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

(11) EP 2 275 034 B1

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:
04.04.2012 Bulletin 2012/14

(51) Int Cl.:
A61B 5/151 *(2006.01)* ***A61B 5/00*** *(2006.01)*
G01N 33/487 *(2006.01)*

(21) Application number: **10169404.0**

(22) Date of filing: **13.07.2010**

(54) **Blood glucose sensor**

Blutzuckersensor

Capteur de glycémie

(84) Designated Contracting States:
AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO SE SI SK SM TR

(30) Priority: **14.07.2009 US 502594**

(43) Date of publication of application:
19.01.2011 Bulletin 2011/03

(73) Proprietor: **Becton, Dickinson and Company**
Franklin Lakes, NJ 07417 (US)

(72) Inventors:
- **Mondro, Jason**
  Franklin Lakes, NJ 07417 (US)
- **Schiff, David**
  Franklin Lakes, NJ 07417 (US)
- **Albert, Jonathan**
  Franklin Lakes, NJ 07417 (US)

(74) Representative: **von Kreisler Selting Werner**
Deichmannhaus am Dom
Bahnhofsvorplatz 1
50667 Köln (DE)

(56) References cited:
EP-A1- 1 360 935
EP-A1- 1 801 584
EP-A2- 1 714 614
WO-A1-2006/100265
US-A1- 2006 100 543

EP 2 275 034 B1

Printed by Jouve, 75001 PARIS (FR)

Description

BACKGROUND OF THE INVENTION

Field of the Invention

[0001] The invention is in the field of fluid sample acquisition and testing. In particular, the invention is directed to an apparatus useful for acquisition of a blood sample from a site on a subject's body and testing the blood glucose content of the blood sample utilizing a test strip. The strip may be incorporated into a device adapted for both sampling and sensing in a single step. Methods of using the apparatus are also disclosed.

DESCRIPTION OF RELATED ART

[0002] Self monitoring of blood glucose generally requires the user to extract a volume of capillary blood and place it on a disposable element for analysis.

[0003] Devices for lancing a subject at an extraction site to obtain a small quantity of blood for testing on a test strip are known in the prior art. For example, U.S. Patent No. 6,558,402 B1 discloses a lancer having suitable mechanisms for piercing a subject's skin and obtaining a sample.

[0004] Generally, once an incision is made, the extraction site must be "milked" to express fluid from the site, and the fluid must then be transferred to a strip. The trend in test strip devices is toward using ever smaller sample volumes to obtain a measurement. However, even as the sample volume required to obtain a measurement has fallen to the sub-microliter range, it is still generally necessary to express the fluid from the extraction site and transfer the sample to the test strip. Devices and techniques for expressing blood from an incision made by a lancer are disclosed in the prior art, for example in U.S. Patent Nos. 6,793,633 B2, 6,071,251, and 6,752,817 B2.

[0005] Test strip sensing elements using amperometric and other techniques for determining the concentration of blood glucose in a blood sample are known in the prior art. U.S. Patent Nos. 6,258,229 B1, 6,143,164 and 5,437,999 each disclose examples of test strip construction for electrochemical measurement of blood glucose.

[0006] An integrated lancet/sensor is disclosed in U.S. Patent Application Publication No. U.S. 2004/0064068. However, it would be desirable, and would represent an advance over the current state of the art, to provide a more convenient apparatus to obtain a blood sample from an extraction site on a subject, express the blood from the site, and to transport the sample to a measurement site on a test strip without complicated interaction required from the user.

[0007] EP 1 714 614 A2, to which the preamble of independent claim 1 refers, discloses a blood glucose sensor for measuring blood glucose in a blood sample withdrawn from a blood sample extraction side on a subject's body. The sensor includes a test strip.

SUMMARY OF THE INVENTION

[0008] The subject of the invention is defined by each of independent claims 1 and 12.

[0009] According to the present invention, a test strip is provided which can be integrated with a lancer so that sample acquisition and testing are facilitated in a single device. The test strip component of the invention is adapted to detect an adequate sample volume for testing, and for relative movement while in a bent state with respect to a blood sample, to facilitate the transport of the blood sample to a measurement site on the test strip.

[0010] Specifically, a sensor according to the invention comprises a test strip having conductive contacts positioned thereon defining a blood sample volume detection area. The test strip further has a blood transport channel having a mouth at one end in fluid communication with the blood sample volume detection area and a measurement site at an opposite end of the blood transport channel. The test strip is movable in a bending state between a first position in which the blood sample volume detection area is opposite the blood sample extraction site and a second position in which the mouth of the blood transport channel is opposite the blood sample extraction site. A blood sample bridging the contacts defining the blood sample volume detection area permits electrical communication between the contacts to detect a blood sample volume, and the detected blood sample volume is sufficiently large that the blood sample moves through the blood transport channel to contact the measurement site when the mouth of the blood transport channel is moved to the blood sample extraction site.

[0011] A method of using the sensor requires positioning a test strip having a bending portion in a first position over a blood sample extraction site on a subject's body, so that the bending portion of the test strip is opposite the blood sample extraction site. A lancet is passed through the test strip and into a subcutaneous space in the subject's body beneath the sample extraction site and a blood sample is extracted. Blood accumulates in a blood sample volume detection area defined by conductive contacts on the test strip such that contacting the conductive contacts with the blood sample generates a signal when a minimum blood sample volume is detected. As the strip moves, the blood sample is moved through a blood transport channel to a blood glucose measurement site while maintaining the blood transport channel in a bending state and blood glucose in the blood sample is measured at the measurement site.

BRIEF DESCRIPTION OF THE FIGURES

[0012] Fig. 1 depicts a continuous test strip according to the invention.

[0013] Fig. 2A, Fig. 2B, Fig. 2C, and Fig. 2D each depict the test strip in a bending state at different positions

during the use of the test strip to obtain a measurement.

[0014] Fig. 3 depicts a discrete test strip according to the invention.

[0015] Fig. 4 depicts an alternative embodiment in which a lancet and a continuous test strip are contained within a housing.

[0016] Fig. 5 depicts a cartridge for holding a plurality of discrete test strips.

DETAILED DESCRIPTION OF THE INVENTION

[0017] Referring to **Fig. 1**, test strip **10** generally comprises a blood sample volume detection area 12. In the embodiment shown, a blood sample may be introduced into the volume detection area **12** when piercing hole **14** is pierced by a lancet (not shown in **Fig. 1**).

