(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
8 June 2006 (08.06.2006)

PCT

(10) International Publication Number
WO 2006/059241 A2

(51) International Patent Classification: Not classified

(21) International Application Number:
PCT/IB2005/004101

(22) International Filing Date:
7 November 2005 (07.11.2005)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/625,500 5 November 2004 (05.11.2004) US

(71) Applicant *(for all designated States except US)*: **ALBATROS TECHNOLOGIES GMBH & CO. KG** [DE/DE]; Lise-Meitner-Strasse 7, 48161 Münster (DE).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: **BARTETZKO, Norbert** [DE/DE]; Beverfördering 54, 59071 Hamm (DE).

(74) Agent: **STELLBRINK, Axel**; Vossius & Partner, POB 86 07 67, 81634 Munich (DE).

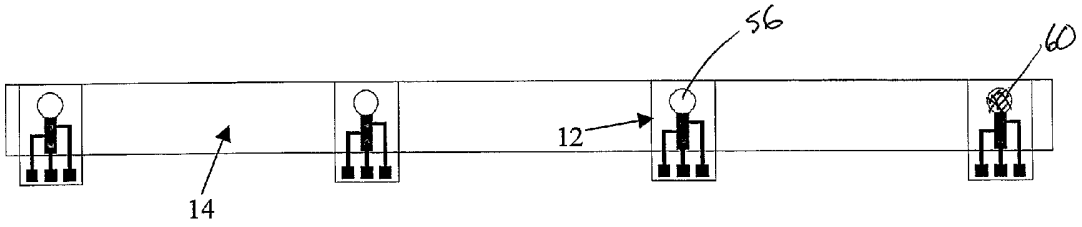
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) **Title:** ANALYTE SENSING DEVICE MOUNTED ON A FLEXIBLE SUBSTRATE



(57) **Abstract:** A device is provided for use with a meter for measuring analyte levels. In one embodiment, the device comprises a film and a plurality of analyte sensing devices mounted on the film. The device may also include a first container housing film having unused analyte sensing devices and a second container configured for holding film with used analyte sensing devices, wherein the film extends from the first container to the second container to transport used analyte sensing devices between the containers. The analyte sensing devices may have a plurality of electrodes electrically coupled to contact pads configured to transmit the signal to the meter.

WO 2006/059241 A2

ANALYTE SENSING DEVICE MOUNTED ON A FLEXIBLE SUBSTRATE

BACKGROUND OF THE INVENTION

Technical Field:

The technical field relates to analyte detecting devices, and more specifically, to sample capture and the use of analyte detecting devices.

Background Art:

Test strips are known in the medical health-care products industry for analyzing analyte levels such as but not limited to, glucose levels in blood. For this type of analysis, a drop of blood is typically obtained by making a small incision in the fingertip, creating a small wound, which generates a small blood droplet on the surface of the skin. A test strip is brought by the user to the blood droplet at the wound and engaged in a manner to bring blood to an analysis site on the test strip. The test strip is then coupled to a metering device which typically uses an electrochemical technique to determine the amount of glucose in the blood.

Early methods of using test strips required a relatively substantial volume of blood to obtain an accurate glucose measurement. This large blood requirement made the monitoring experience a painful one for the user since the user may need to lance deeper than comfortable to obtain sufficient blood generation. Alternatively, if insufficient blood is spontaneously generated, the user may need to "milk" the wound to squeeze enough blood to the skin surface. Neither method is desirable as they take additional user effort and may be painful. The discomfort and inconvenience associated with such lancing events may deter a user from testing their blood glucose levels in a rigorous manner sufficient to control their diabetes.

A further impediment to patient compliance is the amount of time that it takes for a glucose measurement to be completed. Known devices can take a substantial amount of time to arrive at a glucose level. The more time it takes to arrive at a measurement, the less the likely that the user will stay with their testing regime. A further impediment to patient compliance is the amount of time that at lower volumes, it becomes even more important that

blood or other fluid sample be directed to a measurement device without being wasted or spilled along the way. Known devices do not effectively handle the low sample volumes in an efficient manner. Accordingly, improved sensing devices are desired to increase user compliance and reduce the hurdles associated with analyte measurement.

SUMMARY OF THE INVENTION

The present invention provides solutions for at least some of the drawbacks discussed above. Specifically, some embodiments of the present invention provide an improved apparatus for measuring analyte levels in a body fluid. The present invention also provided improved techniques for sample capture used with such analyte detecting devices. Some embodiments may present an orthogonal arrangement of penetrating and sensing module including sample capture. At least some of these and other objectives described herein will be met by embodiments of the present invention.

