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A SENSOR MODULE***A61B 5/00* (2006.01)*A61B 5/1486* (2006.01)(71) Applicant: **PEPEX BIOMEDICAL, INC.**, St.
Louis, MO (US)(52) **U.S. Cl.**CPC *A61B 5/157* (2013.01); *A61B 5/6848*
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A61B 5/150389 (2013.01); *A61B 5/15142*
(2013.01); *A61B 5/15105* (2013.01); *A61B*
5/14532 (2013.01)(72) Inventor: **James L. SAY**, Breckenridge, CO (US)(21) Appl. No.: **14/649,132**(22) PCT Filed: **Dec. 3, 2013**(86) PCT No.: **PCT/US2013/072846**

§ 371 (c)(1),

(2) Date: **Jun. 2, 2015****Related U.S. Application Data**(60) Provisional application No. 61/732,783, filed on Dec.
3, 2012.**Publication Classification**(51) **Int. Cl.***A61B 5/157* (2006.01)*A61B 5/145* (2006.01)*A61B 5/15* (2006.01)*A61B 5/151* (2006.01)(57) **ABSTRACT**

A sensor module is disclosed herein. The sensor module includes a skin piercing member carried by the carrier. The skin piercing member has a skin piercing end positioned opposite from a base end. The skin piercing member defines a lumen that extends along the central longitudinal axis from the skin piercing end toward the base end and the lumen having a lumen axis. The sensor module also includes a blood sample analysis zone located entirely within the lumen of the skin piercing member and a capillary flow stop for stopping capillary flow at a predetermined location within the lumen of the skin piercing member. The sensor module includes an elongated working electrode positioned within the lumen. The working electrode has a length that extends along the lumen axis where at least a section of the working electrode is positioned within the analysis zone. The working electrode includes sensing chemistry.

