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STERILIZED REUSABLE WEARABLE DEVICES AND WEARABLE DEVICE FORMING METHODS IN CONTINUOUS ANALYTE MONITORING

Abstract

In one or more embodiments, a continuous analyte monitoring wearable device includes a disposable base unit having a power source and an analyte sensor, and a reusable transmitter unit that includes electronic circuitry configured to bias the analyte sensor, measure current through the analyte sensor, and may even compute analyte values based on measured current through the analyte sensor. The disposable base unit is configured to couple to the reusable transmitter unit and supply electrical power to the electronic circuitry of the reusable transmitter unit for continuous analyte monitoring. Numerous other embodiments are provided.

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Background/Summary

CROSS-REFERENCE TO RELATED APPLICATIONS [0001] This patent application is a continuation application claiming priority benefit, with regard to all common subject matter, of U.S. patent application Ser. No. 17/156,500, filed Jan. 22, 2021, and entitled “STERILIZED REUSABLE WEARABLE DEVICES AND WEARABLE DEVICE FORMING METHODS IN CONTINUOUS ANALYTE MONITORING” (“the '500 Application”). The '500 Application claims priority to, and the benefit of, U.S. Provisional Patent Application No. 62/965,682, filed Jan. 24, 2020, and entitled “METHODS AND APPARATUS FOR REUSING TRANSMITTER ELECTRONICS OF A CONTINUOUS ANALYTE MONITORING DEVICE,” and U.S. Provisional Patent Application No. 63/111,347, filed Nov. 9, 2020, and entitled “STERILIZED REUSABLE WEARABLE DEVICES AND WEARABLE DEVICE FORMING METHODS IN CONTINUOUS ANALYTE MONITORING.” The above-referenced applications are hereby incorporated by reference in their entirety into the present application.

FIELD
[0002] The present disclosure relates to continuous analyte monitoring methods, apparatus, and systems.
BACKGROUND
[0003] In-vivo continuous analyte monitoring (CAM), such as continuous glucose monitoring (CGM), has become a routine sensing operation, particularly in diabetes care. By providing real-time monitoring of glucose concentrations, therapeutic/clinical actions may be applied in a more timely way and the glycemic condition may be better controlled.
[0004] During CGM operation, a biosensor of a CGM wearable device, which is typically inserted subcutaneously, is continuously operated in an environment surrounded by tissue and interstitial fluid. The biosensor inserted under the skin provides a signal to a wireless CGM transmitter of the CGM wearable device, and that signal is indicative of the user's blood glucose level. These measurements may be made automatically many times throughout the day (e.g., every few minutes or at some other suitable interval).
[0005] The CGM wearable device may adhere to the outer surface of a user's skin, such as on the abdomen, or the back of the upper arm, while the biosensor is inserted through the skin so as to contact interstitial fluid. The biosensor interacts with the interstitial fluid, generating electrical signals that are proportional to the amount of glucose present in the interstitial fluid. These electrical signals are communicated to the CGM transmitter and may be further communicated to an external device such as a CG M reader device or a smart phone containing a software application, and may be used to make glucose value determinations and display/communicate glucose readings in various desired formats.
[0006] Fabricating CGM wearable devices that are both comfortable for patients and cost effective still remains a challenge. As such, improved CGM wearable devices, CGM systems, and CGM methods are desired.
SUMMARY

[0007] In some embodiments, a continuous analyte monitoring wearable device is provided. The continuous analyte monitoring wearable device includes a base unit, comprising: a base, at least one power source, and an analyte sensor assembly; and an encapsulation extending over the base and the at least one power source to form an encapsulated base, the encapsulated base including an attachment region configured to allow a reusable transmitter unit to be coupled to, and decoupled from, the encapsulated base, wherein the encapsulated base, at least one power source, and the analyte sensor form a disposable unit, and the disposable unit is sterilized.
[0008] In further embodiments, a method of forming a continuous analyte monitoring wearable device is provided. The method includes providing a base having a power source support location, a sensor assembly support location, and a transmitter unit support location; placing at least one power source at the power source support location; placing a sensor assembly including an analyte sensor at the sensor assembly support location; providing an encapsulation layer over the at least one power source, at least a portion of the sensor assembly, and at least a portion of the base, to form a sealed, disposable unit, wherein the sealed, disposable unit is configured to allow a transmitter unit to be attached to, and detached from, the transmitter unit support location; and sterilizing the sealed, disposable unit.
[0009] In some additional embodiments, a method of forming a wearable device configured to be used in continuous analyte monitoring is provided. The method includes providing a base having a transmitter unit support location, a power source support location, and a sensor assembly support location, placing at least one power source at the power source support location, placing a sensor assembly including an analyte sensor at the sensor assembly support location, providing an encapsulation portion having an opening, placing the base within the opening of the encapsulation portion such that the base and encapsulation portion form a sealed, disposable base unit, wherein the sealed, disposable base unit is configured to allow a transmitter unit to be attached to and detached from the transmitter unit support location, and sterilizing the sealed, disposable unit.
[0010] Other features, aspects, and advantages of embodiments in accordance with the present disclosure will become more fully apparent from the following detailed description, the claims, and the accompanying drawings by illustrating a number of example embodiments and implementations. Various embodiments in accordance with the present disclosure may also be capable of other and different applications, and its several details may be modified in various respects, all without departing from the scope of the disclosure.

Description

BRIEF DESCRIPTION OF THE DRAWINGS
[0011] The drawings, described below, are for illustrative purposes and are not necessarily drawn to scale. Accordingly, the drawings and detailed description are to be regarded as illustrative in nature, and not as restrictive. The drawings are not intended to limit the scope of the disclosure in any way.
[0012] FIGS. **1**A and **1**B illustrate a top perspective and a side view, respectively, of a continuous analyte monitoring wearable device configured for use in a CAM system in accordance with embodiments provided herein.
[0013] FIG. **1**C illustrates an exploded perspective view of a first example embodiment of a wearable device with a disposable base unit and a reusable transmitter unit, with the encapsulation shown as a separate element in perspective, as provided herein.
[0014] FIG. **1**D illustrates an enlarged perspective view of a base and transmitter unit of FIG. **1**C coupleable and detachable therefrom, as provided herein.
[0015] FIG. **1**E illustrates an enlarged perspective view of a base and transmitter unit of FIG. **1**C with the transmitter unit positioned within a transmitter unit support location and power sources positioned on power source support locations, respectively, of the base, as provided herein.

[0016] FIG. **1**F illustrates a different side perspective view of a sensor coupled to a connector as the sensor extends through a sensor opening at a sensor assembly support location, as provided herein.
[0017] FIG. **1**G illustrates an exploded view of an alternative embodiment of wearable device including a disposable base and reusable transmitter unit, as provided herein.
[0018] FIGS. **1**H and **1**I illustrate side plan views of an alternative embodiment of a wearable device in which a transmitter unit may attach to a disposable base unit at an attachment region of an encasement layer in accordance with embodiments, as provided herein, wherein FIG. **1**H illustrates the transmitter unit being detached and FIG. **1**I shows the transmitter unit being attached.
[0019] FIG. **2** illustrates an exploded view of an example transmitter unit and base according to embodiments, as provided herein.
[0020] FIG. **3**A illustrates a cross-sectioned side view of a wearable device prior to inserting a transmitter unit into a base unit in accordance with some embodiments.
[0021] FIG. **3**B illustrates a cross-sectioned side view of a wearable device after insertion of a transmitter unit into a base unit in accordance with some embodiments.
[0022] FIGS. **4**A and **4**B illustrate a top perspective view and an exploded side perspective view, respectively, of another example wearable device, as provided herein.
[0023] FIG. **4**C illustrates a bottom perspective view of another wearable device, as provided herein.
[0024] FIG. **4**D illustrates a bottom perspective view of an alternative embodiment of a wearable device in which a single microneedle is employed in accordance with embodiments, as provided herein.
[0025] FIG. **4**E illustrates an enlarged and cross-sectioned view of a portion of the wearable device of FIG. **4**A illustrating a transmitter unit inserted within a base unit in accordance with embodiments, as provided herein.
[0026] FIG. **5** illustrates a flowchart of an example method for continuous analyte monitoring in accordance with embodiments provided herein.
[0027] FIG. **6** illustrates a flowchart of another example method for continuous analyte monitoring in accordance with embodiments provided herein.
[0028] FIG. **7** illustrates a flowchart of an example method of forming a wearable device for use during continuous analyte monitoring in accordance with embodiments provided herein.
[0029] FIG. **8** is a flowchart of another example method of forming a wearable device for use during continuous analyte monitoring in accordance with embodiments provided herein.
[0030] FIG. **9** is a flowchart of another example method of forming a wearable device for use during continuous analyte monitoring in accordance with embodiments provided herein.
[0031] FIG. **10**A illustrates a high-level block diagram of an example CGM system in accordance with embodiments provided herein.
[0032] FIG. **10**B illustrates an example CGM system that is similar to the embodiment illustrated in FIG. **10**A, but having a different partitioning of components in accordance with embodiments provided herein.
[0033] FIG. **1**I is an exploded bottom view of a wearable device wherein the base unit has an opening that allows a transmitter unit to be inserted in or removed from base unit in accordance with some embodiments provided herein.
[0034] FIG. **12**A illustrates a top perspective view of another wearable device for use during continuous analyte monitoring in accordance with embodiments provided herein.
[0035] FIG. **12**B is a top view of a base unit of FIG. **12**A without an insertion device, a transmitter unit or power sources in accordance with embodiments provided herein.
[0036] FIG. **12**C is a cross-sectioned side view of a portion of the wearable device of FIG. **12**A in accordance with embodiments provided herein.
[0037] FIGS. **13**A and **13**B are top views of another example of disposable base unit in accordance with embodiments provided herein.

