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Pushpala et al.

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(54) **SYSTEM FOR MONITORING BODY CHEMISTRY**

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(73) Assignee: **Sano Intelligence, Inc.**, San Francisco, CA (US)

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(21) Appl. No.: **15/601,204**

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(65) **Prior Publication Data**

US 2017/0251958 A1 Sep. 7, 2017

Related U.S. Application Data

(63) Continuation-in-part of application No. 15/412,229, filed on Jan. 23, 2017, which is a continuation of (Continued)

(51) **Int. Cl.**

A61B 5/1473 (2006.01)

A61B 5/145 (2006.01)

(Continued)

(52) **U.S. Cl.**

CPC **A61B 5/1451** (2013.01); **A61B 5/0022** (2013.01); **A61B 5/0537** (2013.01); (Continued)

(58) **Field of Classification Search**

CPC **A61B 5/14532**; **A61B 5/14865**; **A61M 5/1723**

See application file for complete search history.

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Primary Examiner — Etsub D Berhanu

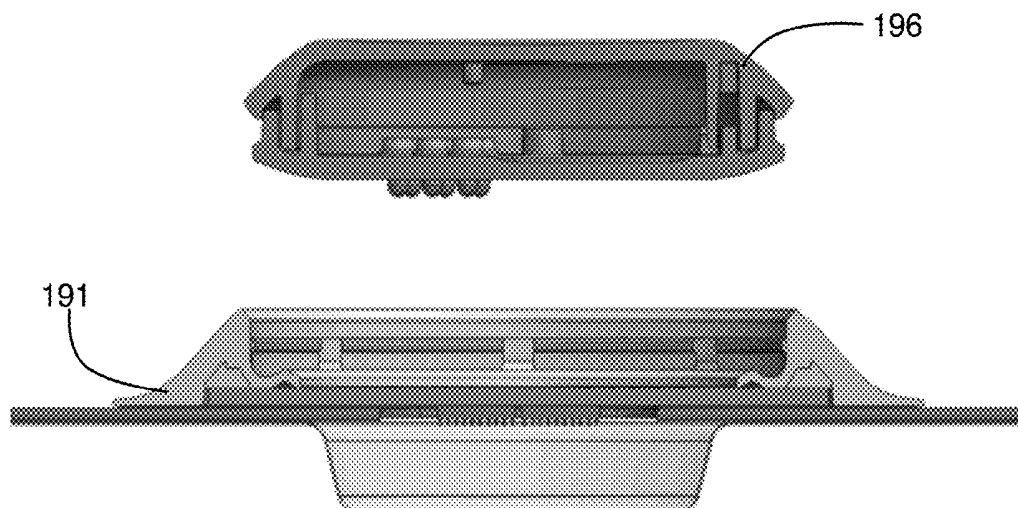
Assistant Examiner — Michael A Catina

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(57) **ABSTRACT**

A system and method for monitoring body chemistry of a user, the system comprising: a housing supporting: a microsensor comprising a first and second working electrode, a reference electrode, and a counter electrode, and configured to access interstitial fluid of the user, and an electronics subsystem comprising a signal conditioning module that receives a signal stream, from the microsensor, wherein the electronics subsystem is configured to detect an impedance signal derived from two of the first working electrode, the second working electrode, the reference electrode, and the counter electrode; and a processing subsystem comprising: a first module configured to generate an analysis indicative of an analyte parameter of the user and derived from the signal stream and the impedance signal, and a second module configured to transmit information derived from the analysis to the user, thereby facilitating monitoring of body chemistry of the user.

20 Claims, 31 Drawing Sheets



Related U.S. Application Data

- application No. 14/657,973, filed on Mar. 13, 2015, now abandoned.
- (60) Provisional application No. 61/952,594, filed on Mar. 13, 2014, provisional application No. 62/012,874, filed on Jun. 16, 2014, provisional application No. 62/025,174, filed on Jul. 16, 2014.

(51) Int. Cl.*A61B 5/00* (2006.01)*A61B 5/053* (2006.01)*G16H 40/67* (2018.01)**(52) U.S. Cl.**

CPC *A61B 5/0538* (2013.01); *A61B 5/1473* (2013.01); *A61B 5/14532* (2013.01); *A61B 5/14546* (2013.01); *A61B 5/685* (2013.01); *A61B 5/688* (2013.01); *A61B 5/6833* (2013.01); *A61B 5/6849* (2013.01); *A61B 5/7275* (2013.01); *A61B 5/7278* (2013.01); *A61B 5/746* (2013.01); *G16H 40/67* (2018.01); *A61B 5/0002* (2013.01); *A61B 5/6885* (2013.01); *A61B 5/7285* (2013.01); *A61B 2562/028* (2013.01); *A61B 2562/0214* (2013.01); *A61B 2562/046* (2013.01); *A61B 2562/164* (2013.01)

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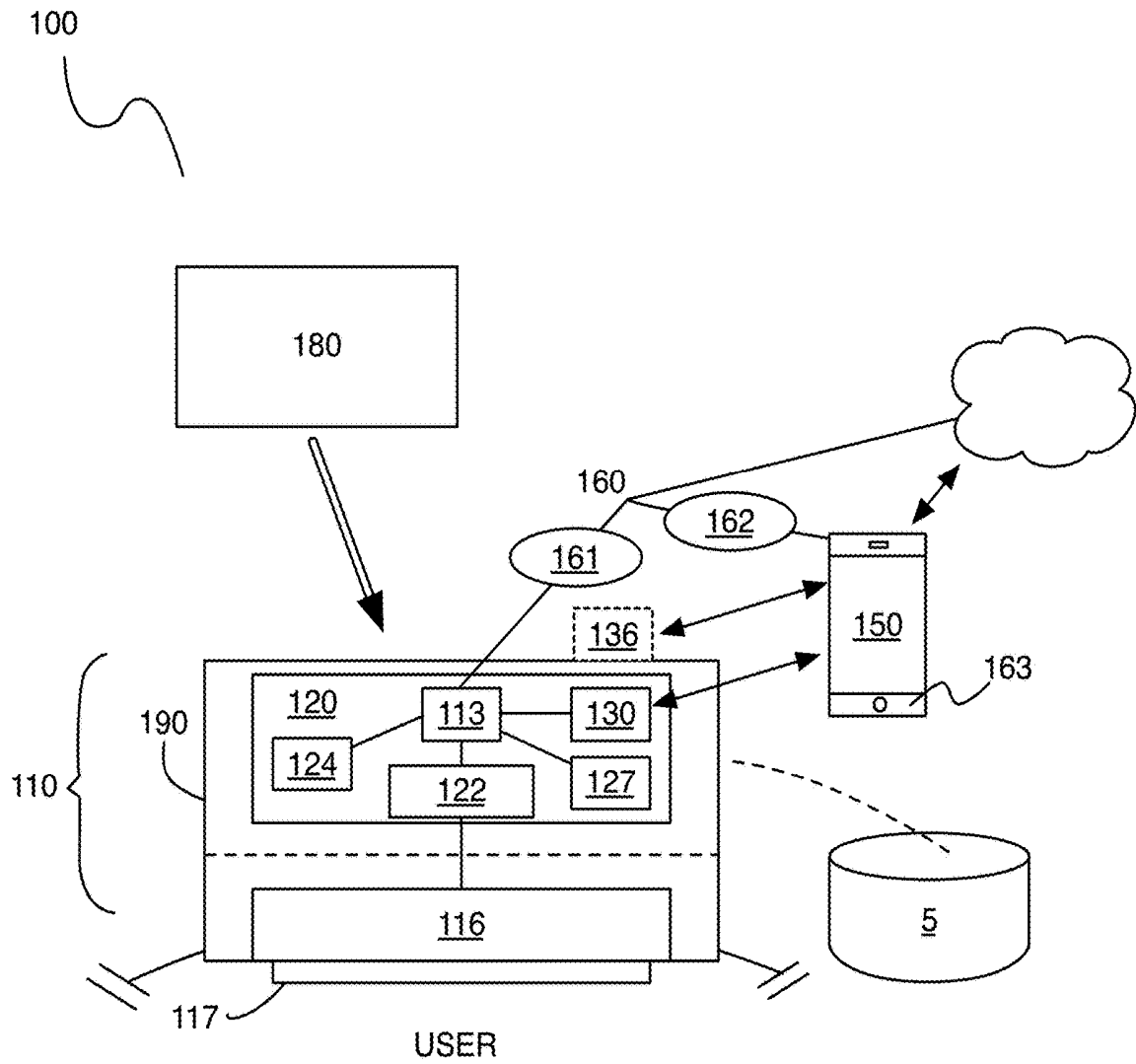
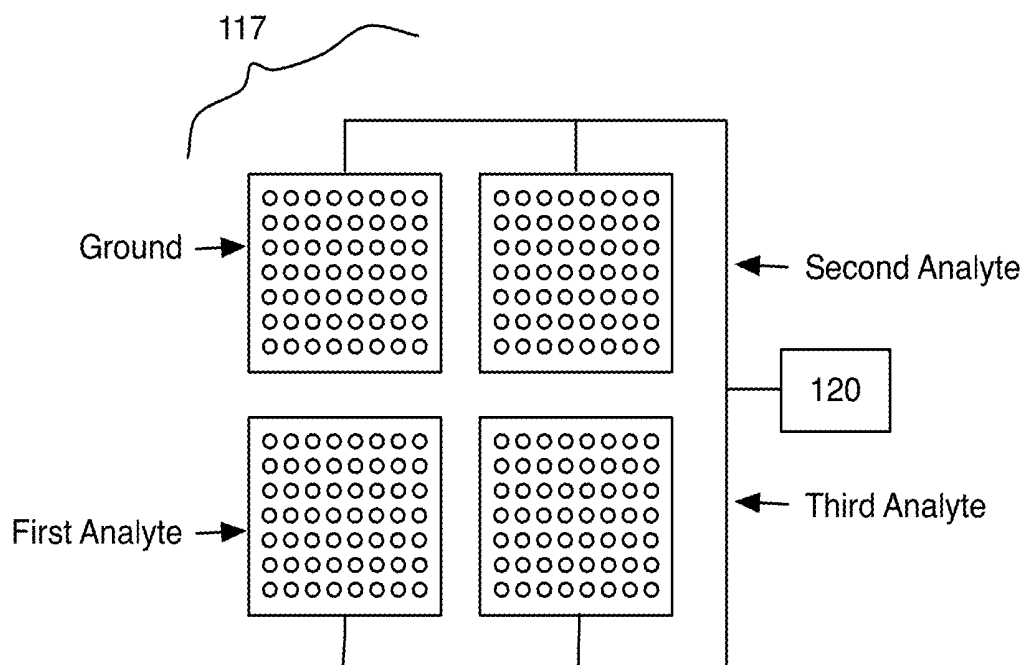
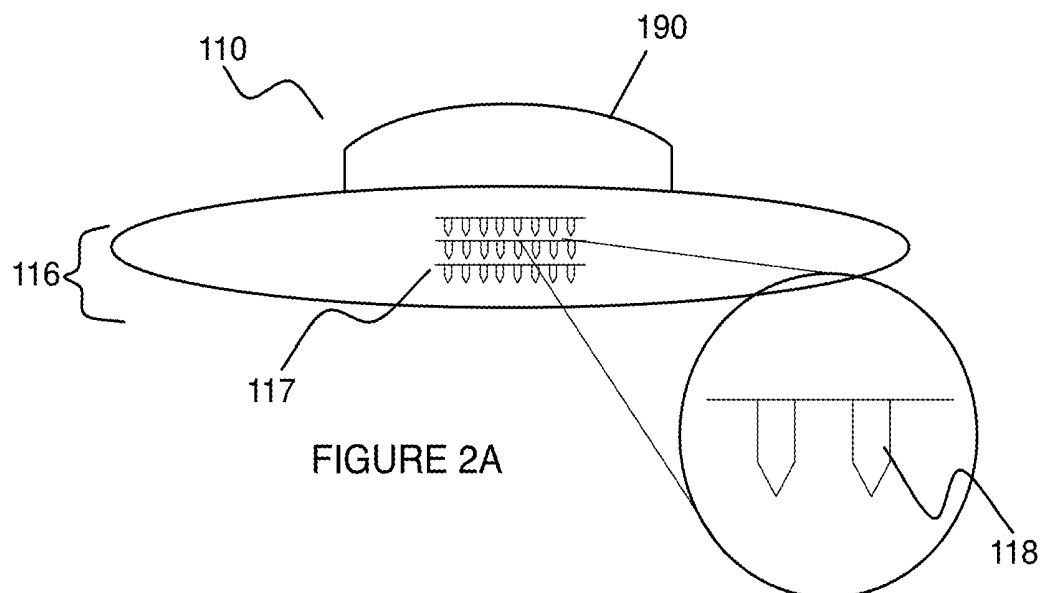


