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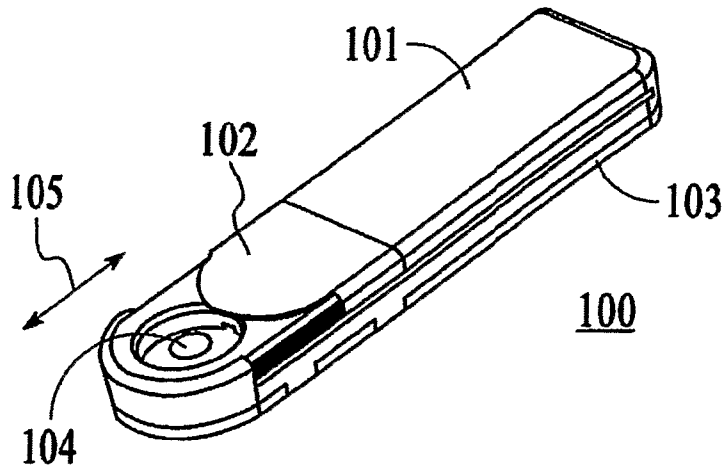

(57) Abstract: Method and apparatus for inserting at least a portion of a sensor into a patient is provided.

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INTEGRATED INTRODUCER AND TRANSMITTER ASSEMBLY AND METHODS OF USE

PRIORITY

This PCT application claims priority to United States Patent Application No. 11/240,259, filed September 30, 2005 and is hereby incorporated by reference.

BACKGROUND

Continuous glucose monitoring systems generally include a sensor such as a subcutaneous analyte sensor, at least a portion of which is inserted under the skin for fluid contact with interstitial fluid, for detecting analyte levels such as glucose levels, a transmitter (such as an RF transmitter) in communication with the sensor and configured to receive the sensor signals and to transmit them to a corresponding receiver unit by for example, using RF data transmission protocol. The receiver may be operatively coupled to a glucose monitor that performs glucose related calculations and data analysis.

The transmitter is in signal communication with the sensor. Generally, the sensor is configured to detect and measure the glucose levels of the patient over a predetermined period of time, and the transmitter is configured to transmit data corresponding to or associated with the measured glucose levels over the predetermined period of time for further analysis. To initially deploy the sensor so that the sensor contacts and electrodes are in fluid contact with the patient's analyte fluids, a separate deployment mechanism such as a sensor inserter or introducer is used. More specifically, the introducer includes a sharp needle shaped inserter that is configured to pierce through the skin of the patient and substantially concurrently guide the sensor through the patient's skin so as to place at least a portion of the sensor in fluid contact with the target biological fluid of the patient.

The sharp inserter is typically used only during the sensor insertion process, and once the sensor is properly and accurately positioned, the inserter and the introducer are discarded. This requires a level of care as the inserter is sharp and may damage other parts of the patient's skin if not properly discarded. Further, since the tip of the inserter has come into fluid contact with the

patient's biological fluids, it is important to take particular precautions in the handling of the sharp inserter.

Further, to minimize data errors in the continuous or semi-continuous monitoring system, it is important to properly insert the sensor through the patient's skin and securely retain the sensor during the time that the sensor is configured to detect analyte levels. In addition to accurate positioning of the sensor through the skin of the patient, it is important to minimize the level of pain associated with the insertion of the sensor through the patient's skin. Additionally, for the period of continuous or semi-continuous monitoring which can include, for example, 3 days, 5 days or 7 days, it is important to have the transmitter in proper contact with the analyte sensor so as to minimize the potential errors in the monitored data.

In view of the foregoing, it would be desirable to have method and apparatus which provides for simple handling of the sensor introducer during sensor deployment and also after the sensor deployment. More specifically, it would be desirable to have method and apparatus that minimizes the potential physical contact with the inserter mechanism and the patient to minimize the potential for disseminating the biological fluids that has come into contact with the inserter, and also, that provides for an easy to use sensor insertion mechanism that minimizes the pain to the patient.

SUMMARY OF THE INVENTION

In one embodiment, there is provided a method and apparatus for providing an integrated sensor introducer mechanism and transmitter unit for use in continuous or semi-continuous monitoring systems such as glucose monitoring systems which includes a disposable sensor introducer provided within the integrated sensor/transmitter assembly and which is retained within the assembly during the time period of the sensor in active mode.

More specifically, in one embodiment of the present invention, there is provided an integrated sensor introducer mechanism which may be triggered by a single depression or activation of a switch to deploy the sharp sensor introducer through the skin of the patient. The single depression trigger mechanism is configured to return to its original position upon firing

the sensor and the introducer, so that the sharp sensor introducer is removed from the patient after placing the sensor in the patient.

