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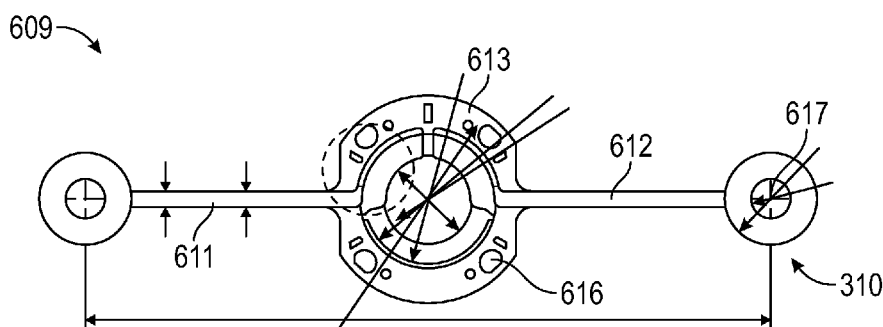


FIG. 10A

(57) **Abstract:** The present disclosure relates to a device configured to be adhered to the surface of a mammal for recording physiological signals and systems/methods relating to same. The device may include a housing enclosing a circuit board and a flexible wing extending from the housing. The device may include an electrode coupled to the flexible wing and an electrical trace for transmitting an electrical signal between the electrode and the circuit board. The electrical trace may have an insulator with a conductive material and resistors printed on the surface of the insulator. The trace layer may include conductive vias for transmitting the signal from a bottom of the trace layer to a top of the trace layer. The housing may include a battery having a battery terminal connector configured to provide electrical access to both terminals on a single side of the battery. The housing may include a floating trigger button.



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ELECTRICAL COMPONENTS FOR PHYSIOLOGICAL MONITORING DEVICE

Cross-Reference To Related Applications

[0001] This application claims priority from provisional U.S. Pat. App. No. 63/062,314, filed on August 6, 2020, which is hereby incorporated by reference in its entirety.

[0002] For purposes of this disclosure, certain aspects, advantages, and novel features of various embodiments are described herein. It is to be understood that not necessarily all such advantages may be achieved in accordance with any particular embodiment. Thus, various embodiments may be or carried out in a manner that achieves one advantage or group of advantages as taught herein without necessarily achieving other advantages as may be taught or suggested herein.

Field of the Invention

[0003] Disclosed herein are materials, devices, methods, and systems for monitoring physiological signals. For example, such physiological signals may include heart signals, such as an electrocardiogram signal.

[0003A] The present invention relates to an electronic device for monitoring physiological signals in a user.

Background of the Invention

[0004] Abnormal heart rhythms, or arrhythmias, may cause various types of symptoms, such as loss of-consciousness, palpitations, dizziness, or even death. An arrhythmia that causes such symptoms is often an indicator of significant underlying heart disease. It is important to identify when such symptoms are due to an abnormal heart rhythm, since treatment with various procedures, such as pacemaker implantation or percutaneous catheter ablation, can successfully ameliorate these problems and prevent significant symptoms and death. For example, monitors such as Holter monitors and similar devices are currently in use to monitor heart rhythms.

[0005] It is desired to address or alleviate one or more disadvantages or limitations of the prior art, or to at least provide a useful alternative.

Summary of the Invention

[0005a] One or more embodiments of the present invention include an electronic device for monitoring physiological signals in a user, the device comprising:

- a housing enclosing a circuit board, the housing further comprising a rigid shell surrounding a flexible frame and forming a peripheral exterior of at least a portion of the housing, wherein a button is formed within an opening of the flexible frame, the button being configured to be manually depressed by the user into the flexible frame; and

- an electrode configured to detect physiological signals of the user when the electrode is engaged with a surface of the user.

[0005b] One or more embodiments of the present invention include an electronic device for monitoring physiological signals in a user, the device comprising:

- a housing, the housing comprising:

- a rigid shell forming a peripheral exterior of at least a portion of the housing,

- a flexible frame surrounded at least partially by the rigid shell, and

- a button is formed within an opening of the flexible frame, the button being configured to be manually depressed by the user into the flexible frame; and

- an electrode configured to detect physiological signals of the user when the electrode is engaged with a surface of the user.

[0005c] One or more embodiments of the present invention include an electronic device for monitoring physiological signals in a user, the device comprising:

- a housing, the housing comprising:

- a rigid shell forming a peripheral exterior of at least a portion of the housing,

- a flexible frame disposed within a central opening of the rigid shell, and

- a button disposed on a top surface of the flexible frame, the button being configured to be manually depressed by the user into the flexible frame; and

- a sensor configured to detect physiological signals of the user when the sensor is engaged with a surface of the user.

[0005d] Embodiments described herein are directed to a physiological monitoring device that may be worn continuously and comfortably by a human or animal subject for at least one week or more and more typically two to three weeks or more. In one embodiment, the device is specifically designed to sense and record cardiac rhythm (for example, electrocardiogram, ECG)

data, although in various alternative embodiments one or more additional physiological parameters may be sensed and recorded. Such physiological monitoring devices may include a number of features to facilitate and/or enhance the patient experience and to make diagnosis of cardiac arrhythmias more accurate and timely.

[0006] In some embodiments, an electronic device for monitoring physiological signals in a mammal comprises: at least two flexible wings extending laterally from a housing, wherein the flexible wings comprise a first set of materials which enable the wings to conform to a surface of the mammal and the housing comprises a second set of materials; a printed circuit board assembly housed within the housing, wherein the housing is configured to prevent deformation of the printed circuit board in response to movement of the mammal; at least two electrodes embedded within the flexible wings, the electrodes configured to provide conformal contact with the surface of the mammal and to detect the physiological signals of the mammal; at least two electrode traces embedded within the wings and mechanically decoupled from the housing, the electrode traces configured to provide conformal contact with the surface of the mammal and transmit electrical signals from the electrodes to the printed circuit board assembly; and, at least one hinge portion connecting the wings to the housing, the hinge portions configured to flex freely at the area where it is joined to the housing.