FIGURE 1



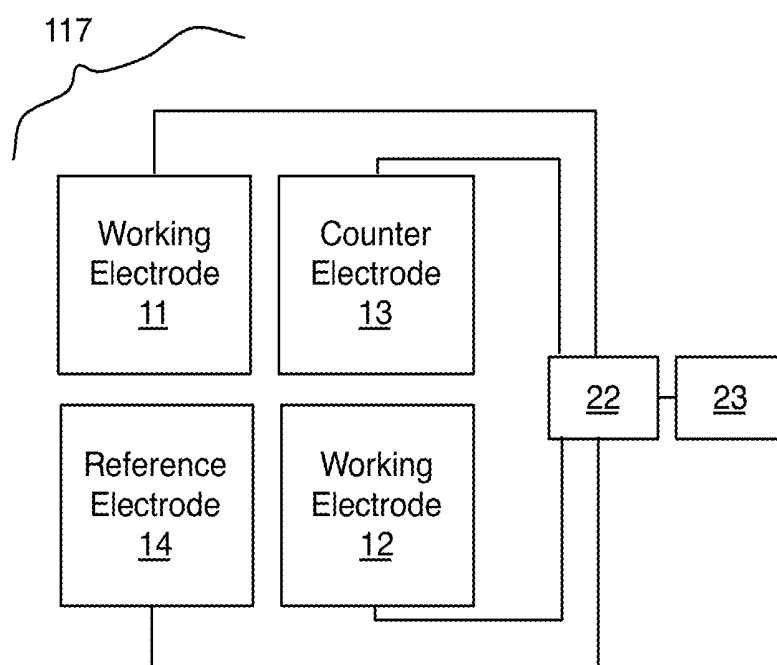


FIGURE 2C

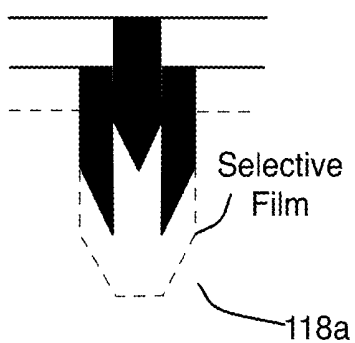


FIGURE 3A

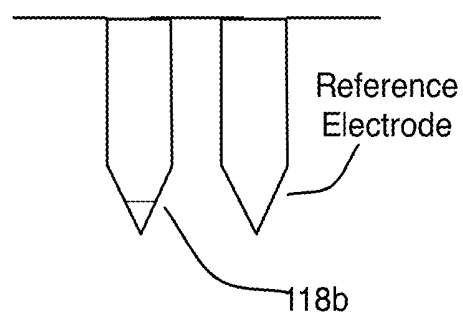


FIGURE 3B

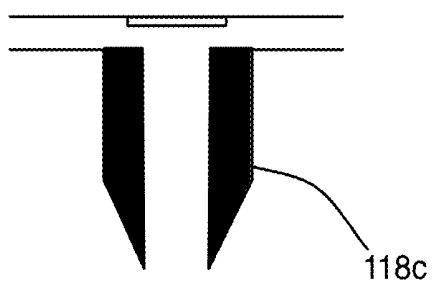


FIGURE 3C

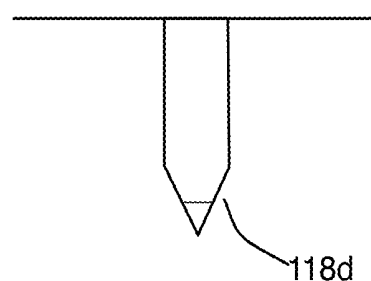


FIGURE 3D

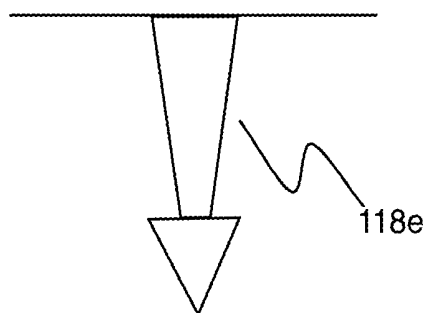


FIGURE 3E

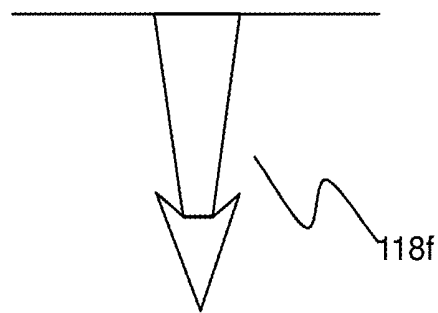


FIGURE 3F

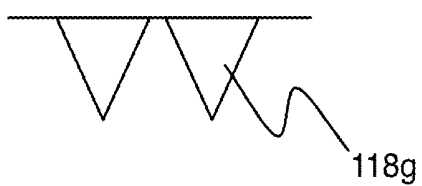


FIGURE 3G

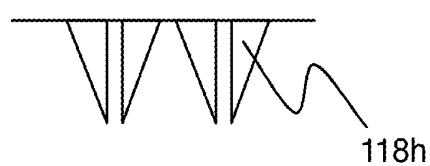


FIGURE 3H

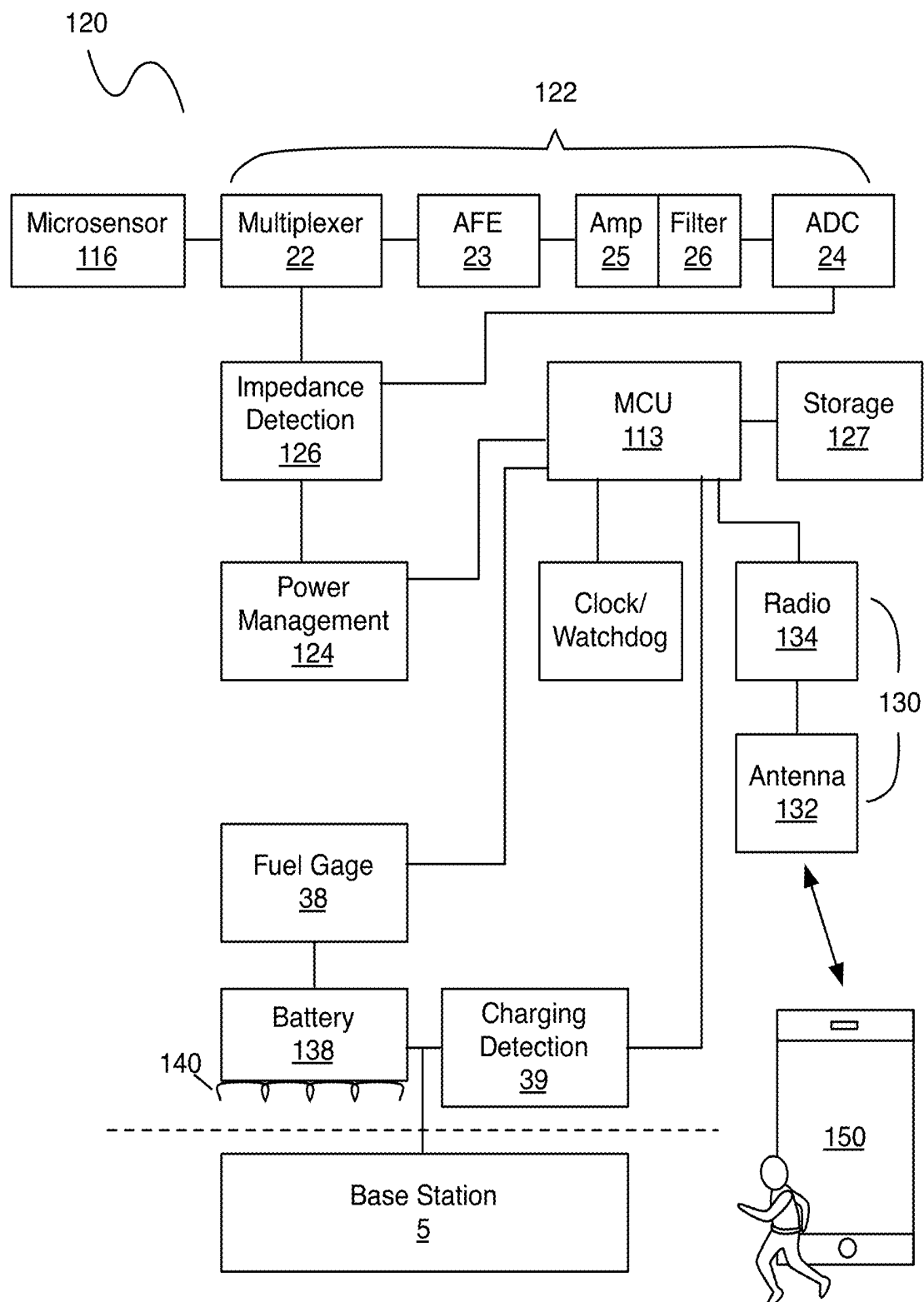


FIGURE 4

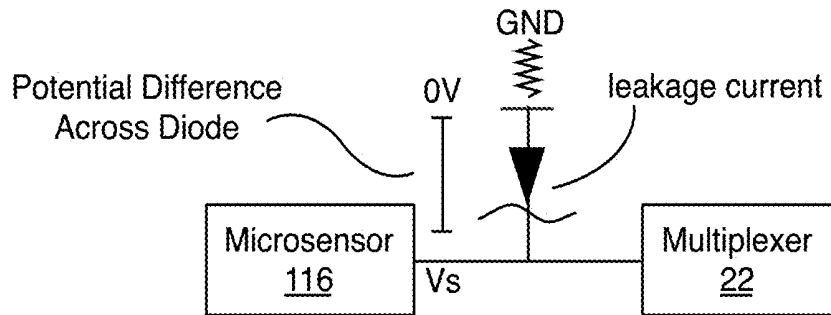


FIGURE 5A

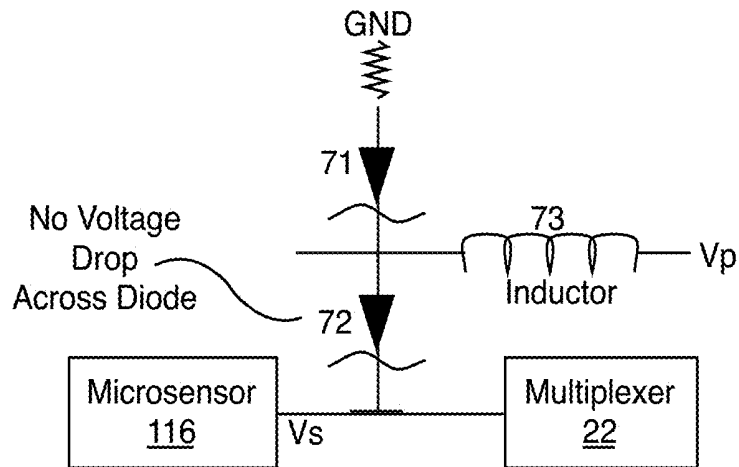


FIGURE 5B

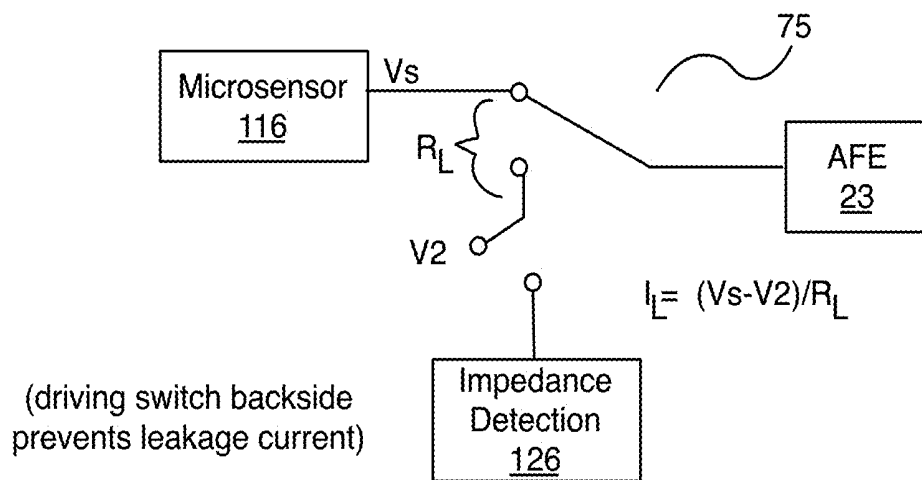


FIGURE 5C

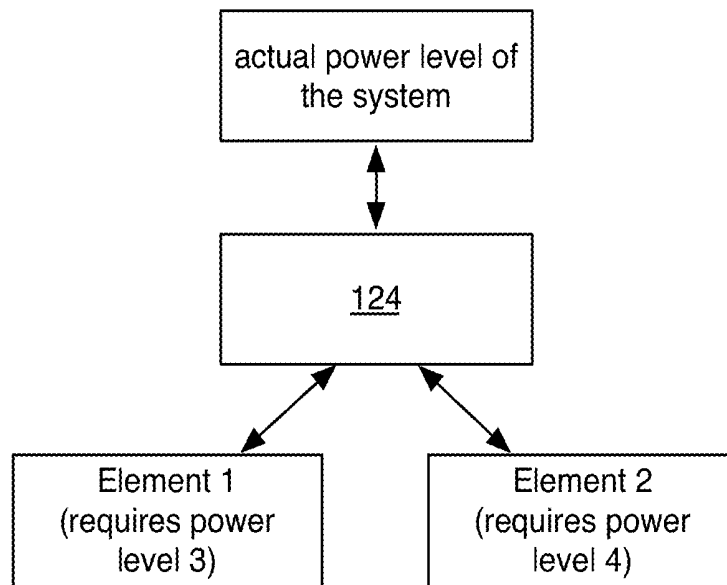


FIGURE 6A

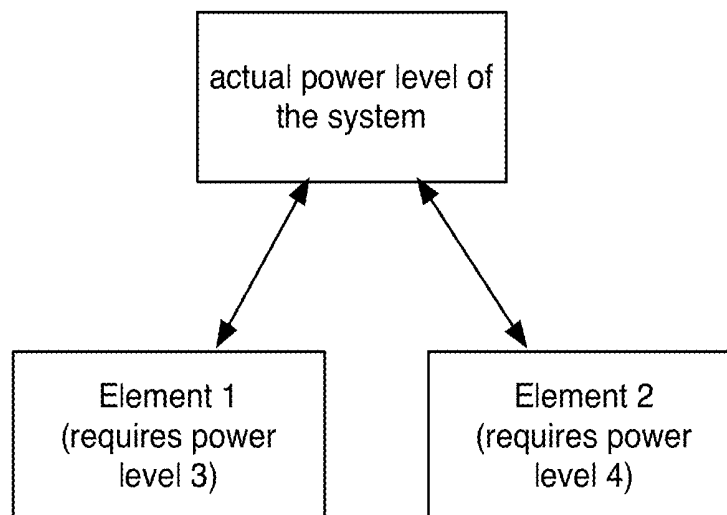


FIGURE 6B

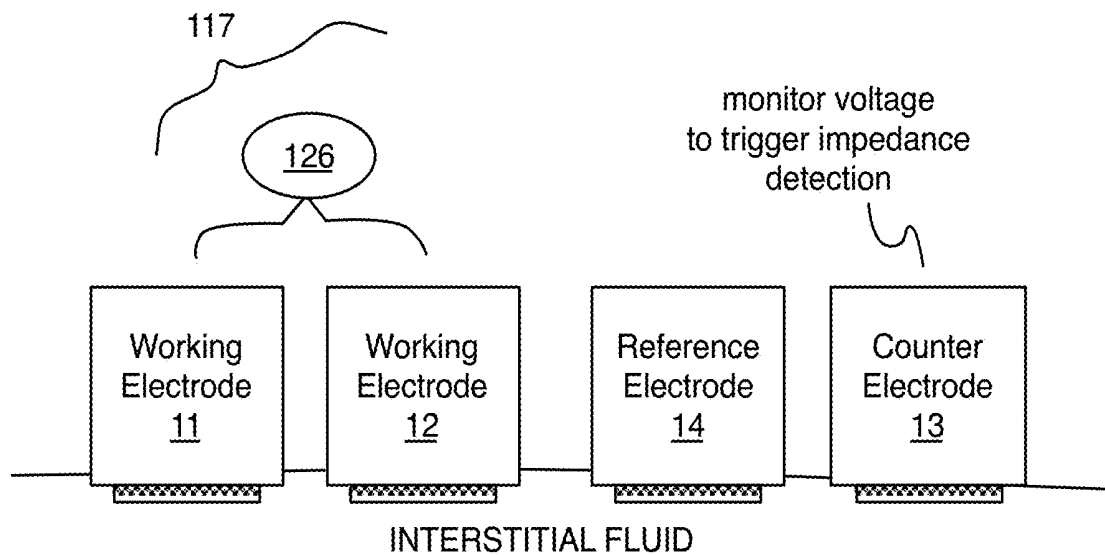


FIGURE 7

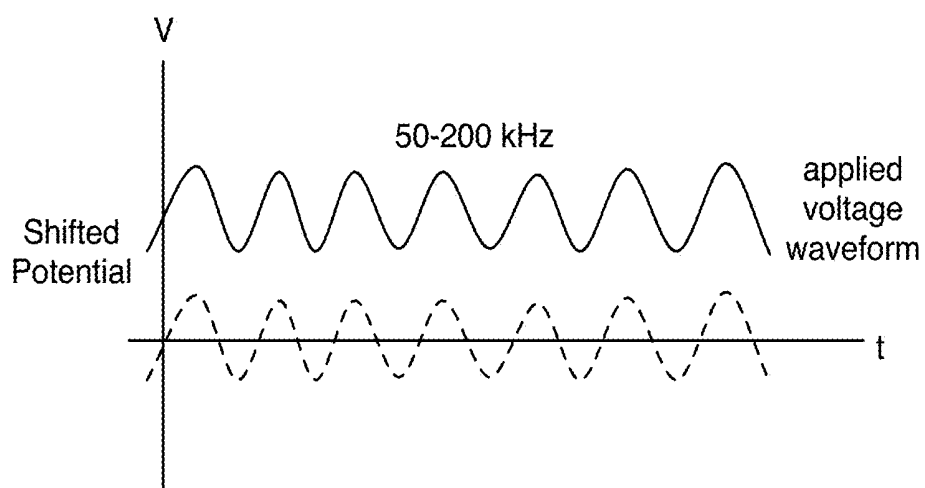


FIGURE 8

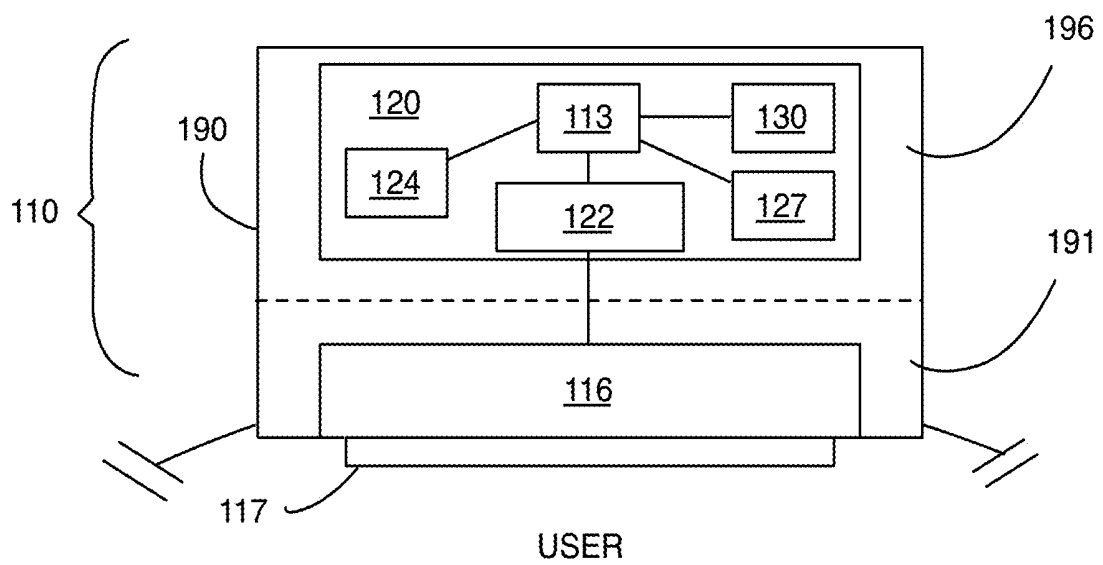


FIGURE 9

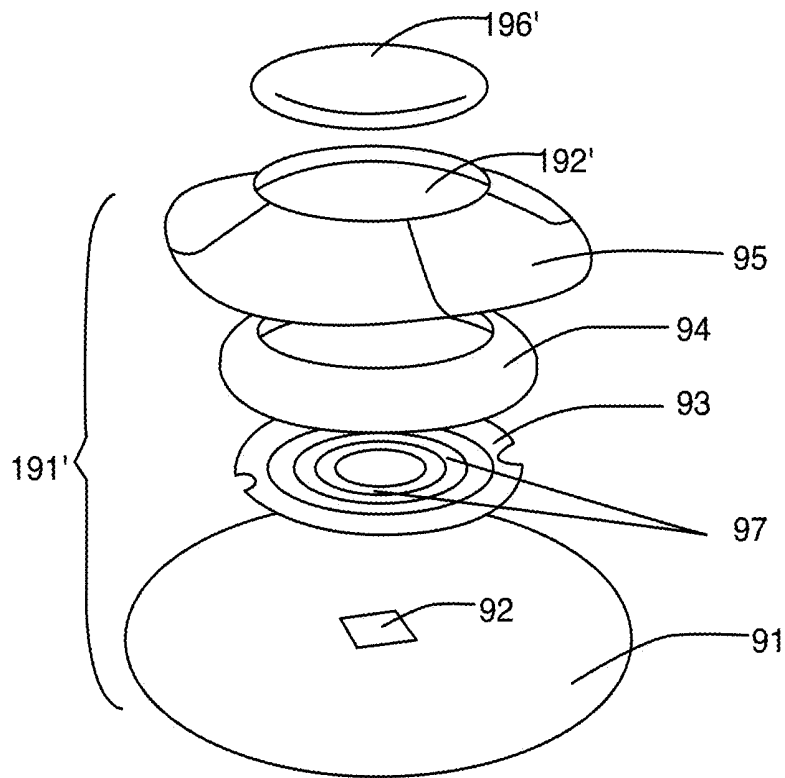


FIGURE 10A

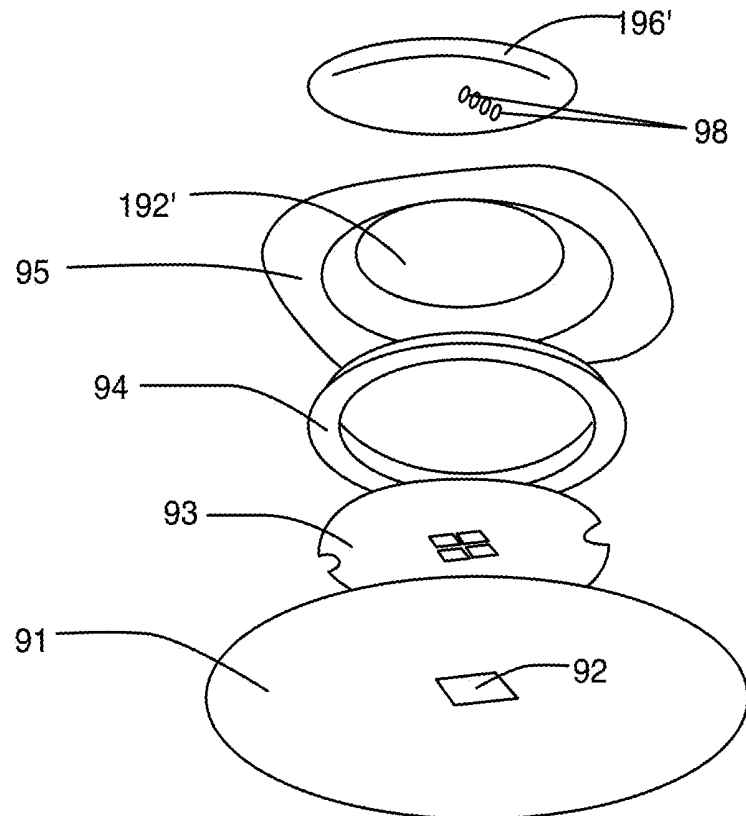


FIGURE 10B

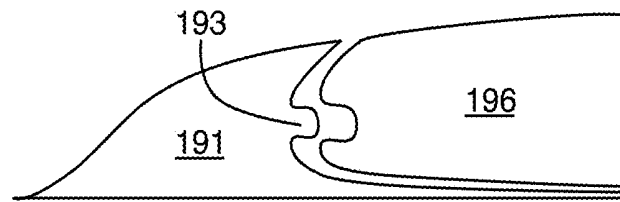


FIGURE 10C

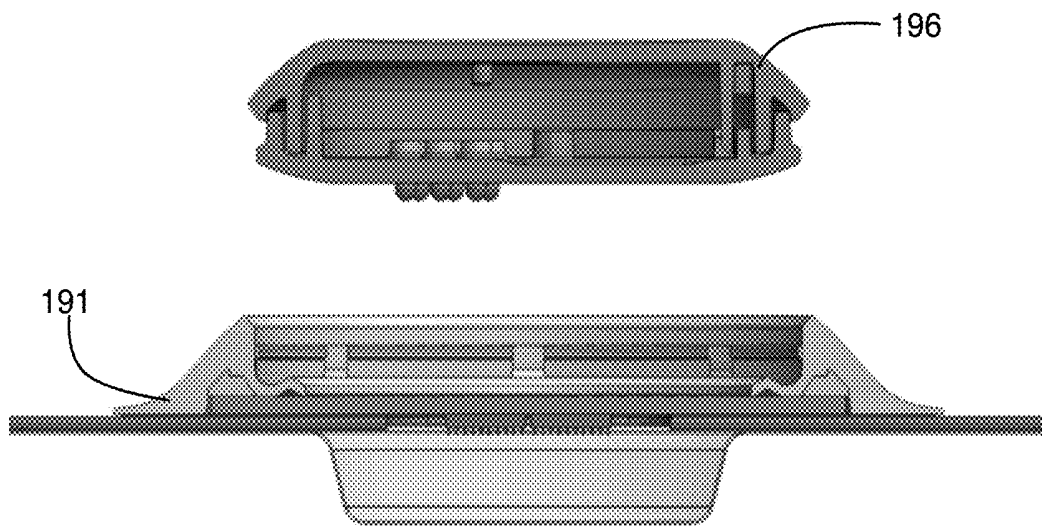


FIGURE 10D

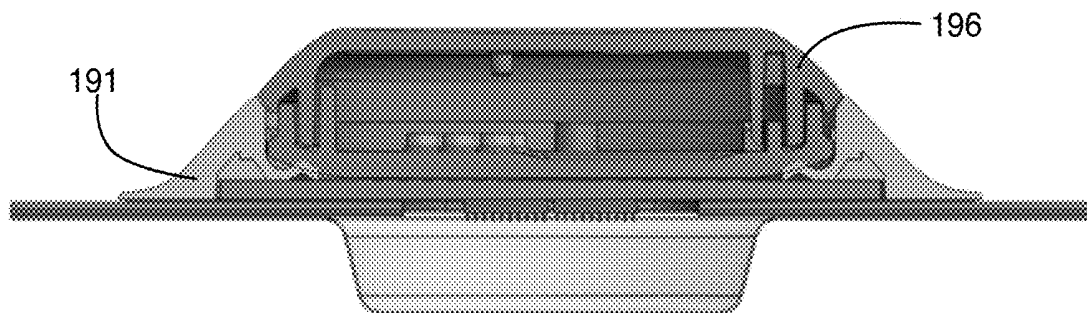


FIGURE 10E

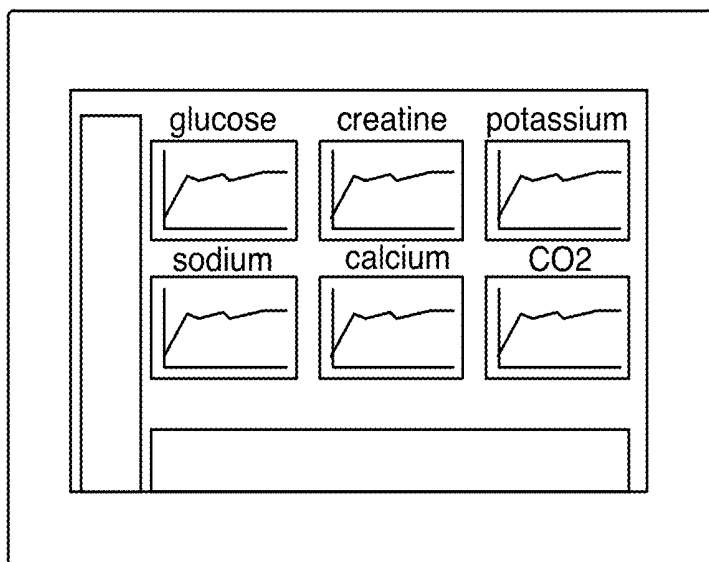