[0018] The blood sample detection area **12** is defined by contacts **16**, such that when a blood sample bridges the contacts, an electrical current flows between the contacts sufficient to indicate that a blood sample of sufficient volume to obtain a measurement has been obtained. The dimensioning and positioning of contacts **16** with respect to the sample detection area **12** is such that only a blood sample of the desired minimum volume will cause electrical current (a volume detection current) to flow between the contacts. The contacts **16** are placed so that they are electrically insulated from one another when a blood sample volume is not present, so the contacts do not short. Further, instrument contacts (not shown) are adapted to receive the signal obtained from the volume detection current for processing. In embodiments, a blood sample sufficient to obtain a measurement is in a range of about 0.2 μL to about 3.0 μL, preferably between about 0.2 μL to about 1 μL, and more preferably in a range of about 0.2 μL to about 0.5 μL.

[0019] Blood transport channel **18** has a mouth at one end in fluid communication with the blood sample volume detection area **12.** The blood transport channel **18** permits capillary movement of blood sample from the mouth of the channel to measurement site **20.** The blood sample detection area **12**, the blood transport channel **18** and the measurement site **20** are all located on a functional area **100** of the test strip.

[0020] In embodiments, functional areas **100** may be separated by neutral, or non-functional, areas **200**, which permits successive functional areas to be located on a single continuous strip. Likewise, seals **24**, **42** may be provided between functional areas, or between functional and non-functional areas, to isolate used portions of a strip, or to maintain unused functional areas in a desiccated state within a housing (not shown in **Fig. 1**). These isolation means (and their equivalents known to those of ordinary skill in the art, or hereafter developed), are useful when a continuous strip is to be used in combination with a housing.

[0021] The strip is capable of moving to enable a blood sample to move from the blood sample volume detection area **12** to the blood transport channel **18** and thereafter, by capillary action, to the measurement site **20.** In **Fig. 1,** a direction of movement of the strip is indicated at **30.** In the preferred embodiments, the volume of the blood sample detection area **12** and the blood transport **18** channel, taken together, is in a range between about 0.250 μL to about 0.5 μL. The channel may be sized, or tuned, so that the blood sample volume needed to obtain a measurement is just sufficient to allow for the sample to reach the measurement site by capillary motion.

[0022] **Fig. 2A** depicts the test strip **10** in a bending state positioned over a blood sample **32** at an extraction site **40.** The inflection **36** of the bend is positioned opposite the extraction site. A "bending state" means that when the strip contacts a sample, the profile of the strip is not a straight line.

[0023] Fig. **2B** depicts the test strip **10** with respect to the extraction site **40** in the next position from the position shown in **Fig. 2A**, after the strip is indexed, or moved. Blood sample **32** is shown accumulated in the blood sample volume detection area **12** defined by conductive contacts **16** on the test strip, such that the blood sample contacts the contacts. Electrical current flowing between the contacts **16** generates a signal, causing indexing of the strip to the next position. Maintaining the test strip in a bent state as the strip contacts the blood sample is believed to maintain the integrity of the blood droplet for a longer period of time, so that the surface tension of the blood sample droplet facilitates the movement of the blood sample toward the blood transport channel **18** with a smaller volume of blood sample than would otherwise be necessary. In effect, the surface tension of the droplet in combination with the movement of the test strip pulls the blood sample in a direction from the blood sample detection area **12** toward the mouth of the blood transport channel **18.**

[0024] **Fig. 2C** depicts the test strip **10** with respect to the extraction site **40** in the next position from the position shown in **Fig. 2B**, after the strip is indexed, in response to the blood volume detection step. The inflection **36** in the strip is at the mouth of the blood transport channel **18**, which is positioned over the extraction site.

[0025] **Fig. 2D** depicts the inflection **36** in the strip close to the measurement site at a still further position of the strip during use. The blood sample moves by capillary action through the blood transport channel to the reagent wells **44** at the measurement site.

[0026] To facilitate the movement of the blood sample **32** by capillary action in the blood transport channel **18**, the strip **10** should be constructed of appropriate materials and size. Conveniently for this purpose, the test strip depicted in **Fig. 3** (which in this case is a discrete strip) comprises a flexible plastic substrate layer **62** bearing an electrode layer **64** thereon defining separate electrodes: for example, a working electrode, reference electrode and/or counter electrode located in reagent wells **44** at the measurement site. Contacts **16** defining the blood volume detection area, as required, may likewise be defined in the conductive electrode layer. These electrodes

must make electrical contact with elements external to the strip so that the strip can be indexed in response to a volume detection signal, and so that the measurement can be obtained, displayed or recorded as desired. A channel forming layer **66**, defines a blood transport channel. Surface **12** is advantageously a hydrophobic plastic material.

[0027] As shown in Figs. **2B**, **2C** and **2D**, reagent wells **44** are positioned over electrodes on the test strip. Many configurations of working electrodes, reference electrodes and counter electrodes are known to effect electrochemical measurement of blood glucose content by passing a current between such electrodes in contact with a blood sample. Other methods of measurement are known, including optical methods, wherein a sample induces a color change in a substrate, and the color change is then evaluated by appropriate instrumentation to obtain a value relating to blood glucose content. The structure of the test strip described herein relates to acquisition of a blood sample and the transport of the blood sample to the measurement site 20, and is independent of the method of obtaining a measurement from the strip.

[0028] However, as explanation and not by way of limitation, a suitable electrochemical cell for measurement of blood glucose may be made using two relatively inert electrodes formed in areas **44** at the measurement site **20.** In a sufficiently sensitive test strip device, the wells defining a working area of the electrodes may have an area of about 0.19 mm^2 to about 1.8 mm^2. On at least the working electrode, a glucose-responsive reagent is deposited: generally including glucose oxidase enzyme, a redox mediator, and components to permit the reagent to be effectively coated on the electrodes, such as a surfactant and binder. Various reagent chemistries are known in the art and will not be elaborated upon herein

[0029] When at least the working electrode and counter electrode are in contact with the sample, a reaction at the working electrode occurs involving the blood glucose analyte in the sample. A variable related to the reaction at the working electrode, and the relative potential of the counter or reference electrode with respect to the working electrode may be measured, and the resulting signal may be processed to obtain the glucose concentration. Various algorithms are known to obtain these values, and to correct the values obtained for environmental factors. It is not critical, for example, that current is the measured variable, how that signal is processed or what method of measurement is used in the apparatus, and any such method known in the art or hereafter developed may be employed.

[0030] An important aspect of the invention is that the test strip is held in a bent state as it contacts the blood sample, and the inflection **36** of the bend moves along the strip during use, causing the blood sample to move with it. To achieve this, several configurations are possible.