In this manner, the patient is not required to handle the cumbersome and potentially dangerous and sharp sensor introducer microneedle, for example. In this manner, a convenient, simple and sanitary sensor insertion and analyte monitoring system is provided.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1A illustrates a perspective view of the overall assembly including integrated introducer and transmitter coupled to the transmitter mount with the switch cover in a closed position in accordance with one embodiment of the present invention;

FIG. 1B illustrates a perspective view of the overall assembly including integrated introducer and transmitter coupled to the transmitter mount with the switch cover in an open position in accordance with one embodiment of the present invention;

FIG. 2 illustrates a perspective view of the overall assembly including integrated introducer and transmitter coupled to the transmitter mount with the switch cover in a closed position provided on an adhesive patch in accordance with one embodiment of the present invention;

FIGS. 3A and 3B illustrate the open and closed positions, respectively, of the transmitter unit opening portion on the transmitter unit housing in accordance with one embodiment of the present invention;

FIG. 4 illustrates a close up perspective view of the switch opening in the open position exposing the sensor introducer trigger mechanism and mounted on the transmitter unit base portion in accordance with one embodiment of the present invention;

FIGS. 5A-5B illustrate a side view and a perspective view, respectively, of the sensor introducer trigger mechanism with the sensor positioned in the pre-deployment position in accordance with one embodiment of the present invention;

FIG. 6 illustrates a perspective view of the sensor introducer trigger mechanism and the transmitter unit base portion in cooperation with the sensor in pre-deployment position in accordance with one embodiment of the present invention;

FIG. 7A illustrates a perspective view of the sensor introducer trigger mechanism and the transmitter unit base portion in post deployment position in accordance with one embodiment of the present invention;

FIG. 7B illustrates a side view of the sensor introducer trigger mechanism in post sensor deployment position in accordance with one embodiment of the present invention;

FIG. 8A is a cross sectional view of the sensor introducer trigger mechanism before the sensor insertion in accordance with one embodiment of the present invention;

FIG. 8B is a cross sectional side view of the sensor introducer trigger mechanism before the sensor insertion in accordance with one embodiment of the present invention; and

FIGS. 9A and 9B are cross sectional views of the sensor introducer trigger mechanism after sensor insertion and withdrawal of the introducer for retention within the integrated sensor introducer and transmitter assembly in accordance with one embodiment of the present invention.

DETAILED DESCRIPTION

FIG. 1A illustrates a perspective view of the overall assembly including integrated introducer and transmitter coupled to the transmitter mount with the switch cover in a closed position in accordance with one embodiment of the present invention, and FIG. 1B illustrates a perspective view of the overall assembly including integrated introducer and transmitter coupled to the transmitter mount with the switch cover in an open position in accordance with one embodiment of the present invention. Referring to FIGS. 1A-1B, integrated sensor introducer and transmitter assembly 100 in one embodiment of the present invention includes a transmitter unit 101, a transmitter unit opening portion 102, and transmitter mount base portion 103. As shown, the transmitter unit 101 is configured to physically couple to the transmitter mount base portion 103 so as to provide an integrated assembly. The transmitter mount base portion 103 is configured to be placed on the skin of a patient, and as will be discussed in further detail, and includes a sensor introducer and the sensor pre-assembled therein.

Referring to FIGS. 1A-1B, the transmitter unit opening portion 102 is configured in one embodiment to be slidably displaced between an open position and a closed position, along the

directional arrow 105. As can be seen, when the transmitter unit opening portion 102 is in the open position, a sensor introducer trigger mechanism 104 is exposed to the patient. More specifically, the patient is able to slidably move the transmitter unit opening portion 102 between the open position and the closed position to operate the sensor introducer trigger mechanism 104, and upon successfully deploying the sensor transcutaneously to the desired position, the patient may place the transmitter unit opening portion 102 in the closed position so as to provide cover and protection to the sensor introducer trigger mechanism 104, and also, to avoid potential inadvertent interaction with the sensor introducer trigger mechanism 104. Within the scope of the present invention, the sensor introducer trigger mechanism 104 may include a plug or stopper with latch mechanism.

Referring back to FIGS. 1A-1B, while the transmitter unit opening portion 102 is shown with a slidable movement so as to be displaced between the open position and the closed position, within the scope of the present invention, the transmitter unit opening portion 102 may include other types of mechanisms to open and close the area exposing the sensor introducer trigger mechanism 104. For example, the transmitter unit opening portion 102 may include a hinge portion pivotally mounted to the transmitter unit 102 so that the transmitter unit opening portion 102 may pivotally move to expose and to close the sensor introducer trigger mechanism.

Additionally, a latch mechanism may also be provided so as to securely place the transmitter unit opening portion 102 in a closed and latched position so as to avoid potential inadvertent exposure of the sensor introducer trigger mechanism 104. Within the scope of the present invention, the latch mechanism may include a Velcro type fastener, a button type latching mechanism, a tongue and groove type latch mechanism, a snap, a détente, a hook, or any other type of latching mechanism that would securely place the transmitter unit opening portion 102 in the closed position in the event of inadvertent application of pressure thereto.

FIG. 2 illustrates a perspective view of the overall assembly including integrated introducer and transmitter coupled to the transmitter mount with the switch cover in a closed position provided on an adhesive patch in accordance with one embodiment of the present invention. Referring to FIG. 2, there is shown an adhesive patch 201 that is configured to receive the transmitter unit base portion 103 on its upper surface, while the lower surface is

provided with an adhesive material, and where the lower surface is configured to be securely attached to the skin of the patient, thus effectively providing a firm and secure mounting of the integrated sensor introducer and transmitter assembly 100. As shown, the adhesive patch 201 in one embodiment of the present invention is substantially flexible and configured to substantially follow the contour of the patient's skin where the integrated sensor introducer and transmitter assembly 100 is to be placed for the predetermined period of time that the patient will be wearing the assembly 100 (for example, 3 days, 5 days, 7 days and so on). In this manner, comfort can be provided to the patient while not substantially hindering the patient's daily activities.