FIGURE 11A

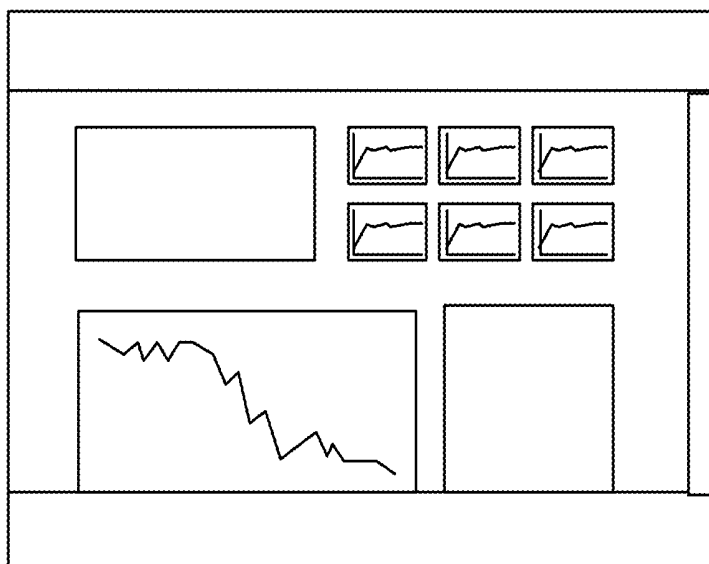


FIGURE 11B

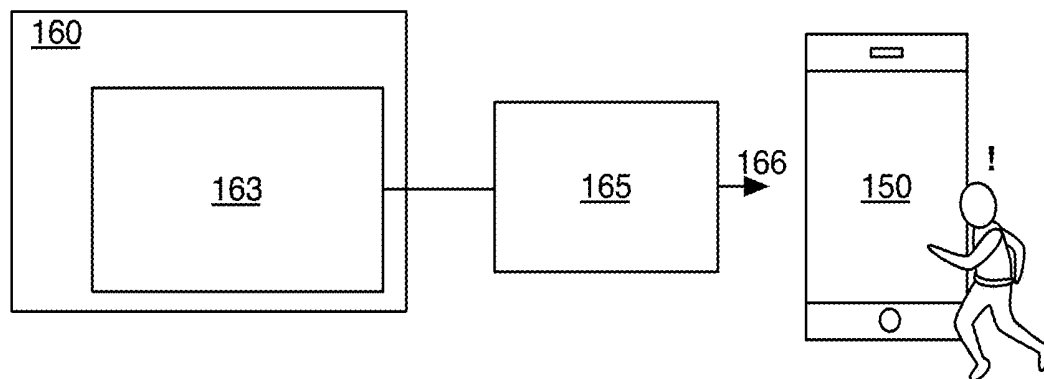


FIGURE 12A

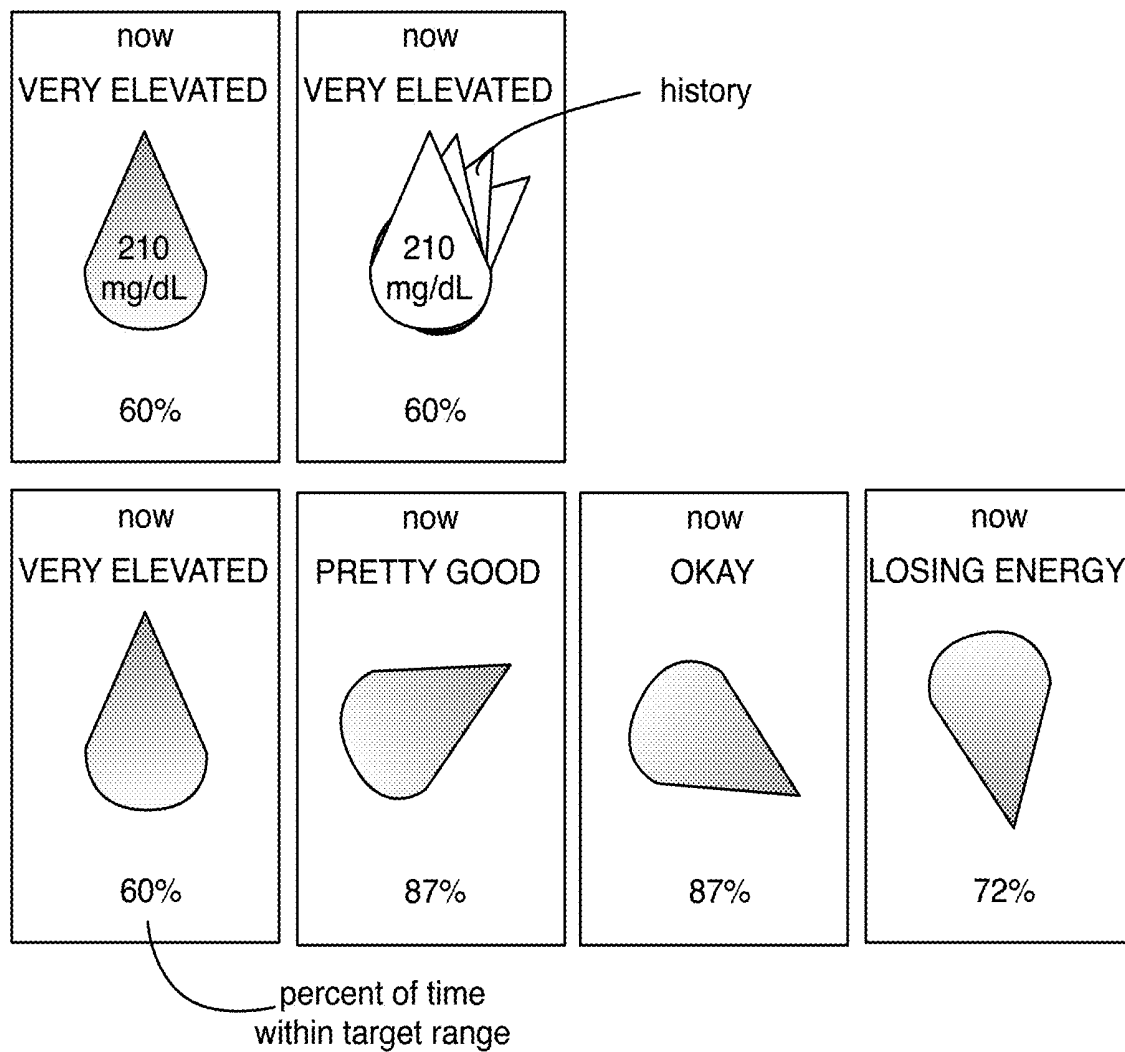


FIGURE 12B

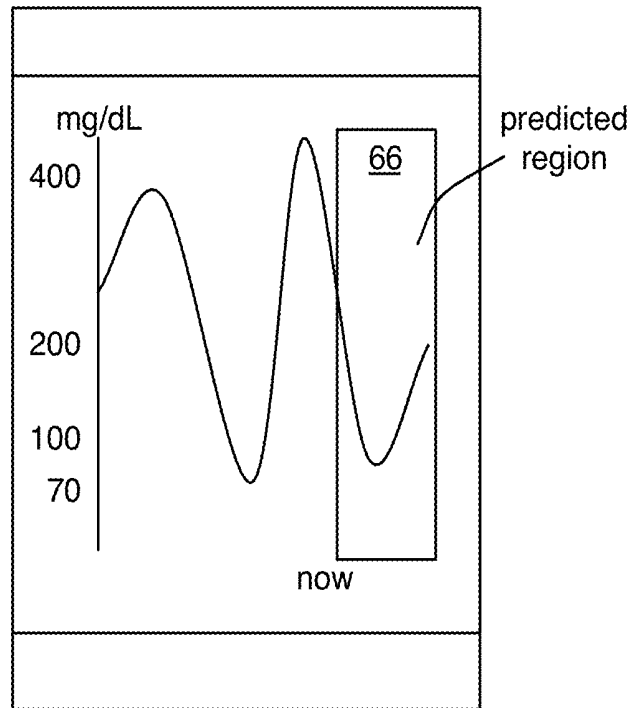


FIGURE 12C

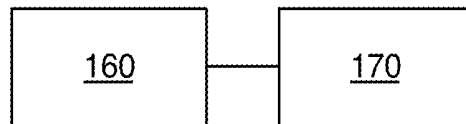


FIGURE 13

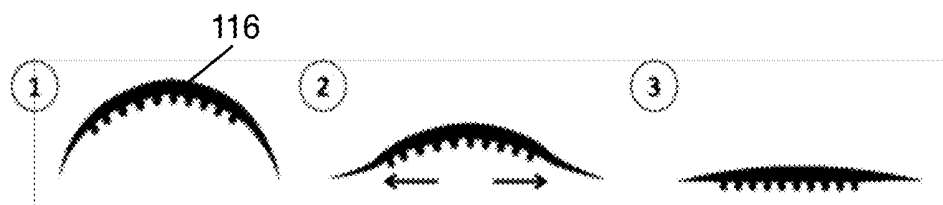


FIGURE 14A

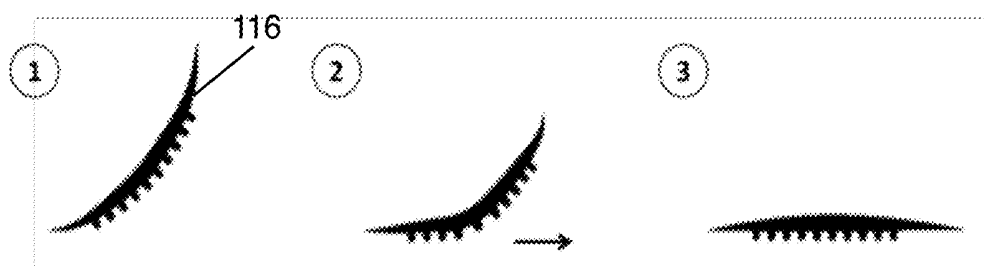


FIGURE 14B

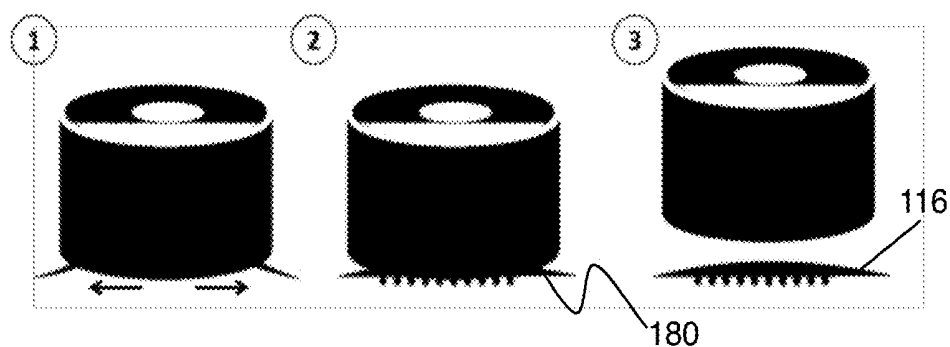


FIGURE 14C

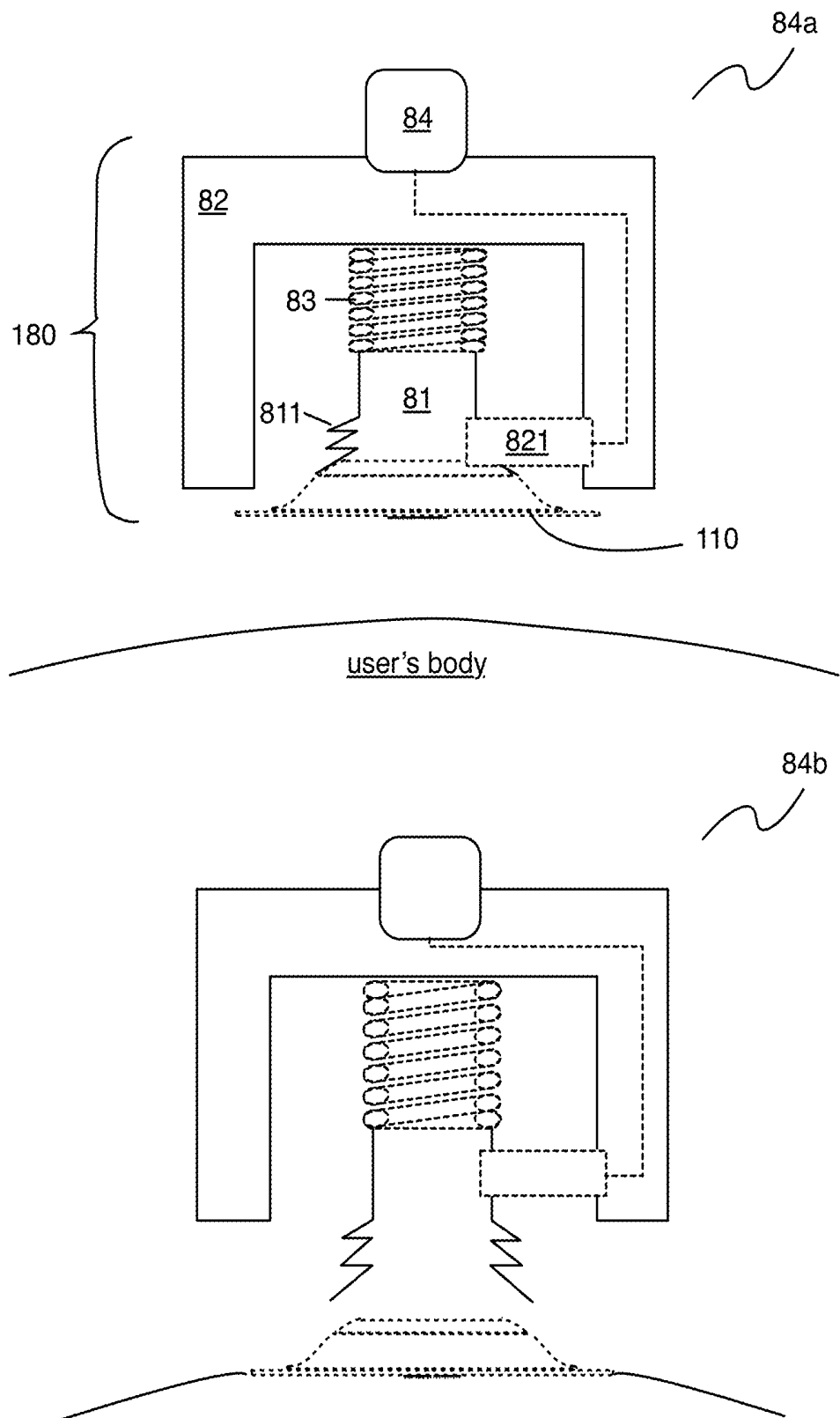


FIGURE 15

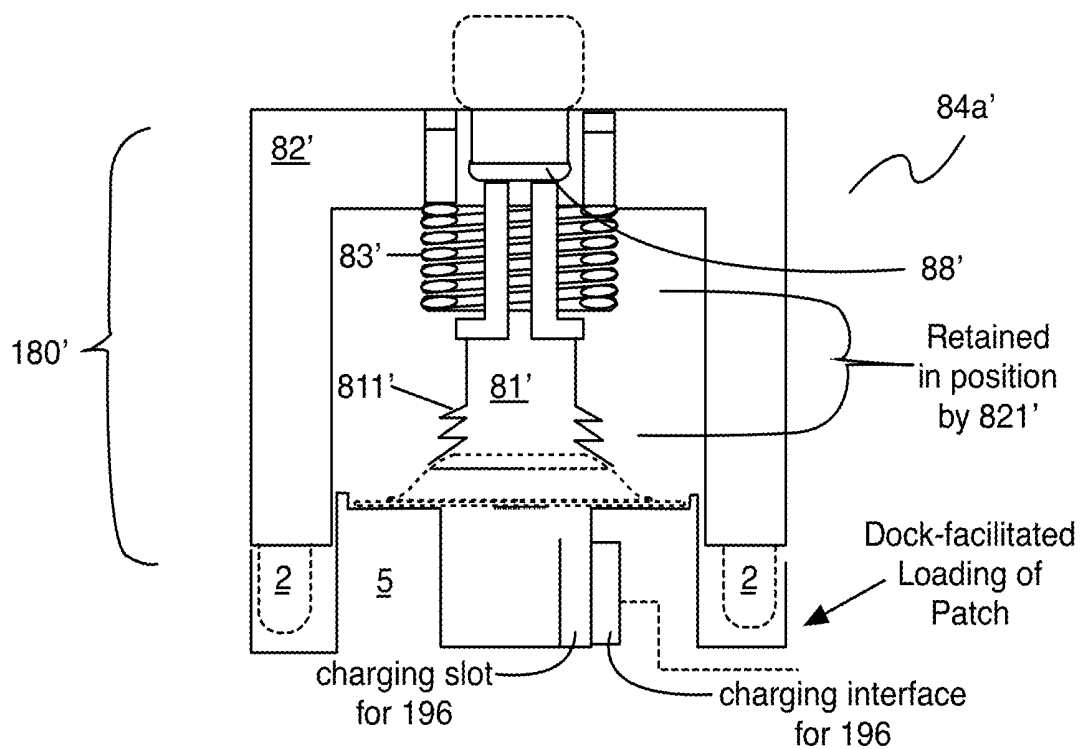


FIGURE 16A

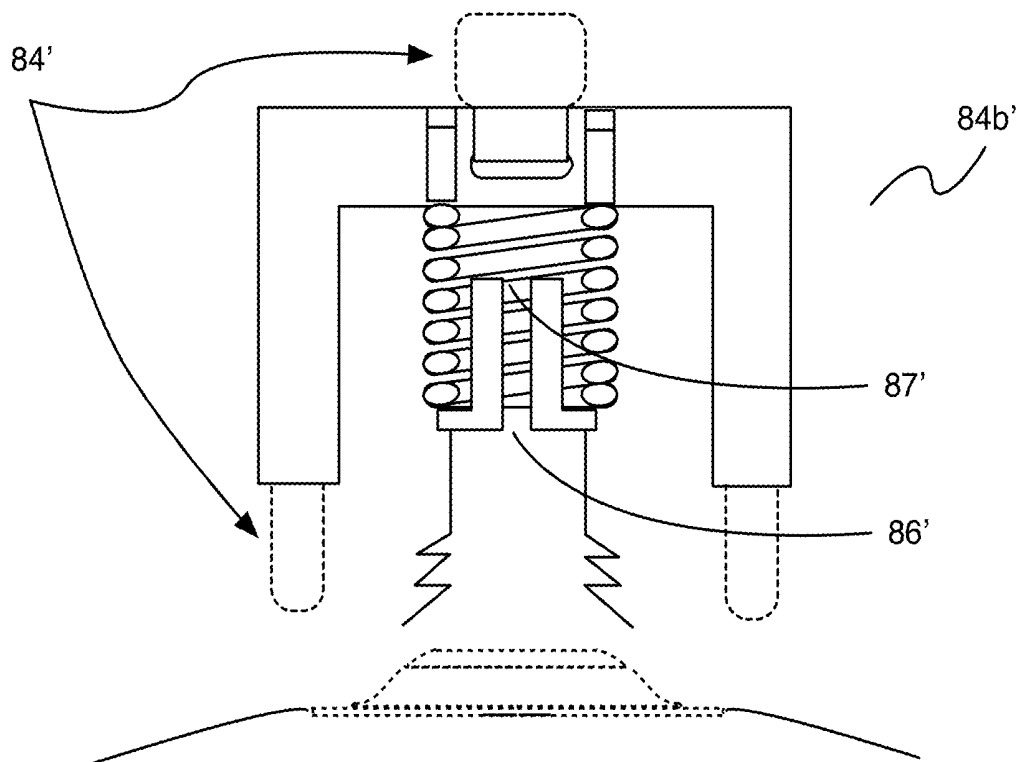


FIGURE 16B

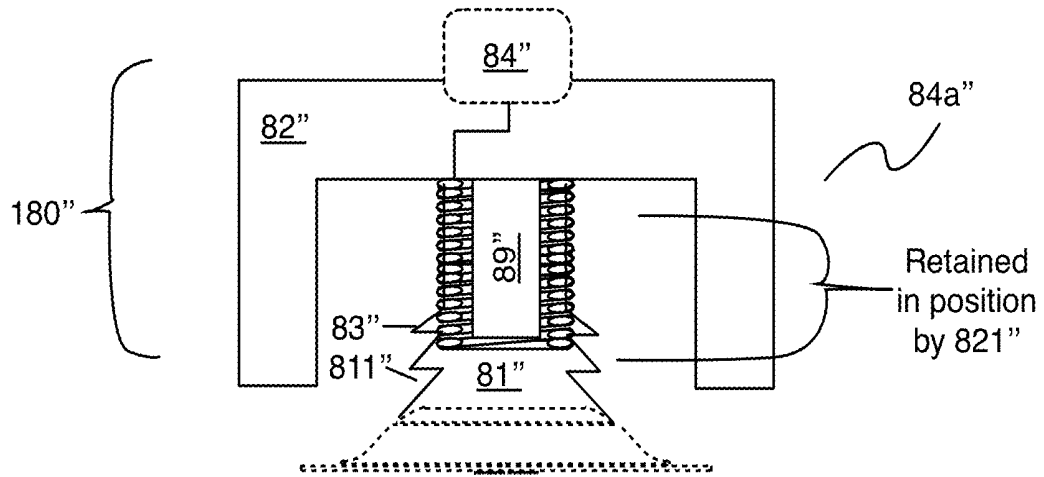


FIGURE 17A

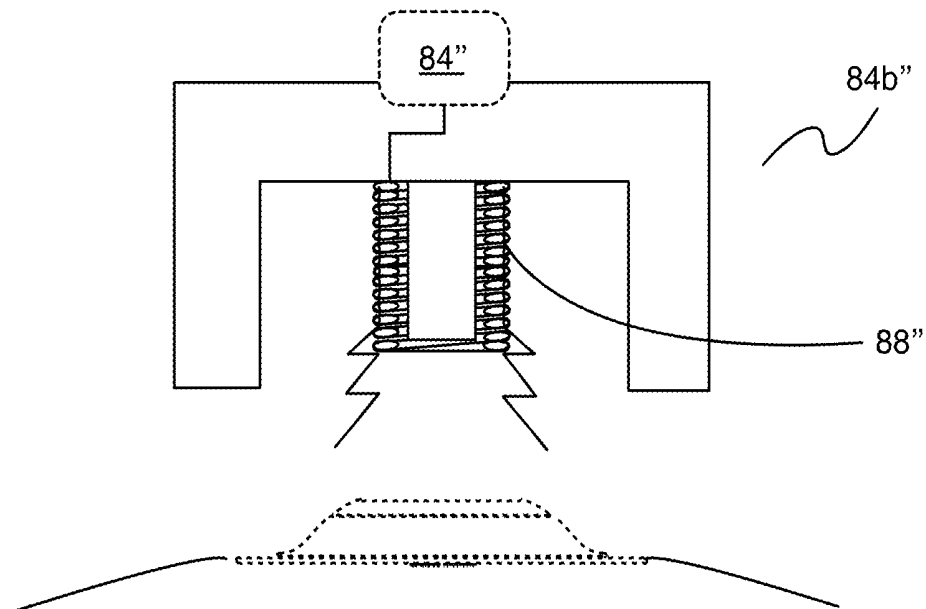


FIGURE 17B

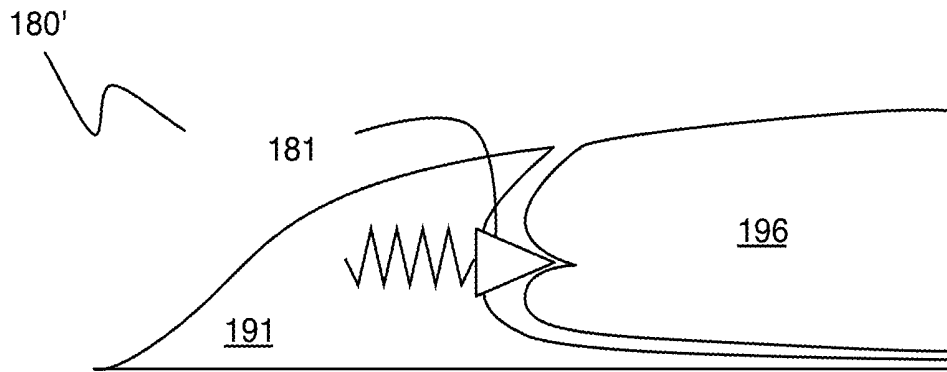


FIGURE 18A

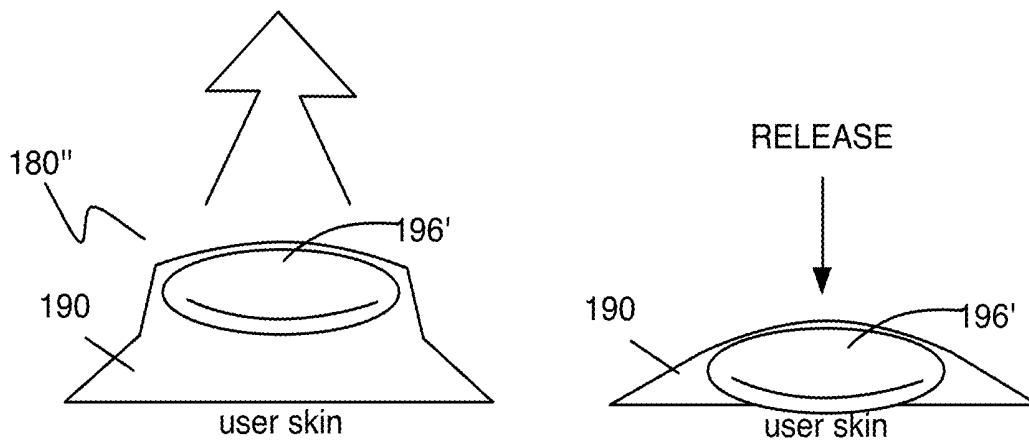


FIGURE 18B

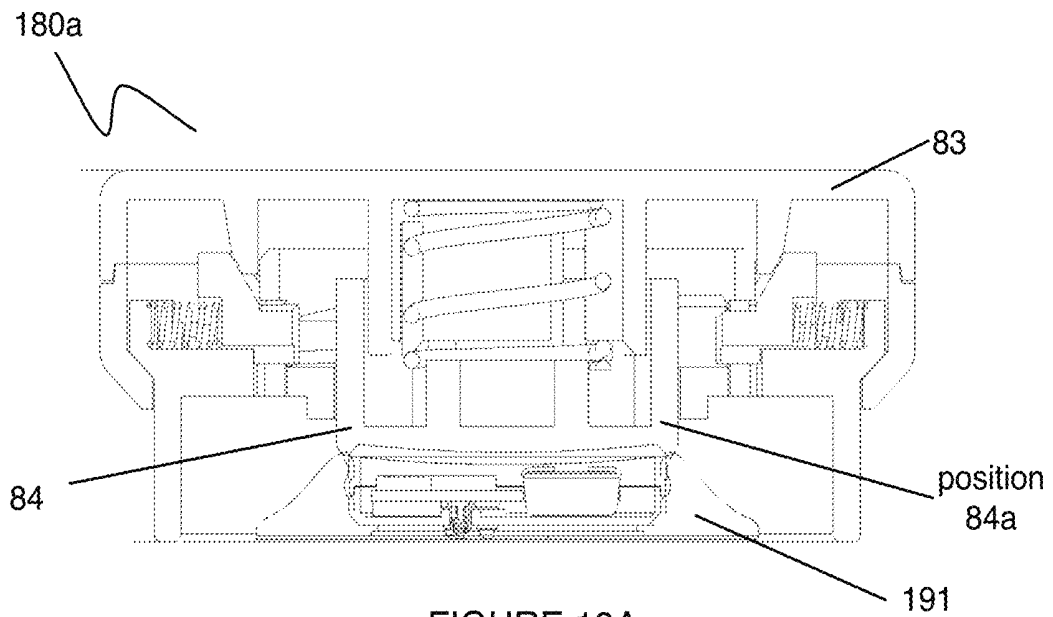


FIGURE 19A

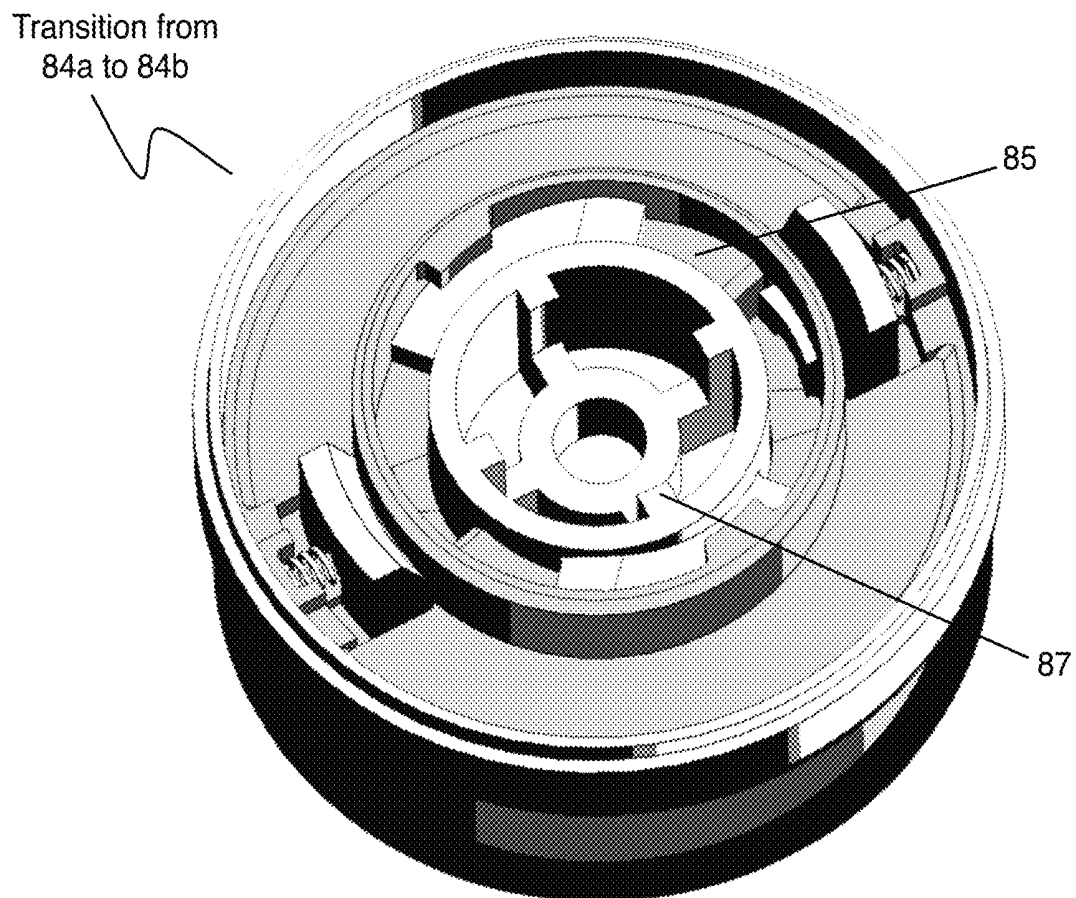


FIGURE 19B

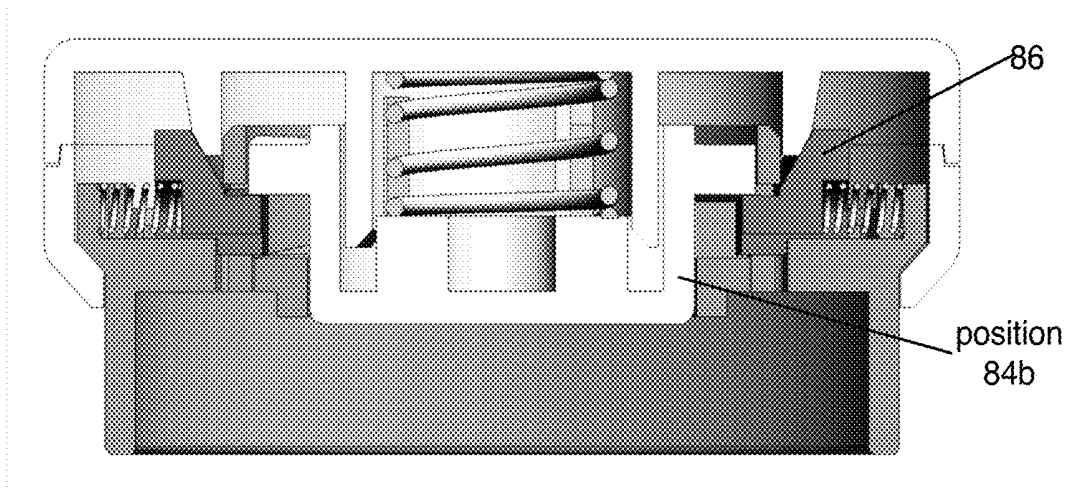


FIGURE 19C

downward force places outward biasing
force on triggers, 86

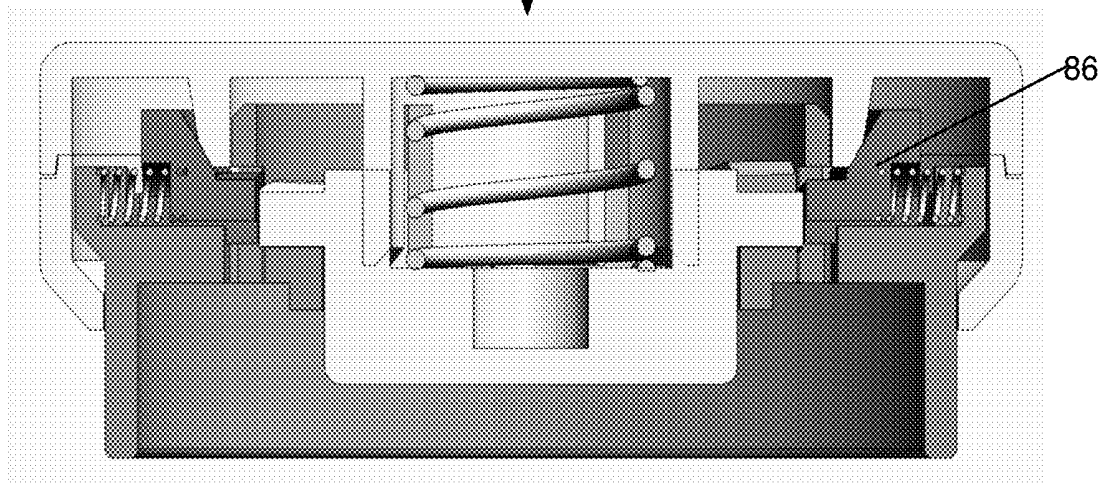
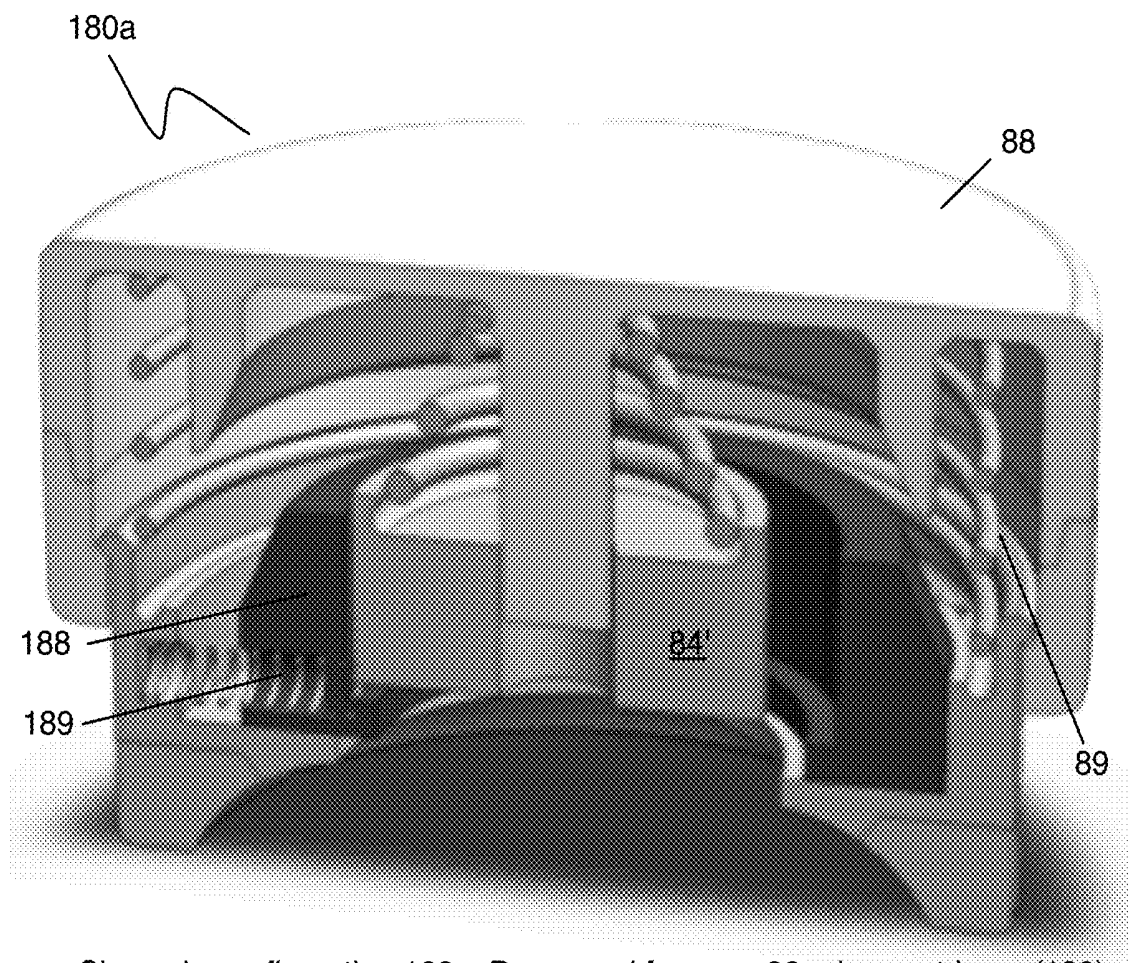


FIGURE 19D



Shown in configuration 188a. Downward force on 88 releases trigger (188) to accelerate plunger (84') downward in configuration 188b.