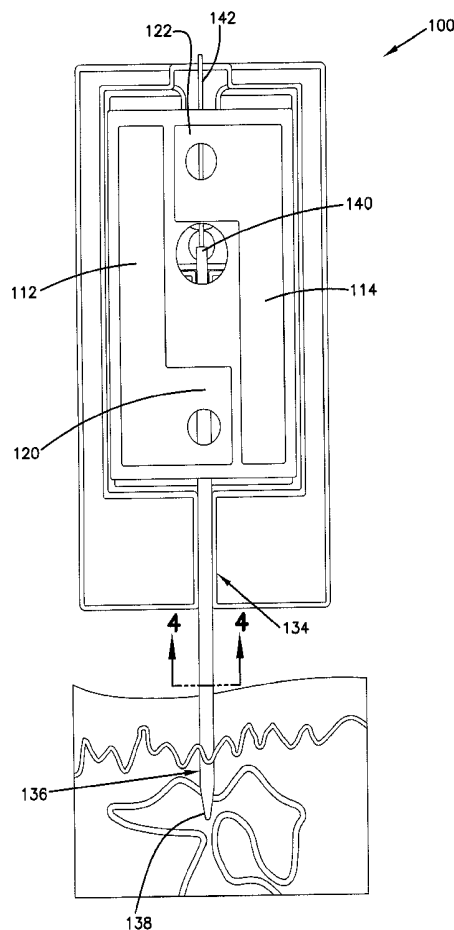


FIG. 1

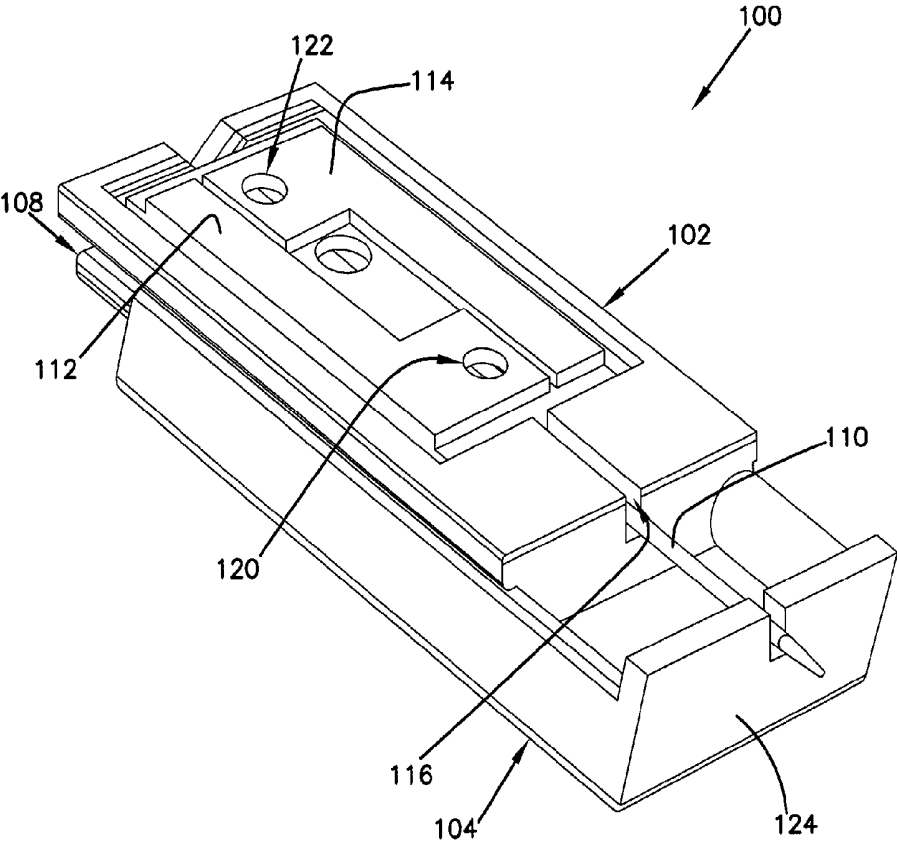


FIG. 2

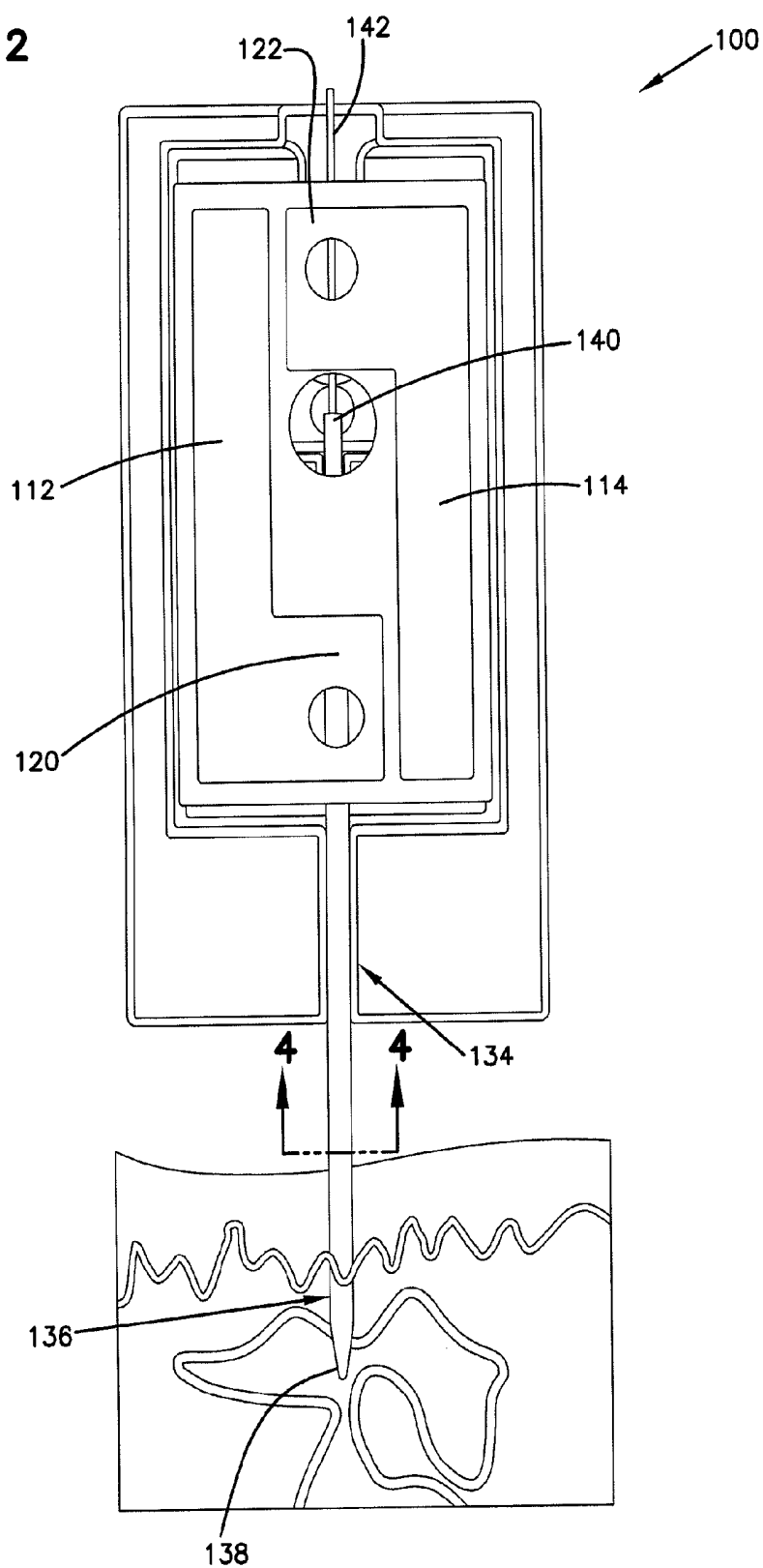


FIG. 3

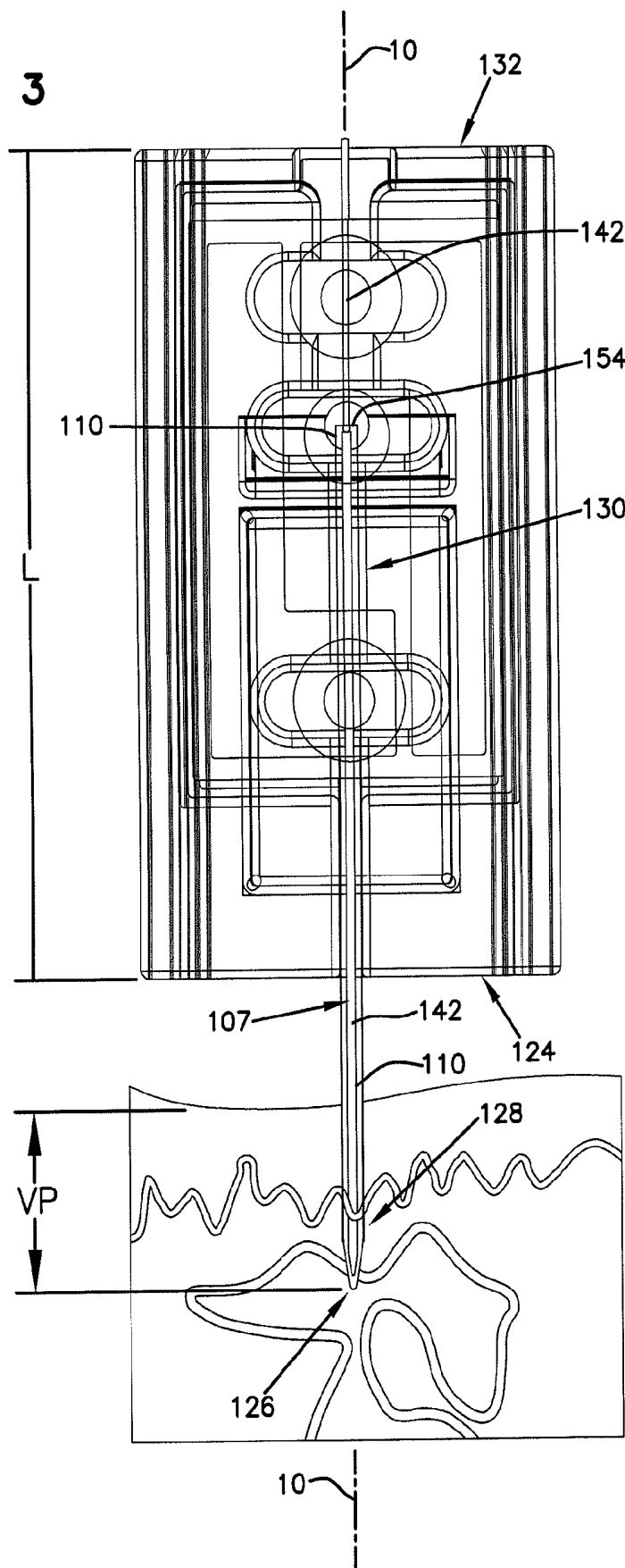


FIG. 5

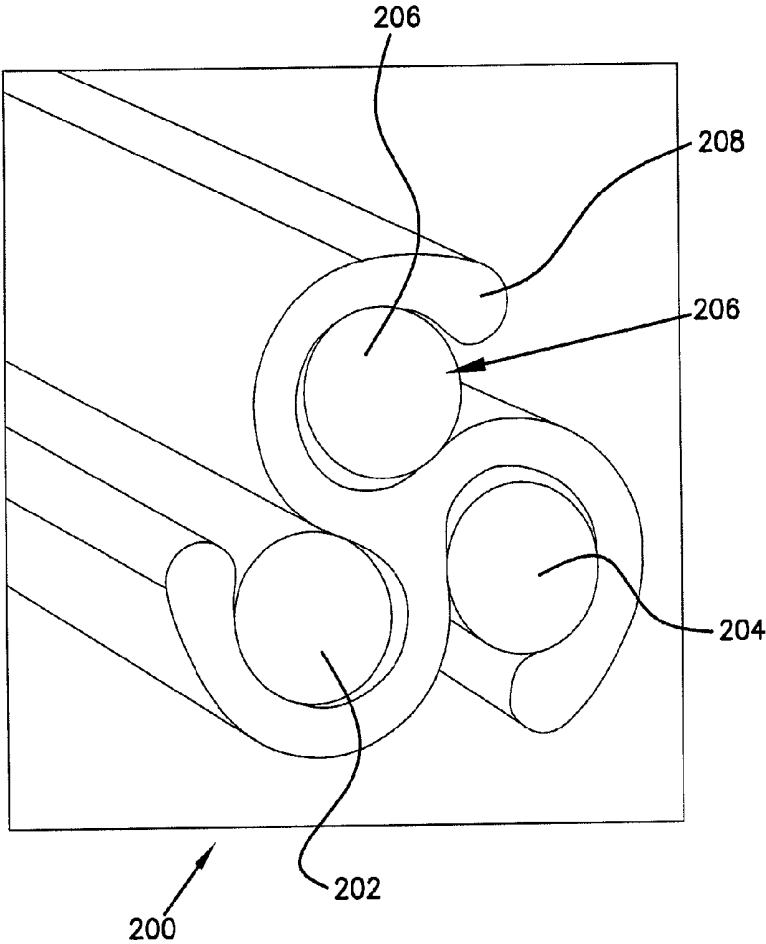


FIG. 6

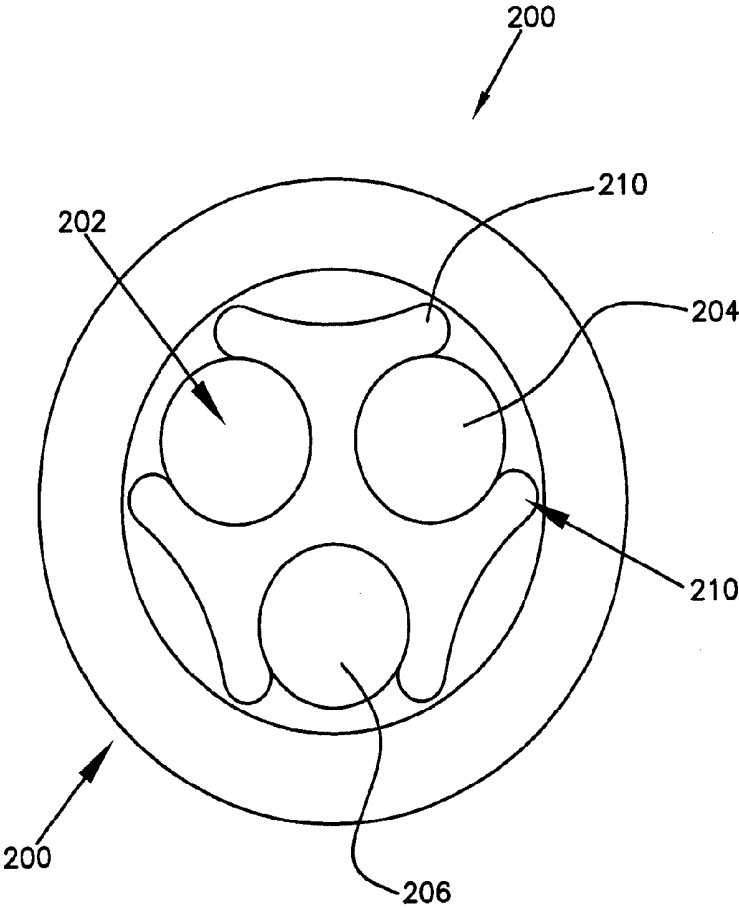


FIG. 7

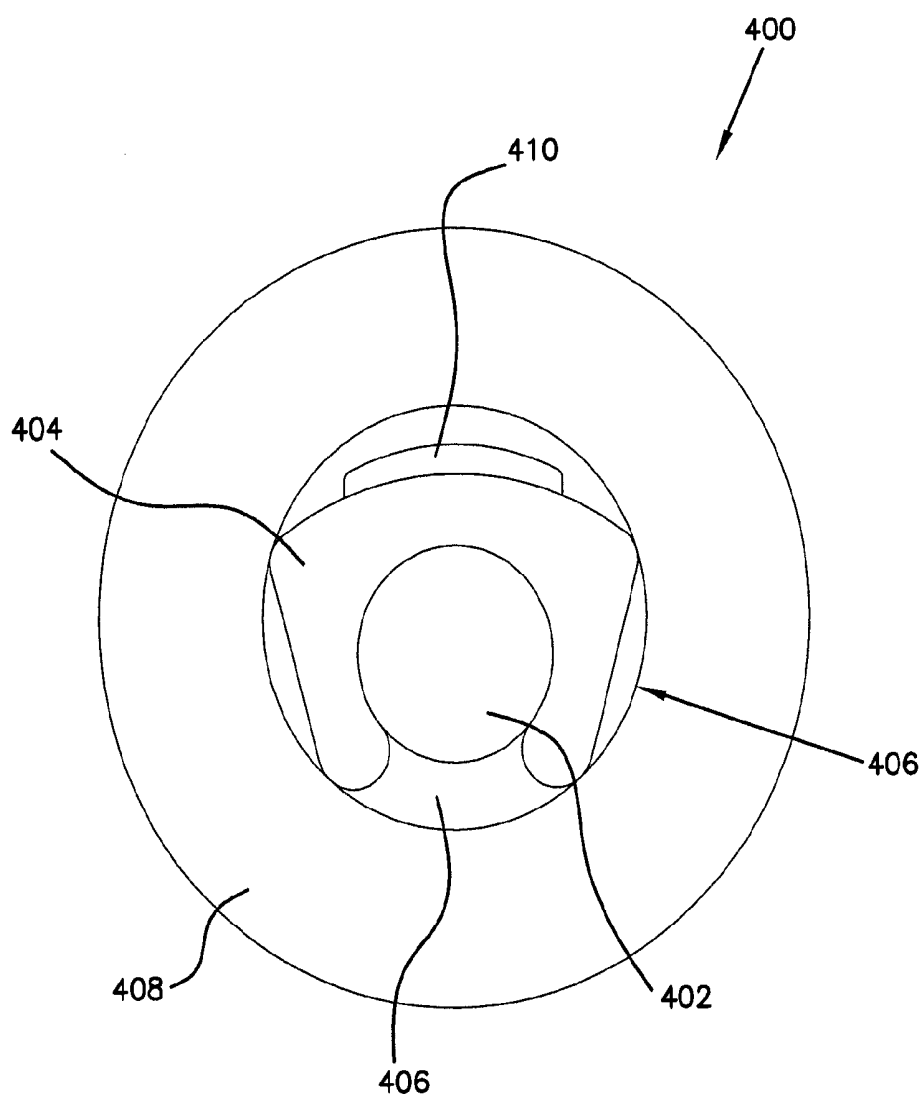


FIG. 8

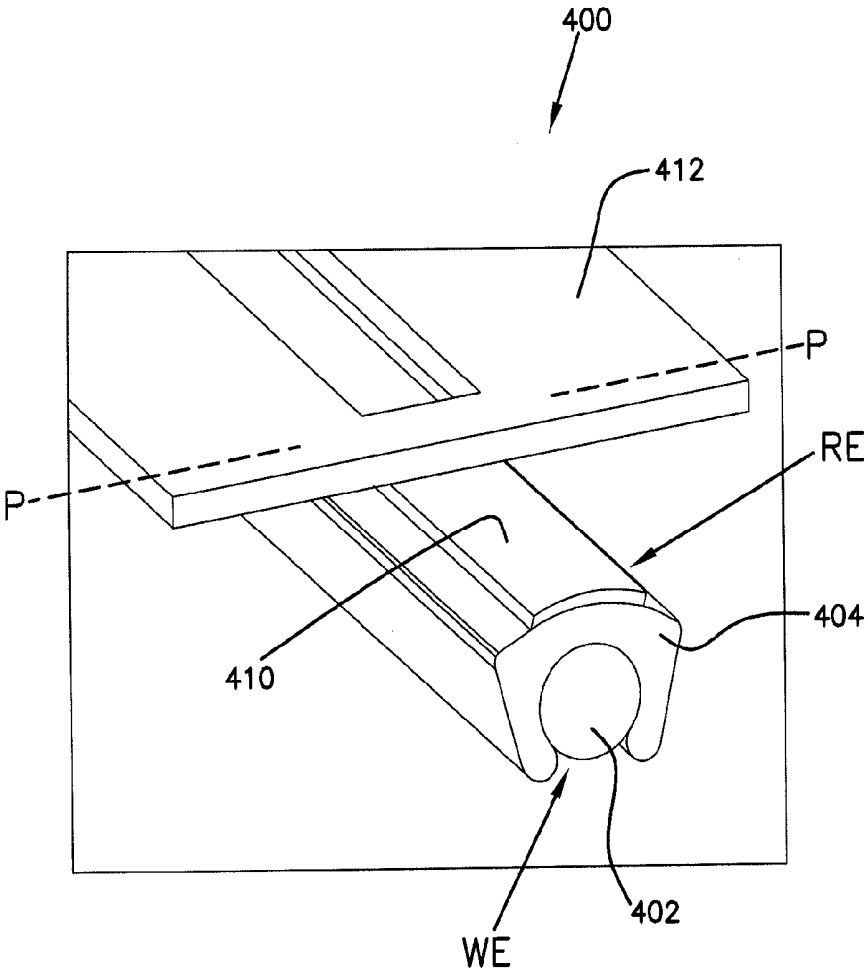


FIG. 9

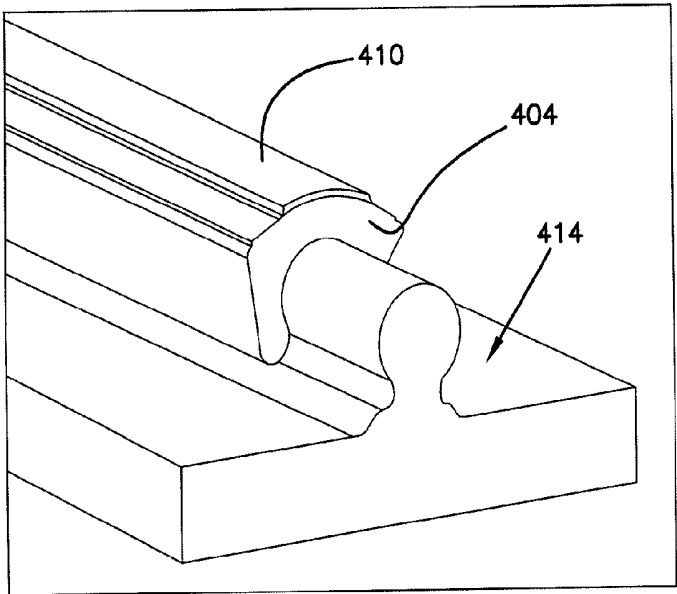


FIG. 10

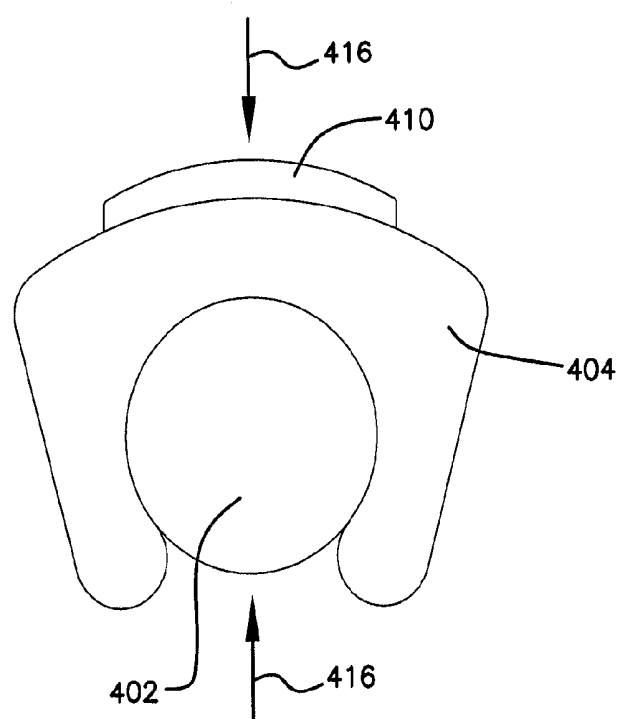


FIG. 11

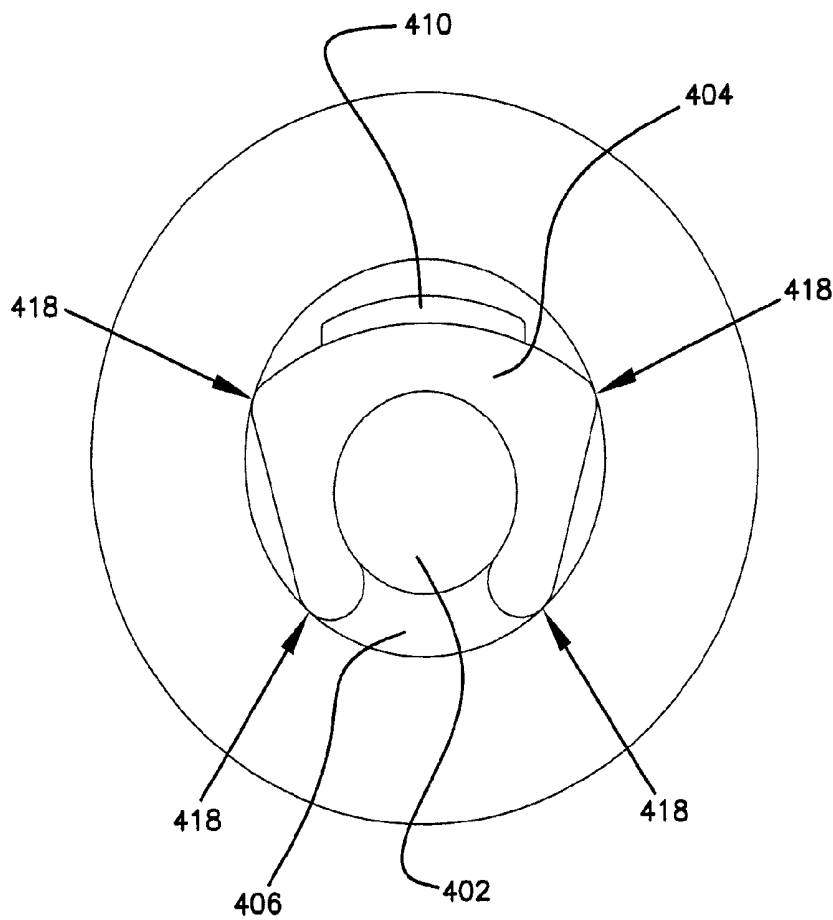


FIG. 12

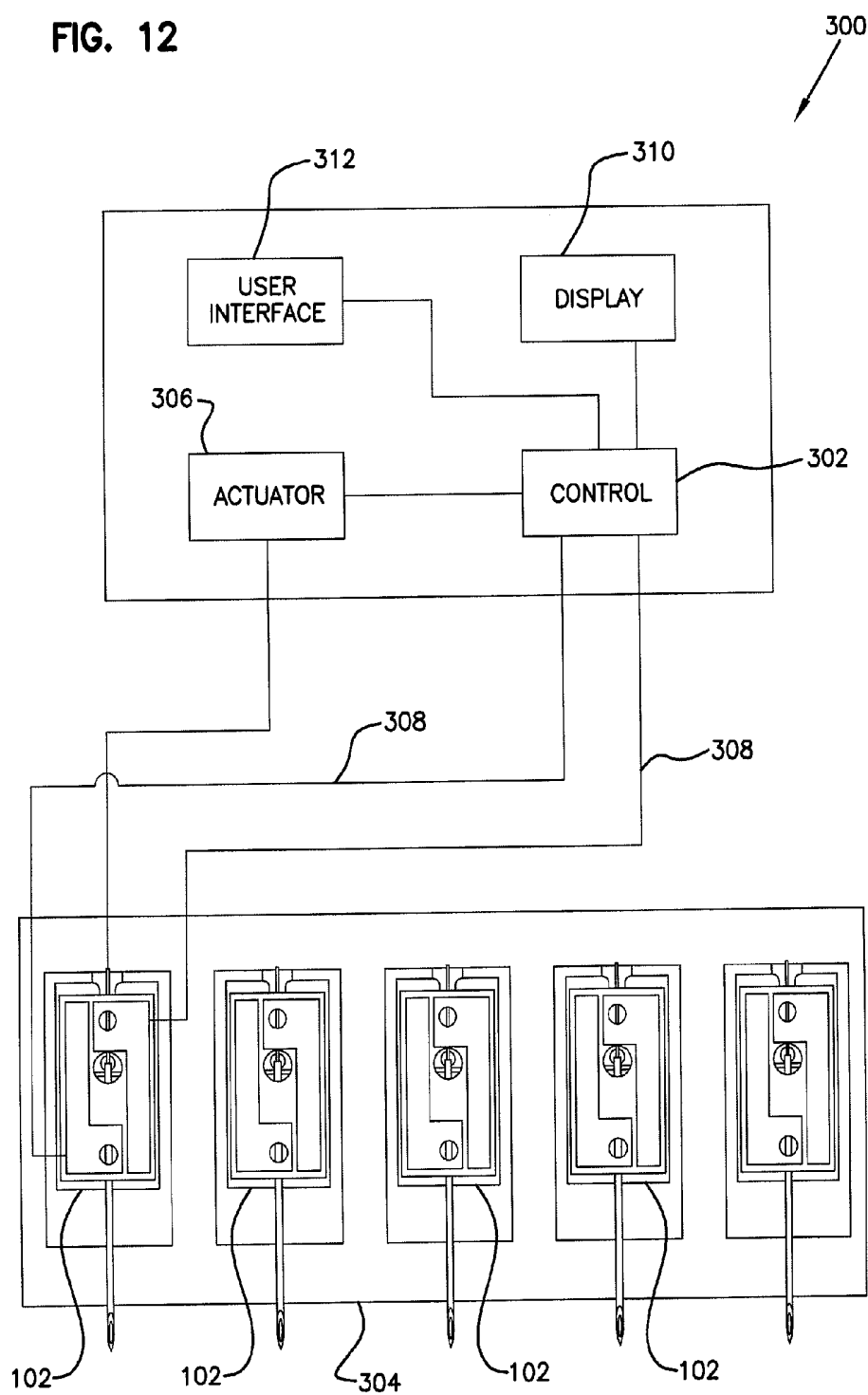
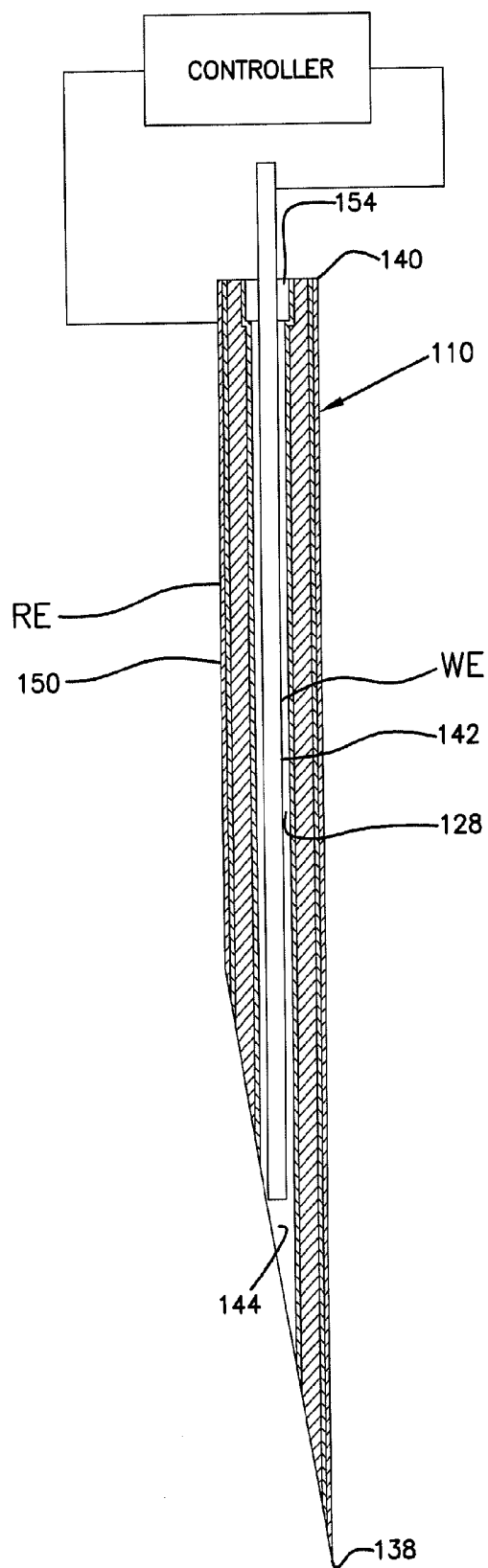


FIG. 13



SENSOR MODULE AND METHOD OF USING A SENSOR MODULE

[0001] This application is being filed on 3 Dec. 2013, as a PCT International patent application and claims priority to U.S. Provisional Application No. 61/732,783, filed Dec. 3, 2012, which application is incorporated herein by reference in its entirety.

TECHNICAL FIELD

[0002] The present disclosure relates generally to sensors. More particularly, the present disclosure relates to sensors for measuring bio-analyte concentrations in blood samples.

BACKGROUND

[0003] Electrochemical bio-sensors have been developed for sensing (e.g., detecting or measuring) bio-analyte concentrations in fluid samples. For example, U.S. Pat. Nos. 5,264,105; 5,356,786; 5,262,035; 5,320,725; and 6,464,849, which are hereby incorporated by reference in their entireties, disclose wired enzyme sensors for sensing analytes, such as lactate or glucose. Wired enzyme sensors have been widely used in blood glucose monitoring systems adapted for home use by diabetics to allow blood glucose levels to be closely monitored. Other example types of blood glucose monitoring systems are disclosed by U.S. Pat. Nos. 5,575,403; 6,379,317; and 6,893,545.

SUMMARY

[0004] In general terms, this disclosure is directed to a sensor and a method of using the same.

[0005] One aspect of the present disclosure relates to a sensor module that includes a carrier and a skin piecing member carried by the carrier. The skin piecing member has a skin piecing end positioned opposite from a base end. The skin piecing member defines a lumen that extends along the central longitudinal axis from the skin piecing end toward the base end where the lumen has a lumen axis. The sensor module includes a blood sample analysis zone located entirely within the lumen of the skin piecing member and a capillary flow stop for stopping capillary flow at a predetermined location within the lumen of the skin piecing member. The sensor module further includes an elongated working electrode positioned within the lumen. The working electrode has a length that extends along the lumen axis where at least a section of the working electrode is positioned within the analysis zone and the working electrode includes sensing chemistry.