[0038] FIG. **14** illustrates a flowchart of a method of forming a wearable device for use during continuous analyte monitoring in accordance with embodiments provided herein.
[0039] FIG. **15** illustrates a flowchart of another method of forming a wearable device for use during continuous analyte monitoring in accordance with embodiments provided herein.
[0040] FIGS. **16** and **17** illustrate packaging of a continuous analyte monitoring wearable device in accordance with embodiments provided herein.
[0041] FIG. **18** illustrates a method of forming a continuous analyte monitoring wearable device in accordance with embodiments provided herein.

DETAILED DESCRIPTION

[0042] In order to more closely monitor a person's glucose level and detect any shift in glucose level, methods, apparatus, and systems for continuous glucose monitoring (CGM) have been developed. While CGM systems generate glucose signals “continuously” during operation, such as continuous electrochemically-generated signals, measurements of the generated glucose signals are typically performed every few minutes, rather than being truly continuous.
[0043] CGM systems generally have a wearable portion (a “wearable device”) that communicates wirelessly with an external device, such a hand-held monitor or reader, smart phone, or other computing device. The wearable device may be worn for days before being removed and replaced (e.g., after 7 days or more). The wearable device includes a sensor that is inserted so as to be located under the skin. The wearable device also includes circuitry (e.g., analog circuitry) configured to bias the sensor and measuring current signals generated by the sensor when in contact with interstitial fluid. The wearable device further includes processing circuitry configured to process the current signals, such as for determining glucose values based on the measured current signals, as well as for communicating glucose values to an external device of the CGM system, wherein the CGM system is made up of the wearable device and the external device. The wearable device can be adhered to the outer surface of the skin, for example the abdomen, the back of the upper arm, or other suitable body location. Unlike a blood glucose monitoring (BG M) system that measures glucose concentration in blood, CGM systems measure glucose concentration in interstitial fluid (including non-direct capillary blood).
[0044] CGM systems may provide frequent measurements of a person's glucose levels without the need for each such measurement to be accompanied by the drawing of a blood sample, such as by finger sticks. CGM systems may still employ occasional finger sticks and the use of a BG M system, such as the Contour NEXT One® by Ascensia Diabetes Care AG of Basel Switzerland, for calibrating the CGM system.
[0045] The wearable device of a continuous analyte monitoring system is generally worn for seven days or more, ten days or more, or even 14 days or more, and then is removed and replaced with a new wearable device. Having to replace the wearable device of a continuous analyte monitoring system every seven days or more significantly increases the costs associated with performing continuous analyte monitoring.
[0046] Thus, in view of the problems of the prior art, embodiments described herein provide a wearable device for use with an external device during continuous analyte monitoring that includes a disposable portion and a reusable portion. The disposable portion includes the power source for the wearable device, as well as the analyte sensor, while the reusable portion includes electronic circuitry used, for example, to provide a bias to the analyte sensor, measure current signals through the analyte sensor, and/or transmit signals and/or information to the external device. The electronic circuitry of the reusable portion of the wearable device can further compute analyte concentration values, such as glucose concentration values, based upon the measured current signals. These analyte concentration values may be transmitted to the external device in some embodiments.
[0047] The reusable portion may also be referred to herein as a reusable transmitter unit. Example circuitry within the transmitter unit may include an analog front end configured to bias the analyte sensor and sense current that passes through the analyte sensor. The front end may include one or

more operational amplifiers, current sensing circuitry, etc. Other circuitry within the transmitter unit may include processing circuitry such as analog-to-digital converters for digitizing current signals, memory for storing digitized current signals, a controller such as microprocessor, microcontroller, or the like for computing analyte concentration values based on measured current signals, and transmitter circuitry for transmitting signals and/or analyte concentration values to the external device.

[0048] Electronic circuitry is generally the most expensive portion of the wearable device and can last significantly longer than the period in which the wearable device is employed. For example, wearable devices are typically discarded after about seven days or more, while the circuitry within the transmitter unit may last indefinitely in some cases.

[0049] The two components most likely to need replacing in a wearable device used for continuous analyte monitoring are the power source (e.g., one or more batteries that power the electrical components of the wearable device) and the analyte sensor. By placing the power source (e.g., battery) and sensor in the disposable portion (also called a "disposable base unit") of the wearable device, the two components most likely to need replacing may be replaced after each use, while the reusable transmitter unit containing the electronics of the wearable device may be reused 10, 20, 50, 100, or even more than 100 times.

[0050] For example, in some embodiments, a wearable device for use during continuous analyte monitoring may include a disposable base unit having a sensor assembly and a power source, and a reusable transmitter unit configured to interface with the disposable base unit and receive power from the power source of the disposable base unit. The disposable base unit is configured to be disposed of after a single analyte monitoring period (e.g., after 7-14 days after the start of use, for example), and the reusable transmitter unit is configured to be detached from the disposable base unit after the single analyte monitoring period and re-used with another disposable base unit. The analyte monitoring period as used herein is the elapsed period of time that a sensor of a disposable unit is operable to monitor an analyte. These wearable devices and other embodiments, continuous analyte monitoring systems, as well as methods for making and/or using such wearable devices, are described below with reference to FIGS. **1**A-**15**.

[0051] FIGS. **1**A and **1**B illustrate a top perspective view and a side plan view, respectively, of a wearable device **100** configured to be used during continuous analyte monitoring in accordance with embodiments provided herein. With reference to FIG. **1**A, wearable device **100** includes a disposable base unit **102** and a reusable transmitter unit **104** that interfaces with disposable base unit **102**. The reusable transmitter unit **104** may be configured to receive electrical power from a power source disposed within disposable base unit **102** and electrical signals from an analyte sensor associated with disposable base unit **102**, as described further below. In some embodiments, disposable base unit **102** is configured to be disposed of after a single analyte monitoring period (e.g., 7 days, 10 days, 14 days, or some other suitably-long time period), while reusable transmitter unit **104** is configured to be removed from disposable base unit **102** after the single analyte monitoring period and re-used with a new disposable base unit. For example, transmitter unit **104** may be re-used 2, 5, 10, 50, 100, or even more than 100 times. Example embodiments of disposable base unit **102** and transmitter unit **104** are described below herein.

[0052] FIG. **1**C illustrates an exploded perspective view of a first example embodiment of disposable base unit **102** and reusable transmitter unit **104** also shown in perspective, as provided herein. With reference to FIG. **1**C, disposable base unit **102** includes a base **106** having one or more power source support locations **108***a*-**108***b*, a transmitter unit support location **110**, and a sensor assembly support location **112**. FIG. **1**D illustrates an enlarged perspective view of the base **106** and the transmitter unit **104** of FIG. **1**C.

[0053] In some embodiments, base **106** may be formed from a moldable plastic, for example, such as, but not limited to, acrylonitrile butadiene styrene (ABS), polycarbonate, nylon, acetal, polyphthalamide (PPA), polysulfone, polyethersulfone, polyetheretherketone (PEEK),

polypropylene, high-density polyethylene (HDPE), and low-density polyethelene (LDPE). Other materials may be used.

[0054] Power support locations **108***a*-**108***b* provide a location for supporting one or more power sources used to supply electrical power to transmitter unit **104**. For example, one or more power sources **114***a*-**114***b* may be positioned at power source support locations **108***a*, **108***b*. Power source support locations **108***a*, **108***b* may be any suitable shape in top plan view (e.g., rectangular, square, round, etc.) and can include any suitable configuration of electrical contacts that are configured to make electrical contact with the respective poles of the one or more power sources **114***a*-**114***b*, such as multi-prong connectors shown. Such multi-prong connectors can be formed of any conductive material, such as metal or metalized tape, for example. Further, support locations **108***a*, **108***b* may include any suitable configuration of conductive electrical contact traces enabling power connections to the connector **122** from the electrical contacts and thus to the transmitter unit **104**.

[0055] FIG. **1**E further illustrates an enlarged perspective view of base **106** and transmitter unit **104** of FIG. **1**C with transmitter unit **104** positioned within transmitter unit support location **110** and power sources **114***a* and **114***b* positioned on power source support locations **108***a* and **108***b* (FIG. **1**D), respectively, of base **106**. In some embodiments power source **114***a* or **114***b* may be a battery, a storage capacitor, a solar cell, a generator, or the like. While two battery power sources **114***a*, **114***b* are shown in FIGS. **1**C and **1**E, it will be understood that fewer, more and/or different power sources may be used. Further, any suitable construction of electrical contact for securing and connecting to the power sources **114***a* and **114***b* may be used.

[0056] Transmitter unit support location **110** is configured to retain transmitter unit **104** coupled or otherwise attached to disposable base unit **102** during continuous analyte monitoring. In some embodiments, transmitter unit support location **110** may include one or more retention features **116***a*-**116***d* that interface with and/or press against transmitter unit **104** to retain the coupling of the transmitter unit **104** to base **106**, as shown, for example, in FIG. **1**E. Fewer, more, and/or different retention features may be used to secure transmitter unit **104** to base **106**. Retention features **116***a*-**116***d* may include, for example, projections that engage openings in transmitter unit **104**, openings that engage projections in transmitter unit **104**, magnets, Velcro, surfaces with adhesives, or any other suitable coupling feature. Optionally, projections can be formed on the transmitter unit **104** and can be received in openings formed in the transmitter unit support location **110** of the base.

[0057] In some embodiments, transmitter unit support location **110** may include a break location **118** (FIGS. **1**C, **1**D, and **1**E), such as a channel, groove, scribe line, or the like, that allows base **106** to bend and/or break such that retention features **116***a*-**116***d* disconnect and/or release transmitter unit **104** when transmitter unit **104** is to be removed from disposable base unit **102**/base **106** for re-use with another disposable base unit. Other release and/or break locations or release mechanisms may be used.

[0058] A substrate **120**, such as a circuit board, a flexible circuit board, etc., may be at least partially located within transmitter unit support location **110** and can include a connector **122** that provides an electrical interface to connect to transmitter unit **104**. For example, connector **122** may be electrically connected via conductive paths (not shown) with power sources **114***a*, **114***b* and allow power sources **114***a*, **114***b* to provide electrical power to transmitter unit **104** when transmitter unit **104** is positioned within transmitter unit support location **110**. Such conductive paths may be formed in part on the formed on substrate **120** and/or on the base **106**.