A further understanding of the nature and advantages of the invention will become apparent by reference to the remaining portions of the specification and drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 shows one embodiment of the present invention.

Figure 2 shows a top down cross-sectional view of the device of Figure 1.

Figure 3 is a perspective view of a device according the present invention used with a cartridge containing a plurality of penetrating members.

Figure 4 is an exploded perspective view of another embodiment of the present invention with a housing with a display.

Figures 5 and 6 show a plurality of testing devices arranged in linear configurations.

Figure 7 shows one embodiment of a flexible substrate having a plurality of testing devices.

Figure 8 shows another embodiment of a flexible substrate having a plurality of testing devices.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the invention, as claimed. It may be noted that, as used in the specification and the appended claims, the singular forms "a", "an" and "the" include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to "a material" may include mixtures of materials, reference to "a chamber" may include multiple chambers, and the like. References cited herein are hereby incorporated by reference in their entirety, except to the extent that they conflict with teachings explicitly set forth in this specification.

In this specification and in the claims which follow, reference will be made to a number of terms which shall be defined to have the following meanings:

"Optional" or "optionally" means that the subsequently described circumstance may or may not occur, so that the description includes instances where the circumstance occurs and instances where it does not. For example, if a device optionally contains a feature for analyzing a blood sample, this means that the analysis feature may or may not be present, and, thus, the description includes structures wherein a device possesses the analysis feature and structures wherein the analysis feature is not present.

In one embodiment of the present invention, integration is at the level of the device rather that on the disposable. In one embodiment, there will be two modules; multiple analyte sensing devices on a film, which is dispensing in a film canister mode, and the penetrating members are arranged on a radial cartridge or disk. Actuation of the penetrating member is through the film or flexible substrate where the penetrating members transect at the sample import of the analyte sensing devices mounted on the film. The contamination/hygiene issue is resolved because the finger touches only a new front end for each testing event. In a sense, this has disintegrated the integrated M2 disposable. Packaging and desiccant issues are solved. In one embodiment, a vial with a cap containing desiccant may be used. Embodiments of the present invention may get around the problem of having to individually seal the analyte sensing devices and open them at the same time as the penetrating member chambers are opened.

Referring now to Figure 1, one embodiment the invention according to the present invention will now be described. In this embodiment, the invention comprises of a canister 10 having a plurality of analyte sensing devices 12 on a film 14 instead of a disk. The analyte sensing devices may be linearly spaced and may be coupled to a mesh for improved sample capture. After (or before) each use, the film is advanced to present a fresh unused analyte sensing device 12 and mesh combination. By way of example and not limitation, analyte sensing devices 12 may be spaced on a film such that at any point only one analyte sensing device 12 is exposed to the open environment or available for use. New, unused analyte sensing devices 12 may be housed in a storage container 16 and used analyte sensing devices 12 may be placed in another container 18. The containers 16 and 18 may each or both have seals mounted at the openings to keep their interior environment in a sealed condition. As seen in Figure 1, the film 14 may also include holes 20 along the edges of the film. For example and not limitation, these holes 20 may be used to act as guides for the film. In other embodiments, they may be used as tractor holes to advance the film. The holes may be round, square, triangular, other shaped, or combination of any of the above. Still other embodiments may use the holes for indexing to determine position of the film and whether an analyte sensing device 12 is properly positioned.

Figure 2 shows a top down, cross-sectional view of the embodiment of Figure 1. As seen in Figure 2, the film 14 may support an analyte sensing device 12. The film 14 may rolled inside the containers 16 and 18 to maximize the number of analyte sensing devices 12 that may be held in each container 16 or 18. There may be a spool 17 or other device in the center of the containers 16 or 18 to manage the film with the analyte sensing devices. There may be seal elements 19 (shown in phantom) to maintain a seal against the film 14 to minimize exposure of the environment inside the container to the outside environment. These may be rubber flaps or polymer elements.

Referring now to Figure 3, another aspect of the present invention will now be described. Figure 3 shows the canister 10 positioned so that a penetrating member 22 from the radial cartridge 24 will pass through an opening on the analyte sensing device 12 and pierce tissue to sample body fluid. The tip of the penetrating member 22 extends through the

plane of the sensing device 12 without having to pierce it. In other embodiments, the tip will pierce a mesh placed in the opening to facilitate sample capture.