FIGS. 3A and 3B illustrate the open and closed positions, respectively, of the transmitter unit opening portion on the transmitter unit housing, and FIG. 4 illustrates a close-up, perspective view of the switch opening in the open position exposing the sensor introducer trigger mechanism and mounted on the transmitter unit base portion in accordance with one embodiment of the present invention. Referring to FIGS. 3A-3B and 4, it can be seen that the sensor introducer trigger mechanism 104 is positioned substantially within the housing of the integrated sensor introducer and transmitter assembly 100, shown in one embodiment as including the transmitter unit 101 coupled with the transmitter unit base portion 102.

Moreover, while the transmitter unit 101 is provided with a substantially circular opening corresponding to the position of the sensor introducer trigger mechanism 104, within the scope of the present invention, any suitable shape may be integrated to the housing of the transmitter unit 101 so as to effectively be opened and closed to respectively expose and seal off the sensor introducer trigger mechanism 104 as desired by the patient. For example, the circular opening on the transmitter unit 101 may alternatively be formed in an oblong shape, a triangular shape, a rectangular shape, and so on.

FIGS. 5A-5B illustrate a side view and a perspective view, respectively, of the sensor introducer trigger mechanism with the sensor positioned in the pre-deployment position in accordance with one embodiment of the present invention. Referring to FIGS. 5A and 5B, as can be seen, the sensor introducer trigger mechanism 104 in one embodiment includes a trigger portion 501 operatively coupled to an introducer portion 502. As shown, the trigger portion 501 of the sensor introducer trigger mechanism 104 is configured to displace the introducer portion

502 in a substantially skin-inserting direction, e.g., a substantially vertical direction relative to the patient's skin surface. Further, as shown in the Figures, an analyte sensor 503 is provided in cooperation with the introducer portion 502 such that in one embodiment, when the trigger portion 501 is activated by the patient, for example, by the application of downward pressure on the outer surface of the trigger portion (the outer surface of the "dome shaped" area), the introducer portion 502 is in turn configured to be driven in a substantially complimentary direction to the direction of the applied pressure, and further, displacing at least a portion of the sensor 503 with the introducer portion 502. In other words, the introducer portion 502 is configured in one embodiment to transcutaneously place a portion of the sensor 503 so that the portion of the sensor is in fluid contact with the biological fluid (for example, interstitial fluid) of the patient.

Referring to FIGS. 5A-5B, the sensor 503 is in one embodiment also provided with one or more contact points 504 which are configured to be in electrical contact with the corresponding electrical contacts of the transmitter unit 101. That is, in the case of analyte sensors, the working, reference, and counter electrodes (in certain embodiments an electrode may function as both reference and counter electrodes) are each coupled to a respective one of the contact points 504, and in turn, each of which are in electrical communication with the respective contacts on the transmitter unit 101.

In this manner, in one embodiment, the sensor detected analyte levels are provided to the transmitter unit 101, for example, as current signals, and which are in turn, converted to respective digital signals for transmission (including, for example, RF transmission) to a receiver unit for further data processing and data analysis (including drug (e.g., insulin) therapy management, infusion control, and health monitoring and treatment, for example). That is, the monitored analyte data may be used by the patient and/or the patient's healthcare provider to modify the patient's therapy such as an infusion protocol (such as basal profile modifications in the case of diabetics) as necessary to improve insulin infusion therapy for diabetics, and further, to analyze trends in analyte levels for better treatment.

While glucose is described as an example of the detected and/or monitored analyte, within the scope of the present invention, analytes that may be detected or monitored also

include, for example, acetyl choline, amylase, bilirubin, cholesterol, chorionic gonadotropin, creatine kinase (e.g., CK-MB), creatine, DNA, fructosamine, glucose, glutamine, growth hormones, hormones, ketones, lactate, peroxide, prostate-specific antigen, prothrombin, RNA, thyroid stimulating hormone, and troponin. The concentration of drugs, such as, for example, antibiotics (e.g., gentamicin, vancomycin, and the like), digitoxin, digoxin, drugs of abuse, theophylline, and warfarin, may also be detected and/or monitored.

FIG. 6 illustrates a perspective view of the sensor introducer trigger mechanism and the transmitter unit base portion in cooperation with the sensor in pre-deployment position in accordance with one embodiment of the present invention. As shown, the one or more contact points 504 of the sensor 503 (which in one embodiment may correspond to a respective one of the working electrode, a counter electrode, and a reference electrode, for example), are configured to couple to a respective contacts on the transmitter unit 101 (FIGS. 3A-3B) such that the sensor 503, which is in fluid contact with the patient's biological fluids, is in electrical communication with the transmitter unit 101.