FIGURE 20

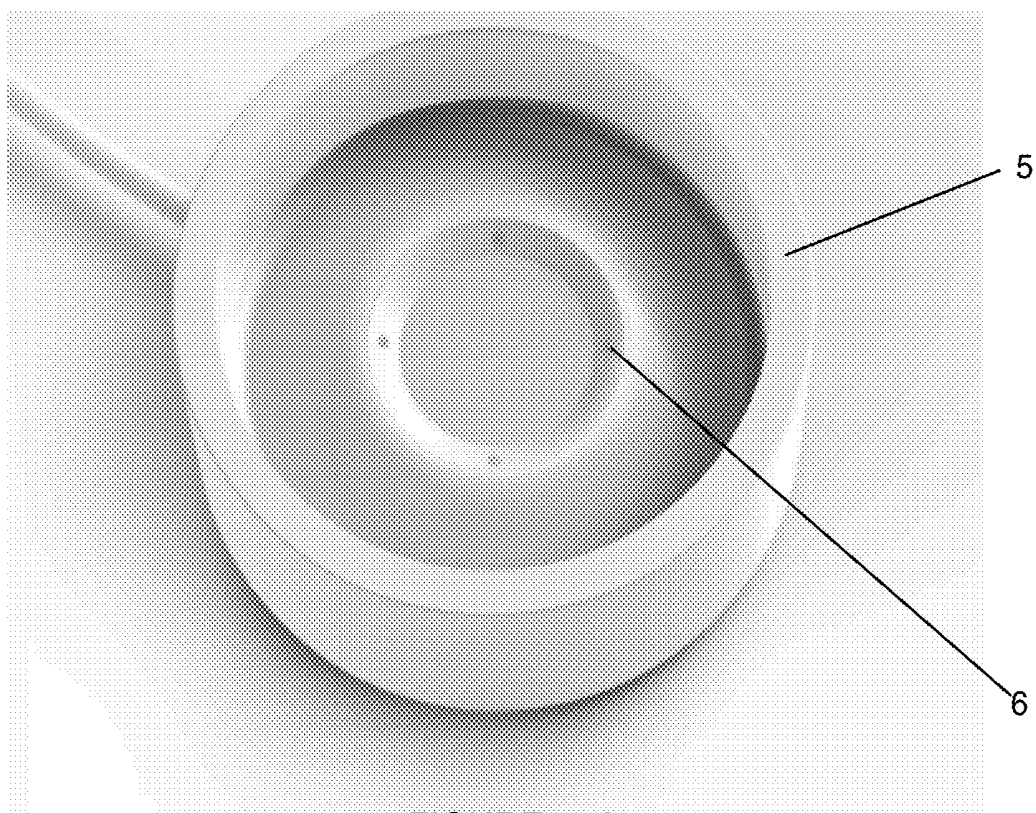


FIGURE 21A

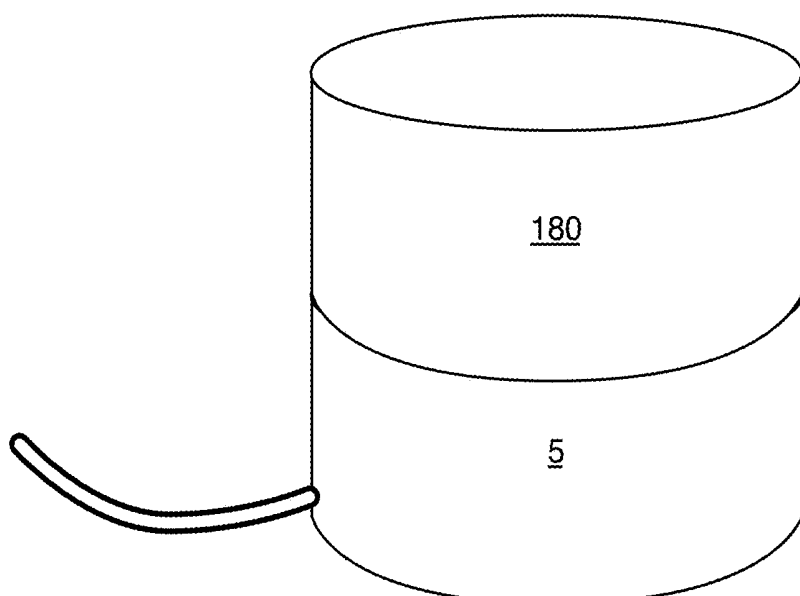


FIGURE 21B

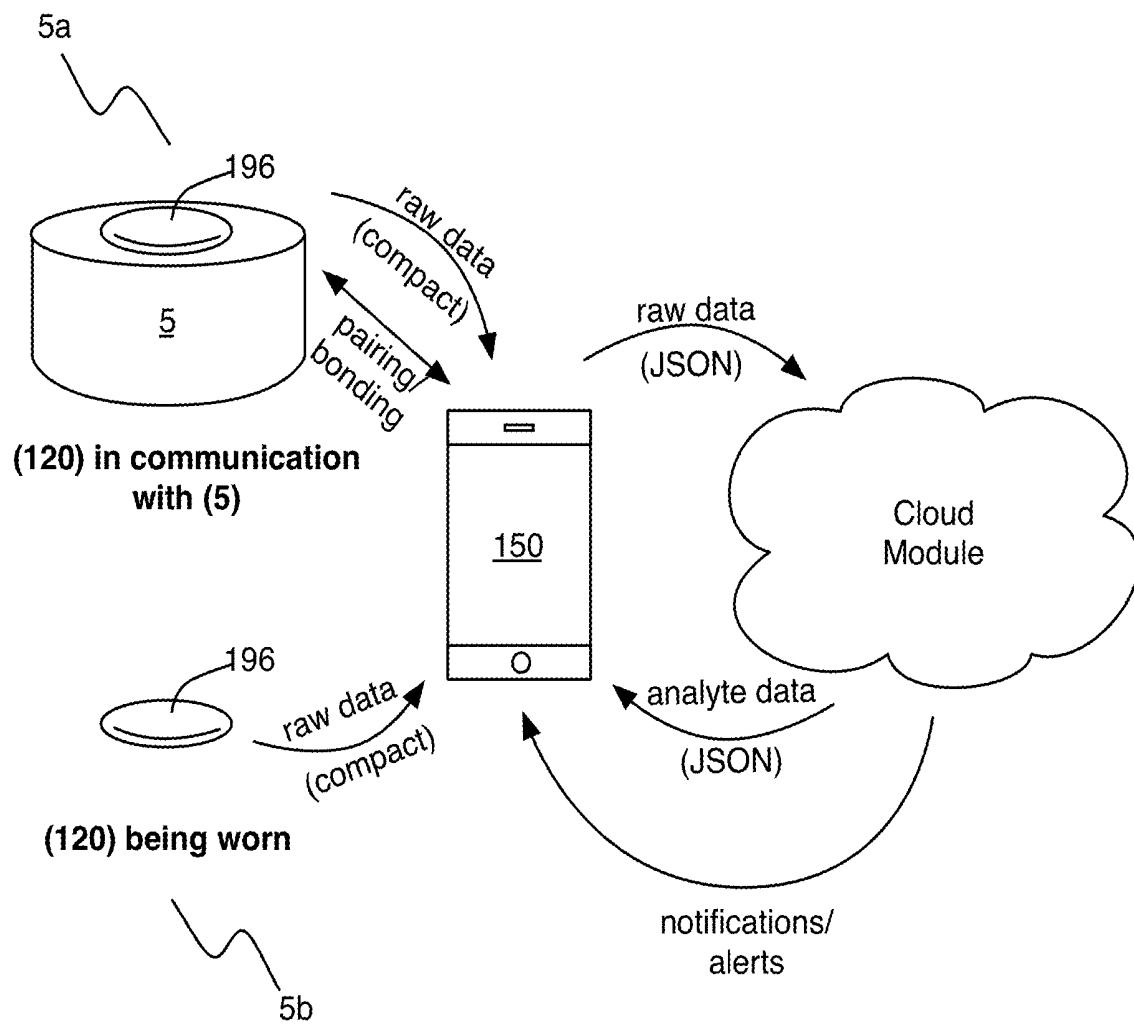


FIGURE 22

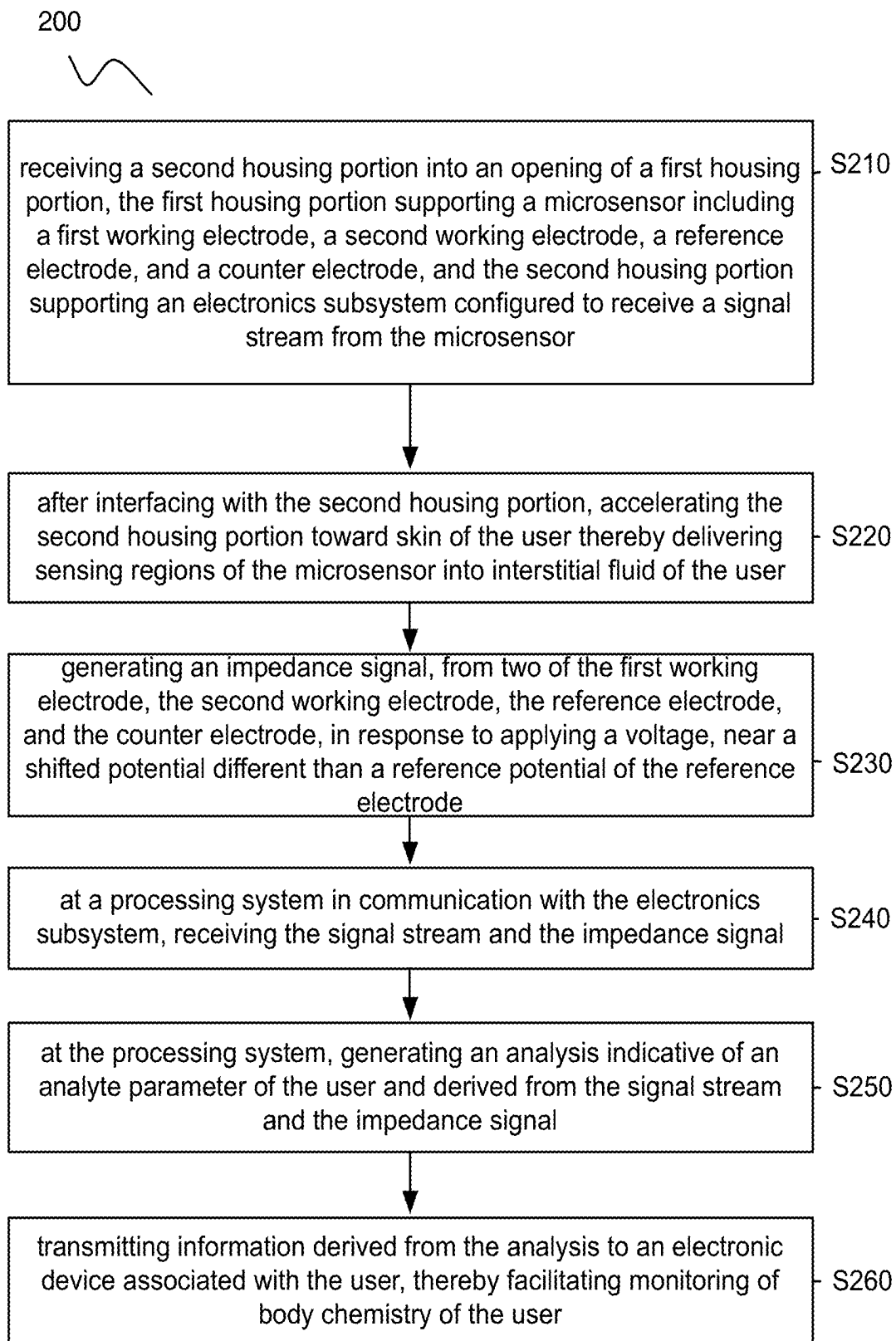


FIGURE 23

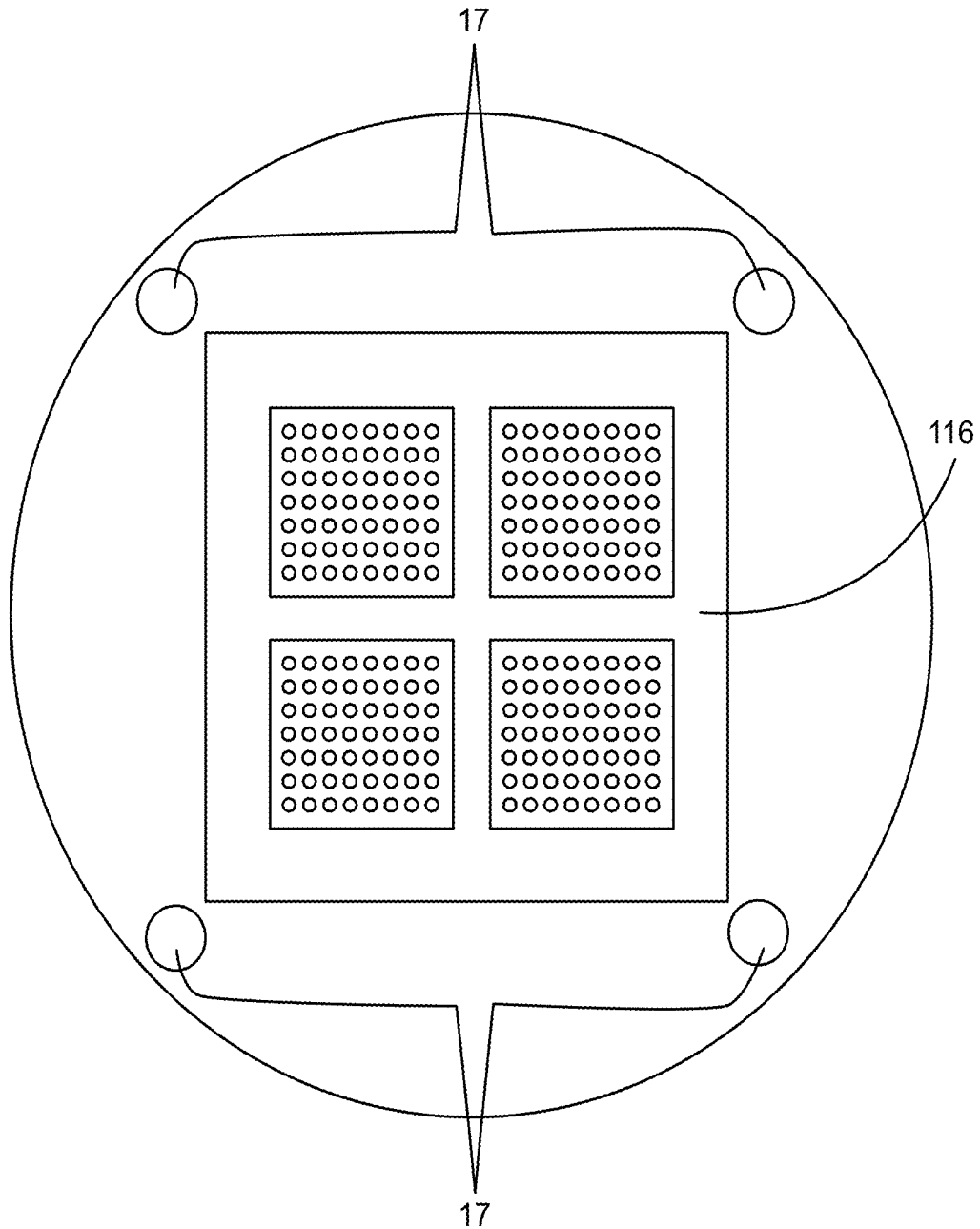


FIGURE 24

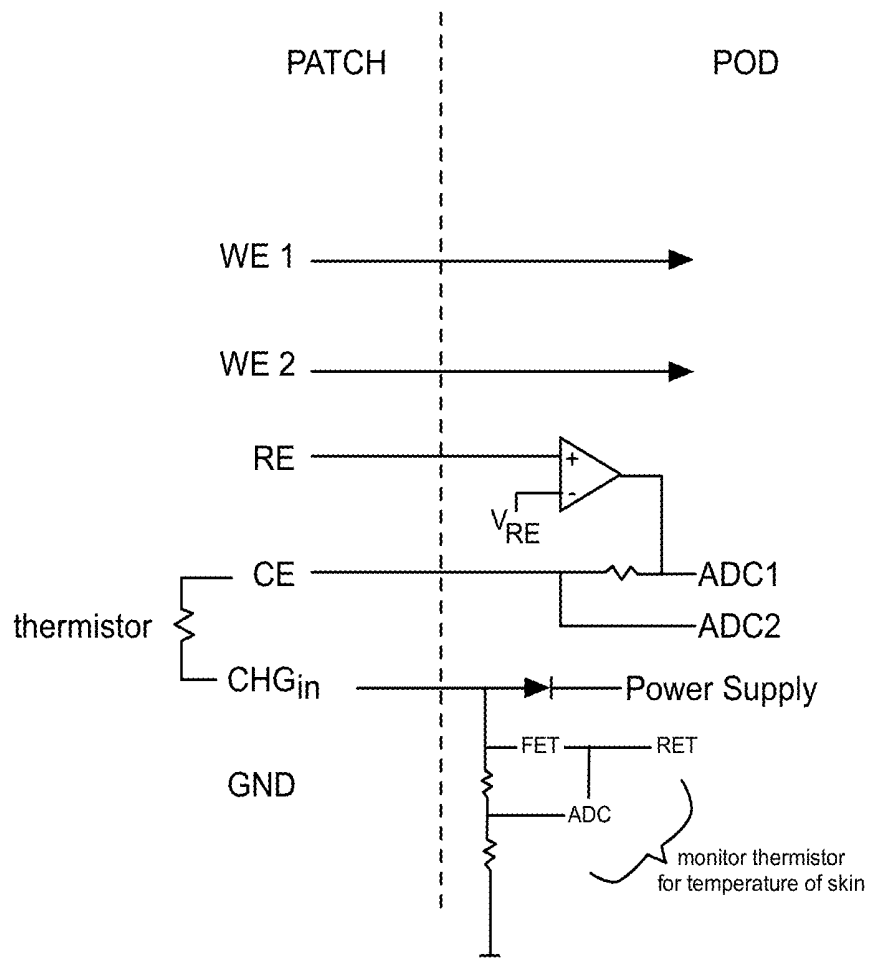


FIGURE 25

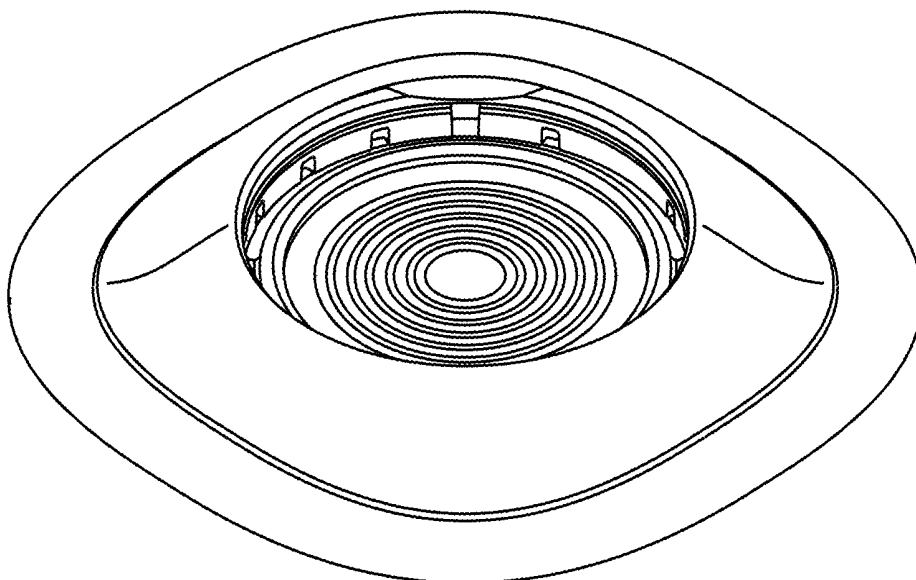


FIGURE 26A

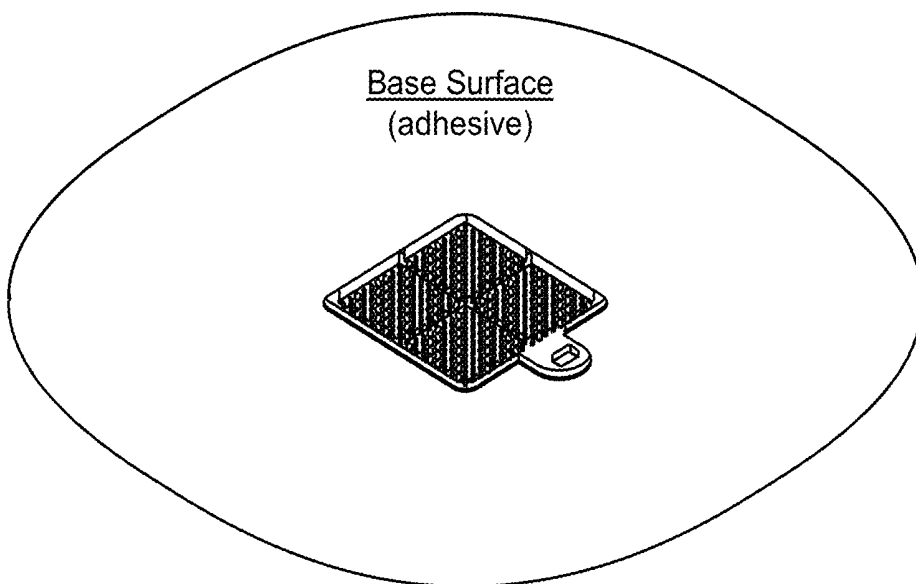


FIGURE 26B

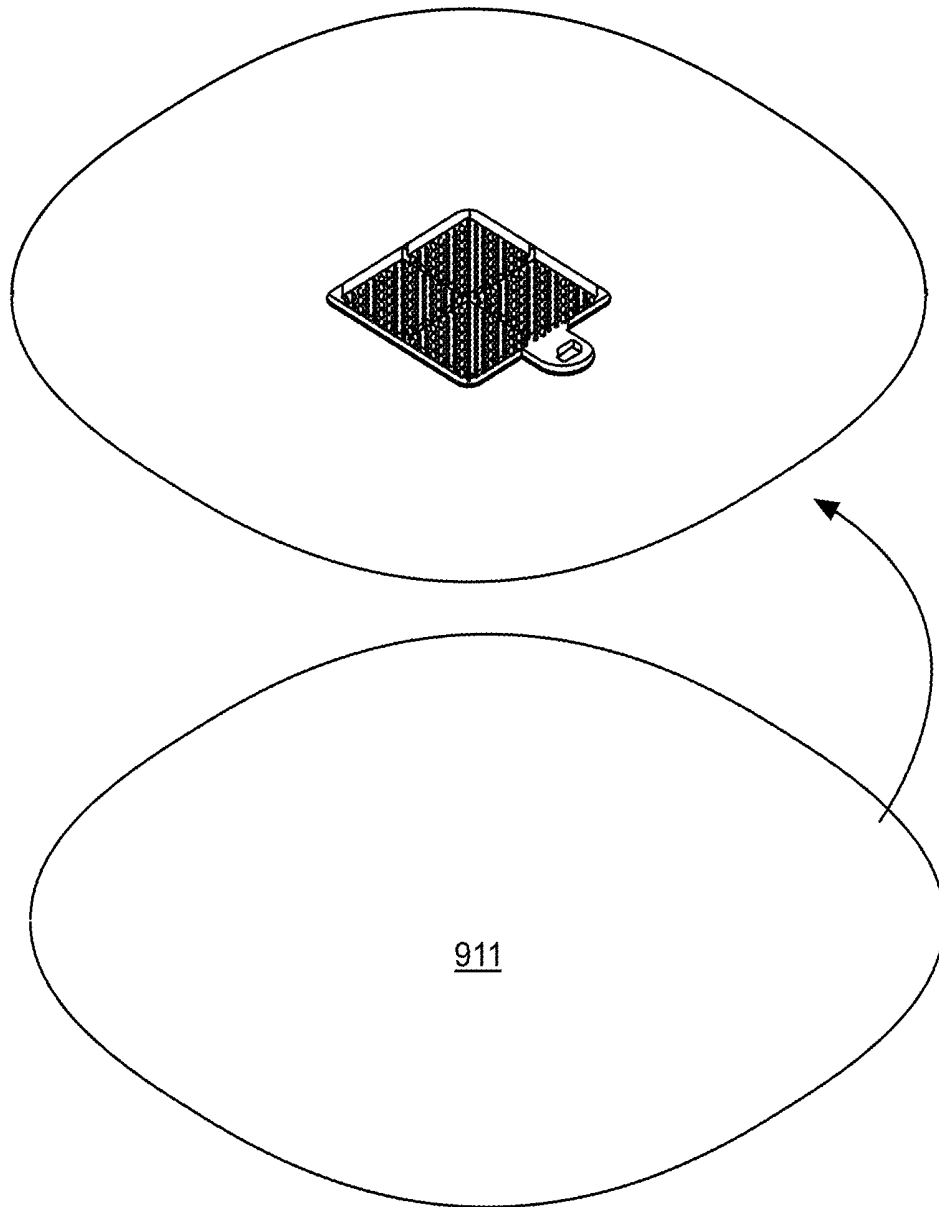


FIGURE 27

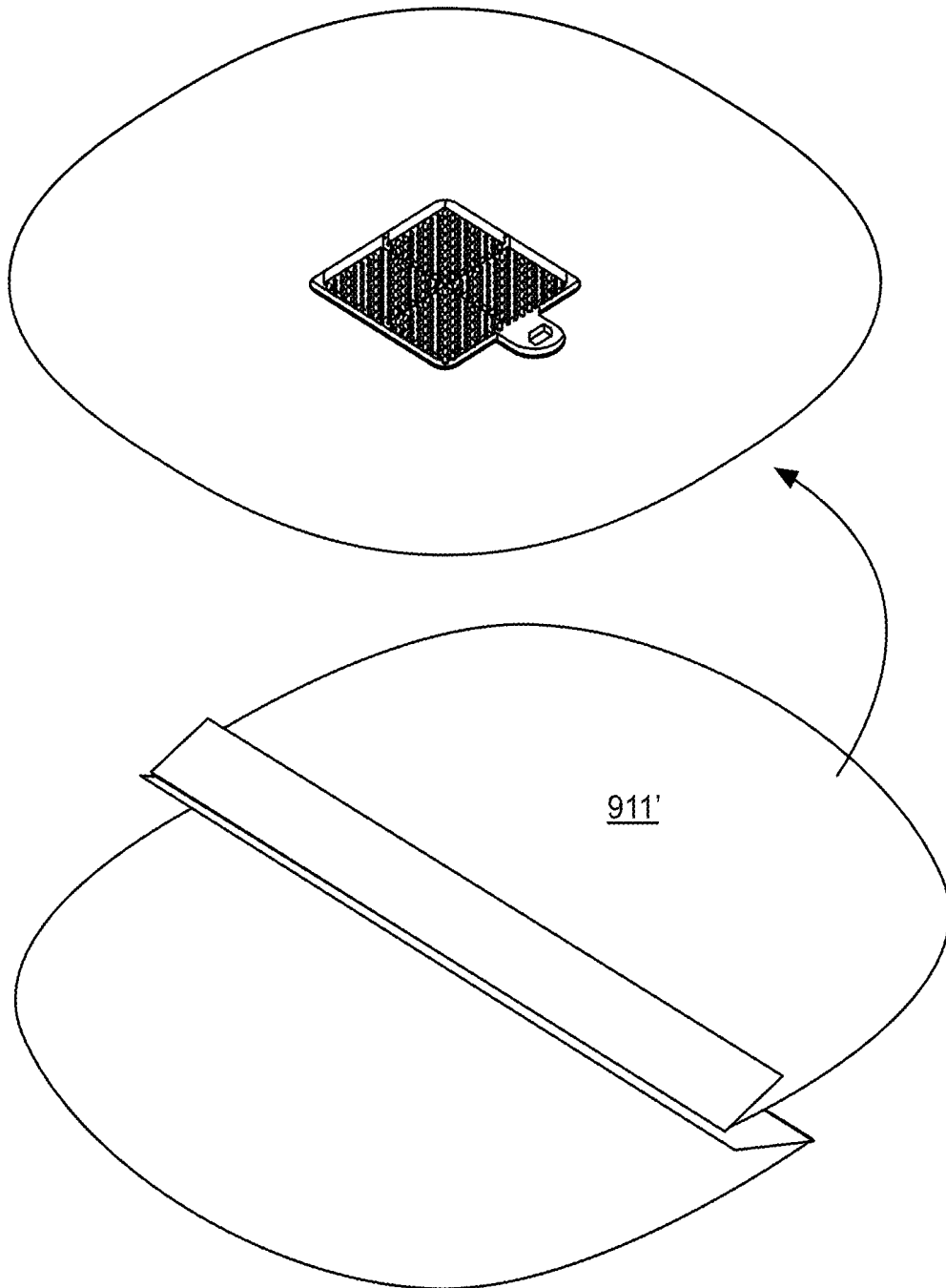


FIGURE 28A

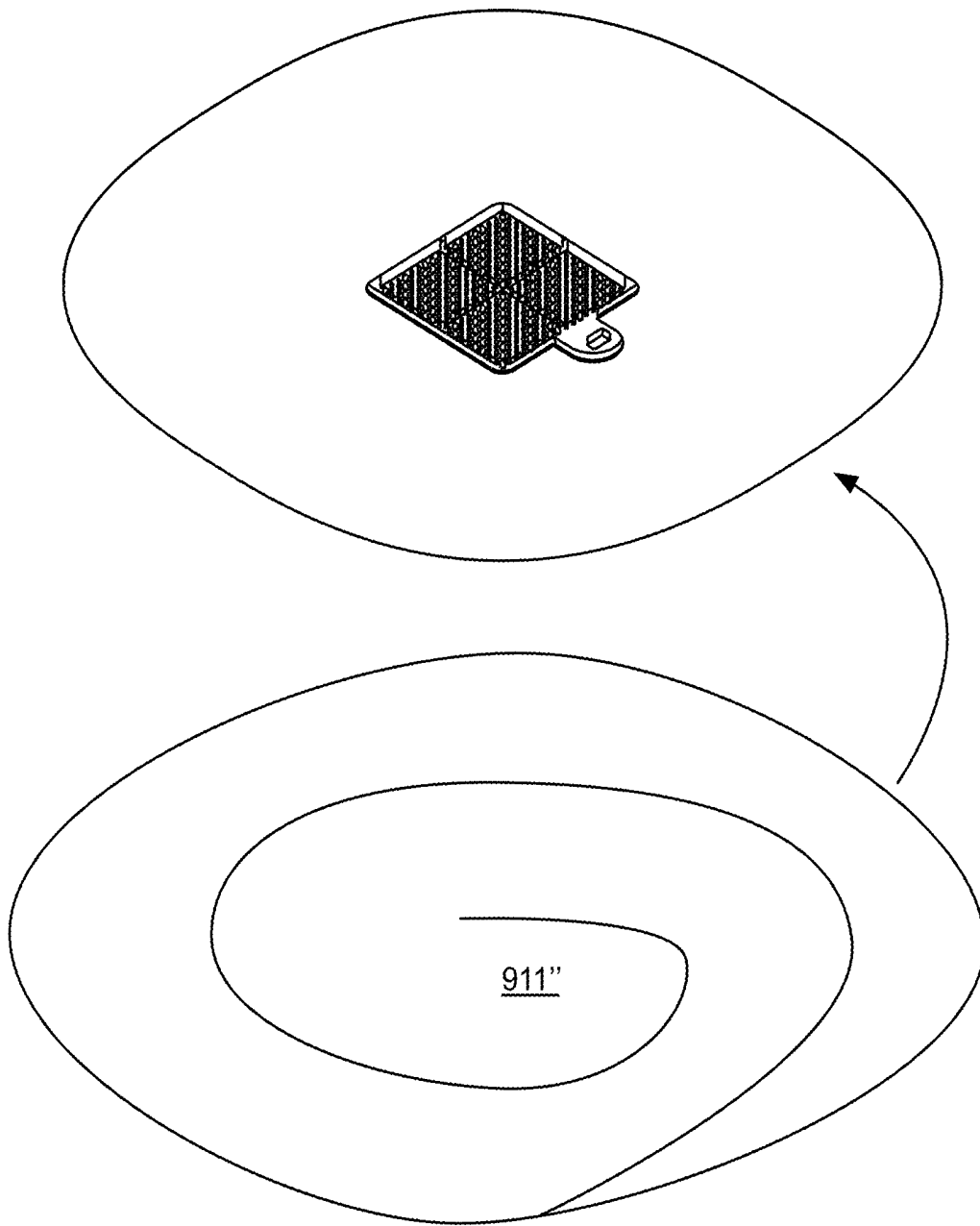


FIGURE 28B

1

SYSTEM FOR MONITORING BODY CHEMISTRY

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of U.S. patent application Ser. No. 15/412,229, filed 23 Jan. 2017, which is a continuation of U.S. patent application Ser. No. 14/657,973, filed 13 Mar. 2015, which claims the benefit of U.S. Provisional Application Ser. No. 61/952,594, filed on 13 Mar. 2014, U.S. Provisional Application Ser. No. 62/012,874, filed on 16 Jun. 2014, and U.S. Provisional Application Ser. No. 62/025,174, filed on 16 Jul. 2014, which are each incorporated herein in its entirety by this reference.

