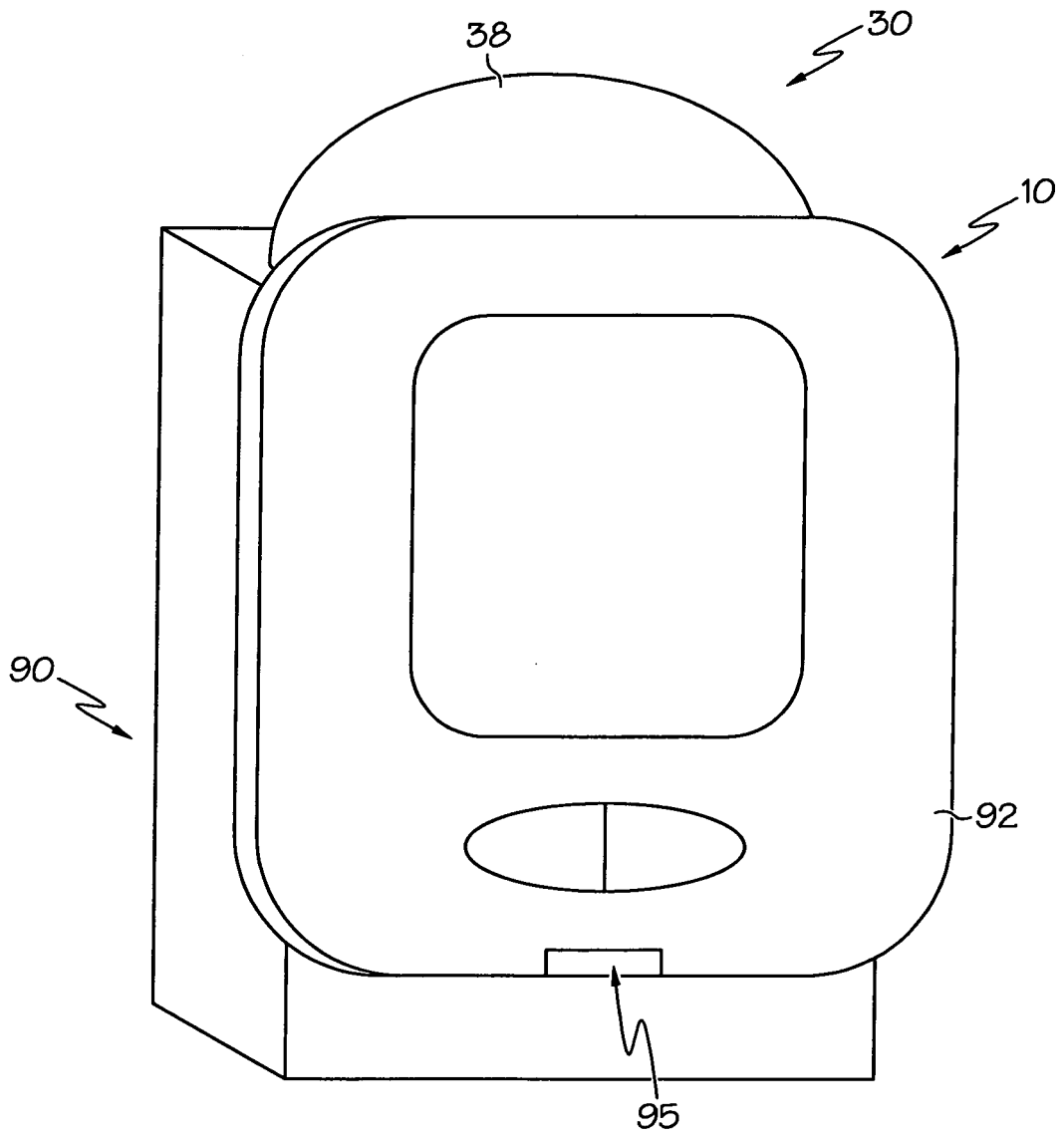


FIG. 1

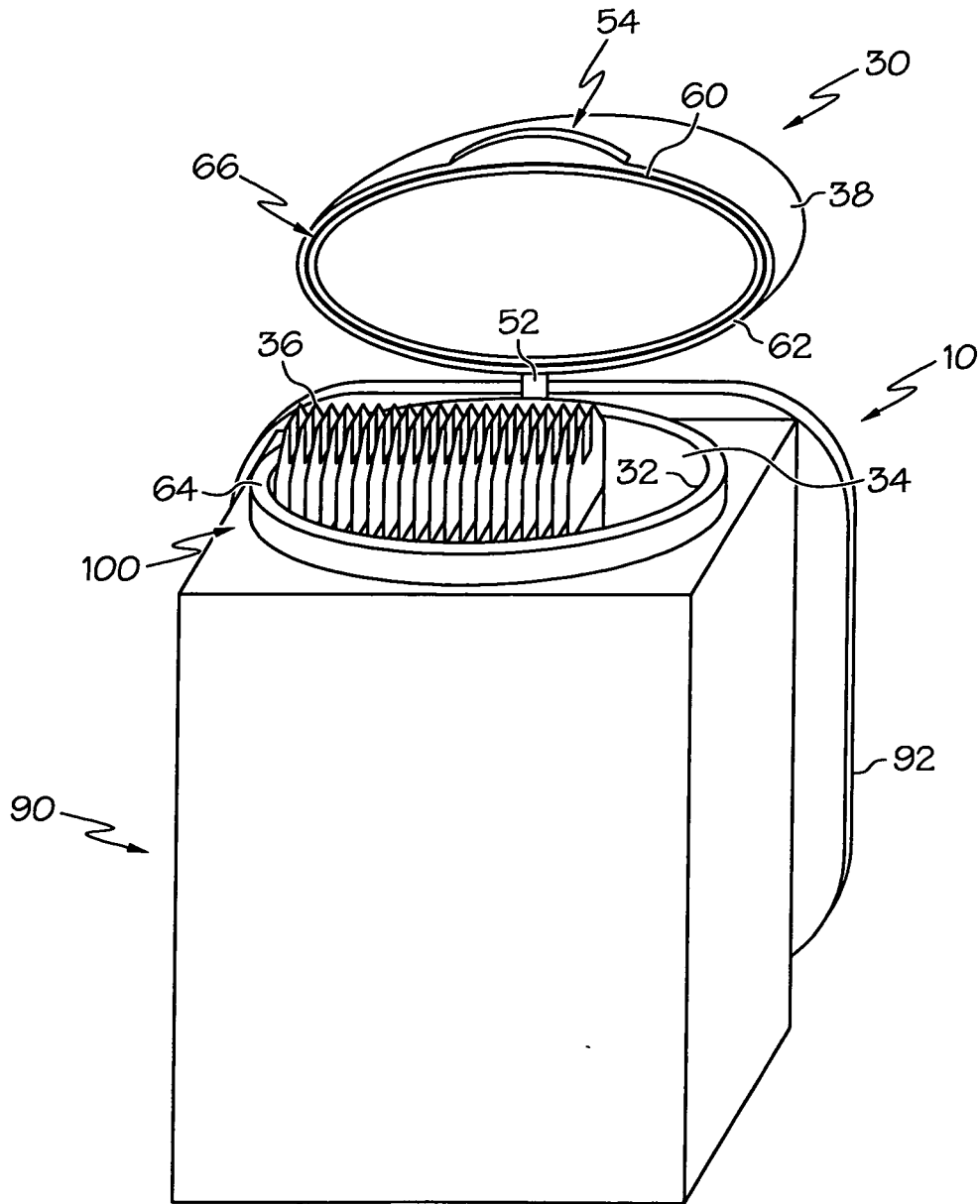


FIG. 2

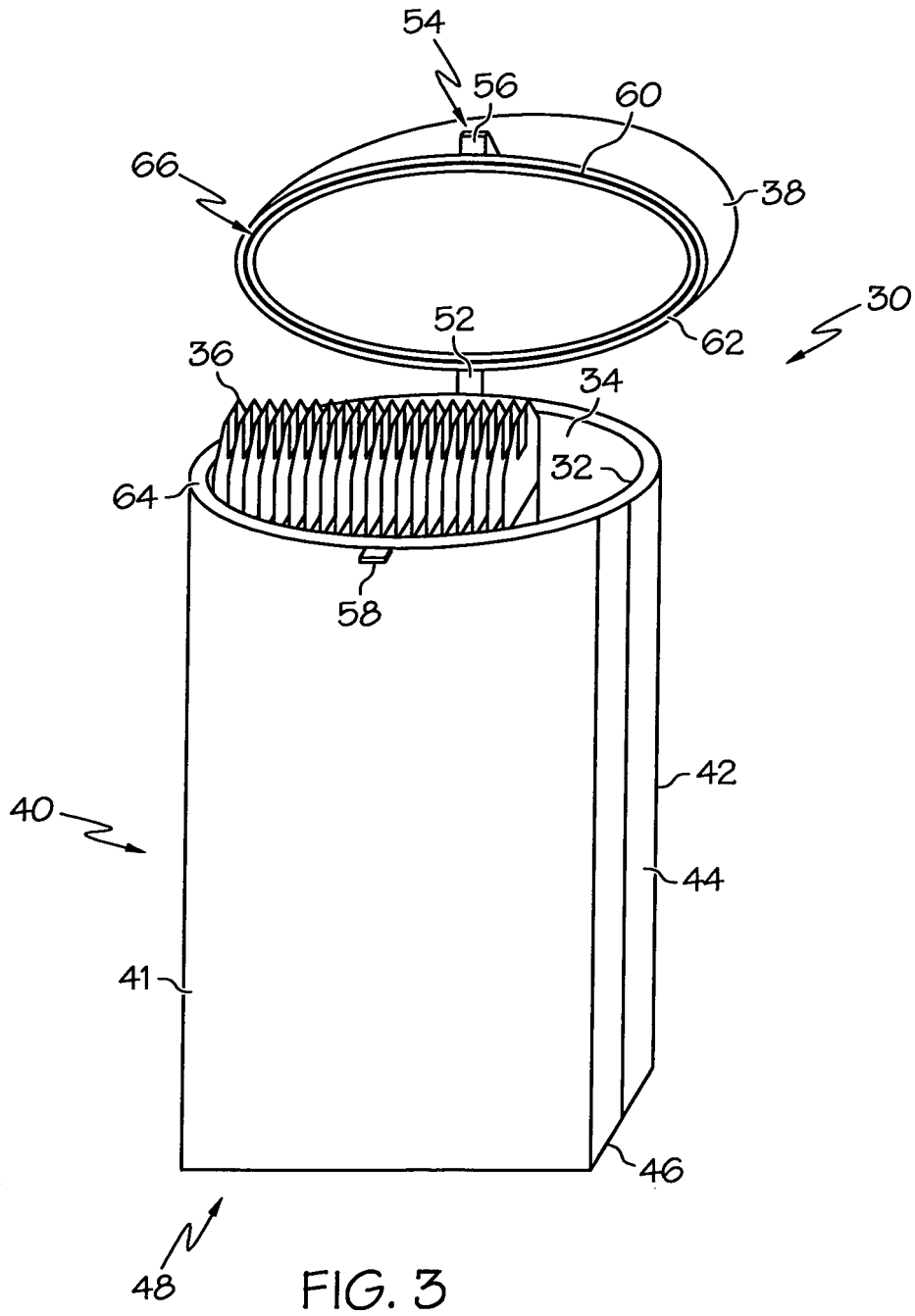


FIG. 3

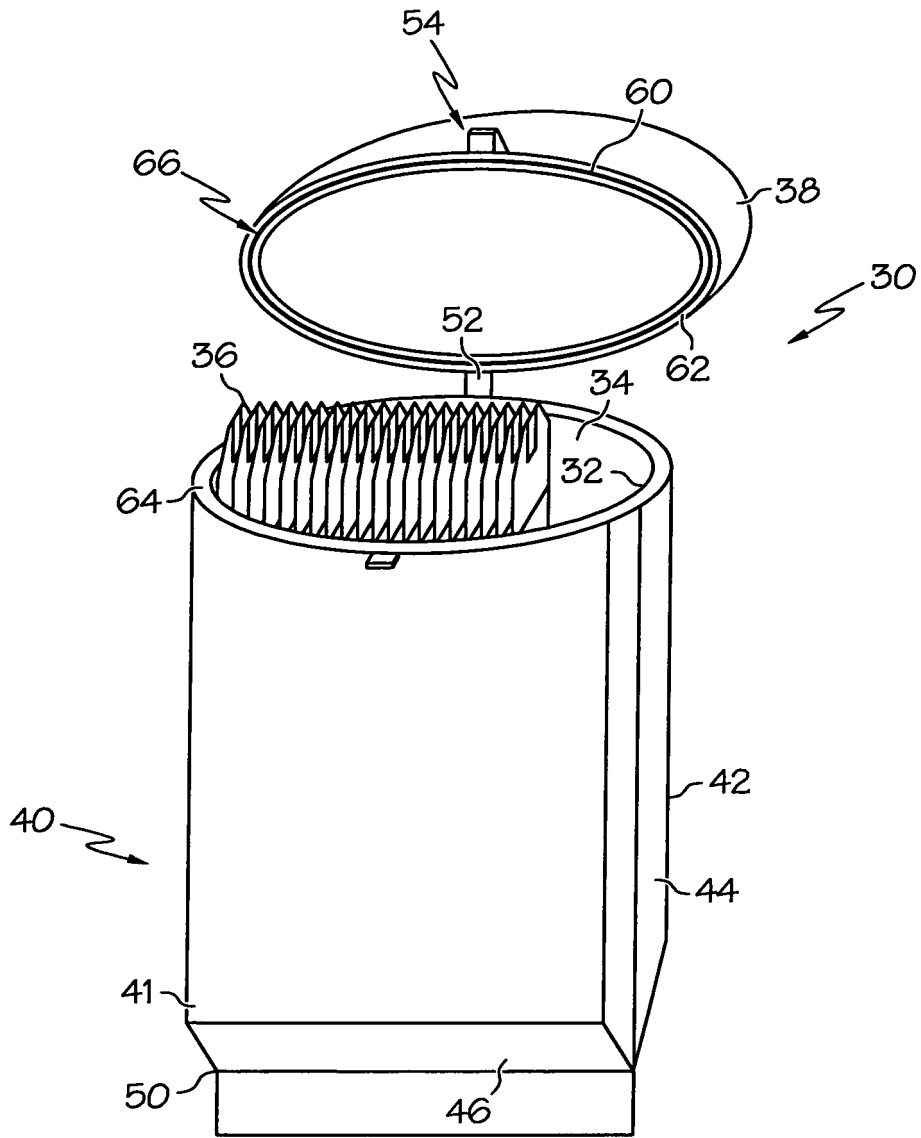