[0007] In certain embodiments, each wing may comprise an adhesive. In embodiments, the electrodes can be in the same plane as the adhesive. In certain embodiments, each wing comprises at least one rim, wherein the rim is thinner than an adjacent portion of each wing. The housing may further comprise dimples or grooves configured to allow for airflow between the housing and the surface of the mammal. In certain embodiments, the rim is configured to prevent the release of a portion of the wing from the surface of the mammal. In some embodiments, an electronic device for monitoring physiological systems may comprise a measuring instrument configured to detect motion signals in at least one axis. This measuring instrument may be an accelerometer that can be configured to detect motion signals in three axes.

[0008] In embodiments, the motion signals can be collected in time with the physiological signals. In certain embodiments, a motion artifact is identified when the physiological signals and the motion signals match. Further embodiments may call for an event trigger coupled to the printed circuit board assembly. In some embodiments, the event trigger input is supported by the housing or floating on a shock absorber such as a spring or foam so as to

prevent mechanical stress on the printed circuit board when the trigger is activated which, in turn, can reduce a source of artifact in the recorded signal.

[0009] In some embodiments, the event trigger may be concave or convex and larger than a human finger such that the event trigger is easily located. In other embodiments the event trigger may be convex within the concave area. In certain embodiments, the electrode traces are configured to minimize signal distortion during movement of the mammal. In particular embodiments, gaskets may be used as a means for sealable attachment to the housing.

[0010] In certain embodiments, a method for monitoring physiological signals in a mammal may comprise: attaching an electronic device to the mammal, wherein the device comprises: at least two electrodes configured to detect physiological signals from the mammal, at least one measuring instrument configured to detect secondary signals, and at least two electrode traces connected to the electrodes and a housing; and, comparing the physiological signals to the secondary signals to identify an artifact.

[0011] In certain embodiments, identification of artifacts comprises a comparison between the frequency spectrum of the physiological signals and the frequency spectrum of the secondary signals. In embodiments, the secondary signals comprise motion signals that may be used to derive the activity and position of the mammal. In certain embodiments, the secondary signals are collected in three axes. In some embodiments, a tertiary signal may also be collected. In certain embodiments, the secondary signals comprise information about the connection between the electronic device and the mammal. In some embodiments, the secondary signals may be used to detect when the mammal is sleeping.

[0012] In some embodiments, a method of removing and replacing portions of a modular physiological monitoring device may comprise: applying the device described above to a mammal for a period of time greater than 7 days and collecting physiological data; using the device to detect a first set of physiological signals; removing the device from the surface of the mammal; removing a first component from the device; and, incorporating the first component into a second physiological monitoring device, the second physiological monitoring device configured to detect a second set of physiological signals.

[0013] In some embodiments, the first component is electrically connected to other device components without the use of a permanent connection. In some embodiments, the device may further comprise spring connections. In certain embodiments, the first component may be

preserved for a second use by a housing to prevent damage. In particular embodiments, the first component is secured within a device by a mechanism that is capable of re-securing a second component once the first component is removed.

[0014] Certain embodiments may concern a system for inferring cardiac rhythm information from time-series data of heart beat intervals, as obtained from either consumer wearable or medical device products. A further aspect concerns improvements to the system to enable cardiac rhythm information to be inferred in a more robust and/or timely manner through the use of additional sources of data. This additional data may include summary statistics or specific signal features derived from an ECG, user activity time series data derived from an accelerometer, information related to user state, or information related to the day/time of the recording.

[0015] In certain embodiments, a system for selective transmission of electrocardiographic signal data from a wearable medical sensor, where QRS refers to the three fiducial points of an ECG recording at the time of ventricle depolarization, may comprise:

[0016] a wearable medical sensor incorporating a QRS detector that produces a real-time estimate of each R peak location in the ECG;

[0017] transmission of an R-R interval time series together with an onset time stamp from the sensor to a smartphone or internet-connected gateway device, according to a predefined schedule;

[0018] transmission of the R-R interval time series and the onset time stamp from the smartphone or internet-connected gateway device to a server;

[0019] server-side algorithmic inference of the most probable rhythms and their onset/offset times from the R-R interval time series data;

[0020] filtering the list of inferred heart rhythms according to specific filter criteria, such that only inferred rhythms matching the given criteria are retained after filtering;

[0021] transmission of the onset/offset time for each rhythm remaining after filtering, from the server to the smartphone or internet-connected gateway device;

[0022] transmission of the onset/offset time for each rhythm remaining after filtering, from the smartphone or internet-connected gateway device to the wearable sensor;

[0023] transmission of the section of recorded ECG corresponding to each onset-offset time pair from the sensor to the smartphone or internet-connected gateway device;

[0024] transmission of the section of recorded ECG corresponding to each onset-offset time pair from the smartphone or internet-connected gateway device to the server;

[0025] The rhythm filter criteria may be specified by a physician or other medical professional prior to the use of the wearable sensor by a patient. In other embodiments, the rhythm filter criteria are dynamic and can be updated during the use of the system according to predefined rules. In some embodiments, these predefined rules may describe an adjustment to the filter criteria based on previous findings during use of the system. In some embodiments, the onset and offset time for each inferred rhythm may be adjusted such that the resulting duration for each rhythm is less than a given maximum permissible duration. Computed confidence measures may be an input to the rhythm filter criteria. In some embodiments, the system comprises inferring cardiac rhythm information from R-R interval time series data. In certain embodiments, the cardiac rhythm inference system is implemented as a cloud service accessible via an API.

[0026] In certain embodiments, the cardiac rhythm inference system is provided through a software library that can be incorporated into a standalone application. The R-R interval values may be estimated from a photoplethysmography signal.