[0031] **Fig 4** depicts a configuration in which the test strip is continuous (as in **Fig. 1**), such that multiple functional areas may be wound on storage roller **56** and contained within a housing **60.** Bending roller **58** provides a bending support supporting the strip in the bending state opposite the blood sample extraction site and used portions of the strip are taken up by take-up roller **54**. Lancet **72** is connected to a lancet plunger system **74**. While not limiting, a suitable plunger and lancet design for use in connection with this invention is disclosed in the aforesaid U.S. Patent No. 6,558,402 B1. The lancet is arranged in housing **60** so that upon suitable triggering, the lancet is plunged through the piercing hole **14** within or near the blood volume detection area **12** and into a subcutaneous space underneath the subject's skin. Given the particular embodiment shown in **Fig. 1,** the glucose sensor element is maintained in a desiccated state within the housing behind one seal **42** while the used sensors are maintained behind second seal **24.** The seals are advantageously made of an elastomeric material to ensure a snug fit in the opening of the housing where they are positioned, such that the seals can be pulled through the openings when the strip is indexed from one position to the next. Appropriate power elements **80** and an associated metering device (not shown) may also be provided within housing **60.**

[0032] Roller **54** may serve as means for advancing the functional areas **100** on the test strip. As shown in **Fig. 4**, roller **54** bearing the test strips is mounted with negator spring **88** preventing free movement of the continuous strip. Sprocket drive **84** engages the strip and functions with gear **82** and with escapement mechanism **86** to index the test strip by a predetermined amount on roller **54** when the device is fired, in response to signals that a blood sample volume has been detected, or in response to a signal generated when a measurement has been completed.

[0033] The drive mechanism is preferably in operative communication with a device for receiving the signal relating to the blood volume detection step and with a device for measuring, displaying and/or recording blood glucose measurements so that every aspect of the acquisition and sensing is integrated. For this purpose a suitable microprocessor may be used.

[0034] When a lancer and a strip are combined in a single device, or within a housing, as described above, the strip should be positioned with respect to the lancer so that the lancer is capable of piercing the test strip at a specified location, such as piercing hole **14**, so that blood is accumulated in the blood sample detection area. It may be desirable to incorporate means for expressing fluid from the blood sample extraction site onto the strip.

[0035] Other bending surfaces may be used to support the bending portion of the test strip in the bending state. **Fig. 5** discloses a cartridge system for containing a plurality of test strips. The cartridge feeds individual test strips past a guide member which serves as the bending surface presenting the test strip in a bending state to the blood sample extraction site **40** on the subject. Thus, the strips need not be contained within a housing together

with the lancet in order to be moved in a bending state. All that is required is means to sense a current from contacts **16** when a minimum volume blood sample is obtained on the strip. Therefore, contacts **16** must be in electrical communication with an element external to the strip at some point during use. One of ordinary skill in the art of test strip design may configure a plurality of test strips or functional areas in a circular configuration on a disc or drum for serial use, provided the strip is capable of presenting a bent portion to the blood sample extraction area.

[0036] The foregoing description of the explanatory embodiments is not to be considered as limiting the subject invention, which is defined by the claims appended hereto.

Claims

1. A blood glucose sensor for measuring blood glucose in a blood sample (32) withdrawn from a blood sample extraction site (40) on a subject's body, comprising a test strip (10);
characterized by
conductive contacts (16) positioned on the test strip (10) and defining a blood sample volume detection area (12);
said test strip (10) having a blood transport channel (18) having a mouth at one end in fluid communication with the blood sample volume detection area (12); and
a measurement site (20) at an opposite end of the blood transport channel (18);
the test strip (10) being movable in a bending state between a first position in which the blood sample volume detection area (12) is opposite the blood sample extraction site (40) and a second position in which the mouth of the blood transport channel (18) is opposite the blood sample extraction site (40),
wherein a blood sample (32) bridging the contacts (16) defining the blood sample volume detection area (12) permits electrical communication between the contacts (16) to detect a blood sample volume; and
wherein the detected blood sample volume is sufficiently large that the blood sample (32) moves through the blood transport channel (18) to contact the measurement site (20) when the mouth of the blood transport channel (18) is moved to said blood sample extraction site (40).

2. The blood glucose sensor of claim 1, further comprising a bending surface supporting the test strip (10) in a bending state opposite the blood sample extraction site (40).

3. The blood glucose sensor of claim 2, wherein the bending surface is a roller and the test strip (10) is movable over the roller between a first position in which the blood volume detection area (12) is opposite the extraction site (40) in a bending state and a second position in which blood is directed through the blood transport channel (18) to the measurement site (20) while the blood transport channel (18) is in a bending state.

4. The blood glucose sensor of claim 3, wherein the test strip (10) arranged on the roller is continuous, having a plurality of functional areas, each functional area on the test strip (10) comprising a volume detection area (12), blood transport channel (18) and measurement site (20), and each functional area is separated by a neutral portion, the functional areas being arranged on the test strip (10) for successive blood glucose measurements.

5. The blood glucose sensor of claim 4, further comprising a housing (60) and a lancet arranged in the housing to pass through the test strip (10) at the blood volume detection area (12) and to withdraw a blood sample from a subcutaneous space in a subject's body beneath the blood sample extraction site (40).

6. The blood glucose sensor of claim 5, further comprising a first seal (42) isolating the functional areas of the test strip (10) that have been used for blood glucose measurement from an environment outside of the housing (60), and a second seal (24) isolating the unused areas of test strip (10) from the environment.

7. The blood glucose sensor of claim 1, further comprising a cartridge containing a plurality of test strips (10), and a guide member maintaining individual test strips (10) in a bending state opposite a blood sample extraction site (40) on a patient's body.

8. The blood glucose sensor of claim 1, wherein the blood sample volume detection area (12) is sized so that a blood sample having a volume of about 0.2 μL to about 1.0 μL causes the blood sample to contact the conductive contacts (16) in the blood sample volume detection area (12) to generate a signal indicating that a minimum blood sample volume has been obtained.

9. The blood glucose sensor of claim 1, wherein a bending portion of the test strip (10) contacts a blood sample on the blood sample extraction site (40) so that surface tension of the blood sample in combination with the movement of the test strip (10) pulls the blood sample in a direction from the blood sample volume detection area (12) to the mouth of the blood transport channel (18).

10. The blood glucose sensor of claim 1, comprising an optical sensor or an electrochemical sensor for measuring blood glucose in the blood sample at the measurement site (20).

11. The blood glucose sensor of claim 2, comprising a plurality of test strips (10) in a circular configuration on a disc or drum.