FIG. 4

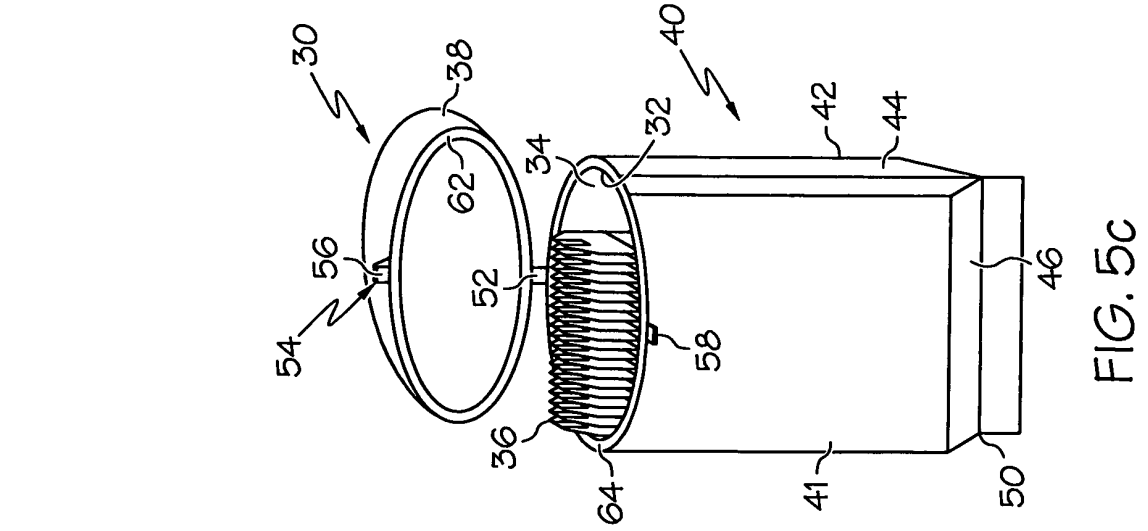


FIG. 5c

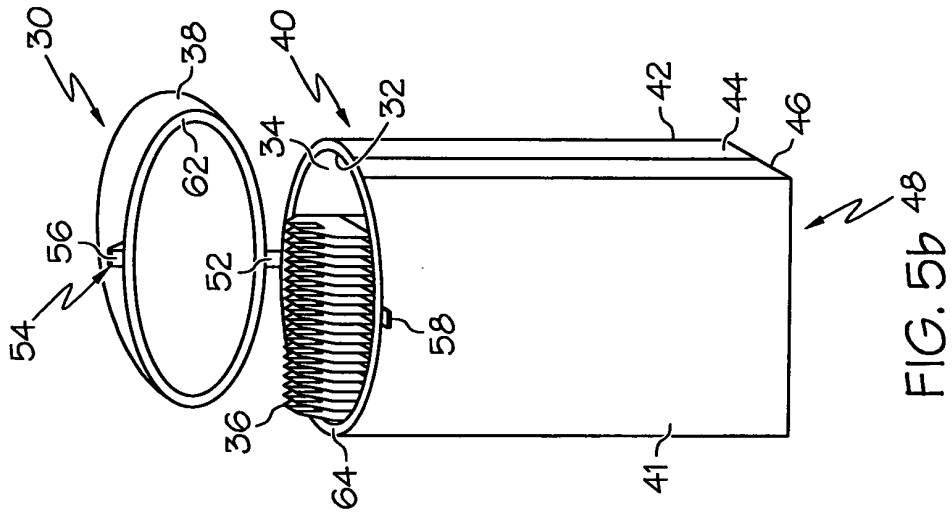


FIG. 5b

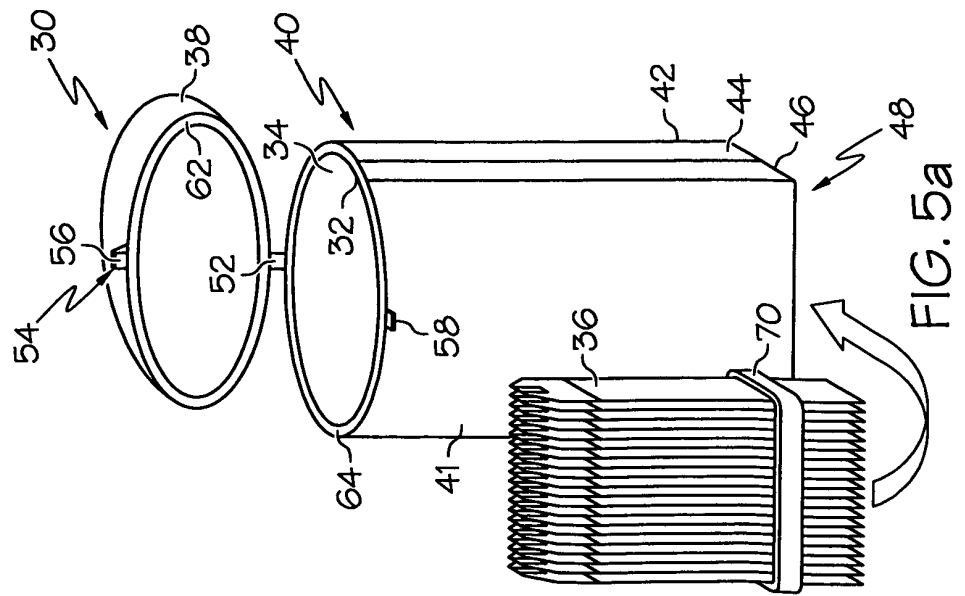


FIG. 5a

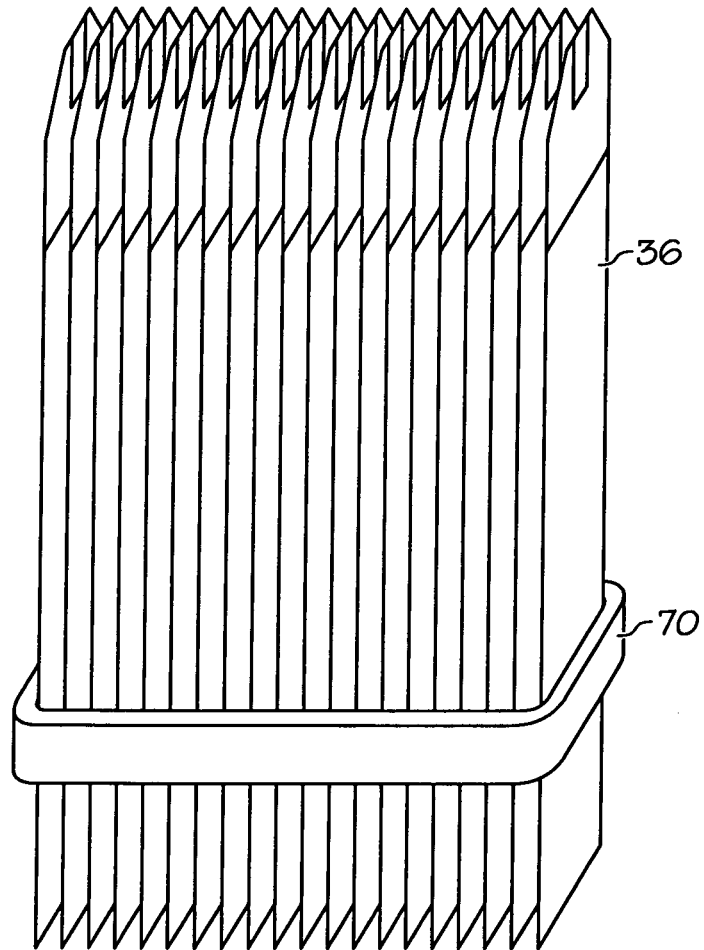