[0027] In certain embodiments of a method for inferring cardiac rhythm information, the cardiac rhythm inference system computes a confidence score for each type of cardiac rhythm, the method comprising:

[0028] computing the frequency and duration of each cardiac rhythm type inferred from the collection of R-R interval time series data for the given user;

[0029] estimating a confidence statistic for each rhythm type based on the inferred frequency and duration of the rhythm across the collection of R-R interval time series for the given user;

[0030] evaluating if the confidence statistic for each inferred rhythm exceeds a pre-determined threshold value;

[0031] providing rhythm information back to the calling software only for those inferred rhythms for which the confidence statistic exceeds the threshold value;

[0032] In certain embodiments, the cardiac rhythm inference system accepts additional sources of data, comprising one or more of:

[0033] user activity time series data measured by an accelerometer;

[0034] information on the specific day and time of each R-R interval time series recording;

[0035] information on user age, gender, clinical indication for monitoring, pre-existing medical conditions, medication information, and medical history;

[0036] ECG signal features and summary statistics, such as the mean, median, standard deviation or sum of the ECG signal sample values within a given time period;

[0037] a confidence rating provided by the measurement device to indicate the quality of heart beat estimation, for example, for each beat or for sequential time periods; and

[0038] intra-beat interval measurements.

[0039] In embodiments, a system for monitoring cardiac signal data, comprises:

[0040] a wearable medical sensor, the wearable medical sensor configured to detect cardiac signals from a mammal and estimate the R-peak location within the cardiac signal;

[0041] wherein the wearable medical sensor is configured to transmit an R-R interval time series and a time stamp to an intermediary device, the intermediary device configured to further transmit the R-R interval time series and time stamp to a server;

[0042] wherein the server is configured to infer the most probable rhythms and their onset/offset times from the R-R interval time series and time stamp, the server configured to filter the most probable rhythms according to a first criteria into a filtered data set;

[0043] wherein the server is configured to transmit the filtered data set back to the wearable sensor via the intermediary device; and

[0044] wherein the sensor transmits the full resolution cardiac signal to the server for a time period surrounding each of the filtered events.

[0045] In certain embodiments, a system for monitoring cardiac signal data comprises:

[0046] a server configured to communicate with a wearable sensor, the wearable sensor configured to detect cardiac signals from a mammal and estimate the R peak location within the cardiac signal;

[0047] wherein the wearable sensor is configured to transmit an R-R interval time series and a time stamp to the server;

[0048] wherein the server is configured to infer the most probable rhythms and their onset/offset times from the R-R interval time series and time stamp, the server configured to filter the most probable rhythms according to a first criteria into a filtered data set; and

[0049] wherein the server is configured to transmit a summary of the filtered data.

[0050] In particular embodiments, a server for monitoring cardiac signal data, comprises:

[0051] a portal configured to communicate with a wearable sensor, the wearable sensor configured to detect cardiac signals from a mammal and estimate the R peak location within the cardiac signal, wherein the wearable sensor is configured to transmit an R-R interval time series and a time stamp to an intermediary device, the intermediary device configured to further transmit the R-R interval time series and time stamp to a server;

[0052] a processor configured to infer the most probable rhythms and their onset/offset times from the R-R interval time series and time stamp, the processor configured to filter the most probable rhythms according to a first criteria into a filtered data set; and

[0053] wherein the server is configured to transmit a summary of the filtered data set.

[0054] In embodiments, a non-transitory storage medium having computer-executable instructions stored thereon, the computer-executable instructions readable by a computing system comprising one or more computing devices, wherein the computer-executable instructions are executable on the computing system in order to cause the computing system to perform operations comprises: receiving, by a computing system through a communication link, physiological sensor data generated by a patient monitoring device, the physiological sensor data associated with a first patient; analyzing, by the computing system, the physiological sensor data to determine whether one or more points in the physiological data that are likely indicative of one or more predetermined set of conditions; and after determining that at least one of the one or more points in the physiological data is likely indicative of at least one of the one or more predetermined set of conditions, generating, by the computing system, an electronic data package for transmission to the patient monitoring device, the electronic data package including location data regarding the at least one of the one or more points in the physiological sensor data that are likely indicative of the at least one of the one or more predetermined set of conditions.

[0055] In certain embodiments, the physiological sensor data may comprise a sampling of interval data measured from the recorded signal data, the sampling of interval data of a data size less than the recorded signal data.

[0056] In particular embodiments, a system for monitoring physiological signals in a mammal may comprise: a wearable adhesive monitor configured to detect and record cardiac rhythm data from a mammal, the wearable adhesive monitor configured to extract a feature from the cardiac rhythm data; and wherein the wearable adhesive monitor is configured to transmit the feature to a processing device, the processing device configured to analyze the feature, identify locations of interest, and transmit the locations of interest back to the wearable adhesive monitor.

[0057] In certain embodiments, a system for assessing physiological sensor data from a patient monitoring device comprises: a computer processor and non-transitory computer-readable media combined with the computer processor configured to provide a program that includes a set of instructions stored on a first server, the set of instructions being executable by the computer processor, and further configured to execute a sensor data inference module of the program; the sensor data inference module of the program storing instructions to: receive physiological sensor data generated by a patient monitoring device, the physiological sensor data associated with a first patient; analyze the physiological sensor data to determine whether one or more points in the physiological data that are likely indicative of one or more predetermined set of conditions; and after determining that at least one of the one or more points in the physiological data is likely indicative of at least one of the one or more predetermined set of conditions, generating an electronic data package for transmission to the patient monitoring device, the electronic data package including location data regarding the at least one of the one or more points in the physiological sensor data that are likely indicative of the at least one of the one or more predetermined set of conditions.

[0058] In certain embodiments, a computerized method may comprise: accessing computer-executable instructions from at least one computer-readable storage medium; and executing the computer-executable instructions, thereby causing computer hardware comprising at least one computer processor to perform operations comprising: receiving, by a server computer through a communication link, physiological sensor data generated by a patient monitoring device, the physiological sensor data associated with a first patient; analyzing, by the server computer, the physiological sensor data to determine whether one or more points in the physiological data that are likely indicative of one or more predetermined set of conditions; and after determining that at least one of the one or more points in the physiological data is likely indicative of at least one of the one or more predetermined set of conditions, generating, by the server computer, an electronic

data package for transmission to the patient monitoring device, the electronic data package including location data regarding the at least one of the one or more points in the physiological sensor data that are likely indicative of the at least one of the one or more predetermined set of conditions.