12. A method for measuring blood glucose, comprising the steps of:

positioning a test strip (10) having a bending portion in a first position over a blood sample extraction site (40) on a subject's body, so that the bending portion of the test strip (10) is opposite the blood sample extraction site (40);
passing a lancet (72) through the test strip (10) and into a subcutaneous space in the subject's body beneath the sample extraction site (40) and extracting a blood sample;
accumulating blood in a blood sample volume detection area (12) defined by conductive contacts (16) on the test strip (10);
contacting the conductive contacts (16) with the blood sample to generate a signal when a minimum blood sample volume is detected;
moving the blood sample through a blood transport channel (18) to a blood glucose measurement site (20) while maintaining the blood transport channel (18) in a bending state;
measuring blood glucose in the blood sample at the measurement site (20).

13. The method of claim 12, wherein the test strip (10) is continuous and mounted on a roller maintaining the test strip (10) in a bent state opposite the blood sample extraction site (40), so that blood glucose measurements can be made on successive functional areas on the test strip (10), and comprising the further step of
advancing the continuous test strip (10) from a first position in response to the signal generated when a minimum blood sample volume is detected to a second position when the blood glucose measurement is made.

14. The method of claim 13, wherein the test strip (10) is positioned within a housing (60) and comprising the further step of advancing the test strip (10) from the second position when the measurement is made to a third position in which the functional areas of the test strip (10) are not exposed to an environment outside of the housing (60).

15. The method of claim 12, comprising the further step of supplying an individual test strip (10) from a cartridge containing a plurality of test strips (10) and maintaining the bending portion of the test strip (10) opposite the blood sample extraction site with a guide.

16. The method of claim 12, wherein the step of measuring the blood glucose is performed with an electrochemical sensor or with an optical sensor.

17. The method of claim 12, wherein the minimum blood sample volume is in a range of about 0.2 μL to about 1.0 μL.

Patentansprüche

1. Blutzuckersensor zur Messung des Blutzuckers in einer Blutprobe (32), die an einer Blutprobenentnahmestelle (40) eines Patientenkörpers entnommen wurde, mit einem Teststreifen (10):

gekennzeichnet durch
leitfähige Kontakte (16), die auf dem Teststreifen (10) angeordnet sind und einen Blutprobenvolumenerkennungsbereich (12) definieren;
wobei der Teststreifen (10) einen Bluttransportkanal (18) aufweist, dessen Mündung in Fluidverbindung mit dem Blutprobenvolumenerkennungsbereich (12) steht; und
eine Messstelle (20) an einem entgegengesetzten Ende des Bluttransportkanals (18);
wobei der Teststreifen (10) in gebogenem Zustand zwischen einer ersten Position, in welcher der Blutprobenvolumenerkennungsbereich (12) sich gegenüber der Blutprobenentnahmestelle (40) befindet, und einer zweiten Position, in welcher sich die Mündung des Bluttransportkanals (18) gegenüber der Blutprobenentnahmestelle (40) befindet, bewegbar ist,
wobei eine Blutprobe (32), welche die den Blutprobenvolumenerkennungsbereich (12) definierenden Kontakte (16) überbrückt, eine elektrische Verbindung zwischen den Kontakten (16) zur Erkennung eines Blutprobenvolumens ermöglicht, und
wobei das erkannte Blutprobenvolumen ausreichend groß ist, um es der Blutprobe (32) zu ermöglichen, sich **durch** den Bluttransportkanal (18) zu bewegen, um in Kontakt mit der Messstelle (20) zu gelangen, wenn die Mündung des Bluttransportkanals (18) zu der Blutprobenentnahmestelle (40) bewegt wird.

2. Blutzuckersensor nach Anspruch 1, ferner mit einer Biegefläche, welche den Teststreifen (10) im gebogenen Zustand gegenüber der Blutprobenentnahmestelle (40) trägt.

3. Blutzuckersensor nach Anspruch 2, bei welchem die

Biegefläche eine Rolle ist und der Teststreifen (10) zwischen einer ersten Position, in welcher sich der Blutprobenvolumenerkennungsbereich (12) im gebogenen Zustand gegenüber der Entnahmestelle (40) befindet, und einer zweiten Position über die Rolle bewegbar ist, in welcher Blut durch den Bluttransportkanal (18) zur Messstelle (20) geleitet wird, während sich der Bluttransportkanal (18) in einem gebogenen Zustand befindet.

4. Blutzuckersensor nach Anspruch 3, bei welchem der auf der Rolle angeordnete Teststreifen (10) endlos ist und mehrere Funktionsbereiche aufweist, wobei jeder Funktionsbereich auf dem Teststreifen (10) einen Volumenerkennungsbereich (12), einen Bluttransportkanal (18) und eine Messstelle (20) aufweist, und wobei die Funktionsbereiche jeweils durch einen neutralen Bereich getrennt sind, wobei die Funktionsbereiche auf dem Teststreifen (10) für aufeinanderfolgende Blutzuckermessungen angeordnet sind.

5. Blutzuckersensor nach Anspruch 4, ferner mit einem Gehäuse (60) und einer in dem Gehäuse angeordneten Lanzette zum Durchdringen des Teststreifens (10) in dem Blutprobenvolumenerkennungsbereich (12) und zum Entnehmen einer Blutprobe aus einem unter der Blutprobenentnahmestelle (40) gelegenen subkutanen Raum eines Patientenkörpers.

6. Blutzuckersensor nach Anspruch 5, ferner mit einer ersten Dichtung (42), welche die Funktionsbereiche des Teststreifens (10), welche zur Blutzuckermessung verwendet wurden, gegenüber einer Umgebung außerhalb des Gehäuses (60) isoliert, und einer zweiten Dichtung (24), welche die unbenutzten Bereiche des Teststreifens (10) gegenüber der Umgebung isoliert.

7. Blutzuckersensor nach Anspruch 1, ferner mit einer Kartusche, die mehrere Teststreifen (10) enthält, und einem Führungselement, das einzelne Teststreifen (10) in einem gebogenen Zustand gegenüber einer Blutprobenentnahmestelle (40) eines Patientenkörpers hält.

8. Blutzuckersensor nach Anspruch 1, bei welchem der Blutprobenvolumenerkennungsbereich (12) derart bemessen ist, dass eine Blutprobe mit einem Volumen von ungefähr 0,2 µl bis ungefähr 1,0 µl einen Kontakt der Blutprobe mit den leitfähigen Kontakten (16) in dem Blutprobenvolumenerkennungsbereich (12) bewirkt, um ein Signal zu erzeugen, das die Entnahme eines Mindestblutprobenvolumens angibt.

9. Blutzuckersensor nach Anspruch 1, bei welchem ein Biegebereich des Teststreifens (10) eine Blutprobe an der Blutprobenentnahmestelle (40) derart berührt, dass die Oberflächenspannung der Blutprobe in Kombination mit der Bewegung des Teststreifens (10) die Blutprobe von dem Blutprobenvolumenerkennungsbereich (12) weg zu der Mündung des Bluttransportkanals (18) zieht.