[0059] Sensor assembly support location **112** provides a mounting and support location for an analyte sensor assembly that may include an insertion device **124** and an insertion device cap **126**, for example. Insertion device **124** may include an insertion portion **128** coupled to a handle portion **130**, for example. Insertion portion **128** of insertion device **124** has a sharpened end **131** (FIG. **1**C) that pierces the skin to introduce an analyte sensor **132** into a subcutaneous region of a user as described further below. Insertion portion **128** also may be referred to as an insertion shaft, needle, trocar, sharp or the like.

[0060] Insertion portion **128** of insertion device **124** may be made, for example, from a metal such as stainless steel, or a non-metal such as plastic. Other materials may be used. In some embodiments, insertion portion **128** may be, but is not limited to, a round C-channel tube, a round U-channel tube, a stamped sheet metal part folded into a square U-profile, a molded/cast, laser cut or machined metal part with a U-channel profile, or a solid metal cylinder with an etched or ground square U-channel therein. Other insertion portion shapes may be used.
[0061] In some embodiments, handle portion **130** of insertion device **124** may be formed from a molded polymer (e.g., plastic), for example, such as, but not limited to, acrylonitrile butadiene styrene (ABS), polycarbonate, nylon, acetal, polyphthalamide (PPA), polysulfone, polyethersulfone, polyether ether ketone (PEEK), polypropylene, high density poly ethylene (HDPE), low density poly ethylene (LDPE), and the like. Other suitable materials may be used.
[0062] Handle portion **130** may reside on a top surface of sensor assembly support location **112** of base **106**, while insertion portion **128** may extend through a sensor opening **134** (FIG. **1**D) in sensor assembly support location **112** of base **106**, for example. Analyte sensor **132** is electrically connected to connector **122** of transmitter unit support location **110**, which electrically connects analyte sensor **132** to any transmitter unit **104** positioned with transmitter unit support location **110**. Electrical conductive paths coupled to connector **122** can further connect to power sources **104***a*, **104***b*.
[0063] FIG. **1**F illustrates an alternative side perspective view of sensor **132** coupled to connector **122** as sensor **132** extends through sensor opening **134** in sensor assembly support location **112**. As shown, a slot **135** may be provided in sensor assembly support location **112** to facilitate the connection of sensor **132** to connector **122**. Connector **122** may be any suitable connector such as an elastomeric connector with metal contacts or another connector type that electrically couples to the analyte sensor **132** and also to the electrical conductors **123***a*, **123***b* providing power from power sources **104***a*, **104***b*.
[0064] Referring again to FIGS. **1**A-**1**C, in some embodiments, the base **106** is sealed. For example, an encapsulation layer **136** (shown separately in FIG. **1**C) may be formed over base **106** and power sources **114***a*, **114***b* as shown in FIGS. **1**A-**1**B. In some embodiments, the encapsulation layer **136** may include an opening **138** formed therein that allows transmitter unit **104** to be installed in and/or removed from transmitter unit support location **110** of base **106** through the opening **138**. In other embodiments, transmitter unit **104** may sit on top of (or otherwise attach to) encapsulation **136** as described further below in FIGS. **1**H-**1**I. In some embodiments, encapsulation layer **136** creates a waterproof seal around base **106** and its internal components, sealing against sensor assembly support location **112** (while leaving an opening **140** (FIG. **1**C) for insertion device **124** to extend through base **106** into insertion device cap **126**). Connector **122** may remain exposed within transmitter unit support location **110** so transmitter unit **104** may make electrical connection to power sources **114***a*, **114***b* and sensor **132**, providing electrical power and current signals from sensor **132** to transmitter unit **104**, respectively.
[0065] The encapsulation layer **136** may be formed from a single layer or multiple layers. For example, the encapsulation layer **136** may be formed from one or more layers of liquid silicone rubber (LSR), a thermoplastic elastomer (TPE), or the like. Other suitable casting or molding materials may be used. In some embodiments, encapsulation layer **136** may be formed at a temperature of less than 100° C., and in some embodiments at a temperature of less than 80° C. In the embodiment of FIGS. **1**A-C, encapsulation layer **136** may be formed from two layers. For example, a bottom, pre-mold encapsulation layer **142** is provided on which base **106** is positioned. Substrate **120** may be positioned within transmitter unit support location **110** with connector **122**, and sensor assembly components such as insertion device **124** and sensor **132** may be positioned within sensor assembly location **112** (with sensor **132** connected to connector **122**). Power source **114***a* and/or **114***b* may be positioned on power source support location **108***a*, and/or **108***b*. Thereafter, a top encapsulation layer **144** may be formed over base **106** and power sources **114***a*,

114*b*, while leaving opening **138** (or another attachment region) that allows transmitter unit **104** to be attached to, detached from, inserted in and/or removed from base **106**. Additional methods for assembling the disposable base unit **102** are described further below with reference to FIGS. **7-9**.

[0066] FIG. **1**G illustrates an alternative embodiment of base **106** and transmitter unit **104** provided herein. In the embodiment of FIG. **1**G, transmitter unit **104** includes two retention features (only retention feature **150** is shown) that interface with corresponding retention features on base **106** (only retention feature **152** is shown). Other retention feature numbers, types and/or locations may be used.

[0067] The retention features described herein secure reusable transmitter unit **104** within disposable base unit **102** during continuous analyte monitoring, while allowing the transmitter unit **104** to be removed and reused after a continuous analyte monitoring period. For example, reusable transmitter unit **104** may be configured to interface with disposable base unit **102** so as to receive power from power source **114***a* and/or **114***b* of disposable base unit **102**. Disposable base unit **102** may be configured to be disposed of after a single analyte monitoring period, while reusable transmitter unit **104** may be configured to be removed from disposable base unit **102** after the single analyte monitoring period and re-used in another disposable base unit. In some embodiments, the single analyte monitoring period may be at least 7 to 10 days (e.g., up to 14 days or longer). Transmitter unit **104** may be removed from a disposable base unit **102** and reused (e.g., 5, 10, 20, 50, 100 or more times), each time with a new disposable base unit that includes a new sensor and a new power source.

[0068] FIGS. **1**H and **1**I illustrate side views of an alternative embodiment of wearable device **100** in which transmitter unit **104** may attach to disposable base unit **102** at an attachment region **154** of encasement layer **136** in accordance with embodiments provided herein. In such an embodiment, transmitter unit **104** may reside on a top of encasement layer **136**, for example. In other embodiments, transmitter unit **136** may attach to an attachment region (not shown) on a bottom of encasement layer **136**.

[0069] FIG. **2** is an exploded view of an example transmitter unit **104** according to embodiments provided herein. With reference to FIG. **2**, transmitter unit **104** can include a substrate **202** that couples to top cover **204** prior to forming a bottom cover **206** (e.g., which can be an overmold portion) to cover and seal the substrate **202** and any electrical or electronic components coupled to or formed thereon. Substrate **202** may be a circuit board, a flexible circuit board, or another mounting location for electronic circuitry used within the transmitter unit **104**.

[0070] In some embodiments, the transmitter unit **104** may include an analog front end **208** configured to apply a voltage to analyte sensor **132** and to sense current flow through analyte sensor **132**. Transmitter unit **104** also may include processing circuitry **210** for processing current signals sensed by analog front end **208** and transmitting signals and/or information to an external device. For example, in some embodiments, processing circuitry **210** may convert analog current signals to digital current signals, store current signals, calculate analyte concentration values based on current signals, transmit current signal and/or analyte concentration information to an external device (e.g., an external CG M device), or the like. In some embodiments, processing circuitry **210** may include a processor such as a microcontroller, a microprocessor, etc., memory, analog to digital converters, transmitter circuitry, and the like. Analog front end **208** and processing circuitry **210** may perform other, fewer, and/or more functions.

[0071] In an example CGM embodiment, processor circuitry **210** may include a processor, a memory coupled to the processor, and transmitter circuitry coupled to the processor. The memory may include computer program code stored therein that, when executed by the processor, causes the transmitter unit **104** and wearable device **100** to (a) measure glucose signals using a glucose sensor; (b) compute glucose values from the measured glucose signals; and (c) communicate the glucose values to an external device communicatively coupled, such as by Bluetooth or other wireless communication protocol, to the wearable device **100**. For example, current sensing

circuitry in transmitter unit **104** coupled to the sensor **132** through connector **122** (and interface **212** described below) may measure glucose (current) signals produced by sensor **132**. Sampling circuitry may be coupled to the current sensing circuitry and configured to generate digitized glucose signals from the measured glucose signals. These digitized glucose signals may then be used to determine glucose values that are transmitted to an external CGM device for communication (e.g., display) to a user. Optionally, raw signals may be sent and external CG M device may generate digitized glucose signals from the transmitted signals.

[0072] Substrate **202** may also include an interface **212** configured to interface with connector **122** of base unit **102** when transmitter unit **104** is positioned at the transmitter unit support location **110** of base **106**. An opening **214** in bottom cover **206** may be provided to allow interface **212** to couple with connector **122** of base unit **102**, for example. In some embodiments, analog front end **208** may couple to sensor **132** through interface **212** and connector **122** of base unit **102**. Likewise, analog front end **208** and processing circuitry **210** may receive electrical power from power source **114***a* and/or **114***b* of base unit **102** through connector **122** and interface **212**.

[0073] In some embodiments, top cover **204** may be a pre-molded base into which substrate **202** is positioned prior to formation of bottom cover **206** (e.g., by a molding process). Alternatively, bottom cover **206** may be a pre-molded base into which substrate **202** is positioned prior to formation or addition of top cover **204**. Other assembly processes may be used.

[0074] In some embodiments top cover **204** and/or bottom cover **206** may be formed from a single layer or multiple layers. For example, the top cover **204** and/or bottom cover **206** may be formed from one or more layers of liquid silicone rubber (LSR), a thermoplastic elastomer (TPE), or the like. Other materials may be used such as, but not limited to, acrylonitrile butadiene styrene (ABS), polycarbonate, nylon, acetal, polyphthalamide (PPA), polysulfone, polyethersulfone, polyether ether ketone (PEEK), polypropylene, high density poly ethylene (HDPE), low density poly ethylene (LDPE), and the like. Other suitable materials may be used.