[0006] Another aspect of the present disclosure relates to a sensor module including a carrier and a skin piecing member carried by the carrier. The skin piecing member has a skin piecing end positioned opposite from a base end. The skin piecing member defines a lumen that extends along the central longitudinal axis from the skin piecing end toward the base end and the lumen defines a lumen axis. The sensor module includes a blood sample analysis zone located within the lumen of the skin piecing member and an elongated working electrode positioned within the lumen. The working electrode having a length that extends along the lumen axis, at least a section of the working electrode is positioned within the analysis zone and the working electrode includes sensing chemistry. The working electrode has an end within 0.5 millimeters of a tip of the skin piecing member.

[0007] A further aspect of the present disclosure relates to a sensor module including a carrier movable relative to a base between a first position and second position and a skin piecing member carried by the carrier. The skin piecing member has a skin piecing end positioned opposite from a base end and the skin piecing member defines a lumen that extends along the central longitudinal axis from the skin piecing end toward the base end. The lumen defines a lumen axis. The sensor module includes a blood sample analysis zone located entirely within the lumen of the skin piecing member and an elongated working electrode positioned within the lumen. The working electrode has a length that extends along the lumen axis where at least a section of the working electrode is positioned within the analysis zone and the working electrode has sensing chemistry.

[0008] A further aspect of the present disclosure relates to a sensor module that includes a carrier and a skin piecing member carried by the carrier. The skin piecing member has a skin piecing end positioned opposite from a base end and the skin piecing member defines a lumen that extends along the central longitudinal axis from the skin piecing end toward the base end. The lumen defines a lumen axis. The sensor module includes a blood sample analysis zone located within the lumen of the skin piecing member and an elongated working electrode positioned within the lumen. The working electrode has a length that extends along the lumen axis where at least a section of the working electrode is positioned within the analysis zone. The working electrode includes sensing chemistry and is formed by a single fiber or wire.

[0009] A further aspect of the present disclosure relates to a method for taking a blood analyte reading that includes puncturing skin with a skin piecing member having a lumen and positioning a tip of the skin piecing member in a capillary blood field less than 3 millimeters beneath the skin. The method includes initiating blood flow into the lumen by a combination of vascular blood pressure and capillary action to passively bring a blood sample to an analysis zone entirely within the lumen and sensing the blood analyte in the analysis zone.