[0059] These and other aspects and embodiments of the invention are described in greater detail below, with reference to the drawing figures.

Brief Description Of The Drawings

[0060] Embodiments of the invention are hereafter described, by way of non-limiting example only, with reference to the accompanying drawings, in which:

[0060a] Figs. 1A and 1B are perspective and exploded profile views, respectively, of a physiological monitoring device, according to one embodiment.

[0061] Figs. 2A and 2B are top perspective and bottom perspective views, respectively, of a printed circuit board assembly of the physiological monitoring device, according to one embodiment.

[0062] Figs. 3A, 3B, 3C, 3D, and 3E are perspective and exploded views of a flexible body and gasket of the physiological monitoring device, according to one embodiment.

[0063] Fig. 4 is an exploded view of a housing of the physiological monitoring device; according to one embodiment.

[0064] Figs. 5A and 5B provide a perspective view of a battery holder of the physiological monitoring device, according to one embodiment.

[0065] Fig. 6A and 6B are cross sectional views of the physiological monitoring device, according to one embodiment.

[0066] Fig. 7 is an exploded view of the physiological monitoring device including a number of optional items, according to one embodiment.

[0067] Figs. 8A and 8B are perspective views of two people wearing the physiological monitoring device, illustrating how the device bends to conform to body movement and position, according to one embodiment.

[0068] Figs. 9A, 9B, 9C, 9D, 9E, and 9F illustrate various steps for applying the physiological monitor to a patient's body, according to one embodiment.

[0069] FIGS. 10A-10C schematically illustrate alternative examples of a trace layer. Figure 10A illustrates a first example of a trace layer and Figure 10B depicts a close-up of the inset A of Figure 10A. Figure 10C illustrates another example of a trace layer.

[0070] FIGS. 11A-11I schematically depict examples of a battery terminal connector. Figure 11A depicts an inner surface of a battery terminal connector configured to contact the battery terminals and Figure 11B depicts an outer surface of the battery terminal connector opposite the surface depicted in Figure 11A. Figure 11C depicts an inner surface of another example of a battery terminal connector configured to contact the battery terminals and Figure 11D depicts an outer surface of the battery terminal connector opposite the surface depicted in Figure 11C. Figure 11E illustrates a side view of a battery to which a battery terminal connector has been coupled. Figures 11F and 11G depict an inner surface of another example of a battery terminal connector configured to contact the battery terminals. Figure 11H and 11I depict an outer surface of the battery terminal connector opposite the surface depicted in Figure 11C.

[0071] FIGS. 12A-12G illustrate multi-perspective views of another example of an upper housing. Figure 12A depicts a partially exploded view of the upper housing. Figure 12B shows a perspective view of a flexible upper frame. Figure 12C shows a side view of the flexible upper frame. Figure 12D shows a top view of the flexible upper frame. Figure 12E depicts a perspective view of an inner surface of the upper housing. Figure 12F depicts a side view of the upper and lower housing. Figure 12G depicts a side view of a ridge configured for sealing the top and bottom portions of the housing.

[0072] FIGS. 13A-13B illustrate multi-perspective views of another example of a lower housing. Figure 13A depicts a perspective view of the lower housing and Figure 13B depicts a side view of the lower housing.

[0073] FIGS. 14A-14B illustrate orthogonal side views of an example of a wave spring.

[0074] FIGS. 15A-15I illustrate multiple views of another example of a physiological monitoring device. Figure 15A depicts a perspective view of the physiological monitoring device. Figure 15B depicts an exploded view of the physiological monitoring device. Figure 15C depicts a side view of the housing in which the upper housing has been removed. Figure 15D depicts a side view of the housing as shown in Figure 15C with flexible upper frame additionally being removed. Figure 15E depicts a side view of the housing as shown in Figure 15D with the lower housing additionally being removed. Figure 15F depicts a side view of the housing as shown in

Figure 15E with the battery and spring additionally being removed. Figure 15G depicts a sectional view of the housing as shown in Figure 15F with the section taken between the circuit board 120 and the spring contact spacer 632. Figure 15H depicts a sectional view of the housing as shown in Figure 15G with the spring contact spacer additionally being removed. Figure 15I depicts a side view of the housing as shown in Figure 15H additionally including the circuit board.

[0075] FIGS. 16A-16D illustrate multiple views of embodiments of a physiological monitoring device. FIG. 16A shows a top perspective view, FIG. 16B shows a bottom view, FIG. 16C shows a top perspective view including liners, FIG. 16D shows a bottom view including liners.

[0076] FIGS. 17A and 17B schematically illustrate cross-sectional views of two examples of an abrader. FIG. 17A depicts an abrader comprising a compressible spring. FIG. 17B depicts an abrader comprising a compressible foam.

[0077] FIG. 18 illustrates a schematic diagram of an embodiment of a cardiac rhythm inference service.

[0078] FIG. 19 is a schematic diagram of an embodiment of a system for extracting and transmitting data features from a physiological monitor.

Detailed Description Of Embodiments Of The Invention

[0079] The following description is directed to a number of various embodiments. The described embodiments, however, may be implemented and/or varied in many different ways. For example, the described embodiments may be implemented in any suitable device, apparatus, or system to monitor any of a number of physiological parameters. For example, the following discussion focuses primarily on long-term, patch-based cardiac rhythm monitoring devices. In one alternative embodiment, a physiological monitoring device may be used, for example, for pulse oximetry and diagnosis of obstructive sleep apnea. The method of using a physiological monitoring device may also vary. In some cases, a device may be worn for one week or less, while in other cases, a device may be worn for at least seven days and/or for more than seven days, for example between fourteen days and twenty-one days or even longer.

[0080] Many other alternative embodiments and applications of the described technology are possible. Thus, the following description is provided for exemplary purposes only. Throughout the specification, reference may be made to the term “conformal.” It will be

understood by one of skill in the art that the term “conformal” as used herein refers to a relationship between surfaces or structures where a first surface or structure adapts to the contours of a second surface or structure.