[0075] In some embodiments, top cover **204** and/or bottom cover **206** may be formed at a temperature of less than 100° C., and in some embodiments at a temperature of less than 80° C., so as not to damage electronics therein. Top cover **204** and bottom cover **206** may seal substrate **202**, analog front end **208**, and processing circuitry **210** (e.g., so that transmitter unit **104** is waterproof, with only the interface **212** being exposed).

[0076] In some embodiments, bottom cover **206** may include a sealing member **216**, such as a lip or similar feature, configured to seal against a sidewall of opening **138** of base unit **102** (see also FIG. **4**E below), such that transmitter unit **104** and base unit **102** form a sealed unit when transmitter unit **104** is positioned within base unit **102**. In some embodiments, top cover **204** may include one or more retention features **218***a*-**218***d* configured to interface with retention features within transmitter unit support location **110** (e.g., one or more of retention features **116***a*-**116***d*, for example). Such retention features may couple and hold transmitter unit **104** securely to base unit **102** during use, and keep connector **122** in contact with interface **212**. In other embodiments, top cover **204** may include a sealing member and/or bottom cover **206** may include one or more retention features.

[0077] FIG. **3**A is a cross-sectioned side view of wearable device **100** prior to inserting transmitter unit **104** into base unit **102** in accordance with some embodiments. FIG. **3**B is a cross-sectioned side view of the wearable device **100** after insertion of transmitter unit **104** into base unit **102** in accordance with some embodiments. As described, both transmitter unit **104** and base unit **102** may be sealed units (e.g., waterproof), with only interface **212** of transmitter unit **104** and connector **122** of base unit **102** being left exposed. Once transmitter unit **104** is inserted into base unit **102**, connector **122** and interface **212** may also be sealed from any external environment, such as by sealing member **216**.

[0078] Because transmitter unit **104** may receive electrical power from base unit **102** (through connector **122** and interface **212**), transmitter unit **104** does not need a separate power source. As

such, transmitter unit **104** may be removed and used repeatedly with other new disposable base units when the disposable base unit **102** is exchanged at the end of the analyte monitoring period.
[0079] Base unit **102** and/or transmitter unit **104** may be any suitable shape (e.g., round, oval, square, rectangular, or the like). For example, FIGS. **4**A and **4**B illustrate a top perspective view and an exploded perspective view, respectively, of example wearable device **400** provided herein. Wearable device **400** has a primarily rectangular shape, and is sized and shaped to resemble a medical bandage. In this case, base unit **102** is rectangular. Transmitter unit **104** may be any suitable shape. As with the other embodiments described herein, base unit **102** is disposable and transmitter unit **104** is reusable. That is, in some embodiments, base unit **102** is configured to be disposed of after a single analyte monitoring period, while transmitter unit **104** is configured to be removed from base unit **102** and re-used many times with other (new) base units that can be exact copies of base unit **102**.
[0080] Now with reference to FIGS. **4**A and **4**B, in some embodiments, wearable device **400** may employ a sensor assembly **402** including one or more microneedles, such as an array of microneedles shown. Fewer or more microneedles may be used. Wearable device **400** includes a bottom member **404** having an opening **405** through which microneedles extend. Bottom member **404** may be formed from any suitable material such as Liquid silicone rubber (LSR), thermoplastic elastomer (TPE), acrylonitrile butadiene styrene (ABS), polycarbonate, nylon, acetal, polyphthalamide (PPA), polysulfone, polyethersulfone, polyether ether ketone (PEEK), polypropylene, high density poly ethylene (HDPE), low density poly ethylene (LDPE), and the like. Other suitable materials may be used. Bottom member **404** may include an adhesive, such as a pressure sensitive adhesive **439** (see FIG. **4**D), used to secure wearable device **400** to the skin of a user.
[0081] Sensor assembly **402** comprising microneedle array may be formed on a suitable substrate **406**, such as plastic or a similar substrate, and may be attached and electrically coupled to a circuit board **408** (e.g., a flexible circuit board) and bottom member **404** by any suitable means such as by adhesive. Power source **114***a* and/or **114***b* may be coupled to circuit board **408** via a base **106** and coupling **122**, which may include suitable electrical contacts thereon configured to secure power source **114***a* and/or **114***b* and provide power to the circuit board **408**. Base **106** may be received in opening **440** as shown in FIG. **4**E.
[0082] Circuit board **408** may include connector **122** that is coupled to microneedle array **402** and also to power source **114***a* and/or **114***b*. Connector **122** is further configured to interface with interface **212** of transmitter unit **104** to provide electrical power to transmitter unit **104** when transmitter unit **104** is installed within base unit **102**. Additionally, connector **122** allows transmitter unit **104** to bias microneedle array **402** and sense current flow through one or more microneedles. Transmitter unit **104** may calculate analyte levels within interstitial fluid using the sensed current flow, as described previously.
[0083] FIG. **4**C illustrates a bottom perspective view of wearable device **400** in accordance with embodiments provided herein. FIG. **4**D illustrates a bottom view of an alternative embodiment of wearable device **400** in which a single microneedle **412** is employed and a transparent tape **439** has been applied that is used to secure the wearable device to the user's skin. FIG. **4**E illustrates an enlarged portion of wearable device **400** illustrating transmitter unit **104** inserted within base unit **102** and including a microneedle array **402** in accordance with embodiments provided herein.
[0084] As shown in FIG. **4**E, in some embodiments, transmitter unit **104** may include sealing member **216** (e.g., a sealing bead or lip) that interfaces with a receiving surface **414**, such as a groove or similar feature, in a sidewall of opening **138** (FIGS. **1**C and **4**E) within base unit **102**. In this manner, base unit **102** and transmitter unit **104** may form a sealed unit (protecting connector **122** and/or interface **212** from liquids, for example).
[0085] FIG. **4**E also shows a cross-sectioned side view illustrating that a retention feature **416** of base unit **102** may interface with a corresponding retention feature **418** of transmitter unit **104** to

securely hold transmitter unit **104** within opening **138** of base unit **102**. The retention features **416** and/or **418** shown may also ensure that connector **122** is held securely within interface **212** during use. Fewer or more retention features may be used (e.g., 2, 3, 4 or more, such as retention features **116***a*-**116***d* previously described). In some embodiments, transmitter unit **104** may be used in base units that have different shapes. For example, transmitter unit **104** may be used in a round base unit atone time period and then re-used with a rectangular base unit, or vice versa. Also shown in FIG. **1**E is that the base **106** is received in opening **440** below opening **138** and secured therein by circuit board **408**.

[0086] FIG. **5** is a flowchart of an example method **500** for continuous analyte monitoring in accordance with embodiments provided herein. With reference to FIG. **5**, method **500** begins in block **502** in which a wearable device is provided having a disposable portion that includes a sensor and a power source and a reusable portion connected to the disposable portion, the reusable portion including a transmitter unit that receives power from the disposable portion. For example, wearable device **100** or **400** may be provided in which disposable base unit **102** includes a sensor (e.g., an analyte sensor, a microneedle, a microneedle array, etc.) and power source (e.g., a battery or other power source). Reusable transmitter unit **104** may interface with disposable base unit **102** and receive power from base unit **102**.

[0087] In block **504**, the sensor, power source, and transmitter unit are employed to monitor analyte levels of a user. For example, after sensor **132** is inserted into a user, sensor **132**, power sources **114***a* and/or **114***b* and transmitter unit **104** may be employed to monitor analyte levels of the user during a continuous analyte monitoring process (e.g., for approximately seven to 21 days, for example). Following analyte monitoring, the wearable device may be detached from the user, including the analyte sensor **132**. In block **506**, the reusable portion of the wearable device is disconnected from the disposable portion of the wearable device. For example, transmitter unit **104** may be removed from base unit **102**, and base unit **102** may be discarded. In general, transmitter unit **104** may be disconnected from base unit **102** before or after base unit **102** is removed from the user. Thereafter, in block **508**, the reusable portion of the wearable device is connected to a new disposable portion. For example, transmitter unit **104** may be disconnected from base unit **102** and inserted into or otherwise coupled to a new base unit **102** (e.g., having a new power source and new analyte sensor). In block **510**, the sensor and power source of the new disposable portion, and the transmitter unit, may be employed to monitor analyte levels of the user. In some embodiments, transmitter unit **104** may be used with at least 10 different sensors and power sources. Transmitter unit **104** may be coupled to base unit **102** before or after base unit **102** is attached to the user.

[0088] FIG. **6** is a flowchart of another example method **600** for continuous analyte monitoring in accordance with embodiments provided herein. With reference to FIG. **6**, method **600** begins in block **602** in which a disposable base unit having a sensor and a power source is provided (e.g., disposable base unit **102** having sensor **132**). Thereafter, in block **604**, the sensor is inserted into an interstitial fluid region of a user, and in block **606**, the base unit is attached to the user (e.g., via an adhesive on the bottom of the wearable device). In block **608**, a reusable transmitter unit is coupled to the disposable base unit such that the reusable transmitter unit receives power from the power source and is coupled to the sensor (e.g., reusable transmitter unit **104** is attached to disposable base unit **102** and receives power and sensor signals through connector **122**). The reusable transmitter unit **104** may be attached to the disposable base unit **102** before or after the sensor **132** is inserted into an interstitial fluid region of the user. In block **610**, the transmitter unit and sensor are employed to monitor analyte levels within the user for a first predetermined time period. For example, the transmitter unit **104** and sensor **132** may be used to monitor glucose or another analyte level for 7, 10, 14 or another number of days.