[0010] Still another aspect of the present disclosure relates to a device for sensing an analyte in a blood sample. The device includes an elongated working electrode having a first portion that is subcutaneous during testing and a second portion that extends outside the body during testing. The device is configured for a one time use in which one analyte reading is taken.

[0011] Another aspect of the present disclosure relates to a device for sensing an analyte in a blood sample. The device includes a working electrode formed by a single conductive fiber or wire having a first portion that is subcutaneous during testing and a second portion that extends outside the body during testing. The working electrode includes a layer of sensing chemistry on the first and second portions of the conductive fiber or wire.

[0012] A further aspect of the present disclosure relates to a device for sensing an analyte in a blood sample. The device includes a working electrode formed by a conductive fiber or wire having a first portion that is subcutaneous during testing and a second portion that extends outside the body during testing. The working electrode includes a layer of sensing chemistry on the first and second portions of the conductive fiber or wire. The device further includes a skin piecing member having a lumen in which the working electrode is

positioned. The conductive fiber or wire has an outer diameter that is at least 10 percent as large as an outer diameter of the skin piercing member.

[0013] A further aspect of the present disclosure relates to a device for sensing an analyte in a blood sample. The device includes a working electrode formed by a conductive fiber or wire having a first portion that is subcutaneous during testing and a second portion that extends outside the body during testing. The working electrode includes a layer of sensing chemistry on the first and second portions of the conductive fiber or wire. The device includes a skin piercing member having a lumen in which the working electrode is positioned. The conductive fiber or wire has an outer diameter that is greater than 0.001 inches.

[0014] Another aspect of the present disclosure relates to a device for sensing an analyte in a blood sample. The device includes an elongated working electrode including a conductive fiber or wire having a first portion that is subcutaneous during testing and a second portion that extends outside the body during testing. The conductive fiber or wire has a cross-dimension greater than 0.001 inches.

[0015] Still another aspect of the present disclosure relates to a device for sensing an analyte in a blood sample. The device includes a working electrode formed by a conductive fiber or wire having a first portion that is subcutaneous during testing and a second portion that extends outside the body during testing. The working electrode includes a layer of sensing chemistry on the first and second portions of the conductive fiber or wire. The device further includes a skin piercing member having a lumen in which the working electrode is positioned. The device is configured such that a blood analysis zone of the device fills passively.