[0081] Since abnormal heart rhythms or arrhythmias can often be due to other, less serious causes, a key challenge is to determine when any of these symptoms are due to an arrhythmia. Oftentimes, arrhythmias occur infrequently and/or episodically, making rapid and reliable diagnosis difficult. As mentioned above, currently, cardiac rhythm monitoring is primarily accomplished through the use of devices, such as Holter monitors, that use short-duration (less than 1 day) electrodes affixed to the chest. Wires connect the electrodes to a recording device, usually worn on a belt. The electrodes need daily changing and the wires are cumbersome. The devices also have limited memory and recording time. Wearing the device interferes with patient movement and often precludes performing certain activities while being monitored, such as bathing.

[0082] Further, Holter monitors are capital equipment with limited availability, a situation that often leads to supply constraints and corresponding testing delays. These limitations severely hinder the diagnostic usefulness of the device, the compliance of patients using the device, and the likelihood of capturing all important information. Lack of compliance and the shortcomings of the devices often lead to the need for additional devices, follow-on monitoring, or other tests to make a correct diagnosis.

[0083] Current methods to correlate symptoms with the occurrence of arrhythmias, including the use of cardiac rhythm monitoring devices, such as Holter monitors and cardiac event recorders, are often not sufficient to allow an accurate diagnosis to be made. In fact, Holter monitors have been shown to not lead to a diagnosis up to 90% of the time ("Assessment of the Diagnostic Value of 24-Hour Ambulatory Electrocardiographic Monitoring", by DE Ward et al. Biotelemetry Patient Monitoring, vol. 7, published in 1980).

[0084] Additionally, the medical treatment process to actually obtain a cardiac rhythm monitoring device and initiate monitoring is typically very complicated. There are usually numerous steps involved in ordering, tracking, monitoring, retrieving, and analyzing the data from such a monitoring device. In most cases, cardiac monitoring devices used today are ordered by a cardiologist or a cardiac electrophysiologist (EP), rather than the patient's primary care physician (PCP). This is of significance since the PCP is often the first physician to see the patient and

determine that the patient's symptoms could be due to an arrhythmia. After the patient sees the PCP, the PCP will make an appointment for the patient to see a cardiologist or an EP. This appointment is usually several weeks from the initial visit with the PCP, which in itself leads to a delay in making a potential diagnosis as well as increases the likelihood that an arrhythmia episode will occur and go undiagnosed. When the patient finally sees the cardiologist or EP, a cardiac rhythm monitoring device will usually be ordered. The monitoring period can last 24 to 48 hours (Holter monitor) or up to a month (cardiac event monitor or mobile telemetry device). Once the monitoring has been completed, the patient typically must return the device to the clinic, which itself can be an inconvenience. After the data has been processed by the monitoring company or by a technician on-site at a hospital or office, a report will finally be sent to the cardiologist or EP for analysis. This complex process results in fewer patients receiving cardiac rhythm monitoring than would ideally receive it.

[0085] To address some of these issues with cardiac monitoring, the assignee of the present application developed various embodiments of a small, long-term, wearable, physiological monitoring device. One embodiment of the device is the Zio® Patch. Various embodiments are also described, for example, in U.S. Patent Numbers 8,150,502, 8,160,682 8,244,335, 8,560,046, and 8,538,503, the full disclosures of which are hereby incorporated herein by reference. Generally, the physiological patch-based monitors described in the above references fit comfortably on a patient's chest and are designed to be worn for at least one week and typically two to three weeks. The monitors detect and record cardiac rhythm signal data continuously while the device is worn, and this cardiac rhythm data is then available for processing and analysis.

[0086] These smaller, long-term, patch-based physiological monitoring devices provide many advantages over prior art devices. At the same time, further improvements are desired. One of the most meaningful areas for improvement is to offer more timely notice of critical arrhythmias to managing clinicians. The hallmark of these initial embodiments was that – for reasons of performance, compliance and cost – the device only recorded information during the extended wear period, with analysis and reporting occurring after the recording completed. Thus, a desirable improvement would be to add the capability of either real-time or timely analysis of the collected rhythm information. While diagnostic monitors with such timely reporting capabilities currently exist, they require one or more electrical components of the system to be either regularly recharged or replaced. These actions are associated with reduced patient

compliance and, in turn, reduced diagnostic yield. As such, a key area of improvement is to develop a physiologic monitor that can combine long-term recording with timely reporting without requiring battery recharging or replacement.

[0087] Patient compliance and device adhesion performance are two factors that govern the duration of the ECG record and consequently the diagnostic yield. Compliance can be increased by improving the patient's wear experience, which is affected by wear comfort, device appearance, and the extent to which the device impedes the normal activities of daily living. Given that longer ECG records provide greater diagnostic yield and hence value, improvements to device adhesion and patient compliance are desirable.

[0088] Signal quality is important throughout the duration of wear, but may be more important where the patient marks the record, indicating an area of symptomatic clinical significance. Marking the record is most easily enabled through a trigger located on the external surface of the device. However, since the trigger may be part of a skin-contacting platform with integrated electrodes, the patient can introduce significant motion artifacts when feeling for the trigger. A desirable device improvement would be a symptom trigger that can be activated with minimal addition of motion artifact.

[0089] Further, it is desirable for the device to be simple and cost effective to manufacture, enabling scalability at manufacturing as well as higher quality due to repeatability in process. Simplicity of manufacture can also lead to ease of disassembly, which enables the efficient recovery of the printed circuit board for quality-controlled reuse in another device. Efficient reuse of this expensive component can be important for decreasing the cost of the diagnostic monitor.