Furthermore, as can be seen from FIG. 6, the substantially dome shaped inserter introducer trigger mechanism 104 is configured to be collapsible when the patient applies downward pressure to drive the introducer portion 502 through the patient's skin. Further, when the downward pressure is removed from the dome shaped inserter introducer trigger mechanism 104, the outer inserter introducer trigger mechanism 104 is configured to return to substantially the original shape, and concurrent therewith, removing the introducer portion 502 from the insertion site of the patient, while leaving behind the subcutaneous portion of the sensor in fluid contact with the patient's biological fluid. This can be seen also with FIGS. 7A-7B as described below.

FIG. 7A illustrates a perspective view of the sensor introducer trigger mechanism and the transmitter unit base portion in post deployment position, and FIG. 7B illustrates a side view of the sensor introducer trigger mechanism in post sensor deployment position in accordance with one embodiment of the present invention. More specifically, it can be seem from FIGS. 7A-7B that when the downward pressure is applied upon the substantially dome shaped inserter introducer trigger mechanism 104, the upper conical portion of the inserter introducer trigger

mechanism 104 takes a substantially inverted conical shape, and with the same force, driving the portion 701 of the sensor 503 (FIG. 5A) through the patient's skin. In one embodiment, the inserter introducer trigger mechanism 104 may be made of one of stainless steel, rubber, polyester, or PET film, or any other suitable material that is flexible and provides the properties described herein, including being reversibly collapsible.

FIG. 8A is a cross sectional view of the sensor introducer trigger mechanism before the sensor insertion, and FIG. 8B is a cross sectional side view of the sensor introducer trigger mechanism before the sensor insertion in accordance with one embodiment of the present invention. As can be seen from FIG. 8A, the portion 701 of the sensor 503 is substantially retained in cooperation with the introducer portion 502 (e.g., a microneedle), all of which are substantially retained within the integrated inserter introducer and transmitter assembly 100 (FIGS. 1A-1B).

Moreover, referring to FIG. 8B, the non-transcutaneously displaced portion of the sensor 503 is also substantially completely retained within the integrated inserter introducer and transmitter assembly 100. That is, in one embodiment of the present invention, the transmitter unit 101 as well as the sensor insertion mechanism (e.g., sensor introducer trigger mechanism 104) are provided within a single integrated housing. Furthermore, as discussed in additional detail below, after the deployment of the sensor 503 transcutaneously so as to have a portion 701 thereof in fluid contact with the patient's biological fluid, the sensor insertion mechanism is retained within the integrated housing itself, so that the patient is not required to further handle the sharp and contaminated needle portion of the sensor introducer assembly.

FIGS. 9A and 9B are cross sectional views of the sensor introducer trigger mechanism after sensor insertion and withdrawal of the introducer for retention within the integrated sensor introducer and transmitter assembly in accordance with one embodiment of the present invention. Referring to FIGS. 9A-9B, it can be seen that after the sensor 503 is placed transcutaneously through the patient's skin at the intended location and in fluid contact with the patient's biological fluid, the introducer portion 502 is retained substantially completely within the dome shaped sensor introducer trigger mechanism 104 provided within the integrated sensor introducer and transmitter assembly 100.

Furthermore, while the sensor 503 is described as substantially transcutaneously placed in the patient, within the scope of the present invention, the sensor may be wholly implantable under the skin of the patient, or at least a portion of the sensor may be provided under the skin of the patient so as to be in fluid contact with the patient's analyte.

In one embodiment, the introducer portion 502 is configured to be retained within the assembly 100 during the entire duration of the sensor 503 in operation for monitoring the patient's analyte levels, and is discarded along with the sensor 503 after use. In this manner, while the transmitter unit 102 may be reusable, in one embodiment of the present invention, the base portion 103 and the sensor introducer trigger mechanism 104 along with the sensor 503 are discarded after each use.

Further, the detected analyte signals from the sensor 503 may be provided to transmitter unit 102, which is, in one embodiment, configured to wirelessly or otherwise transmit data corresponding to the detected analyte levels from the sensor 503 to a receiver unit, where the receiver unit may include an analyte, e.g., glucose, monitor unit and/or an insulin pump unit and/or a computer terminal and/or any other electronic device capable of being configured for wireless communication. A physical connection may be provided in certain embodiments.

Within the scope of the present invention, the receiver unit functions may be integrated into portable electronic devices such as a watch, a pager, a mobile telephone, and a personal digital assistant. Additional information on the detection, monitoring and analysis of analyte levels are described in further detail in U.S. Patent No. 6,175,752 entitled "Analyte Monitoring Device and Methods of Use" the disclosure of which is incorporated herein by reference for all purposes. In certain embodiments, the transmitter may also be capable of wirelessly or otherwise receiving signal from a receiver such that a receiver may also be capable of transmitting information to the transmitter.

In a further embodiment, the transmitter unit 102 may includes a wireless communication unit for wireless transmission of the signal, where the wireless communication unit may include one or more of a radio frequency (RF) communication unit, a Bluetooth communication unit, an infrared communication unit, an 801.11x communication unit, or a Zigbee communication unit.

Similarly, the receiver unit may be configured to support one more or of the above-referenced wireless communication protocols to communicate with the transmitter unit.