[0016] A variety of additional aspects will be set forth within the description that follows. The aspects can relate to individual features and to combinations of features. 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 broad concepts upon which the embodiments disclosed herein are based.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] FIG. 1 is perspective view of a sensor module in accordance with the principles of the present disclosure;

[0018] FIG. 2 is a top view of the sensor module of FIG. 1 with a skin piercing member of the sensor module in an extended position inserted in a vascular plexus;

[0019] FIG. 3. is a plan view of the sensor module of FIG. 2 with various cross-section lines depicted;

[0020] FIG. 4 is a cross-sectional view taken along line 4-4 of FIG. 2;

[0021] FIG. 5 is a perspective view of another embodiment of a sensor module with a three electrode profile in accordance with the principles of the present disclosure;

[0022] FIG. 6 is an alternate configuration of FIG. 5 with a different extrusion profile;

[0023] FIG. 7 is an end view of another embodiment of a sensor module with a two electrode profile;

[0024] FIG. 8 is a perspective view of the two electrode profile of FIG. 7 with a mask;

[0025] FIG. 9 is a perspective view of the two electrode profile of FIG. 7 with an electrode guide;

[0026] FIG. 10 is an end view of a portion of FIG. 7;

[0027] FIG. 11 is an end view of the two electrode profile of FIG. 7 with contact points depicted;

[0028] FIG. 12 is a schematic view of a sensing unit in accordance with the principles of the present disclosure that incorporates a plurality of the sensing modules of FIG. 1; and

[0029] FIG. 13 is a schematic view of a skin piercing member, reference electrode and working electrode configuration of the sensor module of FIGS. 1-3.

DETAILED DESCRIPTION

[0030] Various embodiments will be described in detail with reference to the drawings, wherein like reference numerals represent like parts and assemblies throughout the several views. Reference to various embodiments does not limit the scope of the claims attached hereto. Additionally, any examples set forth in this specification are not intended to be limiting and merely set forth some of the many possible embodiments for the appended claims.

[0031] The following definitions are provided for terms used herein:

[0032] A “working electrode” is an electrode at which the analyte (or a second compound whose level depends on the level of the analyte) is electrooxidized or electroreduced with or without the agency of an electron transfer agent.

[0033] A “reference electrode” is an electrode used in measuring the potential of the working electrode. The reference electrode should have a generally constant electrochemical potential as long as no current flows through it. As used herein, the term “reference electrode” includes pseudo-reference electrodes. In the context of the disclosure, the term “reference electrode” can include reference electrodes which also function as counter electrodes (i.e., a counter/reference electrode).

[0034] A “counter electrode” refers to an electrode paired with a working electrode to form an electrochemical cell. In use, electrical current passes through the working and counter electrodes. The electrical current passing through the counter electrode is equal in magnitude and opposite in sign to the current passing through the working electrode. In the context of the disclosure, the term “counter electrode” can include counter electrodes which also function as reference electrodes (i.e., a counter/reference electrode).

[0035] A “counter/reference electrode” is an electrode that functions as both a counter electrode and a reference electrode.

[0036] An “electrochemical sensing system” is a system configured to detect the presence and/or measure the level of an analyte in a sample via electrochemical oxidation and reduction reactions on the sensor. These reactions are converted (e.g., transduced) to an electrical signal that can be correlated to an amount, concentration, or level of an analyte in the sample. Further details about electrochemical sensing systems, working electrodes, counter electrodes and reference electrodes can be found at U.S. Pat. No. 6,560,471, the disclosure of which is hereby incorporated herein by reference in its entirety.

[0037] “Electrolysis” is the electrooxidation or electroreduction of a compound either directly at an electrode or via one or more electron transfer agents.

[0038] An “electron transfer agent” is a compound that carries electrons between the analyte and the working electrode either directly or in cooperation with other electron transfer agents. One example of an electron transfer agent is a redox mediator.

[0039] A “sensing layer” is a component of the sensor which includes constituents that facilitate the electrolysis of

the analyte. The sensing layer may include constituents such as an electron transfer agent, a catalyst which catalyzes a reaction of the analyte to produce a response at the electrode, or both.

[0040] FIGS. 1-3 are perspective views of an example of a sensor module 100. In this example, the sensor module 100 includes a carrier 102, a skin piercing member 110, a base 104 and two electrical contacts 112, 114. In FIG. 1, the skin piercing member 110 is shown in a retracted position.

[0041] The carrier member 102 is arranged and configured to slideably move along the base 104 within opposite channels 108 defined by the base 104. The channels 108 of the base 104 limit upward or downward movement of the carrier 102 relative to the base 104. The carrier 102 defines a first cavity 116 to mount the skin piercing member 110. In one example, the piercing member 40 is fixed relative to the carrier 102 such that the piercing member 40 is carried by the carrier 102 as the carrier 102 slides relative to the base 104. The carrier 102 is illustrated and described in more detail with reference to FIGS. 2-3.

[0042] The skin piercing member 110 extends along a length L of the carrier 102. The skin piercing member 110 is movable with the carrier 102 between a retracted position and an extended position (see FIG. 2) relative to the base. The skin piercing member 110 is illustrated and described in more detail with reference to FIGS. 2-4.

[0043] The electrical contacts 112, 114 mount on the carrier 102. The contacts 112, 114 respectively have contact tabs 120, 122. Tab 120 can be used to electrically connect the contact 112 to a reference electrode provided on an exterior surface of the member 110. Tab 122 can be used to electrically connect the contact 114 to a working electrode having a portion that extends into the piercing member 110 and a portion that extends axially outwardly from a base end of the piercing member 110. The contacts 112, 114 can include structures for electrically connecting the sensor module 100 to a sensor control system. In one example, the sensor control system applies a voltage across the working and reference electrodes and through a blood sample contained within a lumen of the skin piercing member 110. The reference electrode can be formed as a conductive layer provided on the outer surface of the skin piercing member 110. The electrical contacts 112, 114 are illustrated and described in more detail with reference to FIGS. 2-3.

[0044] FIGS. 2-3 illustrate features of the carrier 102.

[0045] In one example, the skin piercing member 110 is hollow and defines an interior lumen in which a working electrode is positioned. The working electrode can be formed by a conductive fiber or wire. A sensing layer can cover the conductive fiber or wire. A portion of the conductive fiber or wire covered with the sensing layer can form a sensing region located within a sample analysis zone contained entirely within the skin piercing member. The sample analysis zone 130 can provide for specific control of interrelated parameters such as active electrode area, response time, sensitivity, and drift to be engineered in as byproducts of static component features.

[0046] FIG. 13 is a schematic view showing the skin piercing member 110 having the base end 140 and a tip end 138 (e.g., an insertion end). The skin piercing member 110 defines a lumen 144 that extends through the entire length of the skin piercing member 110 along an axis 10 (e.g., a skin piercing member axis or a lumen axis). A capillary stop can be provided adjacent the base end 140. The elongated working electrode

142 can include a conductive fiber or wire coated or otherwise covered with a sensing layer. The working electrode 142 is positioned within the lumen 144 and can have a lower end within 0.5 millimeters of the tip 138 and an upper end portion that extends out of the lumen 144. The conductive fiber or wire of the working electrode can be covered with a sensing layer suitable for sensing an analyte such as glucose. The skin piercing member 110 can include a conductive core material encapsulated within a dielectric layer that prevents electrical connections between the working electrode and the skin piercing member. A reference electrode can be supported on the dielectric outer surface of the skin piercing member. A control unit can be electrically connected to the reference and working electrodes.

[0047] In use, the skin piercing member is inserted into the skin to a depth less than 3 millimeters such that the tip 138 resides in the capillary bed. As so positioned, a first portion of the working electrode is subcutaneous and a second portion extends outside the body beyond the skin. Upon insertion, the combination of vascular pressure and capillary action causes blood to rapidly fill the lumen 144 and surround the portion of the working electrode within the skin piercing member 110. The blood flows up the lumen to the capillary stop. The volume of space defined within the skin piercing member from the tip to the capillary stop forms an analysis zone having a length that corresponds to a length of a wetted surface area of the sensing chemistry supported on the conductive fiber or wire of the working electrode. The capillary stop combined ensures that the wetted surface area is precisely controlled (i.e., the wetted length of sensor chemistry corresponds to the length of the working electrode that extends below the capillary stop). Applying a voltage between reference and working electrodes causes the oxidation/reduction of glucose in the analysis zone thereby generating a current at the working electrode which can be measured to sense a concentration of glucose in the blood sample. Control circuitry can apply the voltage, measure the current, and provide a display showing a reading indicating the glucose level.

[0048] The sensor module 100 is relatively compact and disposable. For example, the sensor module 100 is generally rectangular in shape and has a length that is less than 1 inch. The sensor module 100 includes opposite major sides and opposite minor sides that extend along the length of the sensor module 100.

[0049] The skin piercing member 110 of the sensor module 100 includes a skin piercing end 136 having a sharp tip 138 and a base end 140. The tip 138 of the skin piercing member 100 penetrates the skin of a patient and can be configured to provide a cutting action that generates a wound that self-closes upon removal of the piercing member 110 from the skin. The skin piercing member 110 can be a cannula, needle, or other similar structure preferably having a hollow interior. In this example, the sensor is configured to allow the analysis of the fluid sample to take place entirely within the skin piercing member 110. The skin piercing member 110 provides a volume or reservoir 107 for collecting blood received from a skin puncture site caused by the skin piercing member 110.

[0050] In one example, the skin piercing member 110 has a non-conductive construction. An example of a non-conductive construction includes a conductive base metal body (for strength) encased within a dielectric layer. The skin piercing member 110 includes a metal body 109 (FIG. 4) that can

include a conductive metal, such as, but not limited to, stainless steel, and can be covered by an insulation layer **111** (FIG. 4), such as, but not limited to, parylene, acting to keep the conductive metal from creating a direct electrical pathway from a reference electrode to a working electrode of a two electrode sensor (e.g., a glucose sensor). The skin piercing member **110** can be about 30 gauge or less to allow for an insertion into a patient's skin tissue without creating either a blood producing wound or noticeable pain or discomfort upon insertion. The skin piercing member **110** can have a length of about 12 to 13 mm. In one example, only a relatively short length of the piercing member **100** extends beyond the base **102** when the carrier is slid to an extended position. In one example, the module **100** is configured such that the insertion depth of the skin piercing member **110** will not exceed 2 millimeters. In another example, the skin insertion depth of the skin piercing member **110** is in the range of about 1.5 to 2 mm. This depth of piercing allows for the sensor in the sensor module **100** to communicate with the vascular plexus (VP) dermal layer of tissue. At this depth, the sensor encounters capillary blood that is representative of cellular glucose.