Referring still to Figure 3, the radial cartridge 24 may contain a plurality of penetrating members 22 so that a plurality of analyte sensing devices 10 may be mated with a plurality of penetrating members 22. This allows for multiple lancing and analyte measurement events. For this embodiment, the radial cartridge 24 may rotate to bring a new, unused penetrating member into an active position for lancing. This may occur as the user readies the device for a new lancing event. In other embodiments, this may occur immediately after a lancing event. In yet another embodiment, the canister 10 may also be configured to advance the film 14 in a manner coordinated with the rotation of the radial cartridge 24 so that an unused analyte sensing device is presented when an unused penetrating member is brought to the active position. In some embodiments, the movement of the radial cartridge 24 and the film 14 in canister 10 are not linked. Both the canister 10 and the radial cartridge 24 may be enclosed in one device with one housing, thus creating an integrated device for lancing and for measurement of analytes. In other embodiments, the canister 10 may be in a separate housing that is mated to another housing that contains the radial cartridge 24 with its penetrating members. The penetrating members in the cartridge 24 may be bare lancets without any molded parts which increase manufacturing cost.

Figure 4 shows an exploded perspective view of another embodiment of the present invention. In this embodiment, the canister 10 is contained in a separate housing 30. The housing 30 may include a window 32 that allows for an analyte sensing device 12 to be accessible to the user. A new, unused analyte sensing device 12 positioned in the window 32 is considered to be in an active position. The housing 30 may also include a display 34 for showing analyte measurements. Some embodiments may also show other information such as but not limited to battery status, date/time, number of unused analyte sensing devices 12 remaining in the canister, number of used analyte sensing devices 12, error signals, or other information to the user. The housing 30 may also include buttons to control the device. In the embodiment of Figure 4, there is an on/off button 36 and user setting button 38. A lever 40 may also be on the housing to allow the user to mechanically advance the film 14 that supports the device 12. In other embodiments, an electric motor or other powered actuator

may be used to advance the film 14. A gear 42 in or on the container 10 may be used to rotate a spool 44 of the film 12. Some embodiments may have only one spool of the container 10 that is driven to advance the film, while others may have both spools driven. The housing 30 may be designed to mate with the housing of a penetrating member driver. This penetrating member drive may contain one, two, or two or more penetrating members. Having multiple penetrating members allows the same device to be used for multiple testing events without reloading.

Referring now to Figures 5 and 6, the analyte sensing devices 12 will be described in further detail. In one embodiment, the device includes a hole or opening 50 through which a penetrating member can pass. Body fluid drawn from a patient will be captured and spread over the electrodes 52 on the device. The electrodes 52 are connected by conductive lines to contact pads 54 which can carry electrical signals from the electrodes to a meter that measures the analyte levels in the fluid over the electrodes 52.

Figure 5 shows that the analyte sensing devices 12 may be manufactured one next to another and then separated into individual members 12. The device may include three electrodes 52, each used for a test event. The electrodes 52 may be a working electrode, a reference electrode, and a counter electrode. In one embodiment, only the working electrode includes enzymes or reagents for reacting with the analyte. In other embodiments, hydrophilic film 53 covers all three electrodes. Other embodiments may have a film 55 that only covers two electrodes.

Figure 6 shows that the individual analyte sensing devices may then be placed on a film or other flexible substrate 14 which may then be placed inside canister 10. To cut production costs, it may be desirable to produce a lot of small analyte sensing devices on a sheet (high density production) and than cut the sheet to single members and place the members on a much bigger support for handling reasons. As seen in Figure 6, each analyte sensing device 12 may have an opening 56. The opening may be a true opening or include a mesh 60.

Figure 7 shows that in one embodiment, the analyte sensing devices 12 may be mounted on a film 14 that includes holes 20 which may be used for indexing, tractoring, or

other functions, depending on the device using the film. Some embodiments may have the sensing devices 12 mounted flush with the film 14.

Figures 8A-8E show one embodiment where a mesh 60 may be placed in the opening 50 of the analyte sensing device 12. Blood or body fluid delivery can be aided via a mesh lollipop that may be entirely fill the opening 50 or partially fill the opening 50. Figure 8A shows that the film 14 and member 12 may be mounted to be on a front end of a penetrating member driving device 62. The device 62 may use an electromechanical driver to advance the penetrating member such as that described in US application 10/127,395 fully incorporated by reference herein for all purposes. U.S. Provisional Application 60/625,500 is also fully incorporated herein by reference for all purposes. Figure 8B shows that the device may be arranged in a film canister type configuration. Figure 8C shows three electrodes 52 mounted on a sensing device. Figure 8D dhows that the hole 56 may include a mesh to improve sample capture. The tractor holes 20 may also be used to align the film and the contact pads 63. Figure 8E also shows the contact pads 63.