In the manner described above, an apparatus including an integrated sensor insertion unit includes a base unit, a sensor coupled to the base unit, and an insertion unit disposed on the base unit, the insertion unit operatively coupled to the sensor and configured to place at least a portion of the sensor under a skin of a patient, wherein the insertion unit is configured to remain disposed on the base unit after sensor placement.

In one embodiment, a transmitter unit may be disposed on the base unit, where the transmitter unit is configured to operatively couple to the sensor. Also, the transmitter unit may include an opening portion configured to substantially cover the insertion unit when the transmitter unit is disposed on the base unit, where the opening portion is slidably disposed on the transmitter unit to selectively expose the insertion unit. Further, the opening portion may alternately pivotally mounted to the transmitter unit to selectively expose the insertion unit.

Additionally the base unit, the sensor and the insertion unit in one embodiment may be formed as an integrated disposable unit.

In a further embodiment, the insertion unit may include a sharp portion, the sharp portion configured to couple to a portion of the sensor, the sharp portion further configured to pierce through a skin of the patient to position at least the portion of the sensor in the patient, where the at least the portion of the sensor may be configured to be in fluid contact with a biological fluid of a patient. In one embodiment, the biological fluid includes one of interstitial fluid or blood.

In an additional embodiment, the sensor is an analyte sensor, and which includes a glucose sensor.

An apparatus in still a further embodiment of the present invention includes a transmitter mount, a sensor coupled to the transmitter mount, the sensor configured to be in fluid contact with a biological fluid of a patient, and a sensor introducer coupled to the sensor and configured to place at least a portion of the sensor under the skin of the patient, the sensor introducer integrated with the transmitter mount such that the sensor introducer is retained with the transmitter mount after sensor placement.

Also provided a still a further embodiment is an adhesive layer where the transmitter mount disposed on the adhesive layer, and a transmitter unit coupled to the transmitter mount on the adhesive layer, where the transmitter unit further configured to be in electrical communication with the sensor.

The adhesive layer in one embodiment is positioned substantially around a sensor insertion location on a skin of the patient.

Moreover, the transmitter unit may include an opening portion, the opening portion configured to selectively provide access to the sensor introducer.

Further, the transmitter unit in yet another embodiment may be configured to transmit one or more signals corresponding to a respective one or more sensor signals, where the one or more sensor signals may correspond to or are associated with a respective one or more of analyte levels detected by the sensor.

The one or more analyte levels may include one of a glucose level, a lactate level, or an oxygen level.

In addition, in a further embodiment, there may be provided a receiver unit configured to receive the one or more signals from the transmitter unit.

A method in yet still another embodiment includes the steps of placing at least a portion of a sensor under the skin of a patient, substantially covering the sensor introducer mechanism, and discarding the sensor introducer mechanism with the sensor.

An analyte detection apparatus for use with an analyte sensor in still another embodiment includes a transmitter, and an analyte sensor insertion unit operatively coupled to the transmitter.

A system in accordance with still another embodiment includes a transmitter mount, a sensor coupled to the transmitter mount, the sensor configured to be in fluid contact with a biological fluid of a patient, a sensor introducer coupled to the sensor and configured to place at least a portion of the sensor under the skin of the patient, the sensor introducer integrated with the transmitter mount such that the sensor introducer is retained with the transmitter mount after sensor placement, and a transmitter unit coupled to the transmitter mount, the transmitter unit electrically coupled to the sensor, and configured to transmit one or more signals associated with the biological fluid levels of the patient.

An insertion kit in one embodiment of the present invention includes a base unit, a sensor coupled to the base unit, and an insertion unit disposed on the base unit, the insertion unit operatively coupled to the sensor and configured to place at least a portion of the sensor under a skin of a patient, the insertion unit including a sensor introducer, wherein the sensor introducer is retained substantially disposed on the base unit after sensor placement.

Various other modifications and alterations in the structure and method of operation of this invention will be apparent to those skilled in the art without departing from the scope and spirit of the invention. Although the invention has been described in connection with specific preferred embodiments, it should be understood that the invention as claimed should not be unduly limited to such specific embodiments. It is intended that the following claims define the scope of the present invention and that structures and methods within the scope of these claims and their equivalents be covered thereby.

WHAT IS CLAIMED IS:

1. An apparatus including an integrated sensor insertion unit, comprising:

a base unit;

a sensor coupled to the base unit; and

an insertion unit disposed on the base unit, the insertion unit operatively coupled to the sensor and configured to place at least a portion of the sensor under a skin of a patient, wherein the insertion unit is configured to remain disposed on the base unit after sensor placement.

2. The apparatus of claim 1 further including a transmitter unit disposed on said base unit, the transmitter unit configured to operatively couple to the sensor.

3. The apparatus of claim 2 wherein the transmitter unit includes an opening portion configured to substantially cover the insertion unit when the transmitter unit is disposed on the base unit.

4. The apparatus of claim 3 wherein the opening portion is slidably disposed on the transmitter unit to selectively expose the insertion unit.

5. The apparatus of claim 3 wherein the opening portion is pivotally mounted to the transmitter unit to selectively expose the insertion unit.