[0051] In use of the sensor module **100**, a contact end **124** of the base **104** is placed against a patient's skin at a sampling site where it is desired to take a fluid (e.g., blood) sample. Once the contact end **124** is in contact with the skin, the skin piercing member **110** is moved from the retracted position to the extended position (e.g., by sliding the carrier **102** relative to the base **104**) thereby causing the tip **136** of the skin piercing member **110** to pierce the patient's skin. Upon insertion of the skin piercing member **110**, blood from the capillary field fills the skin piercing member **110**. Blood flow is caused at least in part by vascular pressure within the capillary bed. Capillary action also moves blood upwardly within the piercing member **110** to fill a sample analysis zone **130** within the piercing member **110**. At the sample analysis zone **130**, an analyte level (e.g., blood glucose level) in the blood sample is sensed through the use of a wired enzyme sensor arrangement including an elongated working electrode (WE) **142** (FIG. 4) positioned inside the piercing member **110**. In certain embodiments, the electrode can be a fiber, wire, or other elongated member. In other embodiments, separate working, reference and counter electrodes can be provided in fluid communication with the sample analysis zone **130**.

[0052] In some embodiments, a test is initiated by pressing an actuator button (not shown) on top of a meter (not shown) while holding the sensor module **100** on the test site (i.e., forearm or fingertip). This action causes a sequence of motions moving the sensor module **100** from a position within the sensor module **100** to an opening in the bottom of the meter. The meter can be placed on the approved testing site, (i.e., forearm or finger). The actuator button can be pressed again following a prompt causing the carrier **102** of the sensor module **100** carrying the skin piercing member **110** to move rapidly forward inserting the skin piercing member **110** to a prescribed depth. The skin piercing member **110** of the sensor module **100** enters a depth in tissue where a capillary blood field is encountered. The skin piercing member **110** stops at a capillary depth of about less than 3 mm below the skin surface and can reside for about less than 3 seconds to acquire a blood sample. The sample can be presented to the sensor module **100** by a rapid microfluidic flow initiated automatically by a combination of vascular blood pressure and capillary action. The sensor module **100** requires no other active mechanism to obtain a blood glucose value resulting in

a passive system. Once the test is performed or completed, the carrier can be disposed by the user.

[0053] In one embodiment, the working electrode can include an elongated member that is coated or otherwise covered with a sensing layer and the reference/counter electrode can include any elongated member, such as a wire or fiber that is coated or otherwise covered with a layer, such as silver chloride. Preferably, at least a portion of each elongated member is electrically conductive. In certain embodiments, each elongated member can include a metal wire or a glassy carbon fiber. In still other embodiments, each elongated member can each have a composite structure and can include a fiber having a dielectric core surrounded by a conductive layer suitable for forming an electrode. The core can be made of medical grade polyetheretherketone.

[0054] An example composite fiber is sold under the name Resistat® by Shakespeare Conductive Fibers LLC. This composite fiber includes a composite nylon, monofilament, conductive thread material made conductive by the suffusion of about a 1 micron layer of carbonized nylon isomer onto a dielectric nylon core material. The Resistat® material is comprised of isomers of nylon to create the basic 2 layer composite thread. However, many other polymers are available for the construction, such as: polyethylene terephthalate, nylon 6, nylon 6,6, cellulose, polypropylene cellulose acetate, polyacrylonitrile and copolymers of polyacrylonitrile for a first component and polymers such as of polyethylene terephthalate, nylon 6, nylon 6,6, cellulose, polypropylene cellulose acetate, polyacrylonitrile and copolymers of polyacrylonitrile as constituents of a second component. Inherently conductive polymers (ICP) such as doped polyaniline or polypyrrole can be incorporated into the conductive layer along with the carbon to complete the formulation. In certain embodiments, the ICP can be used as the electrode surface alone or in conjunction with carbon. The Resistat® fiber is availability in diameters of 0.0025 to 0.016 inches, which is suitable for sensor electrodes configured in accordance with the principles of the present disclosure. Example patents disclosing composite fibers suitable for use in practicing sensor modules configured in accordance with the principles of the present disclosure include U.S. Pat. Nos. 3,823,035; 4,255,487; 4,545,835 and 4,704,311, which are hereby incorporated herein by reference in their entireties.

[0055] The sensing layers provided at working electrodes of sensor modules configured in accordance with the principles of the present disclosure can include a sensing chemistry, such as a redox compound or mediator. The term redox compound is used herein to mean a compound that can be oxidized or reduced. Example redox compounds include transition metal complexes with organic ligands. Preferred redox compounds/mediators include osmium transition metal complexes with one or more ligands having a nitrogen containing heterocycle such as 2,2'-bipyridine. The sensing material also can include a redox enzyme. A redox enzyme is an enzyme that catalyzes an oxidation or reduction of an analyte. For example, a glucose oxidase or glucose dehydrogenase can be used when the analyte is glucose. Also, a lactate oxidase or lactate dehydrogenase fills this role when the analyte is lactate. In sensor systems, such as the one being described, these enzymes catalyze the electrolysis of an analyte by transferring electrons between the analyte and the electrode via the redox compound. Further information regarding sensing chemistry can be found at U.S. Pat. Nos.

5,264,105; 5,356,786; 5,262,035; and 5,320,725, which were previously incorporated by reference in their entireties.

[0056] In one embodiment, the skin piercing member 110 defines a lumen 144 that extends along an elongated axis 10 from the skin piercing end 136 of the skin piercing member 110 toward the base end 140. The elongated working electrode 142 is positioned within the lumen 144. The elongated working electrode 142 has a length that extends along the lumen axis 20 and at least a section of the elongated working electrode 142 is positioned within the sample analysis zone 130. The elongated working electrode 142 includes the sensing chemistry.

[0057] The interaction of the skin piercing member 110 in concert with microfluidic forces (e.g., surface tension) within the lumen 144 promotes capillary flow of blood. Flow is initiated by ambient capillary pressure at the proximal lumen of the skin piercing member 110 when the piercing member is inserted into the papillary dermis to a depth of between 1-2 mm below the skin. Flow may also be promoted by the treatment of the lumen 144 with a surfactant compound. When so prepared, the combined factors create a driving mechanism to enable a spontaneous flow of capillary blood to enter the proximal lumen 144 and fill the skin piercing member 110 throughout its length.

[0058] The capillary stop 154 is formed at the skin piercing member 110 to inhibit the spontaneous blood flow from exiting the skin piercing member 110 at the distal end of the lumen 144. The self-limiting action of the flow into the interior passage of the skin piercing member 110 facilitates the lumen 144 to function as both an analysis cell—defined by the volume of the skin piercing member 110 and the length of the wetted working electrode WE portion residing within the skin piercing member 110—and as a counter electrode component of a multi electrode electrochemical cell.

[0059] The lumen 144 of the piercing member 110 may be sized appropriately to the configuration of the electrode bundle within it so as to optimize the microfluidic forces affecting the rate of transport thru the passage to the capillary stop 154. The lumen length must extend far enough above the tissue so as to provide sufficient surface area of the working electrode WE to produce a specified minimal output current. However, the lumen length may not be excessive or the time required to fill the lumen will drop rapidly with falling capillary pressure and fluid resistance slowing the transport rate.

[0060] The above described configuration of the electrode array within the piercing member 110 allows the major portion of the electrode surface to remain above the skin line presenting only the diameter of the piercing member 110 to the enervated tissue of the papillary dermis. This configuration allows the effective current produced by the electrode within the piercing member 110 to be two orders of magnitude larger than a traditional implanted sensor occupying the same footprint within tissue. In certain examples, the electrodes have an operational radius of less than 0.15 mm and a length of between 10 mm and 20 mm.

[0061] Referring to FIG. 4, a cross-sectional view of the skin piercing member 110 of the sensor module 100 is shown.

[0062] In this example, the elongated working electrode 142 is positioned within the lumen 144 of the skin piercing member 110 and includes a monofilament 146 (i.e., fiber) that can be coated with a conductive layer 148 (i.e., gold). The monofilament can be a polymeric material such as medical grade polyetheretherketone. The conductive monofilament 146 (fiber or wire) can have an outer diameter that is at least

10 percent as large as an outer diameter of the skin piercing member 110. The conductive layer 148 may be applied as a continuous Plasma Vacuum Deposition (PVD) process. The conductive layer 148 can be less than about 10 microns. The diameters of the multi-fiber composite can be between 0.001 inches and 0.004 inches. In this example, the elongated working electrode 142 may be coated in a secondary process step over the conductive layer 148 with glucose oxidase or other suitable enzyme chemistry. The elongated working electrode 142 may be inserted into the lumen 144 of the skin piercing member 110.

[0063] In this example, the skin piercing member 110 can include a conductive reference electrode (RE) layer 150 formed as a thick film of silver/silver chloride (Ag/Ag/Cl) on the insulated outer surface of the skin piercing member 110. The monofilament 146 (i.e., fiber) can be an aluminum conductive composite monofilament (CCM) with an enzyme sensing layer 152 which can serve as the elongated working electrode 142. The sensor module 100 can become active when an ionic fluid such as blood simultaneously contacts both the outer surface of the conductive reference electrode layer 150 (RE) and the elongated working electrode 142 (WE) completing an electrical circuit through the fluid path. Once the circuit is established by a passive process of rapid capillary flow into the lumen 144 of the skin piercing member 110, blood continues up a defined open passage space (less than 0.004 inches circumferential clearance) surrounding the fiber until encountering a capillary stop 154 feature formed at the base end 140 of the piercing member 110. The lumen 144 can be kept partially open at the base end 140 to serve as an air vent to promote the capillary flow.