10. Blutzuckersensor nach Anspruch 1, mit einem optischen Sensor oder einem elektrochemischen Sensor zum Messen von Blutzucker in einer Blutprobe an der Messstelle (20).

11. Blutzuckersensor nach Anspruch 2, mit mehreren Teststreifen (10) in kreisförmiger Anordnung auf einer Scheibe oder Trommel.

12. Verfahren zum Messen von Blutzucker mit den folgenden Schritten:

Anordnen eines Teststreifens (10) mit einem Biegebereich in einer ersten Position über einer Blutprobenentnahmestelle (40) an einem Patientenkörper, so dass der Biegebereich des Teststreifens (10) der Blutprobenentnahmestelle (40) gegenüber liegt,
Führen einer Lanzette (72) durch den Teststreifen (10) und in einen unter der Blutprobenentnahmestelle (40) gelegenen subkutanen Raum in dem Patientenkörper und Entnehmen einer Blutprobe,
Sammeln von Blut in einem Blutprobenvolumenerkennungsbereich (12), der durch leitfähige Kontakte (16) auf dem Teststreifen (10) definiert ist;
Bringen der leitfähigen Kontakte (16) in Kontakt mit der Blutprobe zur Erzeugung eines Signals, wenn ein Mindestblutprobenvolumen erkannt wird;
Bewegen der Blutprobe durch einen Bluttransportkanal (18) an einer Blutzuckermessstelle (20), wobei der Bluttransportkanal (18) in einem gebogenen Zustand gehalten wird;
Messen des Blutzuckers in der Blutprobe an der Messstelle (20).

13. Verfahren nach Anspruch 12, bei welchem der Teststreifen (10) endlos ist und an einer Rolle angebracht ist, welche den Teststreifen (10) in einem gebogenen Zustand der Blutprobenentnahmestelle (40) gegenüberliegend hält, so dass Blutzuckermessungen in aufeinanderfolgenden Funktionsbereichen auf dem Teststreifen (10) durchgeführt werden können, und ferner mit dem folgenden Schritt:

bei der Blutzuckermessung, Vorwärtsbewegen des endlosen Teststreifens (10) aus einer ersten Position in Reaktion auf ein Signal, das bei Erkennung eines Mindestblutprobenvolumens erzeugt wird, in eine zweite Position.

14. Verfahren nach Anspruch 13, bei welchem der Teststreifen (10) in einem Gehäuse (60) angeordnet ist, und ferner mit dem weiteren Schritt des Vorwärtsbewegens des Teststreifens (10) aus der zweiten Position bei der Blutzuckermessung in eine dritte Position, in welcher die Funktionsbereiche des Teststreifens (10) einer Umgebung außerhalb des Gehäuses (60) nicht ausgesetzt sind.

15. Verfahren nach Anspruch 12, mit dem weiteren Schritt des Zuführens eines einzelnen Teststreifens (10) aus einer mehrere Teststreifen (10) enthaltenden Kartusche und Halten des Biegebereichs des Teststreifens (10) gegenüber der Blutprobenentnahmestelle mittels einer Führung.

16. Verfahren nach Anspruch 12, bei welchem der Schritt des Messens des Blutzuckers mit einem elektrochemischen Sensor oder mit einem optischen Sensor durchgeführt wird.

17. Verfahren nach Anspruch 12, bei welchem das Mindestblutprobenvolumen sich in einem Bereich zwischen ungefähr 0,2 μl und ungefähr 1,0 μl befindet.

Revendications

1. Capteur de glycémie pour mesurer la glycémie dans un échantillon de sang (32) retiré d'un site d'extraction d'échantillon de sang (40) sur le corps d'un patient, comprenant une bande de test (10) ;
caractérisé par :

des contacts conducteurs (16) positionnés sur la bande de test (10) et définissant une zone de détection de volume d'échantillon de sang (12) ;
ladite bande de test (10) ayant un canal de transport de sang (18) ayant une embouchure au niveau d'une extrémité en communication de fluide avec la zone de détection de volume d'échantillon de sang (12) ; et
un site de mesure (20) au niveau d'une extrémité opposée du canal de transport de sang (18) ;
la bande de test (10) étant mobile dans un état de flexion entre une première position dans laquelle la zone de détection de volume d'échantillon de sang (12) est opposée au site d'extraction d'échantillon de sang (40) et une deuxième position dans laquelle l'embouchure du canal de transport de sang (18) est opposée au site d'extraction d'échantillon de sang (40),
dans lequel un échantillon de sang (32) reliant les contacts (16) définissant la zone de détection de volume d'échantillon de sang (12) permet la communication électrique entre les contacts (16) afin de détecter un volume d'échantillon de sang ; et
dans lequel le volume d'échantillon de sang détecté est suffisamment important de sorte que l'échantillon de sang (32) se déplace à travers le canal de transport de sang (18) pour entrer en contact avec le site de mesure (20) lorsque l'embouchure du canal de transport de sang (18) est déplacée vers ledit site d'extraction d'échantillon de sang (40).

2. Capteur de glycémie selon la revendication 1, comprenant en outre une surface de flexion supportant la bande de test (10) dans un état fléchi opposé au site d'extraction d'échantillon de sang (40).

3. Capteur de glycémie selon la revendication 2, dans lequel la surface de flexion est un rouleau et la bande de test (10) est mobile sur le rouleau entre une première position dans laquelle la zone de détection de volume de sang (12) est opposée au site d'extraction (40) dans un état de flexion et une deuxième position dans laquelle le sang est dirigé à travers le canal de transport de sang (18) jusqu'au site de traitement (20) alors que le canal de transport de sang (18) est dans un état de flexion.

4. Capteur de glycémie selon la revendication 3, dans lequel la bande de test (10) agencée sur le rouleau est continue, ayant une pluralité de zones fonctionnelles, chaque zone fonctionnelle sur la bande de test (10) comprenant une zone de détection de volume (12), un canal de transport de sang (18) et un site de mesure (20), et chaque zone fonctionnelle est séparée par une partie neutre, les zones fonctionnelles étant agencées sur la bande de test (10) pour des mesures successives de glycémie.

5. Capteur de glycémie selon la revendication 4, comprenant en outre un boîtier (60) et une lancette agencée dans le boîtier afin de traverser la bande de test (10) au niveau de la zone de détection de volume de sang (12) et pour retirer un échantillon de sang d'un espace sous cutané dans le corps d'un patient au-dessous du site d'extraction d'échantillon de sang (40).