The advantages of the present design include reduced contamination problem, easy packaging & humidity control, and low blood sample volume. Prevention of air-borne contamination into new detecting members cap may be an issue however. The device desires to have low humidity over 60 days. Detecting-member-to-detecting-member isolation and detecting-member-to-penetrating-member isolation is implicit in the design therefore simplifying sterilization. In addition, no air vent is needed, nor is an additional disposable front end. In one embodiment, low production costs (5 x 5 mm analyte sensing devices) can be achieved by using high density printing of analyte sensing devices 12 which are then placed in the film 14 in a separated manner allowing sample capture without contamination of the nearest neighbor. High volume production may be possible by drawing from electronic and semi-conductor industry: pick and place, robotics, etc. The desiccant will be easy to add. If desired, the present invention may be configured to individually seal each analyte sensing device with desiccant in a blister or in the cap. The electrical contact to the meter should be straightforward. The sensing devices may be located at the instrument front end. In some embodiments, there is no physical connection between lancing and sensing module.

The present invention may include a method of manufacturing of placing the sensing devices 12 onto the film or flexible substrate 14 and then having at least a portion wound into a container to maintain sterility. Desiccant may also be included in the container 16 or 18.

While the invention has been described and illustrated with reference to certain particular embodiments thereof, those skilled in the art will appreciate that various adaptations, changes, modifications, substitutions, deletions, or additions of procedures and protocols may be made without departing from the spirit and scope of the invention. For example, with any of the above embodiments, the low volume analyte sensing device may be used with any of the cartridges disclosed herein or in related patent applications.

The publications discussed or cited herein are provided solely for their disclosure prior to the filing date of the present application. Nothing herein is to be construed as an admission that the present invention is not entitled to antedate such publication by virtue of prior invention. Further, the dates of publication provided may be different from the actual publication dates which may need to be independently confirmed. All publications mentioned herein are incorporated herein by reference to disclose and describe the structures and/or methods in connection with which the publications are cited.

Expected variations or differences in the results are contemplated in accordance with the objects and practices of the present invention. It is intended, therefore, that the invention be defined by the scope of the claims which follow and that such claims be interpreted as broadly as is reasonable.

WHAT IS CLAIMED IS:

1. A device for use with a meter for measuring analyte levels, the device comprising:

a flexible substrate;

a plurality of analyte detectors mounted on the substrate;

wherein the analyte detectors have a plurality of electrodes electrically coupled to contact pads configured to transmit the signal to the meter.

2. A device for use with a meter for measuring analyte levels, the device comprising:

a film;

a plurality of analyte sensing devices mounted on said film;

a first container housing film having unused analyte sensing devices; and

a second container configured for holding film with used analyte sensing devices, wherein the film extends from the first container to the second container to transport used analyte sensing devices between the containers;

wherein said analyte sensing devices having a plurality of electrodes electrically coupled to contact pads configured to transmit the signal to the meter.

3. The device of claim 2 further comprising microfluidics on the analyte sensing device for guiding body fluid to the electrodes.

4. The device of claim 2 where the analyte sensing device has a hole for allowing a penetrating member to pass through the hole.

5. The device of claim 2 where the analyte sensing devices each includes at least three electrodes.

6. The device of claim 2 wherein the analyte sensing devices are adhered to the film.

7. The device of claim 2 wherein the first container and second container are formed from a single housing.

8. The device of claim 2 wherein the first container and second container are coupled together by an intermediate structure.

9. A device comprising:
a substrate;
at least one electrode on said substrate;
printable hydrogel or a hydrogel coating over the electrode; and
microfluidics coupled to the hydrogel for drawing sample fluid to the hydrogel over the electrode; and
a flexible film, wherein said substrate is mounted on said film.

10. The device of claim 9 further comprising a first container and a second container coupled together by an intermediate structure, wherein said film is movable between the first container and the second container.

11. The device of claim 9 further comprising a first container and a second container coupled together by an intermediate structure, wherein said film is movable between the first container and the second container;
at least one spool in each container for rolling said film therein.