[0090] There remain clinical scenarios where still longer-duration and lower-cost solutions may be a valuable addition to a portfolio of cardiac ambulatory monitoring options. Inspiration for a potential solution to these needs can be found in the continuous heart rate sensing functionality that is increasingly being incorporated in a variety of consumer health and fitness products, including smart watches and wearable fitness bands. Although continuous heart rate data can be used to provide the user with information about their general fitness levels, it is more both more challenging and valuable to use this data to provide meaningful information related to their health and wellness. For example, the ability to detect potential arrhythmias from continuous heart rate data would enable consumer devices incorporating heart rate sensing functionality to serve as

potential screening tools for the early detection of cardiac abnormalities. Such an approach could be clinically valuable in providing a long-term, cost-effective screening method for at-risk populations, for example, heart failure patients at risk for Atrial Fibrillation. Alternatively, this monitoring approach could be helpful in the long-term titration of therapeutic drug dosages to ensure efficaciousness while reducing side effects, for example, in the management of Paroxysmal Atrial Fibrillation. Beyond cardiac arrhythmia detection, the appropriate analysis of heart rate information could also yield insight into sleep and stress applications.

[0091] Long-term ambulatory monitoring with a physiologic device, such as an adhesive patch, has a number of clinical applications, particularly when timely information about the occurrence and duration of observed arrhythmias can be provided during the monitoring period. In terms of prevalence, particularly as driven by an aging population, efficiently detecting Atrial Fibrillation (AF) remains the most significant monitoring need. This need is not just evident for patients presenting with symptoms, but also – given the increased risk of stroke associated with this arrhythmia – for broader, population-based monitoring of asymptomatic AF in individuals at risk due to one or more factors of advanced age, the presence of chronic illnesses like Heart Disease, or even the occurrence of surgical procedures. For the latter group, both perioperative and post-procedure monitoring can be clinically valuable, and not just for procedures targeted at arrhythmia prevention (for example, the MAZE ablation procedure, or hybrid endo and epicardial procedures, both for treatment of AF), but also for general surgeries involving anesthesia. For some applications, the goal of ambulatory monitoring for Atrial Fibrillation will sometimes be focused on the simple binary question of yes or no – did AF occur in a given time period. For example, monitoring a patient following an ablation procedure will typically seek to confirm success, typically defined as the complete lack of AF occurrence. Likewise, monitoring a patient post-stroke will be primarily concerned with evaluating the presence of Atrial Fibrillation.

[0092] However, even in those scenarios, if AF occurs, it may be clinically meaningful to evaluate additional aspects to better characterize the occurrence, such as daily burden (% of time in AF each day), and duration of episodes (expressed, for example, as a histogram of episode duration, or as the percentage of episodes that extend beyond a specified limit, say six minutes), both either in absolute terms or in comparison to prior benchmarks (for example, from a baseline, pre-procedure monitoring result). Indeed, measuring daily AF burden, evaluating AF episode duration, and reviewing AF occurrence during sleep and waking periods, and evaluating the

presence of AF in response to the degree of a patient's physical movement can be important in a variety of clinical scenarios, including evaluating the effectiveness of drug-based treatment for this arrhythmia.

[0093] Making this information available in a timely manner during the monitoring period could allow the managing physician to iteratively titrate treatment, for example, by adjusting the dosage and frequency of a novel oral anticoagulant drug (NOAC) until management was optimized. A further example of this management paradigm is for the patient to be notified of asymptomatic AF – either directly by the device through audible or vibration-based alert, through notification from an application connected to the device, or via phone, email or text-message communication from the managing clinician – for the timely application of a “pill in the pocket” for AF management.

[0094] The theme of timely management and/or intervention is certainly evident in situations where clinically significant arrhythmias are observed, for example, asymptomatic second-degree and complete Heart Block, extended pauses, high-rate supraventricular tachycardias, prolonged ventricular tachycardias, and ventricular fibrillation. For example, the clinical scenario where an extended pause or complete heart block causes Syncope is a particularly significant case where the availability of a timely and dependable monitoring method could reduce or even eliminate the need for in-hospital monitoring of at-risk patients. The theme can also extend to more subtle changes in morphology, for example, QT prolongation in response to medications, which has been shown to have significant cardiac safety implications. Timely awareness of such prolongation could lead, for example, to early termination of clinical studies evaluating drug safety and effectiveness or, alternatively, to adjusting the dosage or frequency as a means to eliminate observed prolongation.

Physiological Monitoring Devices

[0095] Referring to Figures 1A and 1B, perspective and exploded profile views of one embodiment of a physiological monitoring device 100 are provided. As seen in Figure 1A, physiological monitoring device 100 may include a flexible body 110 coupled with a watertight, housing 115. As will be understood by one of skill in the art, the housing as described herein and throughout this specification, may be constructed from rigid or flexible materials, thereby rendering the housing rigid, such as to resist deformation or soft such as to flex and/or deform with

force. Flexible body 110 (which may be referred to as “flexible substrate” or “flexible construct”) typically includes two wings 130, 131, which extend laterally from housing 115, and two flexible electrode traces 311, 312, each of which is embedded in one of wings 130, 131. Each electrode trace 311, 312 is coupled, on the bottom surface of flexible body 110, with a flexible electrode (not visible in Figure 1A). The electrodes are configured to sense heart rhythm signals from a patient to which monitoring device 100 is attached. Electrode traces 311, 312 then transmit those signals to electronics (not visible in Figure 1A) housed in housing 115. Housing 115 also typically contains a power source, such as one or more batteries.

[0096] The combination of a highly flexible body 110, including flexible electrodes and electrode traces 311, 312, with a very housing 115 may provide a number of advantages. A key advantage is high fidelity signal capture. The highly conformal and flexible wings 130, 131, electrodes and traces 311, 312 limit the transmission of external energy to the electrode-skin interface. If motion is imparted to the housing 115, for example, the system of conformal adhesion to the skin limits the extent to which that motion affects the monitored signal. Flexible electrode traces 311, 312 generally may help provide conformal contact with the subject’s skin and may help prevent electrodes 350 (electrodes 350 are not visible in Figure 1, but are visible in Figure 6A described below) from peeling or lifting off of the skin, thereby providing strong motion artifact rejection and better signal quality by minimizing transfer of stress to electrodes 350. Furthermore, flexible body 110 includes a configuration and various features that facilitate comfortable wearing of device 100 by a patient for fourteen (14) days or more without removal. Housing 115, which typically does not adhere to the patient in the embodiments described herein, includes features that lend to the comfort of device 100. Hinge portions 132 are relatively thin, even more flexible portions of flexible body 110. They allow flexible body 110 to flex freely at the area where it is joined to housing 115. This flexibility enhances comfort, since when the patient moves, housing 115 can freely lift off of the patient’s skin. Electrode traces 311, 312 are also very thin and flexible, to allow for patient movement without signal distortion.