6. Capteur de glycémie selon la revendication 5, comprenant en outre un premier joint d'étanchéité (42) isolant les zones fonctionnelles de la bande de test (10) qui ont été utilisées pour mesurer la glycémie, d'un environnement à l'extérieur du boîtier (60), et un deuxième joint d'étanchéité (24) isolant les zones non utilisées de la bande de test (10), de l'environnement.

7. Capteur de glycémie selon la revendication 1, comprenant en outre une cartouche contenant une pluralité de bandes de test (10), et un élément de guidage maintenant des bandes de test (10) individuel-

les dans un état de flexion opposé à un site d'extraction d'échantillon de sang (40) sur le corps d'un patient.

8. Capteur de glycémie selon la revendication 1, dans lequel la zone de détection de volume d'échantillon de sang (12) est dimensionnée de sorte qu'un échantillon de sang ayant un volume d'environ 0,2 μL à 1,0 μL amène l'échantillon de sang à entrer en contact avec les contacts conducteurs (16) dans la zone de détection de volume d'échantillon de sang (12) afin de générer un signal indiquant qu'un volume d'échantillon de sang minimum a été obtenu.

9. Capteur de glycémie selon la revendication 1, dans lequel une partie de flexion de la bande de test (10) est en contact avec un échantillon de sang sur le site d'extraction d'échantillon de sang (40) de sorte que la tension de surface de l'échantillon de sang en combinaison avec le mouvement de la bande de test (10) tire l'échantillon de sang dans une direction allant de la zone de détection de volume d'échantillon de sang (12) jusqu'à l'embouchure du canal de transport de sang (18).

10. Capteur de glycémie selon la revendication 1, comprenant un capteur optique ou un capteur électrochimique pour mesurer la glycémie dans l'échantillon de sang sur le site de mesure (20).

11. Capteur de glycémie selon la revendication 2, comprenant une pluralité de bandes de test (10) dans une configuration circulaire sur un disque ou un tambour.

12. Procédé pour mesurer la glycémie, comprenant les étapes consistant à :

positionner une bande de test (10) ayant une partie de flexion dans une première position sur un site d'extraction d'échantillon de sang (40) sur le corps d'un patient, de sorte que la partie de flexion de la bande de test (10) est opposée au site d'extraction d'échantillon de sang (40) ;
faire passer une lancette (72) à travers la bande de test (10) et dans un espace sous cutané dans le corps du patient au-dessous du site d'extraction d'échantillon (40) et extraire un échantillon de sang ;
accumuler du sang dans une zone de détection de volume d'échantillon de sang (12) définie par des contacts conducteurs (16) sur la bande de test (10) ;
faire entrer en contact les contacts conducteurs (16) avec l'échantillon de sang afin de générer un signal lorsqu'un volume d'échantillon de sang minimum est détecté ;
déplacer l'échantillon de sang à travers un canal de transport de sang (18) jusqu'à un site de mesure de glycémie (20) tout en maintenant le canal de transport de sang (18) dans un état de flexion ;
mesurer la glycémie dans l'échantillon de sang au niveau du site de mesure (20).

13. Procédé selon la revendication 12, dans lequel la bande de test (10) est continue et montée sur un rouleau maintenant la bande de test (10) dans un état fléchi opposé au site d'extraction d'échantillon de sang (40), de sorte que les mesures de glycémie peuvent être réalisées sur des zones fonctionnelles successives sur la bande de test (10), et comprenant l'étape supplémentaire consistant à :

faire avancer la bande de test (10) continue, d'une première position en réponse au signal généré lorsqu'un volume d'échantillon de sang minimum est détecté jusqu'à une deuxième position lorsque la mesure de glycémie est réalisée.

14. Procédé selon la revendication 13, dans lequel la bande de test (10) est positionnée à l'intérieur d'un boîtier (60) et comprenant l'étape supplémentaire consistant à faire avancer la bande de test (10) de la deuxième position lorsque la mesure est réalisée jusqu'à une troisième position dans laquelle les zones fonctionnelles de la bande de test (10) ne sont pas exposées à un environnement à l'extérieur du boîtier (60).

15. Procédé selon la revendication 12, comprenant l'étape supplémentaire consistant à fournir une bande de test (10) individuelle d'une cartouche contenant une pluralité de bandes de test (10) et maintenir la partie de flexion de la bande de test (10) opposée au site d'extraction d'échantillon de sang avec un guide.

16. Procédé selon la revendication 12, dans lequel l'étape consistant à mesurer la glycémie est réalisée avec un capteur électrochimique ou avec un capteur optique.

17. Procédé selon la revendication 12, dans lequel le volume d'échantillon de sang minimum est de l'ordre d'environ 0,2 μL à environ 1,0 μL.