[0089] After the first predetermined time period, method **600** includes removing the disposable base unit with the sensor from the user (block **612**) and decoupling (detaching) the reusable transmitter unit from the disposable base unit (block **614**). For example, the transmitter unit **104**

may be decoupled from the base unit **102**, and the base unit **102** may be discarded. The reusable transmitter unit **104** may be decoupled from the disposable base unit **102** before or after the disposable base unit **102** and sensor **132** are removed from the user. In block **616**, the sensor of a new disposable base unit may be inserted into an interstitial fluid region of the user. In block **618**, the new disposable base unit may be attached to the user. In block **620**, the reusable transmitter unit may be coupled to the new disposable base unit so that the transmitter unit receives power from the new disposable base unit and is coupled to the sensor of the new disposable base unit. The reusable transmitter unit **104** may be attached to the new disposable base unit **102** before or after the sensor **132** is inserted into interstitial fluid region of the user. In block **622**, the transmitter unit and sensor of the new disposable base unit may be employed to monitor analyte levels within the user for a second predetermined time period. For example, the transmitter unit **104** and new disposable base unit **102** may be employed for another 7, 10, 14 or other number of days. As mentioned, transmitter unit **104** may be used 10, 20, 50, 100 or more times (each time with a new disposable base unit).

[0090] FIG. **7** is a flowchart of an example method **700** of forming a wearable device for use during continuous analyte monitoring provided herein. With reference to FIG. **7**, in block **702**, a pre-mold portion is provided (e.g., pre-mold encapsulation layer **142**). For example, a liquid silicone rubber (LSR), thermoplastic elastomer (TPE), polyvinyl chloride (PVC), acrylonitrile butadiene styrene (ABS), polyoxymethylene (POM), polycarbonate, high durometer silicone, or another suitable material may be placed in a molding tool. The pre-mold portion **142** may be employed to secure or otherwise support components of the wearable device in their proper position prior to molding (e.g., over molding). In block **704**, a base is placed on the pre-mold portion, the base having a transmitter unit support location and a sensor assembly support location. For example, base **106** may be placed on the pre-mold portion **142**. In block **706**, at least one power source is placed on the pre-mold portion. In some embodiments, power source **114***a* and/or **114***b* may be placed directly on the pre-mold portion **142**, while in other embodiments, power source **114***a* and/or **114***b* may be placed on the power source support locations **108***a* and/or **108***b* of base **106**. In some embodiments, in block **708**, a sensor assembly including an analyte sensor may be placed within the sensor assembly support location. In other embodiments, a dummy insertion device shaped similar to the insertion device **124** may be placed within the sensor assembly support location (prior to molding) to protect the sensor and to ensure that the opening **140** for insertion device **124** is formed properly. When a dummy insertion device is employed, the dummy insertion device may be removed after molding and insertion device **124** may be placed within opening **140**. Placement of the sensor assembly within the sensor assembly support location **112** may include placing connector **122** within the transmitter unit support location **110** and connecting connector **122** to sensor **132**. Connector **122** may also be connected to power source **114***a* and/or **114***b* as described previously.

[0091] In block **710**, an encapsulation layer is formed that extends over the base and the at least one power source and seals against the pre-mold portion. During encapsulation layer formation, an attachment region (e.g., opening **138**, attachment region **154**) is provided that allows a transmitter unit to be attached to and detached from the transmitter unit support location of the base at the attachment region of the encapsulation layer. This may be performed by using a dummy transmitter unit placed within the transmitter unit support location **110** of the base **106** prior to molding, for example.

[0092] In some embodiments, the encapsulation layer may be formed a temperature of less than 100° C., and in some embodiments less than 80° C. Example polymer materials for the encapsulation layer can include, for example, liquid silicone rubber (LSR), thermoplastic elastomer (TPE), or the like.

[0093] The encapsulation layer (e.g., **136**) forms a sealed disposable base unit encapsulation layer (base unit **102**) that may receive a transmitter unit **104** prior to use. Following formation of the encapsulation layer, an adhesive layer may be provided on the bottom of the pre-mold portion and

used to secure the base unit **102** to a user during continuous analyte monitoring with the wearable device. Thereafter, the disposable base unit **102** including the insertion devoice and sensor assembly may be sterilized and packaged for use (e.g., separate from the transmitter unit **104**). For example, e-beam sterilization or another sterilization method may be employed to sterilize the various components of the disposable base unit **102**, such as the sensor **132**, insertion device **124**, insertion device cap **126**, etc. Example packaging **1650** may include a plastic housing **1650**H having a removable plastic or foil seal, or other sealing cover **1650**C such as shown in FIG. **16** sealing the sterilized disposable base unit **102**, although any suitable sterile packaging may be used. In another example, the sterilized disposable base unit **102** may be received and sealed in a laminated foil and plastic sheet **1750** enclosure as shown in FIG. **17**. The wearable device may be employed by removing the sterilized base unit from its sterile packaging, inserting the reusable transmitter unit **104** into the base unit **102**, removing an adhesive strip from the bottom of the base unit **102** and inserting the sensor **132** into a user while attaching the base unit **102** to the user's skin. Any suitable insertion device may be employed for inserting the sensor **132** into an interstitial fluid region of the user.

[0094] FIG. **8** is a flowchart of another example method **800** of forming a wearable device for use during continuous analyte monitoring provided herein. With reference to FIG. **8**, in block **802**, at least one power source and a sensor assembly are coupled to a connector (e.g., power source **114***a* and/or **114***b* may be coupled to connector **122**, as may be sensor **132**). In block **804**, the at least one power source, the sensor assembly, and the connector are placed in the molding tool. In some embodiments, a sensor assembly including an insertion device and an analyte sensor may be placed at the sensor assembly support location of the base **106**. In other embodiments, a dummy insertion device shaped similar to the insertion device **124** may be placed within the sensor assembly support location (prior to molding) to ensure that the sensor **132** is protected and opening **140** for insertion device **124** is formed properly. When a dummy insertion device is employed, the dummy insertion device may be removed after molding and insertion device **124** may be placed within opening **140**.

[0095] In block **806**, the base, the at least one power source, and at least a portion of the sensor assembly are encapsulated using the molding tool to form a sealed unit. Such encapsulation includes forming an attachment region (e.g., **138**) in the sealed unit that allows a transmitter unit **104** to be attached to and detached from the transmitter unit support location **110** of the base **106**. This may be performed by using a dummy transmitter unit placed at the transmitter unit support location **110** of the base **106** during molding, for example.

[0096] In some embodiments, encapsulating the base **106** and the at least one power source **114***a*, **114***b* may be performed at a temperature of less than 100° C., and in some embodiments less than 80° C. Example materials for the encapsulating the base **106** and the at least one power source **114***a*, **114***b* include liquid silicone rubber (LSR), thermoplastic elastomer (TPE), or the like. Other suitable encapsulating materials may be used.

[0097] Encapsulating the base **106** and power source(s) **114***a*, **114***b* forms a sealed disposable base unit (e.g., base unit **102**) that may receive a transmitter unit **104** prior to use. Following formation of the disposable base unit **102**, an adhesive layer may be provided on the bottom of the base unit **102** and used to secure the base unit **102** to a user during continuous analyte monitoring with the wearable device. Thereafter, the disposable base unit may be sterilized and packaged for use (e.g., separate from the transmitter unit) as previously described.

[0098] FIG. **9** is a flowchart of another example method **900** of forming a wearable device for use during continuous analyte monitoring provided herein. With reference to FIG. **9**, in block **902**, a base (e.g., see base **106** of FIGS. **3**A-**3**B) is provided having a transmitter unit support location (e.g., transmitter unit support location **110**), a power source support location (e.g., power source support location **108***a*, **108***b*), and a sensor assembly support location (e.g., sensor assembly support location **112**). In block **904**, at least one power source (e.g., power source **114***a*, **114***b*) is placed at the power source support location (e.g., power source support location **108***a*, **108***b*) of the

base (e.g., base **106**). In block **906**, a sensor assembly including an analyte sensor (e.g., analyte sensor **132**) and/or an insertion device (e.g., insertion device **124**) may be placed within the sensor assembly support location (e.g., sensor assembly support location **112**). Placement of the sensor assembly within the sensor assembly support location **112** may include placing connector **122** within the transmitter unit support location **110** and connecting connector **122** to sensor **132**. Connector **122** may also be connected to power source **114***a* and/or **114***b* as described herein.
[0099] In block **908**, an encapsulation portion (e.g., encapsulation portion **136**) is provided having an opening (e.g., opening **340**) for the base **106**. For example, a liquid silicone rubber (LSR), thermoplastic elastomer (TPE), thermosetting or thermoplastic polymer, or similar encapsulation portion **136** may be provided that includes an opening **440** formed therein, which allows the base **106** to be inserted into the opening **440** of the encapsulation portion **136**. At least one power source (e.g., power sources **114***a*, **114***b*) and/or sensor assembly (e.g., **132**) can be coupled to the base **106**.
[0100] In block **910**, the base (e.g., base **106** with the at least one power source **114***a*, **114***b* and sensor assembly **132** coupled thereto) is placed within the opening **340** of the encapsulation portion **136**. In this embodiment, the base **106** can be sealed to the opening **340**, and the edges of the base **106** can be sealed to the encapsulated portion **136** such that the base **106** and encapsulation portion **136** form a sealed, disposable unit. The sealed, disposable unit is configured to allow a transmitter unit **104** to be attached to and detached from the transmitter unit support location **110** of the base **106**. In some embodiments, insertion device **124** and/or insertion device cap **126** may be coupled to the base unit **102** after the base is inserted into the pre-mold portion comprising the encapsulation portion **136**.
[0101] Placing the base **106**, sensor **132** and power source(s) **114***a*, **114***b* within the encapsulation portion **136** forms a sealed disposable base unit (base unit **102**) that may receive a transmitter unit **104** prior to use. Following formation of the disposable base unit **102**, an adhesive layer may be provided on the bottom of the base unit **102** and used to secure the base unit **102** to a user during continuous analyte monitoring with the wearable device **100**. Thereafter, in block **912**, the sealed, disposable unit (e.g., base unit **102**) may be sterilized and packaged for use (e.g., separate from the transmitter unit), as previously described.
[0102] The wearable devices described herein may be used to monitor analyte concentration of any desired analyte. Example analytes that may be detected and/or monitored include glucose, cholesterol, lactate, uric acid, alcohol, or the like. In some embodiments, sensor **132** and/or sensor assembly **402** (e.g., microneedle array) may be continuously operated at a constant potential against a reference electrode, such as an Ag/AgCl electrode, or a combined reference-counter electrode. Sensor **132** and/or sensor assembly **402** may also be operated with two working electrodes where one is dedicated to measuring a point-of-interest analyte, such as glucose, by a glucose specific enzyme such as glucose oxidase. The other electrode is dedicated to measuring the background signals that result from interference species such as uric acid, acetaminophen or the like. In this dual electrode operation scheme, the interference signal may be constantly subtracted from the main signal of the point-of-interest analyte by either simple subtraction or another algorithmic method.
[0103] FIG. **10**A illustrates a high-level block diagram of an example continuous analyte monitoring (CAM) device **1000** in accordance with embodiments provided herein. Although not shown in FIG. **10**A, it is to be understood that the various electronic components and/or circuits are configured to couple to a power source, such as but not limited to, a battery. CAM device **1000** includes a bias circuit **1002** that may be configured to couple to a CAM sensor **1004**. Bias circuit **1002** may be configured to apply a bias voltage, such as a continuous DC bias, to an analyte-containing fluid through CAM sensor **1004**. In this example embodiment, the analyte-containing fluid may be human interstitial fluid, and the bias voltage may be applied to one or more electrodes **1005** of CG M sensor **1004** (e.g., a working electrode, a background electrode, etc.).
[0104] In some embodiments, the CAM sensor **1004** may include two electrodes and the bias