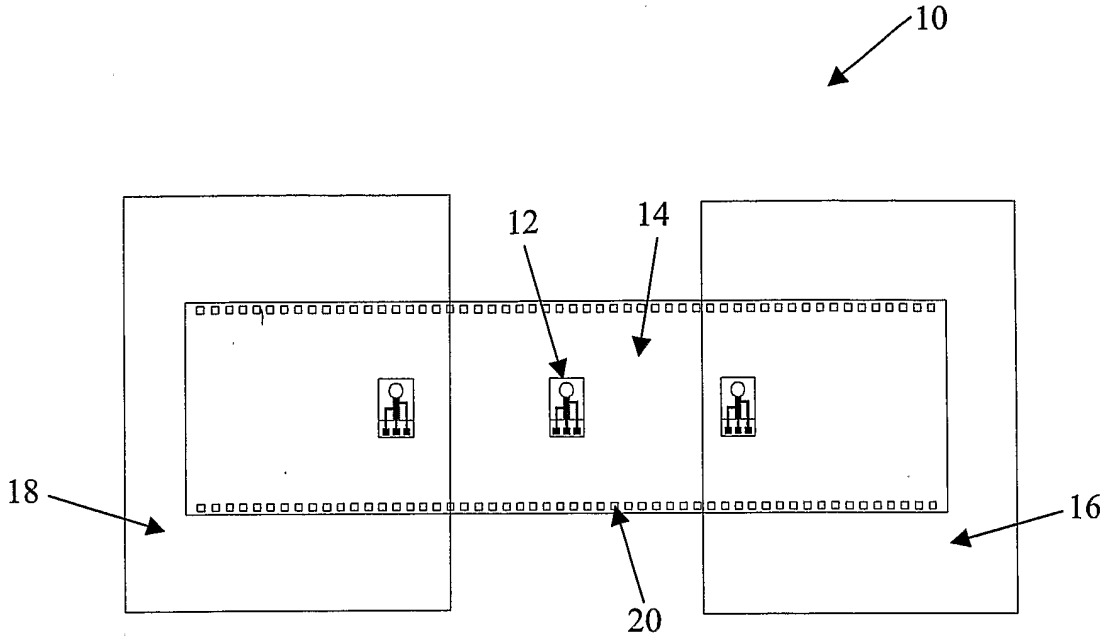


Figure 1

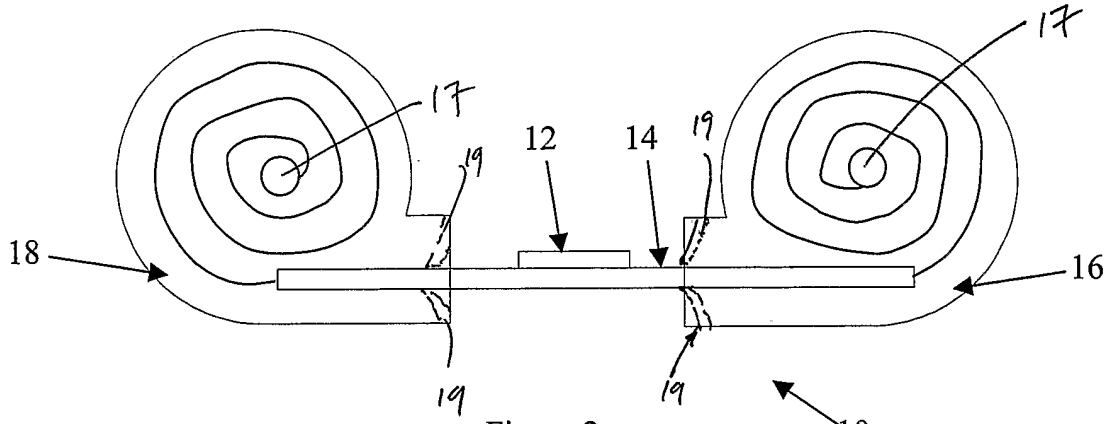


Figure 2

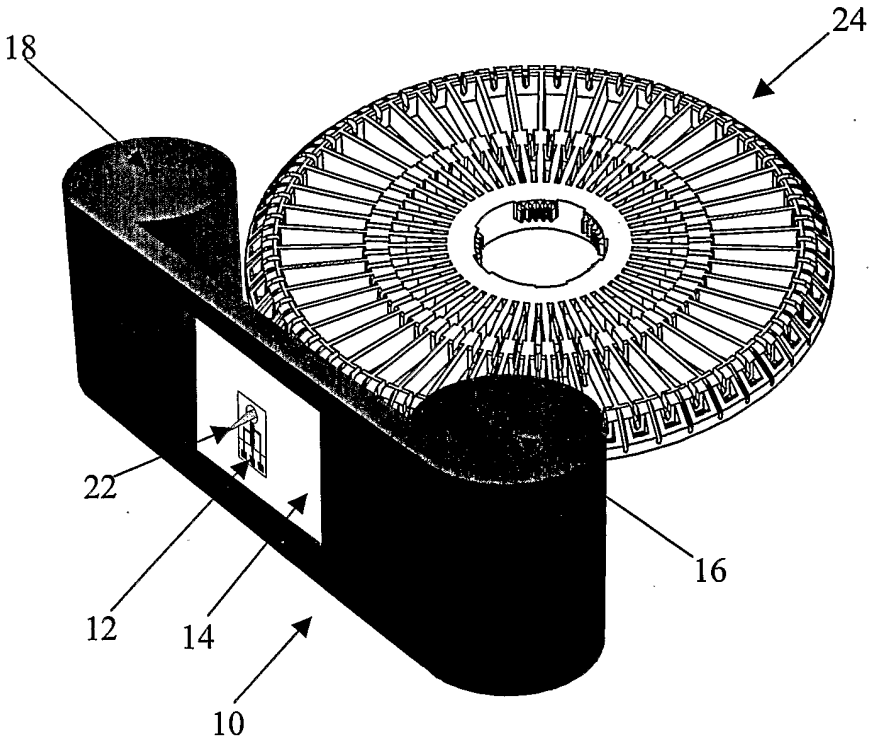


Figure 3