[0097] Referring now to Figure 1B, a partially exploded view of physiological monitoring device 100 illustrates component parts that make up, and that are contained within, housing 115 in greater detail. In this embodiment, housing 115 includes an upper housing member 140, which detachably couples with a lower housing member 145. Sandwiched between upper housing member 140 and lower housing member 145 are an upper gasket 370, and a lower gasket

360 (not visible on Figure 1B but just below upper gasket 370). Gaskets 370, 360 help make housing member and/or body 115 watertight when assembled. A number of components of monitoring device 100 may be housed between upper housing member 140 and lower housing member 145. For example, in one embodiment, housing 115 may contain a portion of flexible body 110, a printed circuit board assembly (PCBA) 120, a battery holder 150, and two batteries 160. Printed circuit board assembly 120 is positioned within housing 115 to contact electrode traces 311, 312 and batteries 160. In various embodiments, one or more additional components may be contained within or attached to housing 115. Some of these optional components are described further below, in reference to additional drawing figures.

[0098] Battery holder 150, according to various alternative embodiments, may hold two batteries (as in the illustrated embodiment), one battery, or more than two batteries. In other alternative embodiments, other power sources may be used. In the embodiment shown, battery holder 150 includes multiple retain tabs and/or protrusions 153 for holding batteries 160 in holder 150. Additionally, battery holder 150 includes multiple feet and/or protrusions 152 to establish correct spacing of batteries 160 from the surface of PCBA 120 and ensure proper contact with spring fingers and/or contacts 235 and 236. Spring fingers 235 and 236 are used in this embodiment rather than soldering batteries 160 to PCBA 120. Although soldering may be used in alternative embodiments, one advantage of spring fingers 235 and 236 is that they allow batteries 160 to be removed from PCBA 120 and holder 150 without damaging either of those components, thus allowing for multiple reuses of both. Eliminating solder connections also simplifies and speeds up assembly and disassembly of monitoring device 100.

[0099] In some embodiments, upper housing member 140 may act as a patient event trigger. When a patient is wearing physiological monitoring device 100 for cardiac rhythm monitoring, it is typically advantageous for the patient to be able to register with device 100 (for example, log into the device's memory) any cardiac events perceived by the patient. If the patient feels what he/she believes to be an episode of heart arrhythmia, for example, the patient may somehow trigger device 100 and thus provide a record of the perceived event. In some embodiments, trigger of perceived events by the patient may initiate transmission of data associated with the triggered event. In some embodiments, trigger of perceived events may simply mark a continuous record with the location of the triggered event. In some embodiments, both transmission of associated data as well as marking of the continuous record may occur. At some

later time, the patient's recorded symptom during the perceived event could be compared with the patient's actual heart rhythm, recorded by device 100, and this may help determine whether the patient's perceived events correlate with actual cardiac events. One problem with patient event triggers in currently available wearable cardiac rhythm monitoring devices, however, is that a small trigger may be hard to find and/or activate, especially since the monitoring device is typically worn under clothing. Additionally, pressing a trigger button may affect the electronics and/or the electrodes on the device in such a way that the recorded heart rhythm signal at that moment is altered simply by the motion caused to the device by the patient triggering. For example, pressing a trigger may jar one or both of the electrodes in such a way that the recorded heart rhythm signal at that moment appears like an arrhythmia, even if no actual arrhythmia event occurred. Additionally, there is a chance that the trigger may be inadvertently activated, for instance while sleeping or laying on the monitoring device.

[0100] In the embodiment shown in Figures 1A and 1B, however, housing 115 is sufficiently rigid, and flexible body 110 is sufficiently flexible, that motion applied to housing 115 by a patient may rarely or ever cause an aberrant signal to be sensed by the electrodes. In this embodiment, the central portion of upper housing member 140 is slightly concave and, when pressed by a patient who is wearing device 100, this central portion depresses slightly to trigger a trigger input on PCBA 120. Because the entire upper surface of housing 115 acts as the patient event trigger, combined with the fact that it is slightly concave, it will generally be quite easy for a patient to find and push down the trigger, even under clothing. Additionally, the concave nature of the button allows it to be recessed which protects it from inadvertent activations. Thus, the present embodiment may alleviate some of the problems encountered with patient event triggers on currently available heart rhythm monitors. These and other aspects of the features shown in Figures 1A and 1B will be described in further detail below.

[0101] Referring now to the embodiments in Figures 2A and 2B, printed circuit board assembly 120 (or PCBA) may include a top surface 220, a bottom surface 230, a patient trigger input 210 and spring contacts 235, 236, and 237. Printed circuit board assembly 120 may be used to mechanically support and electrically connect electronic components using conductive pathways, tracks or electrode traces 311, 312. Furthermore, because of the sensitive nature of PCBA 120 and the requirement to mechanically interface with rigid body 115, it is beneficial to have PCBA 120 be substantially rigid enough to prevent unwanted deflections which may

introduce noise or artifact into the ECG signal. This is especially possible during patient trigger activations when a force is transmitted through rigid body 115 and into PCBA 120. One way to ensure rigidity of the PCBA is in some embodiments, to ensure that the thickness of the PCBA is relatively above a certain value. For example, a thickness of at least about 0.08 cm is desirable and, more preferably, a thickness of at least about 0.17 cm is desirable. In this application, PCBA 120 may also be referred to as, or substituted with, a printed circuit board (PCB), printed wiring board (PWB), etched wiring board, or printed circuit assembly (PCA). In some embodiments, a wire wrap or point-to-point construction may be used in addition to, or in place of, PCBA 120. PCBA 120 may include analog circuits and digital circuits.