voltage may be applied across the pair of electrodes. In such cases, current may be measured through the CAM sensor **1004**. In other embodiments, the CAM sensor **1004** may include three electrodes such as a working electrode, a counter electrode, and a reference electrode. In such cases, the bias voltage may be applied between the working electrode and the reference electrode, and current may be measured through the working electrode, for example. The CAM sensor **1004** can include chemicals which react with the analyte (e.g., glucose) in a reduction-oxidation reaction, which affects the concentration of charge carriers and the time-dependent impedance of the CAM sensor **1004**. Example chemicals for glucose reaction include glucose oxidase, glucose dehydrogenase, or the like. In some embodiments, a mediator such as ferricyanide or ferrocene for glucose reaction may be employed. In some embodiments, CAM sensor **1004** may include a microneedle or a sensor assembly including a plurality of microneedles, such as a microneedle array.

[0105] The bias voltage generated and/or applied by bias circuit **1002** may range from about 0.1 to 1 volts versus the reference electrode, for example. Other bias voltages may be used.

[0106] A current through CAM sensor **1004** in an analyte-containing fluid responsive to the bias voltage may be conveyed from CAM sensor **1004** to a current measurement (I.sub.meas) circuit **1006** (also referred to as current sensing circuitry). Current measurement circuit **1006** may be configured to sense and/or record a current measurement signal that has a magnitude indicative of the magnitude of the current conveyed from CAM sensor **1004** (e.g., using a suitable current-to-voltage converter (CVC), for example). In some embodiments, current measurement circuit **1006** may include a resistor having a known nominal value and a known nominal precision (e.g., 0.1% to 5%, or even smaller than 0.1%, in some embodiments), through which the current conveyed from CAM sensor **1004** is passed. A voltage developed across the resistor of current measurement circuit **1006** represents the magnitude of the current, and may be referred to as the current measurement signal (or raw analyte (e.g., glucose) signal Signal.sub.Raw).

[0107] In some embodiments, a sample circuit **1008** may be coupled to current measurement circuit **1006**, and may be configured to sample the current measurement signal, and may produce digitized time-domain sample data that is representative of the current measurement signal (e.g., digitized glucose signals). For example, sample circuit **1008** may be any suitable A/D converter circuit configured to receive the current measurement signal, which is an analog signal, and convert it to a digital signal having a desired number of bits as an output. The number of bits output by sample circuit **1008** may be sixteen in some embodiments, but more or fewer bits may be used in other embodiments. In some embodiments, sample circuit **1008** may sample the current measurement signal at a sampling rate in the range of about 10 samples per second to 1000 samples per second. Faster or slower sampling rates may be used. For example, sampling rates such as about 10 kHz to 100 kHz may be used and down-sampled to further reduce signal-to-noise ratio. Any suitable sampling circuitry may be employed.

[0108] Still referring to FIG. **10**A, a processor **1010** may be coupled to sample circuit **1008**, and may be further coupled to a memory **1012**. In some embodiments, processor **1010** and sample circuit **1008** are configured to directly communicate with each other via a wired pathway (e.g., via a serial or parallel connection). In other embodiments, the coupling of processor **1010** and sample circuit **1008** may be by way of memory **1012**. In this arrangement, sample circuit **1008** writes digital data to memory **1012**, and processor **1010** reads the digital data from memory **1012**.

[0109] Memory **1012** may have stored therein one or more gain functions **1014** for using in determining glucose values based on raw glucose signals (from current measurement circuit **1006** and/or sample circuit **1008**). For example, in some embodiments, three or more gain functions may be stored in memory **1012**, each for use with different segments (time periods) of CAM collected data. Memory **1012** also may have stored therein a plurality of instructions. In various embodiments, processor **1010** may be a computational resource such as but not limited to a microprocessor, a microcontroller, an embedded microcontroller, a digital signal processor (DSP), a

field programmable gate array (FPGA) configured to perform as a microcontroller, or the like.
[0110] In some embodiments, the plurality of instructions stored in memory **1012** may include instructions that, when executed by the processor **1010**, cause the processor **1010** to (a) cause the CAM device **1000** (via bias circuit **1002**, CAM sensor **1004**, current measurement circuit **1006** and/or sample circuit **1008**) to measure analyte signals (e.g., current signals) from interstitial fluid; (b) store analyte signals in memory **1012**; (c) compute analyte values (e.g., concentrations) based on measured and/or stored analyte signals; and (e) communicate the analyte values to a user.
[0111] Memory **1012** may be any suitable type of memory, such as but not limited to, one or more of a volatile memory and/or a non-volatile memory. Volatile memory may include, but is not limited to a static random access memory (SRAM), or a dynamic random access memory (DRAM). Non-volatile memory may include, but is not limited to, an electrically programmable read-only memory (EPROM), an electrically erasable programmable read-only memory (EEPROM), a flash memory (e.g., a type of EEPROM in either of the NOR or NAND configurations, and/or in either the stacked or planar arrangements, and/or in either the single-level cell (SLC), multi-level cell (MLC), or combination SLC/MLC arrangements), a resistive memory, a filamentary memory, a metal oxide memory, a phase change memory (such as a chalcogenide memory), or a magnetic memory. Memory **1012** may be packaged as a single chip or as multiple chips, for example. In some embodiments, memory **1012** may be embedded, with one or more other circuits, in an integrated circuit, such as, for example, an application specific integrated circuit (ASIC).
[0112] As noted above, memory **1012** may have a plurality of instructions stored therein that, when executed by processor **1010**, cause processor **1010** to perform various actions specified by one or more of the stored plurality of instructions. Memory **1012** may further have portions reserved for one or more “scratchpad” storage regions that may be used for read or write operations by processor **1010** responsive to execution of one or more instructions of the plurality of instructions.
[0113] In the embodiment of FIG. **10**A, bias circuit **1002**, CAM sensor **1004**, current measurement circuit **1006**, sample circuit **1008**, processor **1010**, and memory **1012**, may be disposed within a wearable sensor portion **1016** of CAM device **1000** (e.g., wearable device **100** or **400** described above). In some embodiments, wearable sensor portion **1016** may include a display **1017** for displaying information such as analyte concentration information (e.g., without use of external equipment). Display **1017** may be any suitable type of human-perceivable display, such as but not limited to, a liquid crystal display (LCD), a light-emitting diode (LED) display, an organic light emitting diode (OLED) display, or the like.
[0114] In some embodiments, all electronic circuitry within CAM device **1000** may be contained within a reusable transmitter unit (e.g., reusable transmitter unit **104**) as described herein, such as bias circuit **1002**, current measurement circuit **1006**, sample circuit **1008**, processor **1010**, memory **1012**, transmitter/receiver circuit **1024***a* and/or display **1017**. CAM sensor **1004** and any power source may be located within a disposable base unit (e.g., disposable base unit **102**).
[0115] Still referring to FIG. **10**A, CAM device **1000** may further include a portable user device portion **1018**. A processor **1020** and a display **1022** may be disposed within portable user device portion **1018**. Display **1022** may be coupled to processor **1020**. Processor **1020** may control the text or images shown by display **1022**. Wearable sensor portion **1016**, and portable user device portion **1018**, may be communicatively coupled. In some embodiments the communicative coupling of wearable sensor portion **1016**, and portable user device portion **1018**, may be by way of wireless communication via transmitter circuitry and/or receiver circuitry, such as transmit/receive circuit TxRx **1024***a* in wearable sensor portion **1016** and transmit/receive circuit TxRx **1024***b* in portable user device **1018**, for example. Such wireless communication may be by any suitable means including but not limited to standards-based communications protocols such as the Bluetooth® communications protocol. In various embodiments, wireless communication between wearable sensor portion **1016** and portable user device portion **1018** may alternatively be by way of near-field communication (NF C), radio frequency (R F) communication, infra-red (IR) communication,

or optical communication. In some embodiments, wearable sensor portion **1016** and portable user device portion **1018** may be connected by one or more wires.

[0116] Display **1022** may be any suitable type of human-perceivable display, such as but not limited to, a liquid crystal display (LCD), a light-emitting diode (LED) display, an organic light emitting diode (OLED) display, or the like.