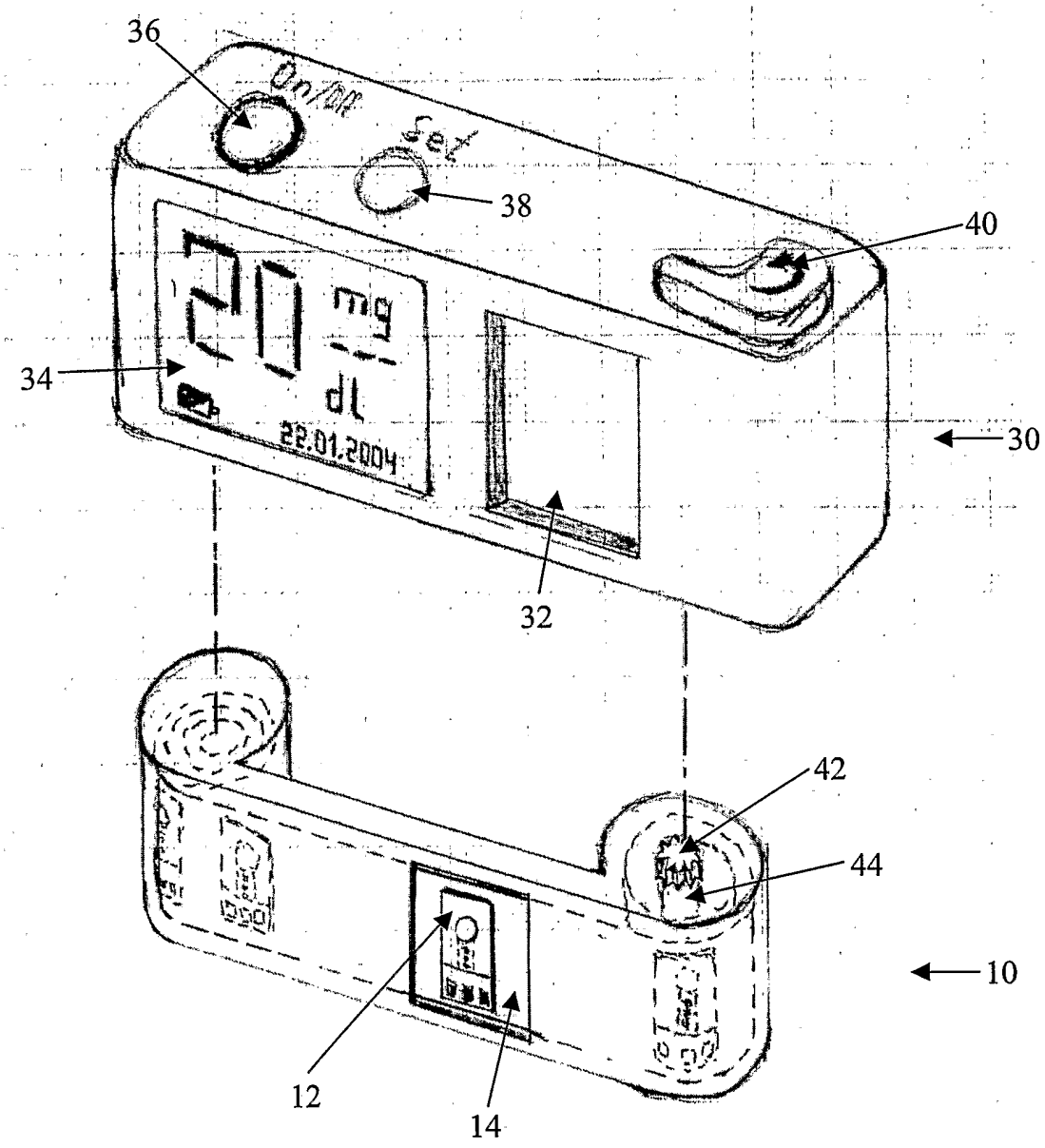


Figure 4

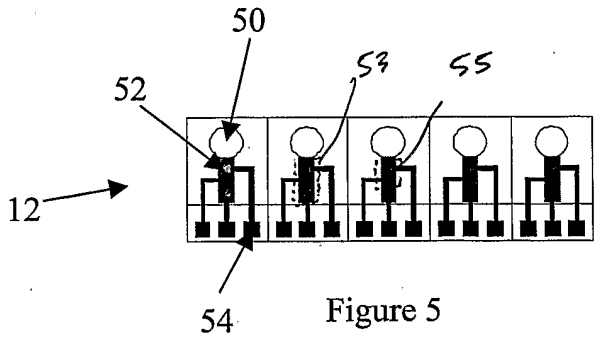


Figure 5

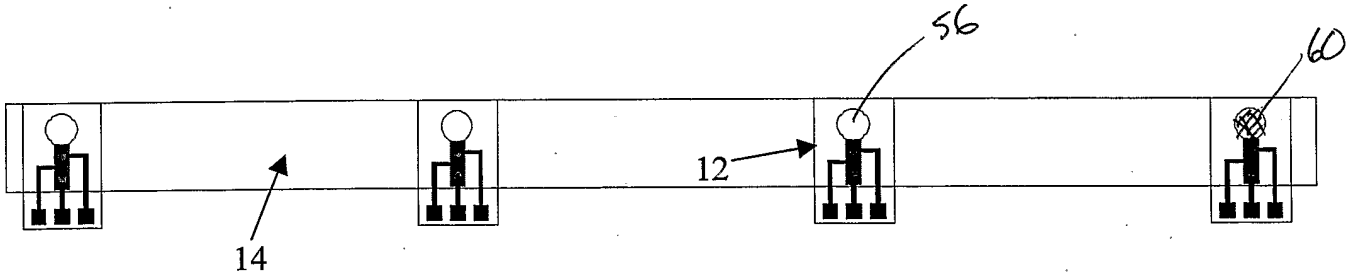


Figure 6