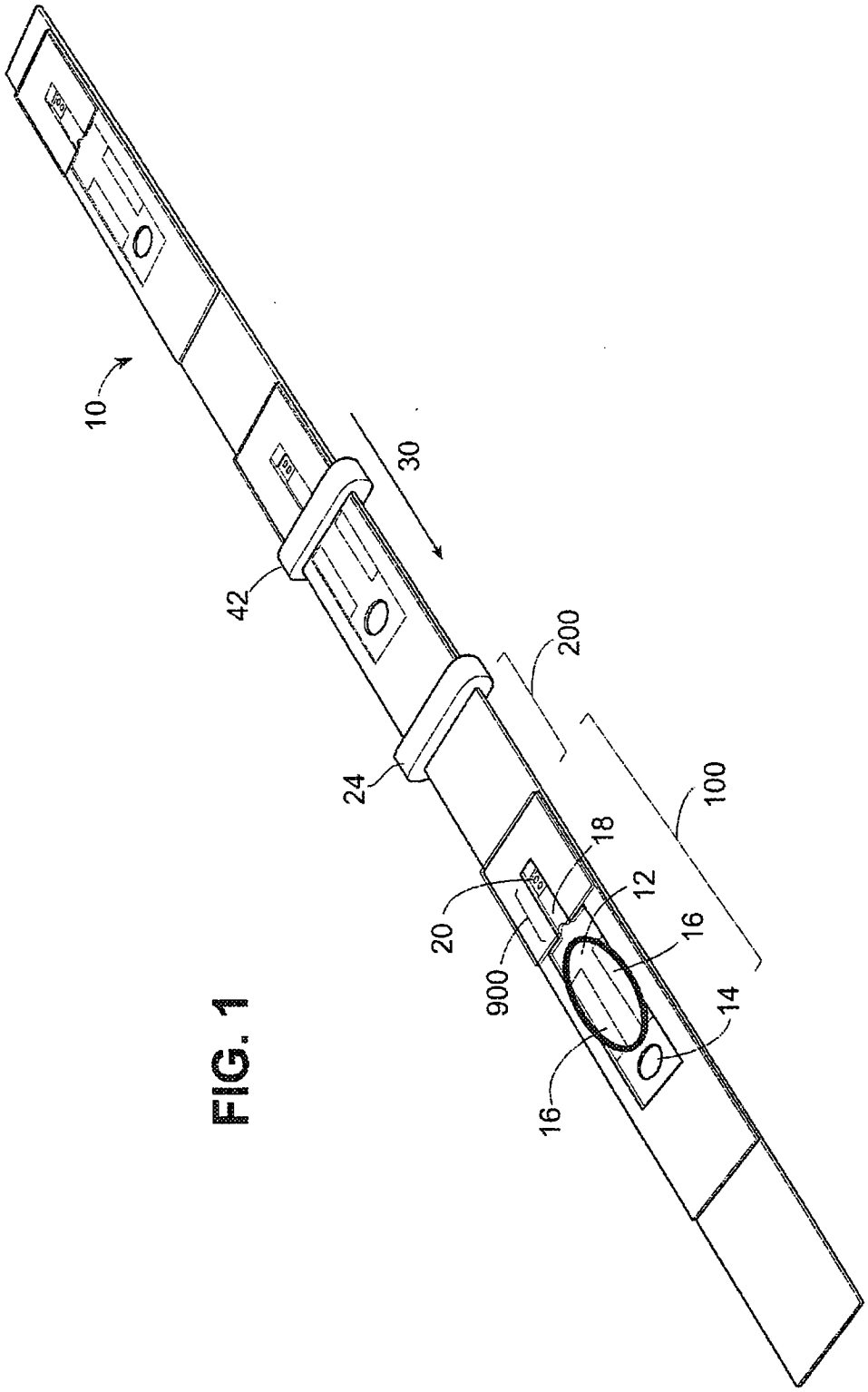


FIG. 1

FIG. 2A

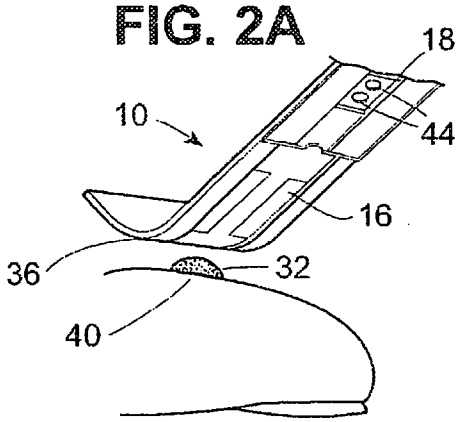


FIG. 2B

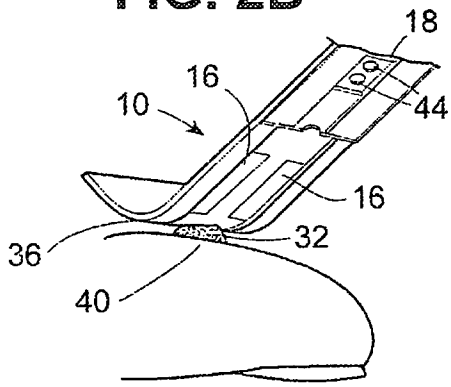


FIG. 2C

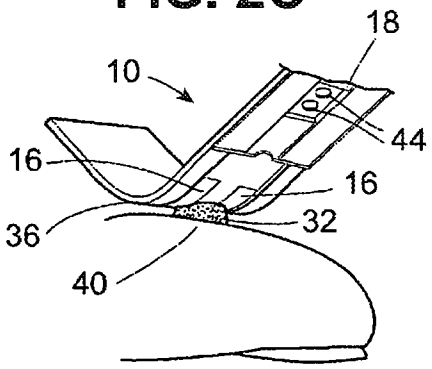


FIG. 2D

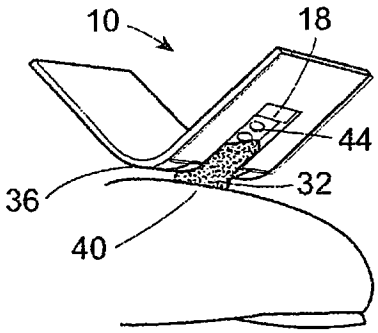


FIG. 3

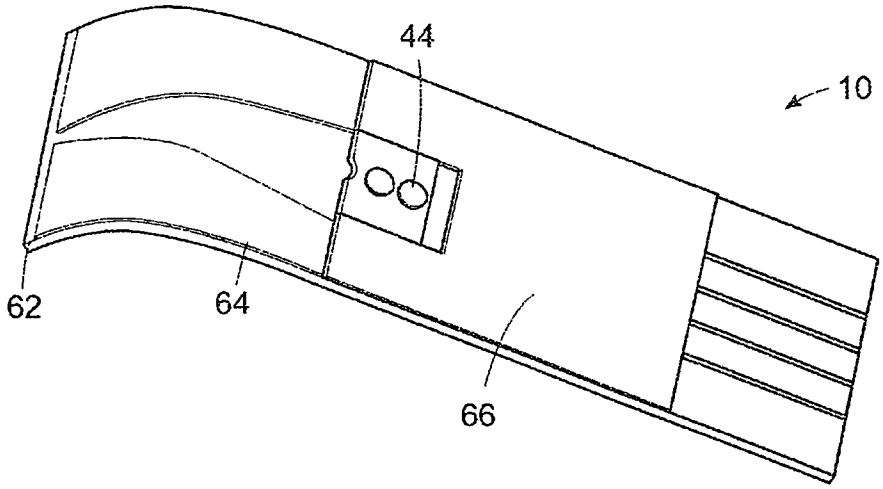


FIG. 5

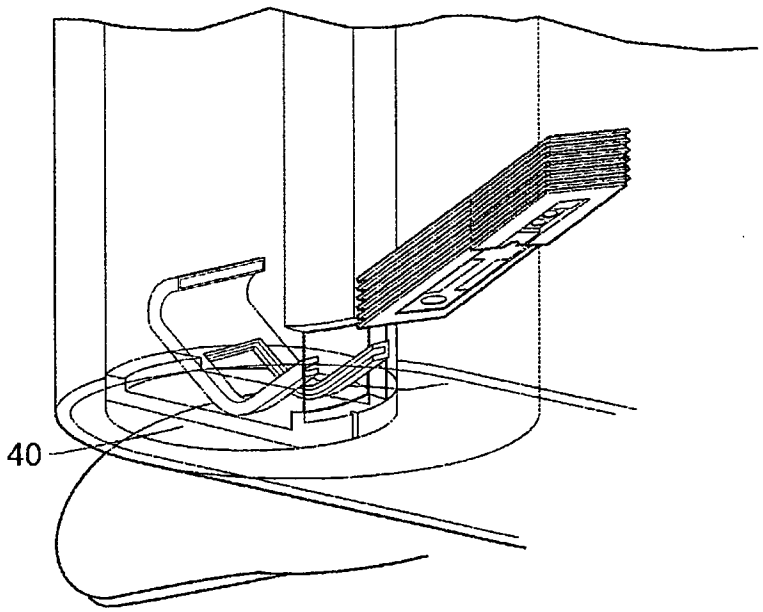
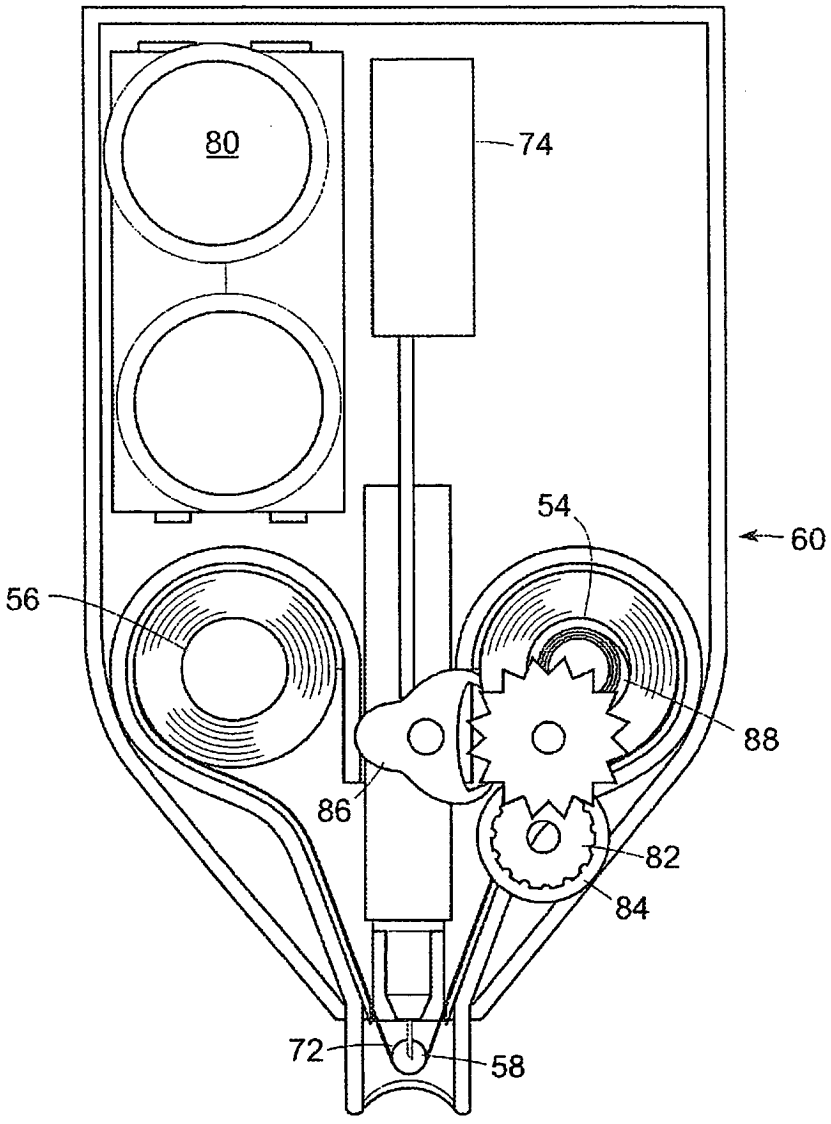


FIG. 4



REFERENCES CITED IN THE DESCRIPTION

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

Patent documents cited in the description

- US 6558402 B1 **[0003] [0031]**
- US 6793633 B2 **[0004]**
- US 6071251 B2 **[0004]**
- US 6752817 B2 **[0004]**
- US 6258229 B1 **[0005]**
- US 6143164 B1 **[0005]**
- US 5437999 B1 **[0005]**
- US 20040064068 A **[0006]**