6. The apparatus of claim 1 wherein the base unit, the sensor and the insertion unit form an integrated disposable unit.

8. The apparatus of claim 1 wherein the insertion unit includes a sharp portion, the sharp portion configured to couple to a portion of the sensor, the sharp portion further configured to pierce through a skin of the patient to position at least the portion of the sensor in the patient.

9. The apparatus of claim 1 wherein at least the portion of the sensor is configured to be in fluid contact with a biological fluid of a patient.

10. The apparatus of claim 9 wherein the biological fluid includes one of interstitial fluid or blood.

11. The apparatus of claim 1 wherein the sensor is an analyte sensor.

12. The apparatus of claim 11 wherein the sensor is a glucose sensor.

13. An apparatus, comprising:

a transmitter mount;

a sensor coupled to the transmitter mount, the sensor configured to be in fluid contact with a biological fluid of a patient; and

a sensor introducer coupled to the sensor and configured to place at least a portion of the sensor under the skin of the patient, the sensor introducer integrated with the transmitter mount such that the sensor introducer is retained with the transmitter mount after sensor placement.

14. The apparatus of claim 13 further including an adhesive layer, the transmitter mount disposed on the adhesive layer, and a transmitter unit coupled to the transmitter mount on the adhesive layer, the transmitter unit further configured to be in electrical communication with the sensor.

15. The apparatus of claim 14 wherein the adhesive layer is positioned substantially around a sensor insertion location on a skin of the patient.

16. The apparatus of claim 14 wherein the transmitter unit includes an opening portion, the opening portion configured to selectively provide access to the sensor introducer.

17. The apparatus of claim 14 wherein the transmitter unit is configured to transmit one or more signals corresponding to a respective one or more sensor signals.

18. The apparatus of claim 17 wherein the one or more sensor signals correspond to a respective one or more of analyte levels detected by the sensor.

19. The apparatus of claim 18 wherein the one or more analyte levels include one of a glucose level, a lactate level, or an oxygen level.

20. The apparatus of claim 17 further including a receiver unit configured to receive the one or more signals from the transmitter unit.

21. The apparatus of claim 13 wherein the biological fluid of the patient includes one of an interstitial fluid or blood.

21. A method, comprising the steps of:
placing at least a portion of a sensor under the skin of a patient;
substantially covering the sensor introducer mechanism; and
discarding the sensor introducer mechanism with the sensor.

22. An analyte detection apparatus for use with an analyte sensor, the apparatus comprising:
a transmitter; and
an analyte sensor insertion unit operatively coupled to the transmitter.

23. A system, comprising:
a transmitter mount;
a sensor coupled to the transmitter mount, the sensor configured to be in fluid contact with a biological fluid of a patient;

a sensor introducer coupled to the sensor and configured to place at least a portion of the sensor under the skin of the patient, the sensor introducer integrated with the transmitter mount such that the sensor introducer is retained with the transmitter mount after sensor placement; and

a transmitter unit coupled to the transmitter mount, the transmitter unit electrically coupled to the sensor, and configured to transmit one or more signals associated with the biological fluid levels of the patient.

24. An insertion kit, comprising:

a base unit;

a sensor coupled to the base unit; and

an insertion unit disposed on the base unit, the insertion unit operatively coupled to the sensor and configured to place at least a portion of the sensor under a skin of a patient, the insertion unit including a sensor introducer, wherein the sensor introducer is retained substantially disposed on the base unit after sensor placement.