[0117] Referring now to FIG. **10**B, an example CAM device **1050** is shown that is similar to the embodiment illustrated in FIG. **10**A, but having a different partitioning of components. In CAM device **1050**, the wearable sensor portion **1016** includes the bias circuit **1002** coupled to the CAM sensor **1004**, and the current measurement circuit **1006** coupled to the CAM sensor **1004**. The portable user device portion **1018** of CAM device **1050** includes the sample circuit **1008** coupled to processor **1020**, and the display **1022** coupled to processor **1020**. Processor **1020** is further coupled to memory **1012** that has the gain function(s) **1014** stored therein. In some embodiments, processor **1020** in CAM device **1050** may also perform the previously-described functions performed by processor **1010** of CAM device **1000** of FIG. **10**A, for example. Wearable sensor portion **1016** of CAM device **1050** may be smaller and lighter, and therefore less invasive, than CAM device **1000** of FIG. **10**A because sample circuit **1008**, processor **1010**, memory **1012**, etc., are not included therein. Other component configurations may be employed. For example, as a variation to the CAM device **1050** of FIG. **10**B, sample circuit **1008** may remain on wearable sensor portion **1016** (such that portable user device **1018** receive digitize analyte (e.g., glucose) signals from wearable sensor portion **1016**).

[0118] While in some embodiments, the transmitter unit **104** is shown as being removable and/or insertable into a top surface of the base unit **102**, it will be understood that in other embodiments, transmitter unit **104** may be removable and/or insertable into other surfaces of the base unit **102**. For example, FIG. **1**I illustrates a bottom perspective view of a base unit **102** having an opening **1102** that allows transmitter unit **104** to be inserted in or removed from base unit **102** in accordance with some embodiments and as described above. Transmitter unit **104** may receive electrical power and analyte signals (e.g., analyte current signals) from base unit **102** in some embodiments. An adhesive layer **1104** may be provided on the bottom of base unit **102** for allowing the wearable device **100** formed by base unit **102** and transmitter unit **104** to be secured to the skin of a user. An opening **1106** in adhesive layer **1104** allows transmitter unit **104** to be inserted into and removed from base unit **102**.

[0119] FIG. **12**A illustrates a top perspective view of another embodiment of wearable device **100** for use during continuous analyte monitoring in accordance with embodiments provided herein. FIG. **12**B is a top view of base unit **102** of FIG. **12**A without the insertion device **124**, transmitter unit **104**, or power sources **114***a* and **114***b* installed in accordance with embodiments provided herein. FIG. **12**C is a perspective side view of a wearable device **100** of FIG. **12**A in accordance with embodiments provided herein.

[0120] With reference to FIGS. **12**A and **12**B, wearable device **100** may be formed by placing base **106** (not separately shown) on pre-mold encapsulation layer **142** and forming top encapsulation layer **144** over base **106**. As shown in FIG. **12**B, during formation of top encapsulation layer **144**, such as by molding, opening **138** is formed for transmitter unit **104**, opening **140** is formed for insertion device **124**, openings **1202***a* and **1202***b* are formed for power sources **114***a* and **114***b*, respectively, and a recess **1204** is formed for a cover **1206** for power sources **114***a* and **114***b* (see FIG. **12**C). In some embodiments, cover **1206** may be coupled to and/or a part of transmitter unit **104** and snap, pivot, and/or hinge into recess **1204** when transmitter unit **104** is placed within opening **138** of disposable base unit **102**. In other embodiments, cover **1206** may be separate from transmitter **104**. Cover **1206** may form part of encapsulation layer **136** when it is positioned to cover power sources **114***a* and **114***b* (e.g., along with pre-mold encapsulation layer **142** and top encapsulation layer **144**). Cover **1206** may be formed from liquid silicone rubber (LSR), thermoplastic elastomer (TPE), polyvinyl chloride (PVC), acrylonitrile butadiene styrene (ABS),

polyoxymethylene (POM), polycarbonate, high durometer silicone, or another suitable material, for example.

[0121] After formation of base unit **102** with opening **138**, opening **140**, openings **1202***a* and **1202***b*, and recess **1204**, power sources **114***a* and **114***b* may be installed in openings **1202***a* and **1202***b* and insertion device **124** may be installed in opening **140**. Base unit **102** then may be sterilized, such as by using e-beam sterilization, for use with transmitter unit **104** during continuous analyte monitoring as previously described. A dummy transmitter unit, insertion device **124**, power sources **114***a* and **114***b* and/or cover **1206** may be employed, such as being provided as mold inserts or the like, during formation of top encapsulation layer **144** so that openings **138**, **140**, **1202***a* and **1202***b*, and recess **1204** are formed.

[0122] In some embodiments, openings **1202***a* and **1202***b* may include electrical connections **1208***a*, **1208***b* that couple power sources **114***a* and **114***b* to connector **122** provided in opening **138** for supplying electrical power to any transmitter unit **104** inserted in opening **138**. Connector **122** may also include electrical connection **1208***c* configured to couple to an analyte sensor to be inserted by insertion device **124** during use of wearable device **100** as previously described.

[0123] FIGS. **13**A and **13**B are top views of another example of disposable base unit **102** in accordance with embodiments provided herein. With reference to FIG. **13**A, the disposable base unit **102** includes an attachment region **1310** configured to allow transmitter unit **104** to be coupled to disposable base unit **102** (for receiving power and for connecting to an analyte sensor), and also decoupled therefrom, as previously described. Attachment region **1310** includes a connector location **1312** at which connector **122** (FIG. **13**B) may be located, and power source locations **1314***a*, **1314***b* at which one or more power sources, such as one or more batteries, may be located. Connector **122** (FIG. **13**B) and power sources **114***a*, **114***b* may be positioned at connector location **1312** and power source locations **1214***a*, **1214***b*, respectively, as shown in FIG. **13**B. When transmitter unit **104** is positioned at attachment region **1310**, it may form a waterproof seal with base unit **102** so that connector **122** and power sources **114***a*, **114***b* are hermetically sealed and/or encapsulated.

[0124] With reference to FIGS. **13**A and **13**B, wearable device **100** (FIG. **13**B) may be formed by providing a pre-mold encapsulation layer **142** and forming top encapsulation layer **144** having connector location **1312** and power source regions **1314***a*, **1314***b* formed therein (as well as attachment location **1310**, such as an opening or recess). As shown in FIG. **13**A, during formation of top encapsulation layer **144**, attachment region **1310** is formed for transmitter unit **104**, opening **140** is formed for receiving insertion device **124**, connector location **1310** is formed for connector **122**, and openings **1314***a* and **1314***b* are formed for receiving power sources **114***a* and **114***b*.

[0125] After formation of base unit **102** with attachment region **1310**, connector location **1312**, opening **140**, and power source locations **1314***a* and **1314***b*, connector **122** may be placed in connector location **1312**, power sources **114***a* and **114***b* may be installed in power source locations **1314***a* and **1314***b* and insertion device **124** may be installed in opening **140**. Power sources **114***a*, **114***b* may be coupled to connector **122**, along with an analyte sensor (e.g., sensor **132** shown dotted) that extends to opening **140** and couples with insertion device **124**.

[0126] Base unit **102** then may be sterilized for use with transmitter unit **104** during continuous analyte monitoring, as previously described. Die plugs or inserts or dummy transmitter unit, insertion device, power sources and/or inserter may be employed during formation (e.g., molding) of top encapsulation layer **144** so that attachment location **1310**, connector location **1312**, opening **140**, and power source locations **1314***a* and **1314***b* are appropriately formed.

[0127] In some embodiments, as shown in the flowchart of FIG. **14**, a method **1400** of forming a wearable device (e.g., wearable device **100**) adapted to use in continuous analyte monitoring includes, in block **1402**, forming an encapsulation layer (e.g., encapsulation layer **136**) having a connector location, at least one power source location, and an inserter opening formed therein (e.g., connector location **1312**, power source locations **1314***a*, **1314***b*, and opening **140**). The method

1400 further includes, in block **1404**, placing a connector (e.g., connector **122**) at the connector location, and, in block **1406**, placing at least one power source (e.g., power sources **114***a* and/or **114***b*); at the at least one power source location (e.g., power source locations **1314***a*, **1314***b*). The placing of the connector **122** can be by any suitable method to achieve the electrical connections to the at least one power source (e.g., power sources **114***a* and/or **114***b*), and may include pin connectors and/or solder connections. In block **1408**, the method **1400** includes coupling the at least one power source (e.g., power sources **114***a* and/or **114***b*) to the connector (e.g., connector **122**), such as through electrical connections between the connector **122** and the at least one power source (e.g., power sources **114***a* and/or **114***b*. The method **1400** includes, in block **1410**, coupling an analyte sensor (e.g., sensor **132** shown dotted) to the connector (e.g., connector **122**). The coupling of the connector **122** can be by any suitable method to achieve the electrical connections between the connector **122** and the analyte sensor (e.g., sensor **132** shown dotted) and may include pin connectors and/or solder connections. The encapsulation layer (e.g., encapsulation layer **136**), connector (e.g., connector **122**), at least one power source (e.g., power source locations **114***a*, **114***b*), and analyte sensor (e.g., sensor **132**) form a disposable unit configured to interface with a reusable transmitter unit (e.g., reusable transmitter unit **104**) and form a sealed unit (e.g., a sealed unit of base unit **102** and reusable transmitter unit **104** of FIG. **13**B, for example).

[0128] In some embodiments, a method **1500** of forming a wearable device (e.g., wearable device **100** of FIGS. **12**A-**12**C) that is configured to use in continuous analyte monitoring is provided, as is shown in the flowchart of FIG. **15**, for example. The method **1500** includes, in block **1502**, providing a pre-mold portion (e.g., a pre-mold encapsulation layer **142**); in block **1504**, placing a base (e.g., base **106**) on the pre-mold portion, the base having a transmitter unit support location (e.g., transmitter unit support location **1210**) and a sensor assembly support location (e.g., sensor assembly support location **112**); and in block **1506**, placing a sensor assembly including an analyte sensor (e.g., sensor **132**) at the sensor assembly support location (e.g., sensor support location **112**); and in block **1508** forming an encapsulation layer (e.g., encapsulation layer **144**) extending over the base (e.g., base **106**), and sealing against the pre-mold portion (pre-mold encapsulation layer **142**).