TECHNICAL FIELD

This invention relates generally to the biometric device field, and more specifically to a new and useful system for monitoring body chemistry in the biometric device field.

BACKGROUND

Biomonitoring devices are commonly used, particularly by health-conscious individuals and individuals diagnosed with ailments, to monitor body chemistry. Such biomonitoring devices perform the tasks of determining an analyte level in a user's body, and providing information regarding the analyte level to a user; however, these current biomonitoring devices typically convey information to users that is limited in detail, intermittent, and prompted by the command of the user. Such biomonitoring devices, including blood glucose meters, are also inappropriate for many applications outside of intermittent use, and place significant burdens on users (e.g., in requiring finger sticks, in requiring lancing, etc.) due to design and manufacture considerations. Additionally, current devices are configured to analyze one or a limited number of analytes contributing to overall body chemistry, due to limitations of sensors used in current biomonitoring devices.

There is thus a need in the biometric device field to create a new and useful system for monitoring body chemistry. This invention provides such a new and useful system.

BRIEF DESCRIPTION OF THE FIGURES

FIG. 1 depicts elements of an embodiment of a system for monitoring body chemistry;

FIGS. 2A and 2B depict embodiments of a microsensor patch, a transmitting unit, a housing, and an array of filaments in an embodiment of a system for monitoring body chemistry;

FIG. 2C depict a variation of electrodes in an embodiment of a system for monitoring body chemistry;

FIGS. 3A-3H depict examples of filament variations in an embodiment of a system for monitoring body chemistry;

FIG. 4 depicts an embodiment of an electronics subsystem in an embodiment of a system for monitoring body chemistry;

FIGS. 5A-5C depict examples of a portion of an electronics subsystem in an embodiment of a system for monitoring body chemistry;

FIGS. 6A-6B depict examples of power management modules in an embodiment of a system for monitoring body chemistry;

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FIG. 7 depicts a variation of an impedance detection module in an embodiment of a system for monitoring body chemistry;

FIG. 8 depicts an example of an applied voltage waveform in an embodiment of a system for monitoring body chemistry;

FIG. 9 depicts a variation of a housing in an embodiment of a system for monitoring body chemistry;

FIGS. 10A-10B depict specific examples of a housing in an embodiment of a system for monitoring body chemistry;

FIG. 10C depicts a specific portion of a housing in an embodiment of a system for monitoring body chemistry;

FIGS. 10D and 10E depict specific portions of a housing in an embodiment of a system for monitoring body chemistry;

FIGS. 11A-11B depict examples of user interfaces implemented using a software module in an embodiment of a system for monitoring body chemistry;

FIG. 12A depicts a notification module of an embodiment of a system for monitoring body chemistry;

FIGS. 12B-12C depict specific examples of notifications in an embodiment of a system for monitoring body chemistry;

FIG. 13 depicts communication between a processing subsystem and a storage module in an embodiment of a system for monitoring body chemistry;

FIGS. 14A-14C depict examples of an arch application method and an end-to-end application method, respectively, in an embodiment of a system for monitoring body chemistry;

FIG. 15 depicts an embodiment of an applicator system in an embodiment of a system for monitoring body chemistry;

FIGS. 16A and 16B depict a first specific example of an applicator system in an embodiment of a system for monitoring body chemistry;

FIGS. 17A and 17B depict a second specific example of an applicator system in an embodiment of a system for monitoring body chemistry;

FIGS. 18A-18B depict variations of a applicator system in an embodiment of a system for monitoring body chemistry;

FIGS. 19A-19D depict a first specific example of a applicator system in an embodiment of a system for monitoring body chemistry;

FIG. 20 depicts a second specific example of a applicator system in an embodiment of a system for monitoring body chemistry;

FIGS. 21A-21B depict a specific example of a base station in an embodiment of a system for monitoring body chemistry;

FIG. 22 depicts operation modes of components of an embodiment of a system for monitoring body chemistry;

FIG. 23 depicts an embodiment of a method for monitoring body chemistry;

FIG. 24 depicts a portion of a variation of a system for monitoring body chemistry;

FIG. 25 depicts an example of a portion of an electronics subsystem in a system for monitoring body chemistry;

FIGS. 26A and 26B depict an example of a portion of a system for monitoring body chemistry;

FIG. 27 depicts an example of a liner in an embodiment of a system for monitoring body chemistry; and

FIGS. 28A-28B depict examples of liners in an embodiment of a system for monitoring body chemistry.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The following description of the preferred embodiments of the invention is not intended to limit the invention to these

preferred embodiments, but rather to enable any person skilled in the art to make and use this invention.

1. System

As shown in FIG. 1, an embodiment of the system **100** for monitoring body chemistry of a user comprises a housing **190** that supports a microsensor **116** and an electronics subsystem **120** in communication with the microsensor **116**; and a processing subsystem **160** configured to generate an analysis indicative of an analyte parameter of the user, wherein the analysis is derived from a signal stream of the microsensor and an impedance signal from the electronics subsystem. In more detail, the housing **190**, microsensor **116**, and the electronics subsystem **120** can be configured as a microsensor patch **110** configured to sense analyte levels in a user's body, wherein the electronics subsystem includes a signal conditioning module **122**, a power management module **124**, a storage module **127**, and a transmitting unit **130** in communication with the processing subsystem **160** and/or an electronic device (e.g., mobile computing device **150**) associated with the user.

In some variations, the system **100** can further include an applicator system **180** configured to facilitate application of the microsensor patch **110** onto the body of a user in a reliable manner. The system **100** functions to provide continuous monitoring of a user's body chemistry through reception and processing of signals associated with one or more analytes present in the body of the user, and to provide an analysis of the user's body chemistry to the user and/or an entity (e.g., health care professional, caretaker, relative, friend, acquaintance, etc.) associated with the user. Alternatively, the system **100** can function to detect a user's body chemistry upon the user's request or sporadically, and/or can provide an analysis of the user's body chemistry only to the user.

The system **100** is configured to be worn by the patient outside of a clinical (e.g., hospital) or research (e.g., laboratory) setting, such that the patient can be in a non-contrived environment as he or she is interfacing with the microsensor patch **110** for monitoring of body chemistry. Furthermore, elements of the system **100** can be reusable or disposable (e.g., based upon modularity of the system **100**), or the entire system **100** can be configured to be disposable. In one specific example, the system **100** adheres to the patient (thus not compelling the patient to hold any part of the system **100** by hand), has a low profile that conforms to the patient, and is configured to receive and transmit signals indicative of body chemistry parameters of the user, for downstream analysis and information transfer to the user. Alternatively, the system **100** can be substantially non-portable, non-wearable, and/or intended for use in a clinical or research setting.

As indicated above and further below, elements of the system can be implemented on one or more computer networks, computer systems, or applications servers, etc. The computer system(s) can comprise one or more of: a cloud-based computer, a mainframe computer system, a grid-computer system, or any other suitable computer system, and the computer system can support collection of data from a wearable device and/or a base station, processing of these data, and transmission of alerts, notifications, and/or user interface updates to one or more electronic computing devices (e.g., mobile computing device, wrist-borne mobile computing device, head-mounted mobile computing device, etc.) linked to or affiliated with an account of the user. For example, the computer system can receive signals indicative of one or more analyte parameters of the user and distribute alerts and notifications over a distributed network, such as

over a cellular network or over an Internet connection. In this example, the computer system can upload alerts and notifications to a native body chemistry monitoring application including the user interface and executing on a mobile computing device associated with the user.

Additionally or alternatively, an electronic computing device (e.g., a laptop computer, a desktop computer, a tablet, a smartphone, a smart watch, a smart eyewear accessory, a personal data assistant, etc.) associated with the system (e.g., with the account of the user) can maintain the account of the user, create and maintain a user-specific model within the account, and execute a native body chemistry monitoring application (including the user interface) with functions including one or more of: generating alerts or notifications, receiving alerts or notifications, displaying alerts or notifications, updating predictions of changes in state of the user, and any other suitable function that enhances body chemistry monitoring of the user. The system **100** is preferably configured to implement at least a portion of the method **200** described in Section 2 below; however, the system **100** can additionally or alternatively be configured to implement any other suitable method.

1.1 System—Microsensor Patch

As shown in FIG. 1, the microsensor patch **110** comprises a microsensor **116** and an electronics subsystem **120** in communication with the microsensor **116**, wherein the microsensor **116** and the electronics subsystem **120** are supported by a housing **190**. The microsensor patch **110** can be configured to detect and sense only a single analyte; however, the microsensor patch **110** can alternatively be configured to detect and sense multiple analytes in order to provide an analysis based on multiple analytes. Preferably, the microsensor patch **110** is configured to be disposable; however, the microsensor patch **110** can alternatively be configured to be reusable for any suitable duration or number of uses. In one variation, the microsensor patch **110** is configured to be a semi-permanent component (e.g., wearable for a week before replacement, wearable for a month before replacement, etc.) configured to sense the user's body chemistry with minimal signal degradation for at least a week post-coupling of the microsensor patch **110** to the body of the user. However, in another variation, the microsensor patch **110** can be configured to be a permanent component configured to permanently couple to a user. Modularity of the microsensor patch **110** is described in further detail below.

1.1.1 System—Microsensor

The microsensor **116** of the microsensor patch **110** preferably comprises an array of filaments **117**, as shown in FIGS. 1 and 2A, and functions to penetrate skin of the user in order to sense one or more analytes characterizing the user's body chemistry. Preferably, the array of filaments **117** is configured to penetrate the user's stratum corneum (i.e., an outer skin layer) in order to sense analytes within interstitial (extracellular) fluid, which is throughout the body; however, the array of filaments **117** can be configured to penetrate the user's skin to any other suitable depth. For instance, the microsensor **116** can alternatively be configured to penetrate deeper layers, or various depth layers of a user's skin in order to sense analytes within any appropriate bodily fluid of the user. The microsensor **116** can be configured to sense analytes/ions characterizing a user's body chemistry using a potentiometric measurement (e.g., for small analytes including potassium, sodium calcium, etc.), using an amperometric measurement (e.g., for large analytes

including glucose, lactic acid, creatinine, etc.), using a conductometric measurement, and/or using any other suitable measurement.

Preferably, sensed analytes result in a signal (e.g., voltage, current, resistance, capacitance, impedance, gravimetric, etc.) detectable by the electronics subsystem 120 in communication with the microsensor 116; however, analyte sensing can comprise any other appropriate mechanism using the microsensor 116. As mentioned earlier, the microsensor 116 is also preferably integrated with the electronics subsystem 120. In a first variation, the microsensor 116 is coupled to the semiconductor architecture of the electronics subsystem 120 (e.g., the microsensor 116 is coupled to an integrated circuit comprising the electronics subsystem 120), in a second variation, the microsensor 116 is more closely integrated into the semiconductor architecture of the electronics subsystem 120 (e.g., there is closer integration between the microsensor 116 and an integrated circuit including the electronics subsystem 120), and in a third variation, the microsensor 116 and the electronics subsystem 120 are constructed in a system-on-a-chip fashion (e.g., all components are integrated into a single chip). As such, in some variations, filaments the array of filaments 117 of the microsensor 116 can be directly or indirectly integrated with electronics components, such that preprocessing of a signal from the microsensor 116 can be performed using the electronics components (e.g., of the array of filaments 117, of the electronics subsystem 120) prior to or after transmitting signals to the electronics subsystem 120 (e.g., to an analog front end, to an analog to digital converter). The electronics components can be coupled to a filament substrate, or otherwise integrated with the filaments in any suitable fashion (e.g., wired, using a contact pad, etc.). Alternatively, the electronics components can be fully integrated into the electronics subsystem 120 and configured to communicate with the microsensor 116, or the electronics components can be split between the microsensor and the electronics subsystem 120. The microsensor 116 can, however, comprise any other suitable architecture or configuration.

The microsensor 116 preferably senses analyte parameters using the array of filaments 117, such that absolute values of specific analytes/ions can be detected and analyzed. The microsensor 116 can additionally be configured to sense analyte parameters using the array of filaments 117, such that changes in values of specific analyte/ion parameters or derivatives thereof (e.g., trends in values of a parameter, slopes of curves characterizing a trend in a parameter vs. another parameter, areas under curves characterizing a trend, a duration of time spent within a certain parameter range, etc.) can be detected and analyzed. In one variation, sensing by the microsensor 116 is achieved at a low frequency at discrete time points (e.g., every minute, or every hour), and in another variation, sensing by the microsensor 116 is achieved substantially continuously at a high frequency (e.g., every picosecond, every millisecond, every second). In one specific example for blood chemistry analysis, the array of filaments 117 of the microsensor 116 is configured to sense one or more of: electrolytes, glucose, bicarbonate, creatinine, body urea nitrogen (BUN), sodium, iodide, iodine and potassium of a user's blood chemistry. In another specific example, the array of filaments 117 of the microsensor 116 is configured to sense at least one of biomarkers, cell count, hormone levels, alcohol content, gases (e.g. carbon dioxide, oxygen, etc.), drug concentrations/metabolism, pH and analytes within a user's body fluid.

As shown in FIG. 2A, the array of filaments 117 is preferably located at the base surface of the microsensor patch 110, and functions to interface directly with a user in a transdermal manner (e.g., in accessing interstitial fluid) in order to sense at least one analyte/ion characterizing the user's body chemistry. The array of filaments 117 is preferably arranged in a uniform pattern with a specified density optimized to effectively penetrate a user's skin and provide an appropriate signal, while minimizing pain to the user. Additionally, the array of filaments 117 can be arranged in a manner to optimize coupling to the user, such that the microsensor firmly couples to the user over the lifetime usage of the system. For example, the filaments 118 can comprise several pieces and/or be attached to a flexible base to allow the array of filaments 117 to conform to a user's body. In one variation, the array of filaments 117 is arranged in a rectangular pattern, and in another variation, the array of filaments 117 is arranged in a circular or ellipsoid pattern. However, in other variations, the array of filaments 117 can be arranged in any other suitable manner (e.g., a random arrangement). The array of filaments 117 can also be configured to facilitate coupling to a user, by comprising filaments of different lengths or geometries. Having filaments 118 of different lengths can further function to allow measurement of different ions/analytes at different depths of penetration (e.g., a filament with a first length can sense one analyte at a first depth, and a filament with a second length can sense another analyte at a second depth). The array of filaments 117 can also comprise filaments 118 of different geometries (e.g., height, diameter) to facilitate sensing of analytes/ions at lower or higher concentrations. In one specific example, the array of filaments 117 is arranged at a density of 100 filaments per square centimeter and each filament 118 in the array of filaments 117 has a length of 250-350 microns, which allows appropriate levels of detection, coupling to a user, and pain experienced by the user.

Each filament 118 in the array of filaments 117 preferably functions to sense a single analyte; however, each filament 118 in the array of filaments 117 can additionally be configured to sense more than one analyte. Furthermore, the array of filaments 117 can be further configured, such that a subarray of the array of filaments 117 functions as a single sensor configured to sense a particular analyte or biomarker, as shown in FIG. 2B. Furthermore, any configuration of subarrays of the array of filaments 117 can additionally or alternatively be configured as one or more of: a working electrode, a counter electrode (i.e., auxiliary electrode), and a reference electrode, for instance, in a two-electrode cell, a three-electrode cell, or a more-than-three-electrode cell. In one variation, as shown in FIG. 2C, the array of filaments 117 of the microsensor 116 is configured as a first working electrode 11 (corresponding to a first subarray of filaments), a second working electrode 12 (corresponding to a second subarray of filaments), a counter electrode 13 (corresponding to a third subarray of filaments), and a reference electrode 14 (corresponding to a fourth subarray of filaments). In a specific example of this variation, each subarray associated with the first working electrode 11, the second working electrode 12, the counter electrode 13, and the reference electrode 14, respectively, is substantially identical in morphology (e.g., area of the microsensor). Furthermore, in the specific example, each subarray has a square footprint, and the subarrays are configured in a 2x2 arrangement to define a larger square footprint. However, the array of filaments 117 can be configured as one or more of: a working electrode, a counter electrode, and a reference electrode in

any other suitable manner, and can furthermore have any other suitable morphology(ies) and/or configuration relative to each other.

Additionally or alternatively, any subarray of the array of filaments **117** can be configured to release biomaterials (e.g., therapeutic substances, drugs) for treating a medical condition of a user (e.g., as facilitated by biomaterial dissolution in interstitial fluid). Multiple subarrays of the array of filaments can then be configured to sense different analytes/biomarkers, or the same analyte/biomarker. Furthermore, a subarray or a single filament **118** of the array of filaments **117** can be configured as a ground region of the microsensor **116**, such that signals generated by the microsensor **116** in response to analyte detection can be normalized by the signals generated by the subarray or single filament **118** serving as a ground region. Preferably, all subarrays of the array of filaments **117** are substantially equal in size and density; however, each subarray of the array of filaments **117** can alternatively be optimized to maximize signal generation and detection in response to a specific analyte. In an example, analytes that are known to have a lower concentration within a user's body fluid can correspond to a larger subarray of the array of filaments **117**. In another example, analytes that are known to have a higher concentration within a user's body fluid can correspond to a smaller subarray of the array of filaments **117**. In one extreme example, an entire array of filaments can be configured to sense a single analyte, such that the microsensor **116** and microsensor patch **110** is configured to sense and detect only one analyte. In another extreme example, each single filament in an array can be configured to detect a single analyte allowing for detection of multiple analytes within a single array (e.g., for a 100-filament array, 100 analytes can be tested).

In other variations, a subarray of the array of filaments **117** can also be used to detect other physiologically relevant parameters, such as electrophysiological signals (e.g., electrocardiogram, electroencephalogram), body temperature, respiration, and skin impedance change (e.g., to measure hydration state or inflammatory response). In these other variations, the subarray can be dedicated to measuring these physiologically relevant parameters, which could be combined with analyte/ion parameter measurements in order to provide meaningful information to a user. As an example, the simultaneous measurement of potassium levels and electrocardiogram measurements, enabled by subarrays of the array of filaments **117**, can provide a more complete diagnosis of cardiovascular problems or events than either measurement by itself.

A filament **118** of the array of filaments can comprise one or more of: a substrate core, the substrate core including a base end coupled to the substrate, a columnar protrusion having a proximal portion coupled to the base end and a distal portion, and a tip region coupled to the distal portion of the columnar protrusion and that facilitates access to the body fluid of the user; a conductive layer, isolated to the tip region of the substrate core and isolated away from the base end and the columnar protrusion as an active region that enables transmission of electronic signals generated upon detection of an analyte; an insulating layer ensheathing the columnar protrusion and base end of the substrate core and exposing a portion of the conductive layer, thereby defining a boundary of the active region; a sensing layer, in communication with the active region, characterized by reversible redox behavior for transduction of an ionic concentration of the analyte into an electronic signal; an intermediate selective layer superficial to the conductive layer and deeper than

the sensing layer, relative to a most distal point of the tip region of the filament, that facilitates detection of the analyte; an intermediate protective layer, superficial to the intermediate selective layer, including a functional compound that promotes generation of a protective barrier; and a selective coating superficial to the intermediate protective layer, having a distribution of molecules that respond to presence of the analyte, superficial to the sensing layer. Thus, a filament can comprise one or more regions, morphologies (examples of which are shown in FIGS. 3A-3H, with elements **118a-118h**), compositions, and/or configurations as described in U.S. Pub. No. 2014/0275897, entitled "On-Body Microsensor for Biomonitoring" and filed on 14 Mar. 2014 and/or U.S. App. No. 62/025,174, and entitled "System for Monitoring Body Chemistry" and filed on 16 Jul. 2014, which are each incorporated herein in their entirety by this reference. However, the filament can additionally or alternatively comprise any other suitable region, composition, morphology, and/or configuration.

In general, the system **100** can include components configured to protect portions of the microsensor **116** during manufacturing, packaging, and/or use of the system **100**. For instance, a mold of impact-absorbing material **17** can be positioned about the edge regions of the microsensor **116**, in order to protect edges of the microsensor **116** from damage (e.g., as a barrier). The mold of impact-absorbing material **17** can additionally or alternatively function to protect skin of the user from irritation caused by edge-regions of the microsensor. The mold can comprise a continuum of material (e.g., polymeric material), or can include a set of bumpers or spacers of material (e.g., polymeric material) to protect the microsensor **116**, an example of which is shown in FIG. 24. Additionally or alternatively, the material of the edge-protecting portion can be dispensed (e.g., as a gel, as an epoxy) during manufacture. However, the system **100** can additionally or alternatively include any other suitable microsensor **116** supporting elements.

1.1.2 System—Electronics Subsystem

The electronics subsystem **120** functions to receive analog signals from the microsensor **116** and to convert them into digital signals to be processed by a microprocessor **113** of the electronics subsystem **120**. In receiving signals, processing signals, regulating function, storing data, and/or transmitting data, the electronics subsystem **120** preferably includes a microprocessor **113** interfacing with one or more of: a signal conditioning module **122**, a power management module **124**, an impedance detection module **126**, a storage module **127**, and a transmitting unit **130**, as shown in FIG. 4. However, the electronics subsystem **120** can additionally or alternatively include any other suitable modules configured to facilitate signal reception, signal processing, and data transfer in an efficient manner.

The microprocessor **113** preferably includes memory and/or is coupled to a storage module **127** (e.g., flash storage). The microprocessor **113** can also include and/or be coupled to a clock/watchdog module (which can be incorporated into a microcontroller unit) for control of timing between different functions of the electronics subsystem **120**. The microprocessor **113** functions to process received signals, enable power distribution, enable impedance monitoring, and enable data transmission from the electronics subsystem **120**, in relation to other portions of the electronics subsystem **120** described below; however, the microprocessor **113** can alternatively or additionally be configured to perform any other suitable function.

The signal conditioning module **122** functions to preprocess signals detected and received using the microsensor

116, thereby producing conditioned data prior to processing at the processing subsystem 160. The signal conditioning module 122 can include one or more of: a signal multiplexer, an analog front end, an amplifier (e.g., a variable gain amplifier), a filter (e.g., low pass filter, high pass filter, band pass filter, etc.), an analog-to-digital converter (ADC), and a digital-to-analog converter (DAC). In one variation, as shown in FIG. 4, the signal conditioning module 122 comprises a multiplexer 22 in communication with the microsensor 116, wherein the multiplexer 22 is configured to communicate an output to an analog front end 23 that interfaces the microsensor 116 with an ADC 24 by way of a variable gain amplifier 25 coupled to a filter 26. In a specific example of this variation, the analog front end 23 circuitry is configured with a shifted potential different than a reference potential of the reference electrode 14 of the microsensor 116, wherein the shifted potential is different (e.g., -2V to 2V different) from the reference potential of the reference electrode 14. The configuration involving a difference between the shifted potential and the reference potential can allow the system 100 to drive redox reactions at the surface of the microsensor 110. However, in alternative variations of the specific example, the analog front end (or any other element of the signal conditioning module 122) can be configured with any other suitable potential relative to potentials of electrodes of the microsensor 116.