FIG. 6

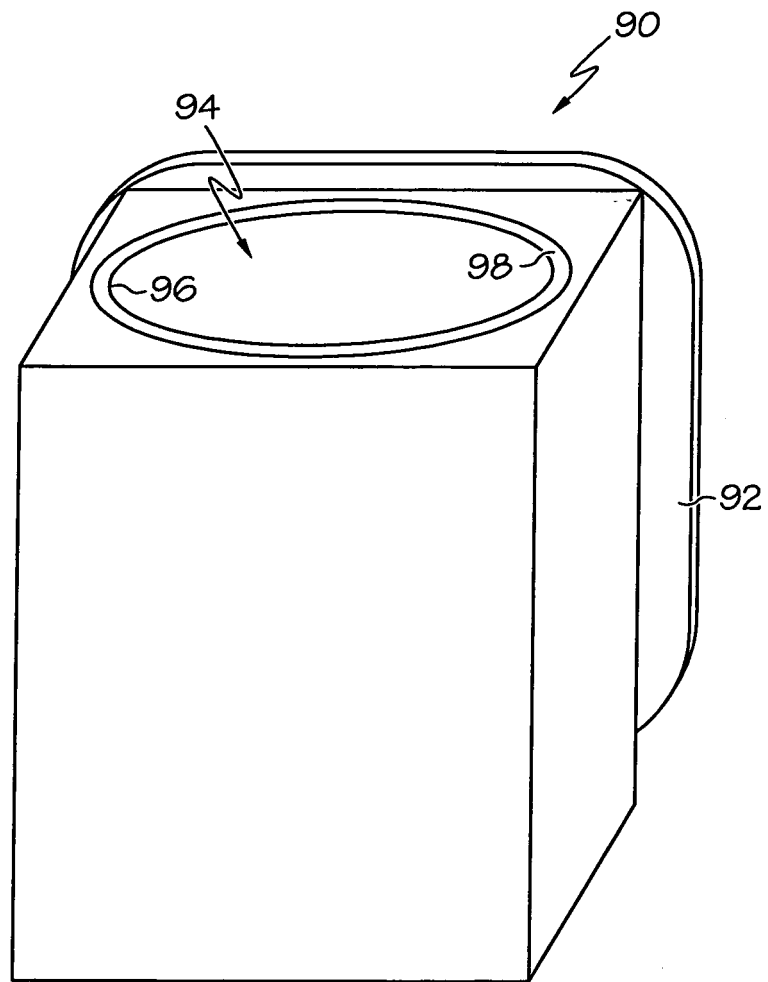


FIG. 7

**REFERENCES CITED IN THE DESCRIPTION**

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**Patent documents cited in the description**