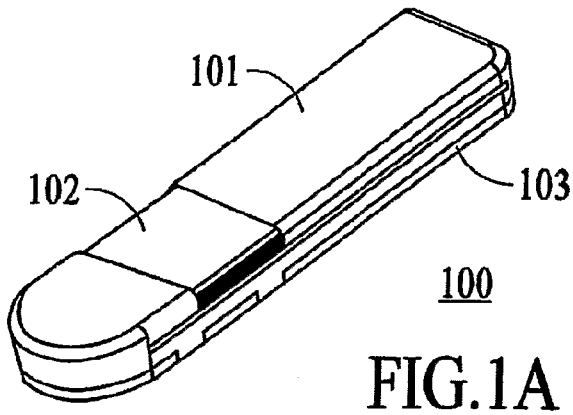

FIG.1A

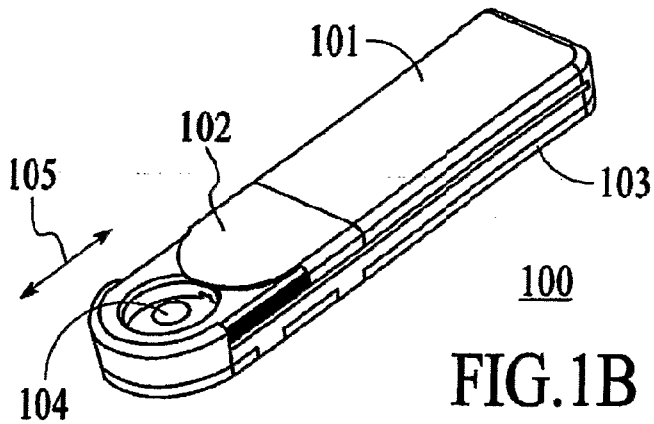

FIG.1B

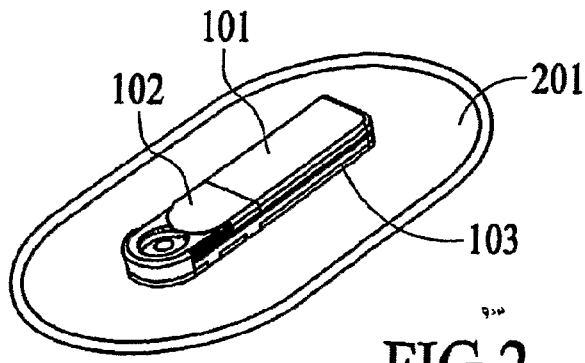

FIG.2

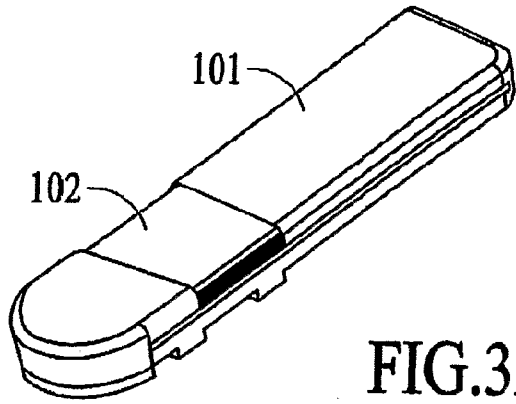

FIG.3A

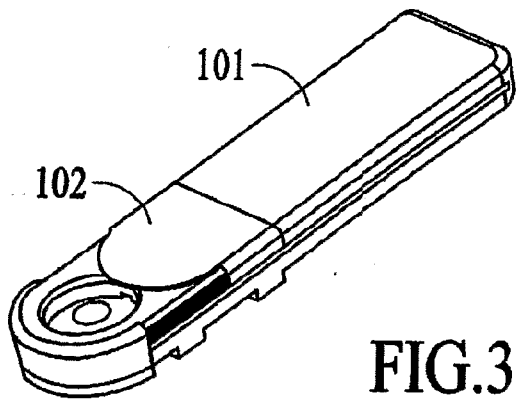

FIG.3B

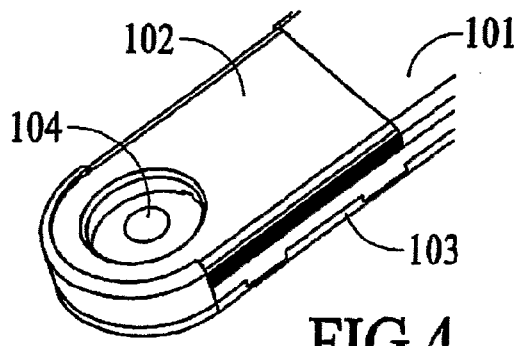

FIG.4

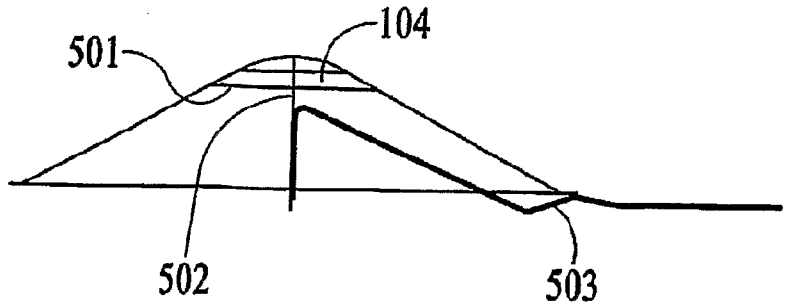

FIG.5A

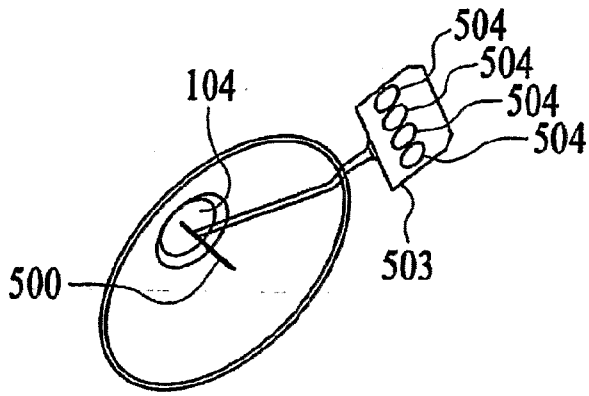