In more detail, the multiplexer 22 of the signal conditioning module 122 is preferably configured to receive multiple signals from the microsensor 116 (e.g., from subarrays of the array of filaments 117) and to forward the multiple signals received at multiple input lines in a single line at the analog front end. The multiplexer 22 thus increases an amount of data that can be transmitted within a given time constraint and/or bandwidth constraint. The number of input channels to the multiplexer 22 is preferably greater than or equal to the number of output channels of the microsensor 116, and can have any suitable relationship between the number of input lines into the multiplexer 22, select lines of the multiplexer, and output lines from the multiplexer 22. In some variations, the multiplexer 22 can include a post-multiplexer gain in order to reduce capacitance values of the analog front end 23 coupled to the multiplexer 22, and which can also be used to limit a number of amplifiers of the electronics 120, such that a single amplifier is coupled to the multiplexer 22 (as opposed to amplifiers coupled to each individual sensor); however, the multiplexer 22 can alternatively not include any gain producing elements. In some variations, the multiplexer 22 can additionally or alternatively include high frequency and/or low frequency limiting elements. However, the multiplexer 22 can additionally or alternatively be configured in any other suitable manner. Furthermore, in alternative variations, the signal conditioning module 122 can omit a multiplexer and/or comprise or omit any other suitable element.

In variations, an interface between the microsensor 116 and other elements of the electronics subsystem 120 can be configured in a manner that prevents or otherwise reduces leakage current effects due to a redox potential of the microsensor 116 in relation to other elements electronics subsystem 120. In a first configuration, a leakage current effect can result when a diode to ground (e.g., an ESD-diode to ground) is configured at an interface between the microsensor 116 and a multiplexer 22, as shown in FIG. 5A. To prevent or otherwise reduce the leakage current effect, a set of diodes 70, comprising a first diode 71 (e.g., a first EST-diode) and a second diode 72 (e.g., a second ESD-diode), configured at an interface between the microsensor

116 and the multiplexer 22 can be coupled to an element 73 (e.g., inductor, ferrite bead, resistor, etc.) that provides a high resistance to transient voltage spikes and directs any discharge through the second diode 72 to ground (instead of damaging the electronics subsystem 120), as shown in FIG. 5B. The multiplexer 22 can also comprise a switch 75, as shown in FIG. 5C, that allows altering of potentials within the analog front end 23. As shown in FIG. 5C, eliminating a voltage difference (i.e., between V_1 and V_2) eliminates or otherwise reduces leakage currents that can affect readings from the microsensor 110.

The power management module 124 functions to provide dynamic modulation of power transfer to and from elements of the microsensor patch 110, in a manner that enables efficient operation of the system 100. Preferably, the power management module 124 interfaces with a battery 138 and elements of the transmitting unit 130 requiring power (e.g., by way of a microprocessor 113, as shown in FIG. 4), as described in further detail below. Additionally, the power management module 124 can further interface with an external processing element of the processing subsystem 160, such that the power management module 124 can be at least partially implemented in firmware. In one such variation of the power management module 124, wherein power management is achieved in firmware, the power management module 124 can be configured to anticipate power requirements of one or more elements, and to automatically operate at the highest demanded power mode (e.g., voltage) required, while never dropping below a minimum power level required by the elements. The power management module 124 can also facilitate efficient switching of components to an "off" state when not needed, in order to contribute to lower current consumption. Additionally or alternatively, the power management module 124 can be configured to dynamically trigger high current draw sensing components (e.g., the impedance detection module 126) to an "on" state, only when needed, by monitoring other system components (e.g., voltage of a counter electrode 13).

In an example, as shown in FIG. 6A, a group of elements requiring different operating power levels can be coupled to the power management module 124, and the power management module 124 can output power at the highest operating power level anticipated among the elements. Disparate elements can also set a minimum level of power they require, and as elements vary their power requirements, the power management module 124 can then automatically adjust power output such that a power level provided never drops below the lowest power level required. In this variation, elements of the microsensor patch 110 requiring power are thus dynamically provided with their highest demanded power level, to substantially limit energy wasted by the system 100 and to satisfy power level requirements of all running elements. In another variation of the power management module 124, wherein power management is achieved in firmware, the power management module 124 can be configured to detect elements requiring power, and to automatically operate at the highest demanded power mode (e.g., voltage) required. In an example, a group of elements requiring different operating voltages can be detected, and the power management module 124 can output power at the highest operating voltage detected. As elements vary their voltage requirements, the power management module 124 can then automatically adjust voltage output to meet the highest demanded voltage. In this variation, elements of the microsensor patch 110 requiring power are thus dynamically provided with their highest demanded voltage, to substantially limit energy wasted by the system 100.

In other variations, power management can be achieved by the power management module 124 without implementation in firmware, such that power management occurs in circuitry. In these other variations, an example of which is shown in FIG. 6B, power management can comprise providing a set amount of power to elements requiring power, and completely eliminating power transfer to elements not requiring power. The system 100 can, however, comprise any other suitable variation of the power management modules 124.

In relation to the power management module 124, the electronics subsystem 120 can comprise a battery 138, which functions to serve as a power source for the electronics subsystem 120. The battery 138 is preferably coupled to a fuel gauge 38 and a charging detection module 39, each of which is coupled to the microprocessor 113 (described in further detail below). The battery 138 is preferably a lithium-ion battery that is configured to be rechargeable, but can be any appropriate rechargeable battery (e.g., nickel-cadmium, nickel metal hydride, or lithium-ion polymer). Alternatively, the battery 138 may not be a rechargeable battery. Preferably, the battery 138 is configured to have a profile with a low aspect ratio, contributing to a thin form factor of the microsensor patch 110. However, the battery 138 can be configured to have any appropriate profile such that the battery 130 provides adequate power characteristics (e.g., cycle life, charging time, discharge time, etc.) for the system 100. In some variations, a thin-film battery can be integrated with the microsensor patch 110 in order to facilitate substantially continuous analyte detection by the system 100, independent of the microprocessor 113 and digital electronics of the electronics subsystem 120.

In embodiments where the battery 138 is rechargeable, the electronics subsystem 120 can also comprise a charging coil 140 that functions to provide inductive charging for the battery 138, and a charging detection module 39, in communication with the microprocessor 113, that enable detection of charging of the battery 138. The charging coil 140 is preferably coupled to the battery 138 and converts energy from an electromagnetic field (e.g., provided by an element of a base station, as described in further detail below), into electrical energy to charge the battery 138. Inductive charging provided by the charging coil 140 thus facilitates user mobility while interacting with the system 100. In alternative variations, however, the charging coil 140 can altogether be omitted (e.g., in embodiments without a rechargeable battery), or replaced by a connection configured to provide wired charging of a rechargeable battery.

Additionally or alternatively, in some variations, the microsensor patch 110 can comprise a semi-active or fully-active power cell (e.g., implementing microelectromechanical system elements) that functions to absorb and/or release generated energy from any one or more of: body heat of the user, body movement of the user (e.g., with piezoelectric elements, with capacitive elements), static voltage from the environment of the user, light in the environment of the user (e.g., using solar cells), magnetic energy flux, galvanic differentials, and any other suitable energy source to provide secondary backup energy for the system 100.

The impedance detection module 126 is in communication with the signal conditioning module 122 and the power management module 124, and functions to enable detection of a proper interface between the microsensor 116 and body fluid (e.g., interstitial fluid) of the user. In facilitating monitoring of impedance, the impedance detection module 126 can thus provide signals that indicate that the microsensor patch 110 is properly coupled to the user (e.g., interfacing

with interstitial fluid and experiencing an ~80% moisture environment) or improperly coupled to the user (e.g., not interfacing properly with interstitial fluid and experiencing a low-moisture environment). Signals from the impedance detection module 126 can further be used to trigger an error correction action (e.g., notification for the user to reapply the microsensor patch 110, automatic manipulation of the microsensor patch 110 to re-establish interface with body fluid, etc.). In one variation, as shown in FIG. 4, the impedance detection module can comprise electronic circuitry configured to communicate with the multiplexer 22, the ADC 24, and the power management module 124, in receiving an impedance signal from the microsensor 116. However, the impedance detection module 126 can additionally or alternatively be configured relative to other elements of the electronics subsystem 120 in any other suitable manner.

In generating the impedance signal, the impedance detection module 126 can be configured to detect impedance between two electrodes of the array of filaments 117 in response to an applied voltage provided in cooperation with the power management module 126 and the microprocessor 113. In one variation, wherein the microsensor 116 comprises a first working electrode 11, a second working electrode 12, a counter electrode 13, and a reference electrode, the impedance detection module 126 can be configured to detect impedance from two of the first working electrode 11, the second working electrode 12, the counter electrode 13, and the reference electrode 14, examples of which are shown in FIG. 7. In a specific example, an applied signal can be injected into the system in a working electrode and detected in the reference electrode 14. However in other configurations of the microsensor 116, the impedance detection module 126 can be configured to detect impedance from electrodes of the microsensor 116 in any other suitable manner.

In relation to the applied voltage used for generation and reception of the impedance signal (i.e., for purposes of perturbation), the electronics subsystem 120 is preferably configured to provide an applied voltage waveform having a characteristic value (e.g., average value) near the operating potential of the signal conditioning module 122 of the electronics subsystem 120. In a variation wherein the signal conditioning module 122 (e.g., an analog front end 23 of the signal conditioning module 122) operates at a shifted potential relative to a potential of an electrode of the microsensor 116 (e.g., a reference potential of a reference electrode), the applied voltage waveform preferably has a characteristic value (e.g., average value) near or equal to that of the shifted potential, in order to improve stability of the microsensor 110 when switching back to a current sensing mode (i.e., the primary detection mode). The offset (i.e., shifted potential) is configured to reduce or minimize any disruption to signal integrity when the microsensor 110 is switched from a current sensing mode to an impedance detection mode, and then back to a current sensing mode. In a specific example, as shown in FIG. 8, the applied voltage waveform is shifted about a characteristic value and has a frequency from 50-200 kHz, in relation to a shifted potential of the analog front end 23 relative to the reference electrode 14. However, the applied voltage can alternatively have any other suitable characteristics (e.g., characteristic voltage values, frequencies, etc.) defined in relation to the operating potential(s) of any other suitable element of the electronic subsystem 120 related to the microsensor 116.

In relation to triggering of a measurement using the impedance detection module 126, triggering can occur with any suitable frequency (e.g., in relation to the lifespan of

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usage of the system 100), any suitable regularity (e.g., at regular time intervals, at irregular time intervals, etc.), and/or upon any suitable triggering event. In one variation, the impedance detection module 126 can be configured to provide an impedance signal in association with monitoring of an electrode (e.g., monitoring voltage of the counter electrode 13) of the microsensor 116, wherein detection of an out-of-range parameter (e.g., voltage) of the electrode triggers the applied voltage waveform and generation of an impedance signal. As such, the electronics subsystem 120 and the processing subsystem 160 (described further below) can be configured to cooperate in continuously detecting a voltage parameter of the counter electrode 13, and the electronics subsystem 120 can be configured to apply the applied voltage waveform and detect the impedance signal when the voltage parameter of the counter electrode satisfies a voltage threshold condition.

Additionally or alternatively, in another variation, the impedance detection module 126 can be configured to provide an impedance signal upon initial application of the system 100 to the body of the user. Additionally or alternatively, in another variation, the impedance detection module 126 can be configured to provide impedance signals at regular time intervals (e.g., once every hour) over the course of use of the system 100 by the user. Additionally or alternatively, in relation to other sensors (e.g., of a mobile computing device associated with the user and the system 100, of a wearable computing device associated with the user and the system 100, of the system 100, etc.) the impedance detection module 126 can be configured to provide an impedance signal in response to a sensor signal that indicates performance of an action by the user. For instance, monitoring of signals provided by an accelerometer and/or gyroscope can be used to indicate that the user is exercising, and that an impedance measurement should be taken (e.g., during exercise, after exercise, etc.) to ensure proper coupling of the system 100 to the user. In another example, monitoring of body temperature of the user can be used to indicate that the user is showering, and that an impedance measurement should be to ensure proper coupling of the system 100 to the user. The impedance detection module 126 can, however, be configured in any other suitable manner.

The impedance detection module 126 can further be used to generate notifications pertaining to impedance signal measurements that indicate improper coupling. For instance, a notification can be generated (and transmitted to a mobile computing device of the user) in response to detection of unsuitable impedance derived from comparison between the impedance signal and an impedance threshold condition. However, use of the impedance signal in performing an error correction action can be performed in any other suitable manner.

The transmitting unit 130 functions to receive signals generated by the microsensor patch 110 (e.g., by way of the microprocessor 113), and to interface with at least one of a mobile computing device 150, a data processing and/or storage module (e.g., a module external to an on-board storage module, a cloud-based computing module, etc.) by outputting signals based on at least one analyte parameter. The transmitting unit 130 thus cooperates with other elements of the electronics subsystem 120 to transmit signals based on sensed analyte parameters, which can be used to facilitate analyses of the user's body chemistry. In variations, the transmitting unit 130 includes an antenna 132, a radio 134 coupling the antenna to the microprocessor 113,

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and can additionally or alternatively include a linking interface 136 (e.g., wireless or wired interface, as described in further detail below).

Preferably, the transmitting unit 130 and the microsensor patch 110 are integrated as a cohesive unit; however, the transmitting unit 130 and the microsensor patch 110 can alternatively form a modular unit, wherein one of the transmitting unit 130 and the microsensor patch 110 is disposable, and wherein one of the transmitting unit 130 and the microsensor patch 110 is reusable. In variations of the microsensor patch 110 and the transmitting unit 130, elements of the microsensor patch 110 aside from the microsensor 116 can alternatively be integrated with the transmitting unit 130, such that the transmitting unit 130 is configured to be reusable and the microsensor 116 of the microsensor patch 110 is configured to be disposable. Modularity in the system 100 is described in further detail in relation to the housing 190 below.

Additionally, the transmitting unit 130 is preferably configured to output signals based on at least one analyte parameter characterizing body chemistry continuously over the lifetime usage of the transmitting unit 130; however, the transmitting unit 130 can alternatively be configured to output signals based on at least one analyte parameter at a set of time points (e.g., minutes, hours, days). Still alternatively, the transmitting unit 130 can be configured to output signals in a manner that does not interfere with other operations (e.g., signal collection operations) of the electronics subsystem 120. In one such example, the transmitting unit 130 can be configured to stop signal transmission whenever the ADC 24 is collecting signal data from the microsensor 116, in coordination with timing enabled by a clock/watchdog module associated with the microprocessor 113. In variations, the transmitting unit 130 can be further configured to output signals upon a user prompt, and/or can comprise a variable sampling rate. For example, the sampling rate can be lower when user is asleep, higher during activity (e.g., exercise), higher when there is a sudden change in a value, higher in response to other stimuli (e.g., if glucose spikes, sampling rate increases for all analytes).

The antenna 132 of the transmitting unit 130 functions to convert electrical signals from the microsensor patch 110 into radio waves, to facilitate communication with one or more devices external to the microsensor patch 110 and/or transmitting unit 130 assembly (e.g., by a Bluetooth Low Energy connection). The antenna 132 preferably interfaces with a radio 134 coupled to the microprocessor 113, as shown in FIG. 4, but can additionally or alternatively interface with other elements of the transmitting unit 130. The antenna is preferably an omnidirectional antenna that radiates radio wave power uniformly primarily in one plane, with the power decreasing with elevation angle relative to the plane; however, the antenna can alternatively be an isotropic antenna that has a spherical radiation pattern. Other variations of the antenna can include any appropriate antenna that can be integrated with the form factor of the transmitting unit, while providing appropriate communication with external devices.

Because the system 100 can transmit in configurations where the system 100 is proximal/near/coupled to the body of the user, the antenna 132 can be configured, with other components of the transmitting unit 130, in order to promote uninterrupted signal transmission due to signal interactions with the body of the user. For instance, one or more of the following can be implemented: the antenna 132 can be decoupled from the ground plane of the printed circuit board of the electronics subsystem, the antenna 132 can be posi-

tioned near an edge region of the housing **190** described below, the antenna/transmitting unit **130** can have a configuration of direct current (DC) coupling to skin of the user (e.g., thereby providing an offset and using the body of the user as a radio frequency (RF) ground), and any other suitable antenna design can be implemented to reduce signal disruption.

The radio **134** functions to transmit and receive signals from the antenna **132**, and also facilitates communication with elements of the transmitting unit **130** and external devices. The radio **134** and the antenna **132** can additionally or alternatively be supplemented with a linking interface **136**, as described in further detail below, but can additionally or alternatively interface with other elements of the electronics subsystem **120**.

The linking interface **136** functions to transmit an output of at least one element of the microsensor patch **110**/transmitting unit **130** assembly to a mobile computing device **150**. Additionally, the linking interface **136** can function to transmit and output of at least one element of the microsensor patch **110** and transmitting unit **130** assembly to another element external to the microsensor patch **110** and transmitting unit **130**. Preferably, the linking interface **136** is a wireless interface; however, the linking interface **136** can alternatively be a wired connection. In a first variation, the linking interface **136** can include a first module that interfaces with a second module included in a mobile computing device **150** or other external element (e.g., wrist-borne mobile computing device, head-mounted mobile computing device), wherein data or signals (e.g., microsensor or transceiver outputs) are transmitted from the transmitting unit **130** to the mobile computing device **150** or external element over non-wired communications. The linking interface **136** of the first variation can alternatively implement other types of wireless communications, such as 3G, 4G, radio, or Wi-Fi communication. In the first variation, data and/or signals are preferably encrypted before being transmitted by the linking interface **136**. For example, cryptographic protocols such as Diffie-Hellman key exchange, Wireless Transport Layer Security (WTLS), or any other suitable type of protocol can be used. The data encryption can also comply with standards such as the Data Encryption Standard (DES), Triple Data Encryption Standard (3-DES), or Advanced Encryption Standard (AES). In variations with data encryption, data can be unencrypted upon transmission to the mobile computing device **150** associated with the user. However, in an alternative variation, data can remain encrypted throughout transmission to a mobile computing device (associated with the user, not associated with the user) and unencrypted at another module of a processing subsystem **160** (e.g., unencrypted in the cloud), wherein information derived from analysis of the data can then be transmitted back to the mobile computing device associated with the user in a secure manner. In this variation, a user can thus pair his/her microsensor patch **110** with a mobile computing device unassociated with the user for transmission of encrypted data, and then later receive personalized body information at his/her own mobile computing device **150** after processing in the cloud.

In a second variation, the linking interface **136** is a wired connection, wherein the linking interface **136** includes a wired jack connector (e.g., a 1/8" headphone jack, a USB connection, a mini-USB connection, a lightning cable connection, etc.) such that the transmitting unit **130** can communicate with the mobile computing device **150** and/or an external element through a complementary jack of the mobile device and/or external element. In one specific

example of the linking interface **136** that includes a wired jack, the linking interface is configured only to transmit output signals from the transmitting unit **130**/microsensor patch **110**. In another specific example, the linking interface **136** is configured to transmit data to and from at least one element of transmitting unit **130**/transdermal path **110** assembly and a mobile computing device **150**. In this example, the linking interface **136** can transmit output signals into the mobile computing device **150** through an input of the jack of the mobile computing device **150** and can retrieve data from an output of the jack of the mobile computing device **150**. In this example, the linking interface **136** can communicate with the mobile computing device **150** via inter-integrated circuit communication (I2C), one-wire, master-slave, or any other suitable communication protocol. However, the linking interface can transmit data in any other way and can include any other type of wired connection that supports data transfer between the transmitting unit **130** and/or microsensor patch **110**, and the mobile computing device **150**.

The electronics subsystem **120** can further include a thermistor/potentiostat component **20**, which functions to enable temperature monitoring of skin of the user, in order to improve signal processing by accounting for thermal fluctuations of the body of the user. The thermistor/potentiostat component **20** can further function to enable detection of proper application of the system **100** at the body of the user, based upon monitoring of the temperature of the body of the user. As shown in FIG. **25**, in one variation, the thermistor/potentiostat component **20** can interface components of the microsensor **116**/first housing portion (e.g., patch coupled to the user) and components of the second housing portion **196** (e.g., pod for signal acquisition and transmission). However, variations of the thermistor/potentiostat component **20** can additionally or alternatively be configured in any other suitable manner. For instance, measurement of temperature using the thermistor/potentiostat component **20** can be additionally or alternatively used to assist with measurement of analyte readings (e.g., glucose readings), in relation to other biological or physiological phenomena of the user (e.g., fertility, fever, diurnal variations in temperature, etc.).

As noted above, the electronics subsystem **120** can include any other suitable module(s) and/or be configured in any other suitable manner. For instance, the electronics subsystem **120** can include or be in communication with an actuator configured to automatically perform an action (e.g., vibration, provision of a biasing force) that biases the microsensor into communication with interstitial fluid of the user, in response to detection of unsuitable impedance derived from comparison between an impedance signal and an impedance threshold condition.

1.1.3 System—Housing

The housing **190** supports the microsensor **116** and the electronics subsystem **120**, and functions to facilitate robust coupling of the microsensor patch **110** to the user in a manner that allows the user to wear the microsensor patch **110** for a sufficient period of time (e.g., one week, one month, etc.). The housing **190** can also function to protect elements of the microsensor patch **110** from physical damage over the lifetime usage of the microsensor patch **110**. Preferably, at least one portion of the housing **190** is flexible to facilitate adhesion to the user and compliance with skin of the user as the user moves in his/her daily life; however, at least a portion of the housing **190** can alternatively be rigid in order to provide more robust protection against physical damage. In an embodiment where a portion of the housing

190 is flexible, other elements of the microsensor patch 110 can also be flexible (e.g., using a thin film battery, using flexible electronics, etc.) to facilitate adhesion to the user and compliance as the user moves about in his/her daily life. In one variation, the housing 190 can comprise a single unit that entirely houses the microsensor 116 and the electronics subsystem 120. In this variation, the housing 190 can be configured to couple to the user using any suitable coupling mechanism (e.g., adhesive coupling mechanism, strap-based coupling mechanism, etc.). However, in other variations, the housing 190 can alternatively be modular and comprise a set of portions, each portion configured to enable coupling of the microsensor 116 to the user and/or to house elements of the electronics subsystem 120. Modularity of the housing 190 can thus allow portions of the system 100 to be disposable and/or reusable.

In some variations, modularity of the housing 190 can include housing components that are configured to break or otherwise prevent future recoupling after separation. For instance, with multiple housing portions, the system 100 can comprise coupled operation modes, wherein the multiple housing portions are coupled together during use (e.g., body chemistry monitoring), but once the system needs to be decoupled from the user and/or the housing portions need to be decoupled from each other (e.g., for charging of a module of the system, etc.), one or more of the multiple housing portions can break in a way that prevents re-coupling. In a first example, microsensor-supporting portions of the housing 190 can be configured to break apart (e.g., an opening of a first housing portion can comprise a perforation or other stress concentration region operable to break apart) after other electronics/power management/signal transmission components of the system 100 are separated from the microsensor-supporting portions of the housing 190. However, the system 100 can additionally or alternatively be configured in any other suitable manner in relation to modularity/reusability.

In one modular variation of the housing 190, as shown in FIG. 9, the housing can comprise a first housing portion 191 and a second housing portion 196, wherein the first housing portion 191 is configured to facilitate coupling of filaments of the microsensor 116 to the user, and the second housing portion 196 is configured to house elements of the electronics subsystem 120 and to couple the electronics subsystem 120 to the microsensor 116 by way of the first housing portion 191. As such, the first housing portion 191 and the second housing portion 196 of this variation are preferably configured to mate with each other in a complementary manner (e.g., with a male-female coupling mechanism, with a magnetic coupling mechanism, with a latch-based coupling mechanism, with a lock-and-key based coupling mechanism, etc.). In a specific example, as shown in FIGS. 10A-10B, the first housing portion 191' includes an opening 192', and a second housing portion 196' is insertable into the opening of the first housing portion in a first configuration, wherein coupling between the first housing portion 191' and the second housing portion 196' provides a hermetic seal between the first housing portion 191 and the second housing portion 196 (e.g., in a manner that prevents water or other fluids from passing into a region between the second housing portion 196 and the first housing portion 191). In more detail, as shown in FIG. 10C, the first housing portion 191 can include an o-ring 193 (e.g., an o-ring co-molded onto the material of the first housing portion) at a perimeter of the opening 192, and a perimeter region of the second housing portion 196 can include a recessed region 197 that interfaces with the o-ring 193 in a manner that provides a

hermetic seal. As such, the o-ring 193 can be physically coextensive with the material of the first housing portion 191 near the opening 192 in order to facilitate coupling between the first housing portion 191 and the second housing portion 196. Alternatively, the o-ring 193 can be physically coextensive (e.g., go-molded) on material of the second housing portion) at a region configured to interface with the opening 192, or can be coupled to one or more of the first housing portion 191 and the second housing portion 196 in any other suitable manner.

In an alternative example, as shown in FIGS. 10D and 10E, the second housing portion 196 can include an o-ring 193 internal to the outer diameter of the second housing portion 196, wherein the second housing portion 196 is configured in a manner that produces a crush seal when the second housing portion 196 is inserted into the opening of the first housing portion 191 (e.g., as in FIG. 10E). In this example, the first housing portion 191 can thus be manufactured (e.g., molded) without undercuts, in order to facilitate manufacturability with respect to reduced tooling complexity and cycle time.

Additionally or alternatively, the interface between the first housing portion 191 and the second housing portion 196 can be sealed using a covering 96 that adequately spans the interface/opening 192 between the first housing portion 191 and the second housing portion 196, in order to prevent water or any other undesired material from entering the interface. In variations, the covering 96 can be flexible or rigid, and can be comprised of any suitable material or composite of materials. Furthermore, the covering 96 can be coupled to one or more of the first housing portion 191 and the second housing portion 196 using an adhesive coupling mechanism or any other suitable coupling mechanics that promotes sealing of the opening/interface. In a specific example, the system 100 can include a covering 96 comprising a flexible polymer layer that is coupled to surfaces of both the first housing portion 191 and the second housing portion 196 proximal the opening 192, wherein the flexible polymer layer is coupled to the housing portions with an adhesive backing. However, variations of the covering 96 can be configured in any other suitable manner, or some variations of the system 100 can entirely omit a covering 96.

The first housing portion 191 preferably exposes the microsensor 116 through a base surface of the first housing portion 191, an example of which is shown in FIGS. 26A and 26B, such that portions of the microsensor 116 for accessing body fluid of the user are exposed at the base surface of the first housing portion 191. In a first variation, only microsensor filament portions operable to penetrate the body of the user may be exposed through the base surface of the first housing portion 191. In another variation, the entire microsensor 116, including portions that do not penetrate the body of the user can be exposed at the base surface of the first housing portion. However, portions of the microsensor 116 can be exposed through the base surface of the first housing portion 191 in any other suitable manner. In variations wherein at least a portion of the microsensor 116 is exposed at the base surface of the first housing portion 191, the system 100 can include a cap that is temporarily coupled to the base surface, wherein the cap protects the microsensor 116 from damage (e.g., in packaging, during shipping, etc.).

The first housing portion 191 can additionally or alternatively include an adhesive substrate 91 that substantially surrounds the microsensor 116 and is coupled to the base surface of the first housing portion 191, wherein the adhesive substrate 91 facilitates coupling of the first housing portion to the user and facilitates retention of a state of

coupling between the microsensor **116** and the user after portions of the microsensor have been inserted into the user's body.