[0129] Forming the top encapsulation layer **144** may include forming an attachment region (e.g., opening **138** or region **154**) that allows a transmitter unit (e.g., transmitter unit **104** of FIG. **12**A) to be attached to, and detached from, the transmitter unit support location **1210** of the base **106**, such as attached to, and detached from, the transmitter unit support location **1210** (and connector **122**). Forming the top encapsulation layer **144** may also include forming at least one power source opening (e.g., opening **1202***a* and/or **1202***b*) for at least one power source (e.g., to be inserted in the top encapsulation layer **144** so as to provide electrical power to the transmitter unit **104** attached at the transmitter unit support location **1210**. The method **1500** may also include forming a connector (e.g., connector **122**) within the transmitter unit support location **1210**, and coupling an analyte sensor (e.g., analyte sensor **132**) to the connector (e.g., connector **122**). The encapsulation layer, connector, at least one power source **114***a*, **114***b*, and analyte sensor **132** form a disposable unit **102** configured to interface with a reusable transmitter unit the transmitter unit and form a sealed wearable device **100**.

[0130] In some embodiments, a wearable device for use during continuous analyte monitoring is formed at a temperature of less than 100° C., and in some embodiments less than 80° C. The wearable device may include a disposable base unit having a power source and a reusable transmitter unit having electronics for the wearable device. The transmitter unit may have no separate power source, receiving electrical power solely from the disposable base unit to which it is coupled.

[0131] In some embodiments, a thumbnail groove, tab, or other grasping or prying feature may be provided on the transmitter unit **104** and/or base unit **102** to facilitate removal of the transmitter unit **104**.

[0132] In one or more embodiments, a wearable device (e.g., wearable device **100** or **400**) for

continuous analyte monitoring may include a disposable base unit (e.g., base unit **102**) that interfaces with a reusable transmitter unit (e.g., transmitter unit **104**). The disposable base unit may include a power source and an analyte sensor, and may be configured to receive the reusable transmitter unit. The reusable transmitter unit may include all electronic circuitry for biasing the analyte sensor, measuring current through the analyte sensor, computing analyte values based on measured current through the analyte sensor, and communicating analyte values to a user (directly or via an external device). The disposable base unit may be configured to receive the reusable transmitter unit and supply electrical power to the electronic circuitry of the reusable transmitter unit. The disposable base unit may be sterilized and packaged separately from the reusable transmitter unit.

[0133] A sensor assembly may include one or more of a sensor, electrical leads that extend from the sensor, and/or an insertion device employed to insert the sensor (e.g., a sensor, a sensor and electrical leads, a sensor and an insertion device, a sensor, electrical leads and an insertion device, etc.).

[0134] According to the disclosure, and as best shown in FIG. **18**, a method of forming a continuous analyte monitoring wearable device is provided. The method **1800** includes, in block **1802**, providing a base having a power source support location, a sensor assembly support location, and a transmitter unit support location, and in block **1804**, placing at least one power source at the power source support location. The method **1800**, further includes, in block **1806**, placing a sensor assembly including an analyte sensor at the sensor assembly support location, and in block **1808**, the method **1800** includes providing an encapsulation layer over the at least one power source, at least a portion of the sensor assembly, and at least a portion of the base, to form a sealed, disposable unit, wherein the sealed, disposable unit is configured to allow a transmitter unit to be attached to, and detached from, the transmitter unit support location. Finally, the method **1800** includes in block **1810** and sterilizing the sealed, disposable unit. is disclosed herein. Sterilization can be accomplished as is disclosed herein.

[0135] Embodiments provided herein allow for flexible and ultra-low profile continuous analyte monitoring systems. In some embodiments, the height of the system may be less than about 2.5 mm. This reduction in overall height may reduce interfere with clothing, be more discreet, and may improve overall wear comfort of the system. The flexible construction and components allow the sensor system to be contoured to a user's body through a range of motions and serves to increase overall user comfort. Critical components can be supported by rigid stiffeners in specific locations while maintaining overall flexibility. The power source(s) employed may be formed from a thin, bendable material, such as multiple batteries arranged in parallel.

[0136] In some embodiments, the materials used (e.g., LSR), flexible circuit boards, etc., provide a device that may be worn comfortably under clothing, has a low profile and avoid impacts, presents a soft flexible feel and appearance, and contours and moves with the dynamics of tissue flex, expansion and contraction. The disclosed devices also may protect sensor sites and internal hardware from fluid ingress and other use hazards, are applied easily and comfortably, provide breathability/airflow at skin adhesive areas and create a generally more user-friendly experience.

[0137] A flexible circuit board may be employed to support electronic components, such as an analog front end circuit and a transmitter module. The flexible circuit board may be fabricated from materials such copper, kapton, polyester (PET), polyethylene naphthalate (PEN), polymides, fiberglass and acrylic adhesives. The flexible circuit board may include electronic components in the form of a printed circuit and electronic components.

[0138] Example power sources include flexible lithium polymer batteries, coin cell batteries such as Lithium Manganese, Silver Oxide, and Alkaline coin batteries (e.g., CR 2032, SR516, and LR60 type coin batteries), or the like. Other circuit board and/or power source types may be used.

[0139] The foregoing description discloses only example embodiments. Modifications of the

above-disclosed apparatus and methods which fall within the scope of this disclosure will be readily apparent to those of ordinary skill in the art.

Claims

1. An analyte monitoring device, comprising: a base unit comprising a base opening configured in a base side, wherein the base side is configured to be adjacent a user's skin during use; an analyte sensor assembly comprising an analyte sensor; wherein the analyte sensor is adjacent the base side and configured to detect an analyte in an interstitial fluid; a transmitter unit configured to wireless transmit data indicative of the analyte; and a transmitter support location configured to selectively secure the transmitter unit within the base unit, wherein the transmitter unit is secured in the transmitter support location through the base opening.
2. The analyte monitoring device of claim 1, further comprising a power source configured to be disposed within the base unit and configured to power the transmitter unit and the analyte sensor assembly.
3. The analyte monitoring device of claim 2, wherein the base unit further comprises electrical connectors configured to contact the transmitter unit providing power to the transmitter unit when the transmitter unit is disposed in the transmitter support location.
4. The analyte monitoring device of claim 3, wherein the analyte sensor assembly and the power source are disposable, and the transmitter unit is reusable.
5. The analyte monitoring device of claim 4, further comprising circuitry configured to measure current indicative of the analyte in the interstitial fluid from the analyte sensor.
6. The analyte monitoring device of claim 5, wherein the circuitry is an analog front end and is configured to bias the analyte sensor and measure the current from the analyte sensor.
7. The analyte monitoring device of claim 1, further comprising: an encapsulation layer and an adhesive layer, wherein the encapsulation layer is configured to at least partially cover the base unit and provide a sealed disposable portion, and wherein the adhesive layer is configured to attach the base side to the user's skin when in use.
8. The analyte monitoring device of claim 1, further comprising: a transmitter connector configured to electrically connect the transmitter unit to the analyte sensor; and a power source connector configured to connect a power source to the transmitter unit.
9. An analyte monitoring device, comprising: a base unit comprising a base opening configured in a base side, wherein the base side is configured to be adjacent a user's skin during use; a power source selectively disposable in the base unit and configured to power electrical components of the base unit; an analyte sensor assembly comprising an analyte sensor and configured to be at least partially disposed within the base unit; wherein the analyte sensor is adjacent the base side and configured to detect an analyte in an interstitial fluid; a transmitter unit configured to wireless transmit data indicative of the analyte; electrical traces configured to connect the power source to the transmitter unit; and a transmitter support location configured to selectively secure the transmitter unit within the base unit and contact the transmitter unit to the electrical traces, wherein the transmitter unit is secured in the transmitter support location through the base opening.
10. The analyte monitoring device of claim 9, wherein the base unit further comprises electrical connectors configured to contact the transmitter unit and provide power to the transmitter unit when the transmitter unit is disposed in the transmitter support location.
11. The analyte monitoring device of claim 10, wherein the analyte sensor assembly and the power source are disposable, and the transmitter unit is reusable.
12. The analyte monitoring device of claim 11, further comprising circuitry configured to measure current indicative of the analyte in the interstitial fluid from the analyte sensor.
13. The analyte monitoring device of claim 12, wherein the circuitry is an analog front end and is configured to bias the analyte sensor and measure the current from the analyte sensor.

14. The analyte monitoring device of claim 9, further comprising: an encapsulation layer and an adhesive layer, wherein the encapsulation layer is configured to support the base unit, and the adhesive layer is configured to attach the base side to the user's skin when in use.
15. The analyte monitoring device of claim 9, further comprising a transmitter connector configured to electrically connect and communicatively couple the transmitter unit to the analyte sensor when the transmitter unit is positioned in the transmitter support location.
16. An analyte monitoring device, comprising: a base unit comprising a base opening configured in a base side, wherein the base side is configured to be adjacent a user's skin during use; an analyte sensor assembly comprising an analyte sensor and configured to be at least partially disposed within the base unit; wherein the analyte sensor is adjacent the base side and configured to detect an analyte in an interstitial fluid; a transmitter unit configured to wireless transmit data indicative of the analyte; and a transmitter support location configured to selectively secure the transmitter unit within the base unit, wherein the transmitter unit is secured in the transmitter support location through the base opening, and wherein the analyte sensor assembly is disposable, and the transmitter unit is reusable.
17. The analyte monitoring device of claim 16, wherein the base unit further comprises electrical connectors configured to contact the transmitter unit when the transmitter unit is disposed in the transmitter support location.
18. The analyte monitoring device of claim 16, further comprising an analog front end configured to bias the analyte sensor and measure current from the analyte sensor.
19. The analyte monitoring device of claim 16, further comprising an adhesive layer configured to attach the base side to the user's skin when in use.
20. The analyte monitoring device of claim 19, wherein the adhesive layer comprises an adhesive hole configured for receiving the transmitter unit therethrough.