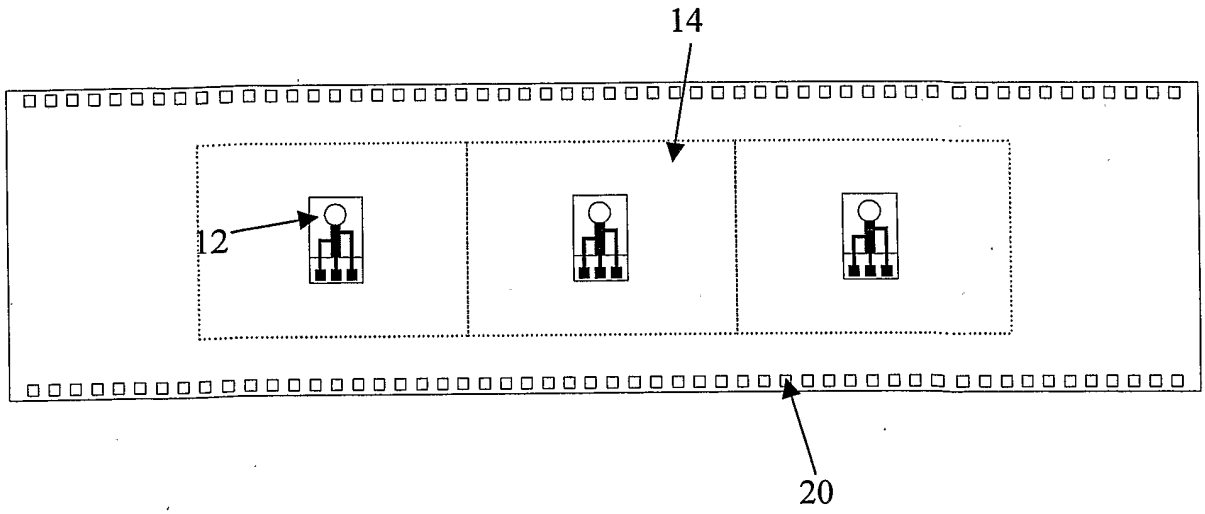


Figure 7

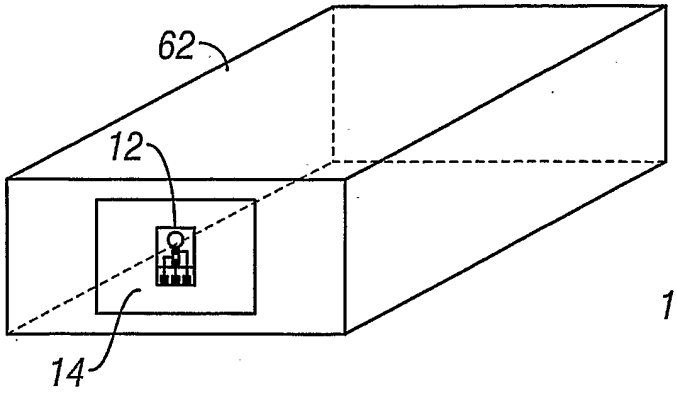


FIG. 8A

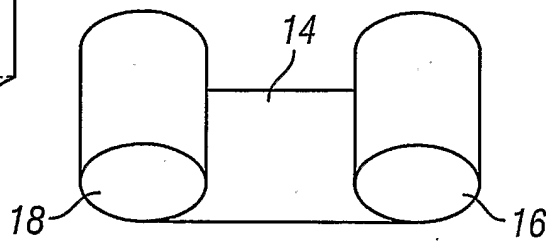


FIG. 8B