Prior to application of the system **100** onto the user's body, the adhesive substrate **91** of the first housing portion **191** can be covered with or otherwise coupled to a liner **911**, as shown in FIG. **27**, wherein the liner **911** prevents the adhesive substrate **91** from prematurely sticking to objects and/or prevents the adhesive substrate **91** from losing its tack. The liner **911** can additionally or alternatively be designed to be easily separated from the adhesive substrate **91** by the user, such that removal of the liner **911** by the user does not interfere with application of the system **100** onto the body of the user. In some variations, the liner **911** can include multiple parts. For instance, the liner **911** can include overlapping or non-overlapping leaves, each leaf configured to be separated from the adhesive substrate **91** independently of the other leaves. Alternatively, the liner **911** can be a single liner designed to be separated from the adhesive substrate along a path that does not interfere with a process for applying the system **100** onto the body of the user. The liner **911** is preferably configured to be separated in a central-to-peripheral direction, in relation to the adhesive substrate **91**. In another variation, the liner **911** can be configured to be separated in a peripheral-to-central direction in relation to the adhesive substrate **91**. However, in still other variations, the liner **911** can be configured to be released from the adhesive substrate **91** in any other suitable direction or along any other suitable path.

In a first example, as shown in FIG. **28A**, the liner **911** includes two overlapping leaves, wherein the two overlapping leaves includes 1) a first leaf spanning a first portion of the adhesive substrate **91** and including a first valley fold configured to be used as a pull-tab, and 2) a second leaf spanning a second portion of the adhesive substrate **91** and including a second valley fold overlapping the first valley fold configured to be used as a pull-tab. As such, in this example, each of the first leaf and the second leaf is configured to be pulled away in a central-to-peripheral direction in relation to the adhesive substrate **91**. In relation to the cap described above, the first leaf and the second leaf can each include cutaways, such that the leaves do not touch exposed portions of the microsensor **116**; however, the first leaf and the second leaf can alternatively be configured in any other suitable manner.

In a second example, as shown in FIG. **28B**, the liner **911** can include a single liner having a spiral path initiating at a central region of the adhesive substrate and terminating at a peripheral region of the adhesive substrate, wherein the central region portion of the liner has a pull-tab to indicate that this is where separation should initiate. As such, in this example, the liner is configured to be pulled away in a central-to-peripheral direction in relation to the adhesive substrate **91**. In relation to the cap described above, the liner can include a cutaway, such that the liner does not touch exposed portions of the microsensor **116**; however, the liner can alternatively be configured in any other suitable manner.

The opening **192** of the first housing portion **191** and the second housing portion **196** can each have substantially circular footprints; however, the opening **192** and the second housing portion **196** can additionally or alternatively have any other suitable footprints or be configured in any other suitable manner.

In the specific example, as shown in FIGS. **10A-10B**, the first housing portion **191** can comprise an adhesive substrate **91** having a microsensor opening **92**, a microsensor interface substrate **93** superior to the adhesive substrate and config-

ured to pass the microsensor **92** through the microsensor opening **92**, a coupling ring **94** configured to retain the position of the microsensor interface substrate **93** relative to the adhesive substrate **91** and to provide an interface for mating with the second housing portion **196**, and a flexible cover **95** ensheathing the coupling ring **94**, coupled to the adhesive substrate **91**, and configured to maintain coupling between the adhesive substrate **191**, the microsensor interface substrate **93**, and the coupling ring **94**. In relation to the configuration described above, the adhesive substrate **91** is configured to facilitate adhesion of the microsensor patch **110** to the user at an inferior surface of the adhesive substrate, and the flexible cover **95** is configured to provide the opening **192'** that receives the second housing portion **192**.

The second housing portion **196** of the specific example is rigid, and configured to form a shell about the electronics subsystem **120**, while including openings that provide access for a set of contacts **98** that interface the electronics subsystem **120** with the microsensor interface substrate **93** when the first housing portion **191** is coupled to the second housing portion **196**. In relation to the microsensor interface substrate **93** of the first housing portion **191**, and in relation to a circular (or otherwise axially symmetric) configuration of an interface between the second housing portion **196** and the opening **192** of the first housing portion **191**, the microsensor interface substrate **93** of the specific example can include a circular printed circuit board comprising a set of concentric ring contacts **97**, as shown in FIG. **10A**, that interface electronics of the second housing portion **196** with filaments of the microsensor **116**. As such, the set of contacts **98** (e.g., digital contacts) of electronics of the second housing portion **196** can properly interface with the microsensor **116** in any rotational position of the second housing portion **196** within the first housing portion **191**, as shown in FIG. **10B**. In alternative variations of this specific example however, orientation-unspecific coupling between the first housing portion **191** and the second housing portion **196** can be achieved in any other suitable manner. In still alternative variations of this specific example, the first housing portion **191** and the second housing portion **196** can be configured to couple with a set orientation in order to ensure proper communication between the microsensor **116** and the electronics subsystem **120**.

Some variations of the housing **190** can additionally or alternatively include a coating that prevents water permeation (and/or other liquid permeation), but allows electrical contact (e.g., for current passage) to be made between the set of concentric ring contacts **97** of the first housing portion **191** and contacts **98** of the second housing portion **196**. In variations, the coating can include a nanocoating of colloidal suspension of silicon oxide, which allows current passage through a waterproof layer that protects electronic components from shorting; however, the housing **190** can additionally or alternatively include any other suitable coating. For instance, waterproofing of electronics with coatings can additionally or alternatively be achieved using an adhesive coating (e.g., thin film) applied to circuit board components prior to assembly. Additionally or alternatively, the coating can include a nanocoating of another suitable material (e.g., paralene, etc.).

Furthermore, in relation to coupling between printed circuit board (PCB) components and components of either or both the first and the second housing portions **191**, **196**, coupling can be achieved using an adhesive process (e.g., using a glue or other adhesive). Additionally or alternatively, coupling can be achieved using a thermal process (e.g., a

heat staking process) to couple PCB(s) to portions of the first housing portion **191** and/or the second housing portion **196**.

In variations of the housing **190** comprising a first housing portion **191** and a second housing portion **196**, the first housing portion **191** and the second housing portion **196** can be coupled together and/or coupled to the user by way of an applicator system **180**, as described in further detail below. Furthermore, other variations of modularity can comprise any other suitable distribution of the microsensor **116** and elements of the electronics subsystem **120** across portions of the housing in any other suitable manner. For instance, in one such variation, the microsensor **116**, the multiplexer **22**, and the analog front end **93** of the electronics subsystem **120** can be coupled to a separate battery (e.g., a thin film battery) within a disposable portion of the housing **190**, and other elements of the electronics subsystem **120** can be supported by a reusable portion of the housing **190**. The system **100** can, however, comprise any other suitable distribution of elements across the housing **190** in a modular fashion.

1.2 System—Processing Subsystem

The processing subsystem **160** is in communication with the electronics subsystem **120** and functions to generate analyses pertaining to the user's body chemistry, and to transmit information derived from the analyses to the user at an electronic device associated with the user. As shown in FIG. 1, the processing subsystem **160** can be implemented in one or more of: a computer machine, a remote server, a cloud computing system, a microprocessor, processing hardware of a mobile computing device (e.g., smartphone, tablet, head-mounted mobile computing device, wrist-borne mobile computing device, etc.) and any other suitable processing system. In one variation, the processing subsystem **160** comprises a first module **161** configured to generate an analysis indicative of an analyte parameter of the user and derived from a signal stream from the microsensor **116** and an impedance signal from the electronics subsystem **120**. Additionally, in this variation, the processing subsystem **160** comprises a second module **162** configured to render information derived from the analysis at an electronic device (e.g., mobile computing device **150**) associated with the user, thereby facilitating monitoring of body chemistry of the user. In this variation, the modules of the processing subsystem **160** can be implemented in a hardware module and/or a software module. In variations, a software module **163** can be implemented, at least in part, as a native software application executing on a mobile computing device **150** associated with the user, wherein the user has a user account associated with the native software application.

In more detail, the software module **163** functions to analyze an output provided by the transmitting unit **130** of the electronics subsystem **120**, and to communicate an analysis of the output back to the user, so that the user can monitor his/her body chemistry. Preferably, the software module **163** analyzes at least one analyte parameter in order to determine a metric providing information about a user's body chemistry. In one variation, the software module can determine that a body analyte parameter (e.g., glucose level) of the user is too low or less than ideal, and facilitate a behavior change in the user by providing a body chemistry metric indicating a hypoglycemic state. In this variation, the software module can additionally determine that the body analyte parameter (e.g., glucose level) of the user is within a proper range based on a determined metric. The software module of this variation can additionally determine that the body analyte parameter (e.g., glucose level) of the user is too

high and facilitate a behavior change in the user by providing a body chemistry metric indicating a hyperglycemic state.

In another example, the software module can analyze an output provided by the transmitting unit **130** based on a set of parameters for multiple analytes characterizing a user's body chemistry, at a set of time points, and determine at least one metric based on the set of parameters at the set of time points. The software module can then determine and output at least one of a temporal trend in a metric, a temporal trend in an analyte parameter, absolute values of a metric, changes in value of a metric, absolute values of an analyte parameter, and changes in value of an analyte parameter. The software module **163** in this example can further be configured to communicate a suggestion to the user based on an analysis determined from the set of parameters for multiple analytes.

The software module preferably incorporates at least one of user health condition, user characteristics (e.g., age, gender, ethnicity), and user activity in analyzing an output provided by the transmitting unit **130**. In one specific example, if a user sets a desired body glucose level range, which is entered into the software module, the software module can be configured to facilitate provision of alerts notifying the user of short-term risks (e.g., diabetic crash), long-term risks (e.g., worsening diabetic condition), and risk of exiting the desired body glucose level range. In another specific example, the software module can compare analyte parameters and/or a metric characterizing the user's body chemistry to other users with similar health conditions or characteristics (e.g., age, gender, ethnicity). In yet another example, the software module can be able to correlate at least one analyte parameter or metric to a user activity, such that the user is provided with information relating a value of the analyte parameter and/or metric to an activity that he or she has performed. The software module can additionally or alternatively provide an analysis that includes any other health- and/or user-related information that can be useful in treating, maintaining, and/or improving a health condition of a user.

As shown in FIGS. 1, 11A, and 11B, the software module can be implemented, at least in part, as an application executable on a mobile computing device **150**. As described above, the mobile computing device **150** is preferably a smartphone but can also be a tablet, laptop computer, PDA, e-book reader, head-mounted computing device, smart-watch, or any other mobile device. The software module can alternatively be an application executable on a desktop computer or web browser. The software module preferably includes an interface that accepts inputs from the user (e.g., user health condition, user characteristics, user activity), and uses these inputs in analyzing an output provided by the transmitting unit **130**. Preferably, the software module also includes an interface that renders an analysis based on sensed analytes and/or user inputs in some form. In an example, the software module includes an interface that summarizes analyte parameter values in some manner (e.g., raw values, ranges, categories, changes), provides a trend (e.g., graph) in at least one analyte parameter or body chemistry metric, provides alerts or notifications, provides additional health metrics, and provides recommendations to modify or improve body chemistry and health metrics. In another example, the software module can implement two interfaces: a first interface accessible by a user, and a second interface accessible by a health care professional servicing the user. The second interface can provide summarized and detailed information for each user that the health care professional interacts with, and can further include a mes-

sage client to facilitate interactions between multiple users and the health care professional. The software module can additionally or alternatively access a remote network or database containing health information of the user. The remote network can be a server associated with a hospital or a network of hospitals, a server associated with a health insurance agency or network of health insurance agencies, a server associated with a third party that manages health records, or any other user- or health-related server or entity. The software module can additionally or alternatively be configured to accept inputs from another entity, such as a healthcare professional, related to the user.

The software module **163** can additionally or alternatively execute fully or in part on a remote server. In a first variation, the software module can be a cloud-computing-based application that performs data analysis, calculations, and other actions remotely from the mobile computing device **150**. In one example of the first variation, the mobile computing device **150** can receive an output of the transmitting unit **130** via the linking interface **136** and then transfer the output to the remote server upon which the software module executes. In the first variation, signals are preferably transferred via a wireless connection, such as a Bluetooth connection, 3G or 4G cellular connection, and/or via a Wi-Fi internet connection. In another example of the first variation, a mobile computing device **150** can function to transmit data to and/or receive data from the software module. In a second variation, the software module can include a first software component executable on a mobile computing device **150**, such as an application that manages collection, transmission, retrieval, and/or display of data. In the second variation, the software module can further include a second software component that executes on the remote server to retrieve data, analyze data, and/or manage transmission of an analysis back to the mobile computing device **150**, wherein the first software component manages retrieval of data sent from the second software component and/or renders a form of the analysis on a display of the mobile computing device **150**. However, the software module can include any number of software components executable on any mobile computing device **150**, computing device, and/or server and can be configured to perform any other function or combination of functions.

As shown in FIG. **12A**, the software module **163** can further be integrated with a notification module **165** configured to provide an alert or notification to a user and/or health care professional based on the analysis of the output. The notification module **165** functions to access an analysis provided by the software module and to control transmission of a notification **166** to at least one of a user and a healthcare profession interacting with the user. In one variation, the notification module **165** receives an analysis of the software module being executed on a mobile computing device **150**, and generates a notification **166** based upon the analysis. In this variation, a form of the analysis is preferably transmitted from the software module, executing on the mobile computing device **150**, to the notification module **165**, wherein the mobile computing device **150** accesses the analysis either from the software module executing on the mobile computing device **150** or from the software module executing on a remote server and in communication with the mobile computing device **150**. The notification module **165** preferably controls transmission of the notification **166** to the user, such as by triggering a display of the mobile computing device **150** to display a form of the notification, or by generating and/or transmitting an email, SMS, voice-mail, social media platform (e.g., Facebook or Twitter)

message, or any other message accessible by the user and which contains the notification **166**. The notification module **165** can also convey the notification **166** by triggering a vibration of the mobile device **160**, and/or by altering the state (i.e., ON or OFF) of one or more light sources (e.g., LEDs) of the mobile computing device **150**. However, the notification module **165** can alternatively manage the transmission of any other information and function in any appropriate manner.

The notification **166** preferably contains information relevant to a body chemistry status of the user. The notification **166** can additionally include an explicit directive for the user to perform a certain action (e.g., eat, rest, or exercise) that affects the body chemistry of the user. Therefore, the notification **166** preferably systematically and repeatedly analyzes a body chemistry status of the user based on at least one analyte parameter of the user and provides and alert and/or advice to manage and monitor a user's body chemistry substantially in real time. In one example, the notification **166** can further include information related to what or how much to eat, where and how long to run, level of exertion, and/or how to rest and for how long in order to appropriately adjust body chemistry. In other examples, the notification **166** can include any appropriate information relevant to monitoring a body chemistry metric of the user.

In still other examples, as shown in FIG. **12B**, the notification **166** can indicate one or more of: a current level of a measured analyte (e.g., represented in hue, represented in saturation, represented in intensity, etc. of a graphical rendering); a trending direction for the level of the measured analyte (e.g., represented in a feature gradient within a graphical rendering); a lower bounding level and an upper bounding level between which the level of the measured analyte is traversing; a trending direction of a level of a measured analyte (e.g., represented in an arrow of a graphical rendering); a quantification of a level of a measured analyte (e.g., represented as rendered text); a summary of a level of a measured analyte (e.g., represented as rendered text); a percent of time within a time duration (e.g., one day) that the level of the measured analyte is within a target range (e.g., healthy range); and historical behavior of a level of a measured analyte (e.g., represented as historical "ghosting" of a rendering based upon a previous analyte level).

Additionally or alternatively, in still other examples, as shown in FIG. **12C**, the notification **166** can include a graphical rendering that shows analyte data from past to present using a line graph representation, wherein an amount (e.g., concentration) of the analyte is represented along a first axis and time is represented along a second axis. In these examples, the graphical rendering can further include a "predicted region" based upon the analysis of the processing subsystem **160**, wherein the predicted region **66** depicts a prediction of where the analyte level will be at a future time point, and a width of the predicted region **66** indicates confidence in the prediction.

In relation to the processing subsystem **160** and analyses generated at the processing subsystem **160**, the processing subsystem **160** can be coupled to or comprise a data storage unit **170**, as shown in FIG. **13**. The data storage unit **170** functions to retain data, such as an analysis provided by a software module, a notification **166**, and/or any other output of any element of the system **100**. The data storage unit **170** can be implemented with the microsensor patch **110**, transmitting unit **130**, mobile computing device **150**, personal computer, web browser, external server (e.g., cloud), and/or local server, or any combination of the above, in a network configured to transmit, store, and receive data. Preferably,

data from the data storage unit **170** is automatically transmitted to any appropriate external device continuously; however, data from the data storage unit **170** can alternatively be transmitted only semi-continuously (e.g., every minute, hourly, daily, or weekly). In one example, data generated by any element can be stored on a portion of the data storage unit **170** when the linking interface **136** is not coupled to an element external to the microsensor patch **110**/transmitting unit **130** assembly. However, in the example, when a link is established between the linking interface **136** and an external element, data can then be automatically transmitted from the storage unit **170**. In other examples, the data storage unit **170** can alternatively be prompted to transmit stored data by a user or other entity. Operation modes related to device pairing and information transfer are further described in relation to the base station of Section 1.4 below.

1.3 System—Applicator

As shown in FIG. **1**, the system **100** can further comprise an applicator system **180**, which functions to facilitate application of at least one of the microsensor patch **110** and the transmitting unit **130** onto a body region of the user. The applicator system **180** preferably accelerates the a portion of the housing with the microsensor **116** toward skin of the user, thereby causing the microsensor **116** to penetrate skin of the user and sensing regions of the microsensor to access interstitial fluid of the user. However, the applicator system **180** can additionally or alternatively facilitate coupling of the microsensor **116** to the user using one or more of: skin stretching, skin permeabilization, skin abrasion, vibration, and/or any other suitable mechanism, variations of which are shown in FIGS. **14A-14C**.

In variations, as shown in FIG. **15**, the applicator system **180** can include a first applicator portion **81** comprising a coupling interface **811**; a second applicator portion **82** comprising a retainer **821**; an elastic coupler **83** between the first applicator portion **81** and the second applicator portion **82**; and a trigger **84** operable between a loaded mode **84aa** and a released mode **84b**; wherein, in the loaded mode, the elastic coupler is in a first compressed state between the first applicator portion and the second applicator portion, the first applicator portion is retained by the retainer of the second applicator portion, and the coupling interface is coupled to the second housing portion; and wherein, in the released mode, the elastic coupler is in a second compressed state (e.g., a state of lower compression or non-compression) between the first applicator portion and the second applicator portion, the first applicator portion is released from the retainer of the second applicator portion, and the coupling interface is uncoupled from the second housing portion, with the microsensor portions coupled to the user.

These variations of the applicator system **180** function to provide a mechanism that promotes proper application of the microsensor patch **110** at the body of the user. As such, these variations are configured for ease of use and/or error-preventing use in relation to one or more of: transitioning the applicator system into a loaded mode; initial positioning of the microsensor patch **110** at portions of the applicator system; positioning the applicator system **180** with the microsensor patch **110** at a body region prior to insertion of microsensor portions into the body; transitioning the applicator system from the loaded mode to the released mode, thereby properly inserting microsensor into the body of the user; and moving the applicator system **180** away from the body of the user.

1.3.1 Applicator—First Applicator Portion

The first applicator portion **81** functions to reversibly retain the microsensor patch **110** prior to coupling of the microsensor patch **110** to the user. The first applicator portion **81** can thus function to retain the microsensor patch as the microsensor patch is loaded and then accelerated toward the body of the user for microsensor insertion. Then, the first applicator portion **81** can release the microsensor patch **110** such that the microsensor patch **110** can be left at the body of the user.

As such, the first applicator portion **81** can include a coupling interface **811** that couples to one or more portions of the microsensor patch **110** prior to insertion. The coupling interface **811** can include: a suction interface operable to temporarily retain a surface of the microsensor patch **100** using negative pressure and by forming a temporary seal with the surface of the microsensor patch **100**. Additionally or alternatively, the coupling interface **811** can interface with the microsensor patch **110** by any one or more of: an adhesive interface formed by an adhesive region of the first applicator portion and/or the microsensor patch **110**; a magnetic interface between magnetic regions of the first applicator portion and the microsensor patch **110**; a locking interface between the first applicator portion and the microsensor patch **110**, a press-fit interface between the first applicator portion and the microsensor patch **110**; and any other suitable interface between the first applicator portion and the microsensor patch.

The coupling interface **811** preferably couples to the second housing portion **196**, which as described above, supports the electronics subsystem **120** and is insertable into an opening of the first housing portion **191**. However, the coupling interface **81** can alternatively couple to the first housing portion **191** and/or to both the first housing portion **191** and the second housing portion. In a specific example, the coupling interface **811** comprises a suction interface that couples to a surface of the second housing portion **196** opposing a second surface of the second housing portion **196** that interfaces with electronics of the first housing portion **191**; however, variations of the specific example can be configured in any other suitable manner.

In variations of the coupling interface **811** including a suction interface, the coupling interface **811** can further include a venting channel having a first opening into a concave portion of the suction interface (that couples to the microsensor patch) and a second opening at a distal end. The venting channel facilitates release of the microsensor patch **110** from the applicator system **180** during and/or after acceleration of the microsensor patch toward the body of the user. The venting channel preferably has a shaft, an example of which is shown in FIGS. **16A** and **16B**, and a pathway through the shaft that connects the first opening to the second opening. As described below, the second opening of the venting channel preferably interfaces with a sealing interface at one or more of the second applicator portion **82** and the trigger **84** of the applicator system **180** in order to provide 1) a sealed state that supports coupling between the microsensor patch **110** and the applicator system **180** and 2) an unsealed state that supports uncoupling between the microsensor patch **110** and the applicator system **180**. However, the venting channel **86** can alternatively be configured in any other suitable manner.

1.3.2 Applicator—Second Applicator Portion

The second applicator portion **82** functions to support the first applicator portion **81**, the elastic coupler **83**, and the trigger **84**, and functions to cooperate with one or more portions of the applicator system **110** to reversibly lock the

first applicator portion **81** into place and to release the first applicator portion **81** to accelerate a microsensor patch **110** coupled to the first applicator portion **81** along a path toward the body of the user. The second applicator portion **82** can thus circumscribe or otherwise surround the first applicator portion **81** in a manner that controls a path of motion of the first applicator portion **81** within the second applicator portion **82**. However, any other suitable relationship can exist between the first applicator portion **81** and the second applicator portion **82**, such that acceleration of the microsensor patch **110** toward the body of the user occurs as desired.

In relation to retention of the first applicator portion **81** (with the coupled microsensor patch **110**) by the second applicator portion **82**, the second applicator portion **82** can include or be coupled to a retainer **821** that provides a mechanism for reversibly locking the first housing portion **81** with the second housing portion **82** (e.g., during the loading mode described below).

The retainer **821** can include a mechanical latching mechanism, that, when engaged by the first housing portion **81**, retains the position of the first housing portion in a loaded mode; then, with activation of the trigger **84** described below disengages the latching mechanism to release the first housing portion **81**. In specific examples, the retainer can thus include one or more of: a wedge-shaped protrusion biased laterally toward a corresponding recessed region of the first housing portion **81**, whereby the wedge-shaped protrusion engages the recessed region as the first housing portion **81** transitions into the loaded mode; a ram-and-catch mechanism whereby twisting of at least one of the second housing portion **82** and the first housing portion **81** engages a retaining region of the retainer **821**; and any other suitable mechanical latching mechanism. In more detail, a ram-and-catch mechanism (or other twisting mechanism) can be used, in combination with a elastic component (as described below), to adjust the acceleration of the first applicator portion **81**, with the microsensor patch **110**, toward the body of the user. Such an adjustment can be based upon an amount of potential energy stored in a spring that is compressed by the rotation mechanism, or any other suitable mechanism, and can be used to ensure proper insertion of the microsensor for a variety of skin types or user demographics.

The retainer **821** can additionally or alternatively include a magnetic retention mechanism that reversibly retains a position of the first housing portion **81** relative to the second housing portion **82**. The magnetic retention mechanism can include a magnet of a first polarity coupled to the second applicator portion **82** that interfaces with a magnet of a second polarity coupled to the first applicator portion **81**, such that the two magnets provide a configuration that reversibly retains the first housing portion **81** in position relative to the second housing portion **82**. Alternatively, at least one magnet of the magnetic retention mechanism can include an electromagnetic element. In a specific example, as shown in FIGS. **17A** and **17B**, the magnetic retention mechanism can interface with a coil element that passes current in a manner where the current magnitude affects an acceleration profile of the first housing portion **81**, with the coupled microsensor patch **110**, toward the body of the user. This mechanism is described in further detail in relation to the elastic coupler **83** below.

In variations, the second applicator portion **81** can be composed of a polymeric material (e.g., plastic), a metallic material, and/or any other suitable material. In variations of the applicator system **180** incorporating mechanical mechanisms, the second applicator portion **81** can be at least

partially composed of plastic. In variations of the applicator system **180** incorporating magnetic and/or electromagnetic mechanisms, the second applicator portion **81** can be at least partially composed of a metal (e.g., steel, etc.). However, any applicator portion can additionally or alternatively be composed of any other suitable material.

1.3.3 Applicator—Support Elements and Other Elements

The applicator system **180** can also include an elastic coupler **83** between the first applicator portion **81** and the second applicator portion **82**, wherein the elastic coupler **83** functions to store potential energy in the loaded mode of the trigger, which can be released to accelerate the first housing portion **81**, with the microsensor patch **110**, toward the body of the user. In variations wherein the first applicator portion **81** is situated within the second applicator portion **82**, the elastic coupler **83** can be positioned such that translation of the first applicator portion **81** within the second applicator portion **82** adjusts a state of compression of the elastic coupler, thereby transitioning between a state of high potential energy in the loaded mode and a state of low potential energy in the released mode, as described below. In a specific example, as shown in FIGS. **15**, **16A**, and **16B**, the elastic coupler **83** can reside within a space laterally between a venting channel **86** of the first applicator portion **81** and an interior wall of the second housing portion, wherein the elastic coupler **83** is retained in position at either a base surface of the venting channel **86** of the first applicator portion **81** or a base surface of the second applicator portion **82**; however, the elastic coupler **83** can additionally or alternatively be configured relative to the first applicator portion **81** and the second applicator portion **82** in any other suitable manner.

The elastic coupler **83** can include a spring with a suitable spring force in relation to storage of a maximum amount of potential energy to provide proper acceleration of the microsensor patch **110** toward the body of the user. Additionally or alternatively, the elastic coupler **83** can comprise any other suitable material that can transition between a state of high potential energy and low potential energy. In other variations, the elastic coupler **83** can include a pair of magnets with like polarity oriented toward each other, an elastomeric element, or any other suitable component that stores and releases potential energy.

As indicated above, in some variations wherein the second applicator portion **82** includes or is coupled to a magnet, the applicator system **180** can further include a coil of conductive material that passes current in a manner that causes an interaction between a magnetic field formed by the current and the magnet. In a specific example, as shown in FIGS. **17A** and **17B**, the elastic coupler **83** can be replaced or in some manner supplemented by a coil of wire (e.g., voice coil) coupled to a current source and operable to pass a desired amount of current, thereby affecting acceleration parameters (e.g., a velocity profile) of the first applicator portion **81**, with the microsensor patch **110**, toward the body of the user. As such, the second applicator portion can be operable between different modes, each mode associated with a different amount of current passage, wherein the current magnitude changes acceleration parameters of the first applicator portion **81**, with the microsensor patch **110**, toward the body of the user.

In still other variations, however, the elastic coupler **83** can additionally or alternatively include or be replaced with any other suitable element that promotes an acceleration of the first applicator portion **81**, with the microsensor patch **110**, toward the body of the user. In one alternative example, the

first applicator portion can be pneumatically driven using compressed air; however, any other suitable mechanism can be incorporated.