- EP 1714614 A2 **[0007]**

专利名称(译)	血糖传感器		
公开(公告)号	EP2275034B1	公开(公告)日	2012-04-04
申请号	EP2010169404	申请日	2010-07-13
[标]申请(专利权)人(译)	贝克顿·迪金森公司		
申请(专利权)人(译)	碧迪公司		
当前申请(专利权)人(译)	碧迪公司		
[标]发明人	MONDRO JASON SCHIFF DAVID ALBERT JONATHAN		
发明人	MONDRO, JASON SCHIFF, DAVID ALBERT, JONATHAN		
IPC分类号	A61B5/151 A61B5/00 G01N33/487		
CPC分类号	A61B5/14532 A61B5/1486 A61B5/150022 A61B5/150358 A61B5/150412 A61B5/150503 A61B5/1519 A61B5/157 A61B2562/0295 G01N33/48764		
代理机构(译)	VON克莱斯勒SELTING WERNER		
优先权	12/502594 2009-07-14 US		
其他公开文献	EP2275034A1		
外部链接	Espacenet		

摘要(译)

本申请涉及用于血液样本采集和测试的装置和方法。该装置包括具有血液样本体积检测区域（12）的测试条（10），其中累积血液样本并检测最小血液样本体积。一旦检测到最小血液样本量，就将测试条相对于血液样本提取位置移动，使得测试条的弯曲表面呈现给血液样本，利用血液样本液滴的表面张力来促进移动将血液样品送到条带上的测量部位，测量样品中的血糖。

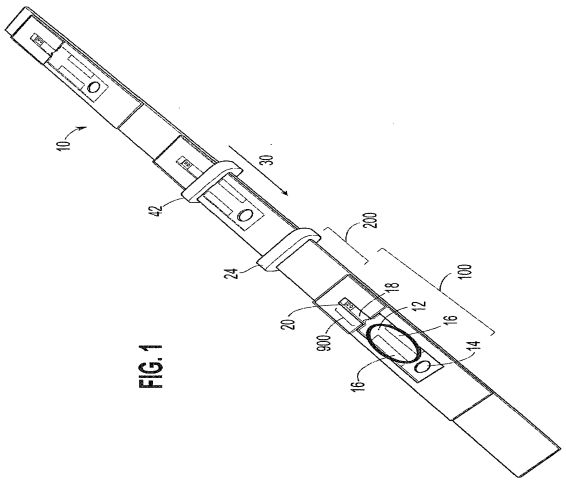


FIG. 1