- US 20080118400 A [0005]
- US 486805 A [0048]
- US 6193873 B [0048]
- US 6475372 B [0048]
- US 6716577 B [0048]
- US 6620310 B [0048]
- US 6558528 B [0048]

专利名称(译)	带保持插入件的集成测试条容器		
公开(公告)号	<a href="#">EP2387941B1</a>	公开(公告)日	2018-10-24
申请号	EP2011003353	申请日	2011-04-21
[标]申请(专利权)人(译)	罗氏诊断公司		
申请(专利权)人(译)	罗氏诊断有限公司 F.HOFFMANN-LA ROCHE AG		
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IPC分类号	A61B5/00		
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优先权	12/768036 2010-04-27 US		
其他公开文献	EP2387941A1		
外部链接	<a href="#">Espacenet</a>		

摘要(译)

本发明公开了一种血糖仪，用于提供对测试条的容易接近和测量血糖，一次性和可移动的盒，用于提供对测试条的容易接近，以及制造和利用它们的方法。用于提供对测试条的容易接近和测量血糖的血糖仪具有一次性和可移除的盒，可释放地将测试条保持在堆叠构造中的保持构件，以及壳体。一次性和可移除的盒子具有连接到柔性主体的刚性盖子。

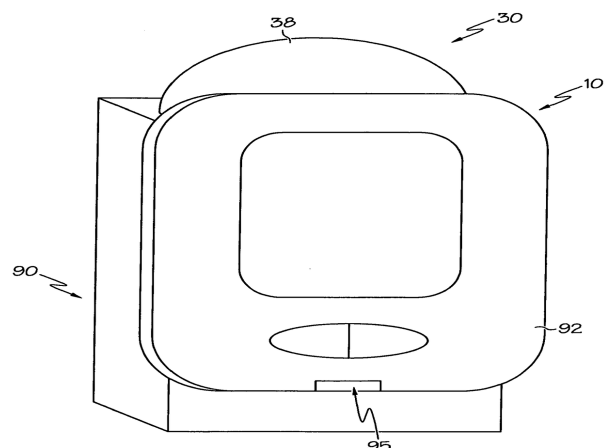


FIG. 1