As indicated above, in some variations, the applicator system **180** can include a trigger **84** operable between a loaded mode **84a** and a released mode **84b**, wherein the trigger **84** functions to enable release of the first applicator portion **81** to accelerate the microsensor patch **110** toward the body of the user. The trigger **84** can be mechanically controlled or electrically controlled. For instance, in a first variation, the trigger **84** can be entirely mechanical and used to transition the retainer **821** of the second applicator portion **82** into a configuration that unlatches the first applicator portion **81** from the second applicator portion **82**, allowing the compressed elastic coupler **83** to be released and accelerate the first applicator portion **81**, with the microsensor patch **110**, toward the user. In a second variation, the trigger **84** can be electronic and, when activated, allow current to pass through a conductive coil about a magnet of the second applicator portion **82**, thereby generating a magnetic field that interacts with the magnet and creating a driving force to accelerate the first applicator portion **81**, with the microsensor patch **110**, toward the user. However, other variations of the trigger **84** can be configured in any other suitable manner, some examples of which are described in Sections 1.3.4 and 1.3.5 below.

The applicator system **180** can additionally or alternatively include any other suitable support elements. For instance, the applicator system **180** can include components that support the microsensor patch **110** and/or the applicator system **180** against the skin of the user prior to coupling of the microsensor to the user. In one variation, the applicator system **180** can include a compressible support material situated behind the coupling interface/suction interface of the first applicator portion **81**, wherein the compressible support material complies with the user's body during the process of coupling the microsensor patch **110** to the user's body. The applicator system **180** can additionally or alternatively include structures that obscure the microsensor patch **110** from the user's view during the insertion process, in order to prevent apprehension of the user during the insertion process. Additionally or alternatively the applicator system **180** can include noise-dampening elements operable to prevent apprehension of the user during the insertion process. Additionally or alternatively, the applicator system **180** can include an audio detection element (e.g., a microphone coupled to an element of the applicator system) operable to detect a sound output from the elastic coupler **83** during a transition from the loaded mode to the released mode, thereby facilitating assessment of proper The system can, however, include any other suitable element(s).

1.3.4 Applicator—Specific Examples

In a first specific example, as shown in FIGS. **16A** and **16B**, the applicator system **180'** includes a first applicator portion **81'** including a suction interface **811'** coupled to a venting channel **86'** with an opening **87'**; a second applicator portion **82'** including a retainer; a spring **83'** between the first applicator portion **81'** and the second applicator portion **82'**; and a trigger **84'** including a sealing interface **88'**, the trigger **84'** operable between a loaded mode **84a'** and a released mode **84b'**; wherein, in the loaded mode, as shown in FIG. **16A**, the elastic coupler is in a first compressed state between the first applicator portion and the second applicator portion, the first applicator portion is retained by the retainer of the second applicator portion, and the suction interface is coupled to the second housing portion with the opening of the venting channel sealed by the sealing inter-

face. As shown in FIG. **16A**, transitioning to the loaded mode **84a'** can be facilitated using an example of the base station **5** described in section 1.4 and shown in FIGS. **1** and **16A**, wherein the base station **5** includes a recessed platform for receiving and positioning the first housing portion **191** within a substantially horizontal plane. In this example, the recessed platform includes a central opening into a cavity, wherein the cavity provides clearance for portions of the microsensor **116** coupled to the first housing portion **191**, and wherein the cavity includes a charging slot that can accept units of the second housing portion **196** for charging (e.g., even when the first housing portion **191** is positioned at the recessed platform). As such, the base station **5** can include a charging station within the cavity and a platform, such that the base station **5** facilitates loading of a patch assembly and charging of a battery of the second housing portion. Then, as shown in FIG. **16A**, pressing the second applicator portion **82'** downward can transition the applicator **180'** to the loaded mode **84a'** by way of a trigger ring **2** of the second applicator portion **82'** that translates upon being compressed by a recessed ring in the base station **5** that is concentric with the trigger ring **2**.

After the applicator **180'** is in the loaded mode **84a'**, it can then be transitioned to the released mode **84b'**, wherein, in the released mode, as shown in FIG. **16B**, the spring **83'** is in a second compressed state (e.g., a state of low compression) between the first applicator portion **81'** and the second applicator portion **82'**, the first applicator portion is released from the retainer **821'** of the second applicator portion, the suction interface **811'** is released from the second housing portion with the opening **87'** of the venting channel **86'** unsealed by the sealing interface **88'**, and microsensor portions of the body chemistry monitor are coupled to the user. In the specific example, pressing the second applicator portion **82'** downward against the user's skin can transition the applicator **180'** to the released mode **84b'** by way of the trigger ring **2** of the second applicator portion **82'** that translates upon being compressed against the user's skin. In variations of this specific example, the trigger ring can have an adjustable set position that affects a travel distance between the loaded patch assembly and skin of the user, such that the acceleration profile of the applicator **180'** can be adjusted depending on specific needs of the user. However, the trigger ring can alternatively be adjusted in any other suitable manner. In the specific example, the velocity of the microsensor **116** upon impact can be between 3 and 15 m/s; however, the velocity can alternatively be any other suitable velocity to provide coupling between the microsensor **116** and skin of the user.

In a broader use case for the applicator system **180'** described above, the microsensor patch **110** can be loaded into the applicator system **180** with the second housing portion **196** coupled to a suction interface of the first housing portion, wherein in the loaded mode the venting channel **86** is sealed by a sealing interface of the second applicator portion **82**/trigger **84**. An adhesive portion of the first housing portion **191** can then be exposed, and the applicator system **180** can be positioned, in the loaded mode **84a** and with the microsensor exposed and facing the body of the user. Then, the trigger **84** can be activated to transition the applicator system **180** to the released mode **84**, thereby using converted potential energy from the compressed spring of the loaded mode **84a** to accelerate portions of the microsensor into the body of the user. However, variations of the use case described above can be configured in any other suitable manner.

In a second specific example, as shown in FIGS. 17A and 17B, the applicator system 180" includes a first applicator portion 81" including a coupling interface 811" that couples to the microsensor patch by suction; a second applicator portion 82" composed of steel and including a magnet 89"; a spring 83" between the first applicator portion 81" and the second applicator portion 82"; a coil 88" operable to pass current and interact with the magnet 89"; and a trigger 84" operable between a loaded mode 84a" and a released mode 84b"; wherein, in the loaded mode, as shown in FIG. 17A, the elastic coupler is in a first compressed state between the first applicator portion and the second applicator portion, the first applicator portion is retained by the retainer of the second applicator portion, and the coupling interface is coupled to the microsensor patch; and wherein in the released mode, as shown in FIG. 17B, the spring 83" is in a second compressed state (e.g., a state of low compression) between the first applicator portion 81" and the second applicator portion 82", the first applicator portion is released from the retainer 821' of the second applicator portion with passage of current through the coil 88", the coupling interface 811" is released from the second housing portion 82", and microsensor portions of the body chemistry monitor are accelerated into to the user.

In a use case for the applicator system 180" described above, the microsensor patch 110 can be loaded into the applicator system 180" with the second housing portion 196 coupled to the coupling interface of the first housing portion. An adhesive portion of the first housing portion 191 can then be exposed, and the applicator system 180" can be positioned, in the loaded mode 84a and with the microsensor exposed and facing the body of the user. Then, the trigger 84 can be activated to transition the applicator system 180 to the released mode 84 with passage of current through the coil 88", thereby using electromagnetic interactions between the magnet 89" and the coil 88 to accelerate portions of the microsensor into the body of the user. However, variations of the use case described above can be configured in any other suitable manner

However, variations of the specific examples and/or use cases described above can be configured in any other suitable manner. For instance, some variations of the applicator system 180 can include speaker components (or other components) operable to generate audible signals (or other signals, such as light signals, haptic signals, etc.) indicative of correct or incorrect application of the microsensor at the user's body.

1.3.5 Applicator—Other Variations

In another variation, as shown in FIG. 18A, the applicator system 180' can be incorporated into a first housing portion 191 of a housing 190 of the system 100 and can comprise an elastic pin 181 (e.g., spring-loaded pin) configured to complement a recess of a second housing portion 196. In this variation, a normal force applied to a broad surface of the second housing portion 196 initially causes the elastic pin 181 to retract, and rebounding of the elastic pin 181 into the recess of the second housing portion 196 biases and accelerates the microsensor 116 into the skin of the user.

In another variation, as shown in FIG. 18B, the applicator system 180" implements elastic portions of the housing 190, which can be used to retract a housing portion with the microsensor 116 and to release the housing portion, thereby accelerating the microsensor 116 into skin of the user.

In another variation, the applicator system cooperates with a first housing portion 191 and a second housing portion 196, wherein the applicator system comprises a first applicator portion configured to surround the housing 190

and interface with the second housing portion 196, and a second applicator portion configured to accelerate the second housing portion toward skin of the user. In a first specific example of this variation, as shown in FIG. 19A, the applicator system 180a comprises a ram-and-catch mechanism, wherein twisting of a rotatable component 83 of the applicator system 180a transitions a plunger 84 of the applicator system 180a from a resting configuration 84a to a loaded configuration 84b, as shown in FIGS. 19B and 19C, and pushing of the rotatable component 83 of the applicator system 180a releases the plunger 84 back to the resting configuration 84a (as shown in FIG. 19D), thereby accelerating the microsensor 116 toward skin of the user during application of the microsensor patch 110 to the user. In more detail, in the first specific example, twisting of the rotatable component 83 transitions the plunger 84 along ramped surfaces 85 of the applicator system 180a to the loaded configuration 84a, where the plunger 84 rests on triggers 86 of the applicator system 180a. Then, as shown in FIG. 19D, pressing of the rotatable component 83 provides an outward biasing force on the triggers 86 (e.g., due to wedge-shaped morphology of the triggers that interacts with a complementary portion of the rotatable component 83), thereby releasing the plunger 84 to the resting configuration 84a. In this specific example, a set of ribs 87 coupled to a wall of the applicator system 180 surrounding the plunger 84 maintain plunger alignment.

In a second specific example of this variation, as shown in FIG. 20, the applicator system 180b comprises an elastic component 89 housed within and coupled to a translating component 88 of the applicator system 180b, wherein the translating component 88 comprises a plunger 84' and is configured to translate along a first axis. The applicator system 180b further comprises a trigger 188 coupled to a biasing spring 189 and configured to translate along a second axis perpendicular to the first axis, between a holding position 188a and a releasing position 188b. In the second specific example, the translating component 88 is biased in holding position 188a, and pushing of the translating component 88 places a lateral biasing force on the trigger 188 against the biasing spring 189 (e.g., due to wedge-shaped morphology of the trigger 188 that interacts with a complementary portion of the translating component 88), thereby releasing the plunger 84' to accelerate the microsensor 116 toward skin of the user. In pushing the translating component 88, compression of the elastic component 89 creates a reverse biasing force that automatically releases the translating component 88 toward the resting configuration 88a.

The applicator system 180 can alternatively be configured to receive the microsensor patch 110, to stretch the skin of the user isotropically in two dimensions to facilitate application, and to push the microsensor patch 110/transmitting unit 130 assembly onto the user's stretch skin. Still alternatively, the applicator system 180 can include any other suitable applicator, variations and examples of which are described in U.S. App. No. 62/025,174 entitled "System for Monitoring Body Chemistry" and filed on 16 Jul. 2014. Still other variations of the system 100 can entirely omit a applicator system 180.

1.4 System—Base Station

As shown in FIG. 1, the system can include a base station 5 that functions to receive the microsensor patch 110 (e.g., within a second housing portion 196). In receiving the microsensor patch 110, the base station 5 can include alignment elements 6 (e.g., protrusions, recesses, magnetic alignment elements, etc.) that facilitate alignment of the microsensor patch 110 within the base station, as shown in

FIG. 18A. The base station **5** can additionally or alternatively facilitate charging of a rechargeable battery of the microsensor patch **110** by including elements that generate an electromagnetic field that interacts with a charging coil coupled to the battery, thereby charging the battery **138**. In more detail, as described above, the base station **5** can include a cavity with a slot that accepts the second housing portion **196** (or any other portion of the system **100** containing the battery) for charging, where by contacts of the charging unit can detect a feedback loop between the analog front end (AFE) circuit of the second housing portion **196** and charging contacts, in order to initiate charging. The base station **5** can additionally or alternatively be used to transition the microsensor patch between different operational states, in relation to data transfer between the microsensor patch **110**, a mobile computing device **150** associated with the user, and modules of a processing subsystem **160** (e.g., cloud module) as shown in FIGS. 21A and 21B. In a first operation mode **5a**, the transmitting unit **130** of the microsensor patch **110** and the mobile computing device **150** can pair/bond only when the second housing portion **196** of the microsensor patch **110** is in communication with the base station **5** (e.g., aligned within the base station **5**). Thus, in the first operation mode **5a**, the microsensor patch **110** can transmit and receive data (e.g., compact raw data compounded into a plurality of bits over Bluetooth communication). In a second operation mode **5b** wherein the microsensor patch **110** is not in communication with the base station **5**, the microsensor patch **110** can be configured to only transmit data (but not receive data), thereby reducing energy usage, preventing man-in-the-middle attack, and preventing tampering. As such, the second operation mode **5b** prevents reading of data from the microsensor patch **110** by a fraudulent entity, without gaining physical access to the microsensor patch **110**.

The operation modes of the system **100** enabled by the microsensor patch, the base station **5**, the mobile computing device **150**, and the processing subsystem **160** are further detailed in FIGS. 21A and 21B and 22. In relation to pairing with the microsensor patch **110** in the first operation mode **5a**, the mobile computing device **150** functions to provide one or more of: data relay, data visualization, data storage, notification, and action functions (e.g., as described in relation to the software module **163** described above). In communicating information between the mobile computing device **150** and a cloud module of the processing subsystem **160**, the mobile computing device **150** can be configured to transmit raw data in Javascript Object Notation (JSON) format (or any other suitable format) to be processed in the cloud, and analyte data, notifications, and alerts (e.g., as derived from an analysis) can be transmitted back to the mobile computing device **150** in JSON format (or any other suitable format). The cloud module of the processing subsystem **160** can thus serve to enable authentication of the user (e.g., in association with a user account of a native application) and/or data, data storage, data processing, notification, and prediction functions, as described in relation to the processing subsystem **160** described above. Thus, the system **100** is configured for fault tolerance, wherein the microsensor patch **110** stores data when faulty operation of the mobile computing device **150** occurs, and failure of the processing subsystem **100** results in data storage at the mobile computing device. The system **100** can, however, be configured in any other suitable manner.

As shown in FIG. 21B, the base station **5** and the applicator system **180** can be configured to couple together, thus facilitating portability of the base station **5** and appli-

cator system **180**. However, the base station **5**, applicator system **180**, and microsensor **110** can alternatively be configured to couple or not couple together in any other suitable manner.

1.5 System—Calibration

The microsensor patch **110** is preferably calibrated to prevent signal degradation and to mitigate the effects of transient effects experienced during analyte sensing. The primary sensing mechanism is potentiometric for small analytes (e.g., potassium, sodium, calcium), and amperometric for large molecules (e.g., glucose, lactic, creatinine). In a first variation, the microsensor patch **110** passively detects analytes by detecting an impedance and/or capacitance change, as well as a voltage change when an analyte or analyte concentration contacts the microsensor **116**. Calibration can occur by normalizing sensing measurements relative to a grounded portion of the microsensor **116**, such as a reference electrode.

In a second variation, the microsensor patch **110** can implement active impedance calibration, wherein a drive voltage is implemented by the electronics subsystem **111** of the microsensor patch **110**, and voltage and impedance and/or capacitance changes are detected. The drive voltage is preferably applied in a sinusoidal pattern, but can alternatively be applied in any appropriate pattern. In the second variation, sensed analytes or analyte concentrations are characterized by changes in impedance, and noise is characteristically distinguished from analyte detection by monitoring changes in voltage unaccompanied by changes in impedance or capacitance. The second variation thus employs a conductometric measurement to calibrate the microsensor patch **110**. Impedance measurements can also be used to address shift in a reference electrode (e.g., in the first variation described above).

In a third variation, the microsensor patch **110** can employ injection of a volume of a calibration solution with a known concentration of at least one analyte, in order to calibrate the microsensor patch **110**. In an example of the third variation, the calibration solution can have a known concentration of at least one analyte, such that changes (e.g., changes in electrical parameters) detected by the microsensor patch **110** in response to the calibration solution can be used to normalize measurements resulting from sensed analytes or analyte concentrations occurring after injection of the volume of calibration solution. In the third variation, the calibration solution can be injected automatically and periodically over the lifetime usage of the transdermal patch; however, the calibration solution can alternatively be injected when prompted by a user or other entity.

In a fourth variation, the microsensor patch **110** can include a membrane comprising a known concentration and/or release profile of at least one analyte, in order to calibrate the microsensor patch **110**. In an example of the fourth variation, the membrane can have a known concentration and release profile of at least one analyte, such that changes (e.g., changes in electrical parameters) detected by the microsensor patch **110** in response to the membrane can be used to normalize measurements resulting from sensed analytes or analyte concentrations. In the fourth variation, the membrane can be a degradable membrane, such that degradation of the membrane over time releases analytes from the membrane. Alternatively, the membrane can be manufactured with specific porosity, contributing to a certain analyte release profile.

In a fifth variation, the microsensor patch **110** can include a coating or a cap comprising a soluble species (e.g., analyte/ion) with a well-known solubility, in order to cali-

brate the microsensor patch **110**. In an example of the fifth variation, the soluble species maintains a known concentration of the species within the vicinity of a filament that can be used to normalize and/or calibrate a signal. Examples of soluble species include low solubility, biocompatible calcium salts, such as calcium carbonate, calcium phosphate, and dicalcium phosphate for calcium sensing. Other suitable soluble species can be used to calibrate other analytes.

In alternative variations, the microsensor patch **110** can use any other suitable calibration method. For instance, the transdermal patch can be pre-staged, prepped, loaded, or activated to have a set calibration state enabling calibration of the system after application to the user within a desired period of time (e.g., an 85 mg/dl calibration state equilibrated after insertion within a period of 2 hours).

As a person skilled in the art will recognize from the previous detailed description and from the figures and claims, modifications and changes can be made to the described embodiments, variations, and examples of the system **100** without departing from the scope of the system **100**.

2. Method

As shown in FIG. **23**, a method **200** for monitoring body chemistry of a user comprises: receiving a second housing portion into an opening of a first housing portion **S210**, the first housing portion supporting a microsensor including a first working electrode, a second working electrode, a reference electrode, and a counter electrode, and the second housing portion supporting an electronics subsystem configured to receive a signal stream from the microsensor; after interfacing with the second housing portion, accelerating the second housing portion toward skin of the user **S220**, thereby delivering sensing regions of the microsensor into interstitial fluid of the user; generating an impedance signal, from two of the first working electrode, the second working electrode, the reference electrode, and the counter electrode, in response to applying a voltage, near a shifted potential different than a reference potential of the reference electrode **S230**, wherein the shifted potential is associated with a signal conditioning module of the electronics subsystem; at a processing system in communication with the electronics subsystem, receiving the signal stream and the impedance signal **S240**; at the processing system, generating an analysis indicative of an analyte parameter of the user and derived from the signal stream and the impedance signal **S250**; and transmitting information derived from the analysis to an electronic device associated with the user, thereby facilitating monitoring of body chemistry of the user **S260**.

The method **200** functions to provide continuous monitoring of a user's body chemistry through reception and processing of signals associated with one or more analytes present in the body of the user, and to provide an analysis of the user's body chemistry to the user and/or an entity (e.g., health care professional, caretaker, relative, friend, acquaintance, etc.) associated with the user. Alternatively, the method **200** can function to detect a user's body chemistry upon the user's request or sporadically, and/or can provide an analysis of the user's body chemistry only to the user. The method is preferably implemented, at least in part, using an embodiment, variation, or example of elements of the system **100** described in Section 1 above; however, the method **200** can additionally or alternatively be implemented using any other suitable system.

Variations of the system **100** and method **200** include any combination or permutation of the described components and processes. Furthermore, various processes of the preferred method can be embodied and/or implemented at least

in part as a machine configured to receive a computer-readable medium storing computer-readable instructions and/or in the cloud. The instructions are preferably executed by computer-executable components preferably integrated with a system and one or more portions of a control module and/or a processor. The computer-readable medium can be stored on any suitable computer readable media such as RAMs, ROMs, flash memory, EEPROMs, optical devices (CD or DVD), hard drives, floppy drives, or any suitable device. The computer-executable component is preferably a general or application specific processor, but any suitable dedicated hardware device or hardware/firmware combination device can additionally or alternatively execute the instructions.

The FIGURES illustrate the architecture, functionality and operation of possible implementations of systems, methods and computer program products according to preferred embodiments, example configurations, and variations thereof. In this regard, each block in the flowchart or block diagrams may represent a module, segment, step, or portion of code, which comprises one or more executable instructions for implementing the specified logical function(s). It should also be noted that, in some alternative implementations, the functions noted in the block can occur out of the order noted in the FIGURES. For example, two blocks shown in succession may, in fact, be executed substantially concurrently, or the blocks may sometimes be executed in the reverse order, depending upon the functionality involved. It will also be noted that each block of the block diagrams and/or flowchart illustration, and combinations of blocks in the block diagrams and/or flowchart illustration, can be implemented by special purpose hardware-based systems that perform the specified functions or acts, or combinations of special purpose hardware and computer instructions.

As a person skilled in the art will recognize from the previous detailed description and from the figures and claims, modifications and changes can be made to the preferred embodiments of the invention without departing from the scope of this invention defined in the following claims.

We claim:

1. A system for sensing body chemistry of a user, the system comprising:

a first housing portion supporting a sensor operable to access interstitial fluid of the user upon coupling of the first housing to the user, the sensor exposed through a base surface of the first housing portion, and the first housing including an opening into an electrical interface with the sensor, the first housing further comprising a perforation proximal the opening;

an adhesive region coupled to the base surface and surrounding the sensor;

a covering for the adhesive region; and

a second housing portion supporting an electronics subsystem comprising a signal conditioning portion and a data transmission portion comprising an antenna, wherein the system is operable between:

a loaded mode wherein the second housing portion is seated within the opening of the first housing portion with the electronics subsystem coupled to the electrical interface and the covering is coupled to the adhesive region, wherein the second housing portion is coupled to an applicator,

a released mode wherein the sensor and the adhesive region are delivered from the applicator with the electronics subsystem of the second housing portion

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transmitting signals from the sensor through the antenna and the covering is uncoupled from the adhesive region, and

an uncoupled mode wherein the second housing portion is released from the first housing portion and wherein the perforation is broken to prevent subsequent coupling between the first housing portion and the second housing portion.

2. The system of claim 1, wherein the sensor comprises a first working electrode, a second working electrode, a reference electrode, and a counter electrode.

3. The system of claim 1, wherein the first housing portion comprises an o-ring co-molded with regions of the first housing portion proximal the opening.

4. The system of claim 1, wherein the covering is operable to be removed in a central-to-peripheral direction from the adhesive region.

5. The system of claim 4, wherein the covering comprises a set of leaves comprising a first leaf spanning a first portion of the adhesive region and including a first valley fold configured as a first pull-tab, and a second leaf spanning a second portion of the adhesive region and including a second valley fold overlapping the first valley fold configured as a second pull-tab.

6. The system of claim 1, further including a set of spacers about edge regions of the sensor, the set of spacers operating as a barrier that is configured to protect at least one of the sensor and skin of the user from damage.

7. The system of claim 1, wherein the antenna is decoupled from a ground plane of a printed circuit board of the electronics subsystem.

8. The system of claim 7, wherein the antenna is positioned near an edge region of the second housing portion.

9. The system of claim 1, further including a thermistor coupled to a counter electrode of the sensor, and wherein the electronics subsystem includes a circuit operable to detect temperature of skin of the user proximal the sensor, by way of the thermistor.

10. The system of claim 1, wherein the sensor comprises a microsensor.

11. A system for sensing body chemistry of a user, the system comprising:

a first housing portion supporting a sensor operable to access interstitial fluid of the user upon coupling of the first housing to the user, the sensor exposed through a base surface of the first housing portion, and the first housing including an opening into an electrical interface with the sensor, the first housing further comprising a perforation proximal the opening;

an adhesive region coupled to the base surface and surrounding the sensor; and

a second housing portion supporting an electronics subsystem comprising a data transmission portion comprising an antenna, wherein the system is operable between:

a loaded mode wherein the second housing portion is seated within the opening of the first housing portion with the electronics subsystem coupled to the electrical interface, wherein the second housing portion is coupled to an applicator, and

a released mode wherein the sensor and the adhesive region are delivered from the applicator with the

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electronics subsystem of the second housing portion transmitting signals from the sensor through the antenna; and

an uncoupled mode wherein the second housing portion is released from the first housing portion, wherein, in the uncoupled mode, the perforation is broken to prevent subsequent coupling between the first housing portion and the second housing portion.

12. The system of claim 11, wherein the first housing portion comprises an o-ring co-molded with regions of the first housing portion proximal the opening.

13. The system of claim 11, further comprising a covering for the adhesive region, the covering operable to be removed in a central-to-peripheral direction from the adhesive region in the loaded mode.

14. The system of claim 13, wherein the covering comprises a set of leaves comprising a first leaf spanning a first portion of the adhesive region and including a first valley fold configured as a first pull-tab, and a second leaf spanning a second portion of the adhesive region and including a second valley fold overlapping the first valley fold configured as a second pull-tab, each of the first leaf and the second leaf including cutaways that expose the sensor.

15. The system of claim 11, wherein the sensor comprises a first working electrode, a second working electrode, a reference electrode, and a counter electrode.

16. The system of claim 15, further including a thermistor coupled to the counter electrode of the sensor, and wherein the electronics subsystem includes a circuit operable to detect temperature of skin of the user proximal the sensor, by way of the thermistor.

17. The system of claim 11, wherein the antenna is decoupled from a ground plane of a printed circuit board of the electronics subsystem, wherein the antenna is positioned near an edge region of the second housing portion.

18. The system of claim 11, further including a set of spacers about edge regions of the sensor, the set of spacers operating as a barrier that is configured to protect at least one of the sensor and skin of the user from damage.

19. The system of claim 11, wherein the sensor includes an array of filaments, each filament including:

a substrate core including a base end coupled to a substrate, a columnar protrusion having a proximal portion coupled to the base end and a distal portion, and a tip region coupled to the distal portion of the columnar protrusion and configured to provide access to interstitial fluid of the user;

a conductive layer, isolated to the tip region of the substrate core and away from the base end as an active region that enables transmission of electronic signals generated upon detection of an analyte within the interstitial fluid;

an insulating layer surrounding the substrate core and exposing a portion of the conductive layer, thereby defining a boundary of the active region; and

a sensing layer, in communication with the active region, configured for at least one of amperometric sensing and potentiometric sensing of the analyte.

20. The system of claim 11, wherein the sensor comprises a microsensor.

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摘要(译)

一种用于监视用户的身体化学的系统和方法，该系统包括：壳体，其支撑：微传感器，该微传感器包括第一和第二工作电极，参比电极和反电极，并且被配置为访问用户的组织液，以及电子子系统包括信号调节模块，该信号调节模块从微传感器接收信号流，其中电子子系统配置为检测从第一工作电极，第二工作电极，参考电极和计数器中的两个得出的阻抗信号 电极；以及处理子系统，包括：第一模块，被配置为生成指示用户的分析物参数的分析，该分析从信号流和阻抗信号导出，以及第二模块，被配置为将从分析的信息传输到用户，从而便于监控用户的身体化学。