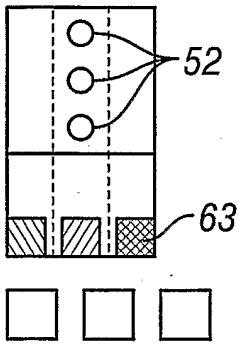


FIG. 8C

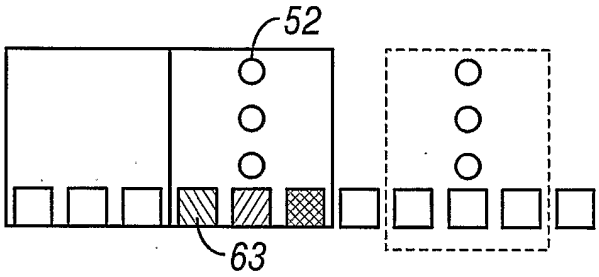


FIG. 8E

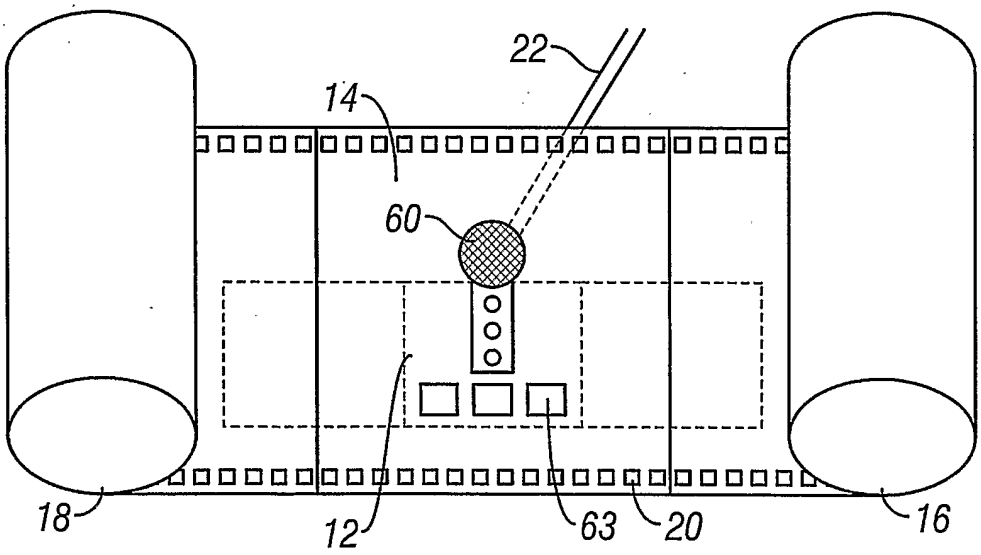


FIG. 8D