[0064] In this example, the insertion end of the lumen 144 should be free of tissue plugs and reside at or below the vascular plexus (VP) between about 1 to 2 mm deep in the dermal layer where capillary vascular pressure is sufficient (about 14 to 22 mm Hg) to promote initial blood flow into the flow passage 128 of the skin piercing member 110. Capillary flow can augment external vascular pressure to rapidly sweep up the interior of the flow passage 128 to the capillary stop 154. Rapid autonomous and complete filling of the sample analysis zone 130—can be defined by the interior volume 107 of the skin piercing member 110 less the volume of the electrode within a space. This filling can be co-determinant of response time and is promoted by the addition of surfactants such as, but not limited to, Triton materials to either the skin piercing member 100 interior surface or to the detector chemistry or both.

[0065] In this example, the sample analysis zone 130 includes a controlled surface area of sensing chemistry that is wetted with blood during testing such that the entire controlled surface area is wetted when the analyte reading is taken. The controlled surface area is at least 10 times as large as a transverse cross-sectional area of the skin piercing member. In other embodiments, the controlled surface area can be at least 20 or 30 times larger than a transverse cross-sectional area of the working electrode.

[0066] Automation suitability can create a sensor configuration that will improve both quality of testing and the reliability of the test procedure for the consumer. The analysis zone method described can rely upon interdependent effects of defined part geometry, spatial relationships of components and specific transitional properties of the enzyme detector chemistry as it is hydrated by the incoming blood matrix. These factors in concert with the dynamic interaction of blood

flowing into the cell in response to vascular pressure and capillary action function as the analysis zone method for establishing a rapid and self-limiting amperometric assay cell formed along a defined section of a long fiber.

[0067] Flow up the lumen **144** of the skin piercing member **110** can be within the microfluidic domain of non-Newtonian laminar flow. This transport dynamic up the circumferential channel **128** defined within the lumen **144** between the working electrode **142** and the inner surface of the skin piercing member **110** can be optimized by promoting low surface energy properties for the WE to allow complete and rapid wetting of the enzyme sensing layer **152**. This surface property in turn can act in concert with the laminar flow dynamics to sweep the entire cavity containing the WE, free of air pockets that could otherwise unpredictably affect the area of blood in contact with the electrode surface causing irreproducible sensor performance.

[0068] The capillary pressure, the viscosity of the blood media plus the surface energy interactions of the electrode coating and the skin piercing member **110** inner wall surface in concert with the distance separating the surfaces can all impact micro capillary flow characteristics.

[0069] The capillary stop **154** can be a mechanism that limits further fluid flow along the enzyme sensing layer **152** forming the WE and provides for venting of air displaced by the rapid filling of the capillary space by blood. In this example, one functional characteristic of the WE is that the dry enzyme detector chemistry can be an effective insulator and can transition in phases from insulator to semiconductor to conductor as it becomes hydrated. This property prevents errant signal contributions to any portion of the CCM fiber kept dry during the time of the glucose assay. By defining the hydrated area of the WE through the combined use of the capillary stop **154** feature with mechanical control of the length of CCM fiber extending down into the skin piercing member passage **134**. This method of defining electrode surface area provides for both manufacturing and functional advantages.

[0070] Referring again to FIGS. 2-3, the electrical contacts **112**, **114** can be made of an electrically conductive material, such as, but not limited to, metals (i.e. copper, silver, aluminum, gold, bronze, and magnesium). During sample analysis at the sample analysis zone, a voltage can be applied between the working and reference electrodes. When the potential is applied, an electrical current will flow through the fluid sample to the working electrode. The current is a result of the oxidation or reduction of an analyte, such as glucose, in the volume of fluid sample located within the sample analysis zone. This electrochemical reaction occurs via the electron transfer agent in the enzyme sensing layer **152** and an optional electron transfer catalyst/enzyme in the enzyme sensing layer **152**. By measuring the current flow generated at a given potential (e.g., with a controller described herein), the concentration of a given analyte (e.g., glucose) in the fluid sample can be determined. Those skilled in the art will recognize that current measurements can be obtained by a variety of techniques including, among other things, coulometric, potentiometric, perometric, voltometric, and other electrochemical techniques.

[0071] In this example, within a few hundredths of a second the defined sample analysis zone **130** is filled and the hydrating WE initiates an exchange electrons with the Ag/AgCl RE pattern on the non-conductive surface of the skin piercing member **110**. A rising current appears at the data acquisition

input of the sensor module **100** causing the software to start a countdown before initiating a data acquisition sequence for a prescribed number of discrete points (currently **500**) taken at intervals over a set time window. The data set can be grouped by taking a mean of the discrete points. An area under the curve analysis can be applied to predict the plateau current for the sensor module **100**. The correlation equates to a calibrated number representing a known glucose concentration at that current. The software then stores the value and can display it to the user on the meter LCD. The entire sequence from initiating actuator button to displayed blood glucose value requires less than 5 seconds. The result of the above testing sequence can be considered to be one reading. In certain examples, the modules **100** are single use and each can be used to provide one glucose reading.

[0072] In certain embodiments, the data can be acquired using wireless device or portable electronic device (PED) such as, but not limited to, cellular phones. The PED can be used to act as a control unit for the sensor module **100**. The sensor module **100** can be configured to interface with the PED which can store and display the glucose concentration to the user. In other embodiments, a separate test unit may be utilized to interface with a wireless device or PED (i.e., cellular phone). A chipset or similar component can be used in a glucose module to link to a PED via a broadband connection. The glucose test module can be connected automatically to the PED to initiate an application that would perform and display all the data management tasks. The glucose test module can be configured to have wide area network (WAN) capability to link to therapeutic software resident on other servers, such as, but not limited to, Cloud, that would completely automate the diabetics provisioning and treatment as well as link to a patient's physician or caregiver in real time. The glucose test module can be about 2.5 inch wide, about 3 inches long and about ¼ inch high.

[0073] Referring to FIG. 5, a perspective view of another embodiment including three CCM electrodes **200**.

[0074] In this example, the three CCM electrodes **200** are arranged and configured such that both RE and WE electrodes **202**, **204** may be simultaneously inserted into a lumen of a skin piercing member. The skin piercing member can have a size between approximately 28 gauge to 30 gauge, preferably a 30 gauge size in the example of home blood glucose testing.

[0075] FIGS. 5-6 show the three CCM electrodes **200** or multi-electrode configurations that are assembled with two different profile extrusions, **208**, **210** capable of insertion into a conductive needle, cannula or tube. In this example, the multi-electrode configuration does not need an insulated coating or a non-conductive piercing member as an RE electrode substrate; but may be only a piercing member, such as, but not limited to, a cannula, acting as the mechanical needle component. The piercing member can be made of a standard stainless steel material or similar material. The multi-electrode configuration may also be used as a catheter insert for continuous or remote monitoring applications.

[0076] The configuration of the multi-electrode may employ slightly different micro extrusion profiles as carriers for the three CCM electrodes **200**, WE and RE fiber electrodes **202**, **204**. The micro extruded carrier profile is so designed in cross section as to maintain electrical isolation of the RE and WE **202,204**—both from each other, and from the stainless steel piercing member (i.e., cannula). In some embodiments, the multi-electrode may have two working electrodes and one RE. The specific properties and profile

extrusions **208, 210** (FIG. 6) combined with dedicated features incorporated into the extruded profile helps provide for unrestricted capillary flow up a flow passage of the skin piercing member, electrical isolation of the conductive components without the co-extrusion of the three CCM electrodes **200** that may be incompatible with such extrusion process, and combining four extrusion components into a single reel structure capable of insertion into the lumen of the skin piercing member. In this example, the profile may be configured to allow three or more electrodes to reside within a skin piercing member and operate as a three electrode enzymatic detection system.

[0077] The multi-electrode configuration allows for the ability to eliminate an Ag/Ag/Cl film coating for the RE **202** and substitute a composite Ag substrate fiber that can be fabricated in the same substrate materials and PVD process as the WE. The multi-electrode configuration can include a third electrode **206** (e.g., a supplemental electrode) that has no need for enzyme or detector chemistry. The third electrode **206** may be employed as a comparison means to determine what portion of the raw sensor current comes from interferent compounds such as vitamin C rather than from glucose. The comparison means can be a result of oxidizing those compounds at the bare Au surface and subtracting the apparent signal from the total sensor output. This function eliminates a developmental step in the electrode design and can help to resolve a common background noise problem for sensor accuracy. In other embodiments, additional electrodes beyond the three electrode profile may be added to the structure for the purpose of multi-parameter assays. Multi-parameter sensors providing more than two analyte targets for use in continuous monitoring can be fabricated. The supplemental electrode can also be used to detect other analytes (e.g., lactate) or to detect oxygen concentration.

[0078] Turning to FIG. 6, a top view of the three CCM electrodes **200** is shown. The fabrication of the profile extrusion **210** can be made by means of micro extrusion technology combined with continuous PVD technology as can be used in the gold coating process for CCM electrodes. The profile extrusions **208, 210** can be used to insulate the three CCM electrodes **200** from one another as well as from the interior wall of a skin piercing member. In this example, the extrusion profiles **208, 210** can be about 0.001 inches thick. The profiles can be configured to maximize fluid transport fully along the interior passage of the skin piercing member.

[0079] Referring to FIG. 7, a perspective view of a two electrode **400** configuration for a sensor module is shown.

[0080] In this example, the two electrodes **400** configuration includes a monofilament **402** (i.e., fiber). The monofilament **402** can be insulated using an insulating substrate layer **404** similar to the embodiments described above. The monofilament **402** is capable of insertion into a lumen **406** of a skin piercing member **408**. As shown, an Ag/Ag/Cl layer **410** can be applied directly onto the insulating substrate layer **404**.

[0081] Referring to FIG. 8, a perspective top view of the two electrodes **400** configuration is shown.

[0082] The Ag/Ag/Cl layer **410** can be applied using fixtures and/or masks **412** to direct a plasma deposition of silver (Ag) travelling perpendicular to the plane P of the mask **412** onto a single surface of the profile for forming the RE. FIG. 9 shows an electrode guide **414** that can be used to help control the position of the profile in transit through the PVD process. The profile having the Ag/Ag/Cl layer **410** deposition surface can act as the RE and the CCM monofilament **402** (i.e., fiber)

coated with enzyme chemistry provides the WE function. FIG. 10 depicts arrows **416** that show features that can guide the profile and prevent both the RE and WE from contacting the conductive surface of the skin piercing member **408**. FIG. 11 show contact points **418** that can be opposing where output contact features can impinge a sensor module and acquire a signal.