FIG.5B

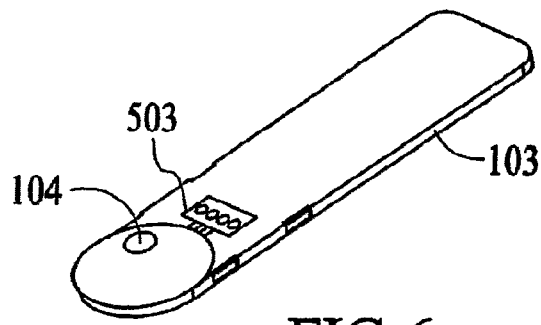

FIG.6

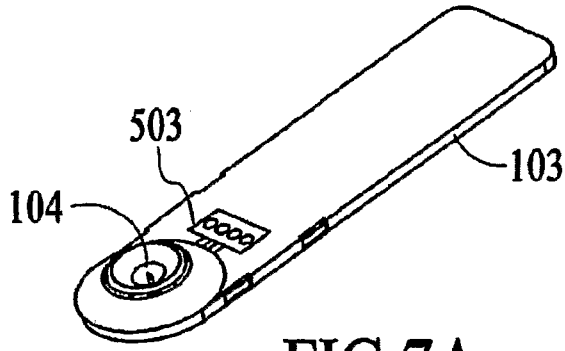

FIG.7A

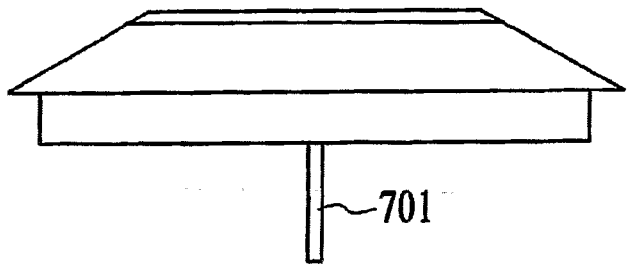

FIG.7B

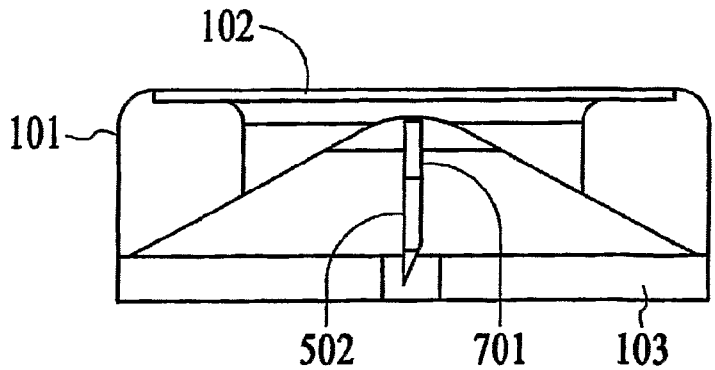

FIG.8A

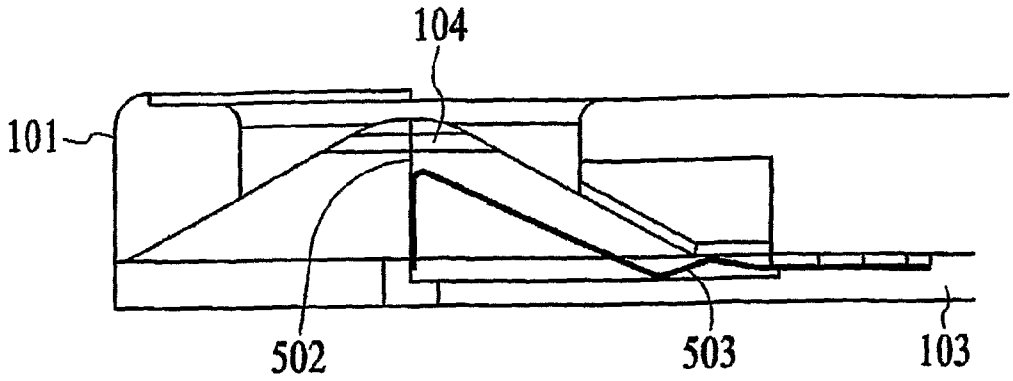

FIG.8B

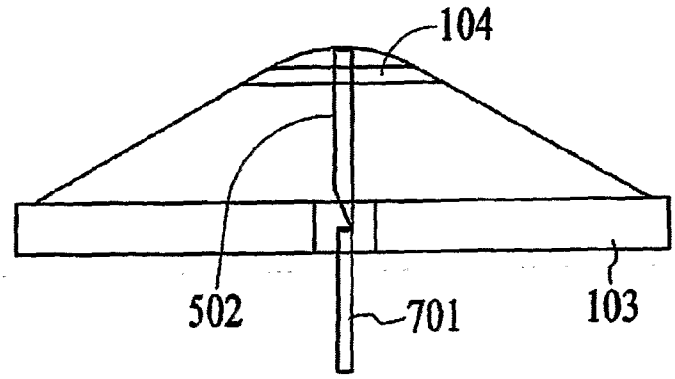

FIG.9A

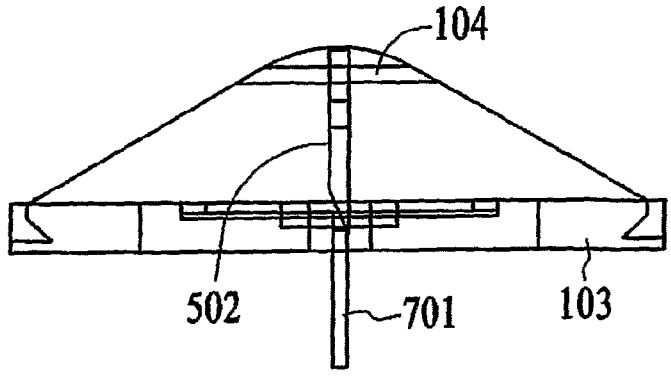

FIG.9B