[0083] Referring to FIG. 12, a schematic of an analyte monitoring unit **300** is shown. The unit **300** where the modules **100** may be arrayed within a cartridge designed to provide a supply of multiple sensors that may be directly positioned on the skin of a patient's forearm or fingertip in order to obtain a blood glucose concentration. It will be appreciated that one or more sensor modules **100** can be incorporated as sub-components into an analyte monitoring unit **300**. The unit **300** includes a controller **302** that couples to a module holder **304**. The module holder **304** is configured to hold one or more sensor modules **100**. Each sensor module **100** is configured to obtain one or more fluid samples, to measure a concentration level for one or more analytes (e.g., glucose, lactate, etc.), and to generate a signal (e.g., an electrical signal) indicating the concentration level. For example, the module holder **304** shown in FIG. 7 contains five sensor modules **100**. In one embodiment, each sensor module **100** is configured to analyze a single fluid sample. In such an embodiment, the sensor module **100** can be removed from the module holder **304** after one use. In other embodiments, each sensor module **100** can be configured to analyze a greater number of fluid samples.

[0084] In general, the unit **300** includes a controller **302**, an actuator **306**, and input lines **308**. The controller **302** controls the actuator **306** for driving the skin piercing members **110** of each sensor module **100** between the extended and retracted positions to obtain a fluid sample. The controller **302** can include a microcontroller, a mechanical controller, software driven controller, a hardware driven controller, a firmware driven controller, etc. The controller can include a microprocessor that interfaces with memory.

[0085] The controller **302** instructs the actuator **306** when to operate the sensor module **100** to obtain a fluid sample for analysis. The controller **302** also can instruct the module holder **304** and/or the actuator **306** to eject the used sensor module **100**.

[0086] The input lines **308** carry the data/signals/readings (e.g., voltage values) generated at the elongated working electrode **142** of the sensor module **100** during analysis of a fluid sample to the controller **302** for analysis. The controller **302** converts the signals to an analyte concentration level (e.g., a blood glucose reading) or other desired information. The controller **302** causes the display **310** to indicate the processed information to the user. Other information also can be presented on the display **310**. In one embodiment, the display **310** is a visual display. In other embodiments, an audio display also can be used. Additional information can be provided to the controller **302** via a user interface **312** (e.g., buttons, switches, etc.).

[0087] From the forgoing detailed description, it will be evident that modifications and variations can be made without departing from the spirit and scope of the disclosure.

1.-76. (canceled)

77. A sensor module comprising:

a carrier;

a skin piercing member carried by the carrier, the skin piercing member having a skin piercing end positioned opposite from a base end, the skin piercing member

- defining a lumen that extends along the central longitudinal axis from the skin piercing end toward the base end, the lumen having a lumen axis;
- a blood sample analysis zone located entirely within the lumen of the skin piercing member;
- a capillary flow stop for stopping capillary flow at a predetermined location within the lumen of the skin piercing member; and
- an elongated working electrode positioned within the lumen, the working electrode having a length that extends along the lumen axis, at least a section of the working electrode being positioned within the analysis zone, and the working electrode including sensing chemistry.
- 78.** The sensor module of claim **1**, further comprising a base to which the carrier is mounted, wherein the carrier can slide relative to the base between a first position where the skin piercing end of the skin piercing member is exposed and a second position wherein the skin piercing member is retracted, wherein the skin piercing member extends no more than 3 millimeters beyond the base when in the first position, wherein the sensor module does not include an active means for drawing blood into the lumen, wherein the skin piercing member defines a diameter less than or equal to a 28 gauge needle, and wherein a first end of the working electrode is within 2 millimeters of a tip of the skin piercing end of the skin piercing member.
- 79.** The sensor module of claim **1**, wherein the blood sample analysis zone extends for at least a majority of a length of the skin piercing member.
- 80.** The sensor module of claim **1**, further comprising a vent positioned at the capillary stop.
- 81.** The sensor module of claim **1**, wherein the blood sample analysis zone extends within the skin piercing member from a tip of the skin piercing member to the capillary stop, wherein the blood sample analysis zone has a length that corresponds to a controlled wetted length of the sensing chemistry supported on the working electrode, wherein the sensing chemistry is a dry sensing chemistry that is hydrated as the blood flows along the lumen, wherein the sensing chemistry is dielectric when dry, and transitions from semi-conductive to conductive as the sensing chemistry hydrates, and wherein the sensing chemistry includes glucose oxidase or glucose dehydrogenase.
- 82.** The sensor module of claim **1**, further comprising an elongated micro extrusion that carries the working electrode and a reference electrode, wherein the micro extrusion maintains separation between the working electrode and the reference electrode and also separates the working and reference electrodes from an interior surface of the skin piercing member.
- 83.** The sensor module of claim **6**, wherein at least one of the electrodes is applied as a layer to the micro extrusion.
- 84.** The sensor module of claim **1**, wherein the sensor module is configured for a one time use in which one analyte reading is taken.
- 85.** The sensor module of claim **1**, wherein the sensor module is configured such that a first portion of the blood sample analysis zone is subcutaneous during testing and a second portion of the blood sample analysis zone is outside the body during testing.

86. The sensor module of claim **1**, wherein the wherein the sensing chemistry has a controlled surface area that is at least 10 times as large as a transverse cross-sectional area of the skin piercing member.

87. The sensor module of claim **1**, wherein the wherein the sensing chemistry has a controlled surface area that is at least 20 times as large as a transverse cross-sectional area of the skin piercing member.

88. The sensor module of claim **1**, wherein the wherein the sensing chemistry has a controlled surface area that is at least 30 times as large as a transverse cross-sectional area of the skin piercing member.

89. The sensor module of claim **1**, wherein the sensor module is configured such that a first portion of the working electrode is subcutaneous during testing and a second portion extends outside the body during testing, the first and second portions of the working electrode including the sensing chemistry.

90. A sensor comprising:

a skin piercing member having a skin piercing end positioned opposite from a base end, the skin piercing member defining a lumen that extends along the central longitudinal axis from the skin piercing end toward the base end, the lumen defining a lumen axis;

a blood sample analysis zone located entirely within the lumen of the skin piercing member, the blood sample analysis zone extending along at least a majority of a length of the skin piercing member; and

an elongated working electrode positioned within the lumen, the working electrode having a length that extends along the lumen axis, at least a section of the working electrode being positioned within the blood sample analysis zone.

91. The sensor of claim **14**, wherein sensor chemistry is positioned within the lumen, and wherein a controlled wetted length of the sensor chemistry corresponds to a length of the blood sample analysis zone.

92. The sensor of claim **15**, wherein the sensing chemistry has a controlled surface area that is at least 10 times as large as a transverse cross-sectional area of the skin piercing member.

93. The sensor of claim **14**, further comprising an elongated micro extrusion that carries the working electrode and a reference electrode, wherein the micro extrusion maintains separation between the working electrode and the reference electrode and also separates the working and reference electrodes from an interior surface of the skin piercing member.

94. The sensor of claim **17**, wherein at least one of the electrodes is applied as a layer to the micro extrusion.

95. A sensor comprising:

a skin piercing member having a skin piercing end positioned opposite from a base end, the skin piercing member defining a lumen that extends along the central longitudinal axis from the skin piercing end toward the base end, the lumen defining a lumen axis;

a blood sample analysis zone located entirely within the lumen of the skin piercing member, wherein sensor chemistry is positioned within the lumen, wherein a controlled wetted length of the sensor chemistry corresponds to a length of the blood sample analysis zone, and wherein the sensing chemistry has a controlled surface area that is at least 10 times as large as a transverse cross-sectional area of the skin piercing member; and

an elongated working electrode positioned within the lumen, the working electrode having a length that extends along the lumen axis, at least a section of the working electrode being positioned within the analysis zone.

96. The sensor of claim **19**, further comprising an elongated micro extrusion that carries the working electrode and a reference electrode, wherein the micro extrusion maintains separation between the working electrode and the reference electrode and also separates the working and reference electrodes from an interior surface of the skin piercing member.

97. A device for sensing an analyte in a blood sample, the device comprising:

an elongated working electrode having a first portion that is subcutaneous during testing and a second portion that extends outside the body during testing, the first and second portions including sensing chemistry, the device being configured for a one time use in which one analyte reading is taken.

98. A device for sensing an analyte in a blood sample, the device comprising:

an elongate working electrode having a first portion that is subcutaneous during testing and a second portion that extends outside the body during testing, the working electrode including a layer of sensing chemistry on the

first and second portions, the device including a skin piercing member having a lumen in which the working electrode is positioned, the device being configured such that a blood analysis zone within the skin piercing member fills passively.

99. A method for taking a blood analyte reading comprising:

puncturing skin with a skin piercing member having a lumen;

positioning a tip of the skin piercing member in a capillary blood field less than 3 millimeters beneath the skin;

initiating blood flow into the lumen by a combination of vascular blood pressure and capillary action to passively bring a blood sample to an analysis zone entirely within the lumen; and

sensing the blood analyte in the analysis zone.

100. The method of claim **23**, further comprising stopping blood flow in the lumen at a capillary flow stop.

101. The method of claim **23**, wherein at least a portion of the analysis zone is positioned outside the body during testing.

102. The method of claim **23**, wherein a first portion of the analysis zone is subcutaneous and a second portion of the analysis zone is outside the body during testing.

* * * * *

专利名称(译)	传感器模块和使用传感器模块的方法		
公开(公告)号	US20150313521A1	公开(公告)日	2015-11-05
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当前申请(专利权)人(译)	PEPEX生物医学, INC.		
[标]发明人	SAY JAMES L		
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IPC分类号	A61B5/157 A61B5/145 A61B5/15 A61B5/151 A61B5/00 A61B5/1486		
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优先权	61/732783 2012-12-03 US		
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摘要(译)

这里公开了一种传感器模块。传感器模块包括由载体承载的皮肤穿刺构件。皮肤穿刺构件具有与基端相对定位的皮肤穿刺端。皮肤穿刺构件限定了内腔，该内腔沿着中心纵向轴线从皮肤穿刺端朝向基端延伸，并且内腔具有内腔轴线。传感器模块还包括完全位于皮肤穿刺构件的内腔内的血液样本分析区域和用于阻止皮肤穿刺构件的内腔内的预定位置处的毛细管流动的毛细管流动止动件。传感器模块包括位于腔内的细长工作电极。工作电极具有沿管腔轴线延伸的长度，其中工作电极的至少一部分位于分析区域内。工作电极包括传感化学物质。