[0102] Patient trigger input 210 may be configured to relay a signal from a patient trigger, such as upper housing member 140 described above, to PCBA 120. For example, patient trigger input 210 may be a PCB switch or button that is responsive to pressure from the patient trigger (for example, the upper surface of upper housing portion 140). In various embodiments, patient trigger input 210 may be a surface mounted switch, a tactile switch, an LED illuminated tactile switch, or the like. In some embodiments, patient trigger input 210 may also activate an indicator, such as an LED. Certain embodiments may involve a remotely located trigger such as on a separate device or as a smart phone app.

[0103] One important challenge in collecting heart rhythm signals from a human or animal subject with a small, two-electrode physiological monitoring device such as device 100 described herein, is that having only two electrodes can sometimes provide a limited perspective when trying to discriminate between artifact and clinically significant signals. For example, when a left-handed patient brushes her teeth while wearing a small, two-electrode physiological monitoring device on her left chest, the tooth brushing may often introduce motion artifact that causes a recorded signal to appear very similar to Ventricular Tachycardia, a serious heart arrhythmia. Adding additional leads (and, hence, vectors) is the traditional approach toward mitigating this concern, but this is typically done by adding extra wires adhered to the patient's chest in various locations, such as with a Holter monitor. This approach is not consistent with a small, wearable, long term monitor such as physiological monitoring device 100.

[0104] An alternate approach to the problem described above is to provide one or more additional data channels to aid signal discrimination. In some embodiments, for example, device 100 may include a data channel for detecting patch motion. In certain embodiments, an

accelerometer or other suitable device may provide patch motion by simply analyzing the change in magnitude of a single axis measurement, or alternatively of the combination of all three axes. The accelerometer may record device motion at a sufficient sampling rate to allow algorithmic comparison of its frequency spectrum with that of the recorded ECG signal. If there is a match between the motion and recorded signal, it is clear that the device recording in that time period is not from a clinical (for example, cardiac) source, and thus that portion of the signal can be confidently marked as artifact. This technique may be particularly useful in the tooth brushing motion example aforementioned, where the rapid frequency of motion as well as the high amplitude artifact is similar to the heart rate and morphology, respectively, of a potentially life-threatening arrhythmia like Ventricular Tachycardia. Other suitable devices described herein this section and elsewhere in the specification may also be utilized to provide motion information.

[0105] In some embodiments, using the magnitude of all three axes for such an analysis would smooth out any sudden changes in values due to a shift in position rather than a change in activity. In other embodiments, there may be some advantage in using a specific axis of measurement such as along the longitudinal axis of the body to focus on a specific type of artifact introduced by upward and downward movements associated with walking or running. In a similar vein, the use of a gyroscope in conjunction with the accelerometer may provide further resolution as to the nature of the motion experienced. While whole body movements may be sufficiently analyzed with an accelerometer on its own, specific motion of interest such as rotational motion due to arm movement is sufficiently complex that an accelerometer alone might not be able to distinguish.

[0106] In addition to detecting motion artifact, an accelerometer tuned to the dynamic range of human physical activities may provide activity levels of the patient during the recording, which can also enhance accuracy of algorithmic true arrhythmia detection. Given the single-lead limitation of device 100, arrhythmias that require observation of less prominent waves (for example P-wave) in addition to rate changes such as Supraventricular Tachycardia pose challenges to both computerized algorithms as well as the trained human eye. This particular arrhythmia is also characterized by the sudden nature of its onset, which may be more confidently discriminated from a non-pathological Sinus Tachycardia if a sudden surge in the patient's activity level is detected at the same time as the increase in heart rate. Broadly speaking, the provision of activity information to clinical professionals may help them discriminate between exercise-induced

arrhythmia versus not. As with motion artifact detection, a single-axis accelerometer measurement optimized to a particular orientation may aid in more specifically determining the activity type such as walking or running. This additional information may help explain symptoms more specifically and thereby affect the subsequent course of therapeutic action.

[0107] In certain embodiments, an accelerometer with 3 axes may confer advantages beyond what magnitude of motions can provide. When the subject is not rapidly moving, 3-dimensional accelerometer readings may approximate the tilt of PCBA 120, and therefore body orientation relative to its original orientation. The original body orientation can be assumed to be in either an upright or supine position which is required for appropriate positioning and application of the device to the body. This information may aid in ruling out certain cardiac conditions that manifest as beat-to-beat morphology changes, such as cardiac alternans where periodic amplitude changes are observed, often in heart failure cases. Similar beat-to-beat morphology changes are observable in healthy subjects upon shift in body position due to the shift in heart position relative to the electrode vector, for example from an upright to a slouching position. By design, the single-channel device 100 does not have an alternate ECG channel to easily rule out potential pathological shifts in morphology, however, correlation with shifts in body orientation will help explain these normal changes and avoid unnecessary treatment due to false diagnosis.

[0108] In other embodiments, the accelerometer may also be used as a sleep indicator, based on body orientation and movement. When presenting clinical events (for example, pauses), it is diagnostically helpful to be able to present information in a manner that clearly separates events that occurred during sleep from those during waking hours. In fact, certain algorithms such as for ECG-derived respiratory rate only make sense to run when the patient is in a relatively motionless state and therefore subtle signal modulation introduced by chest movement due to breathing is observable. Respiratory rate information is useful as one channel of information necessary to detect sleep apnea in certain patient populations.

[0109] In certain embodiments, the accelerometer may also be used to detect free-falls, such as fainting. With an accelerometer, device 100 may be able to mark fainting (syncope) and other free-fall events without relying on patient trigger. In some embodiments, such free-fall event triggers may initiate transmission of associated data. In order to allow timely detection of such critical events, yet considering the battery and memory limitations of a small, wearable device such as device 100, acquisition of accelerometer readings may be done in bursts, where only

interesting information such as a potential free fall is written to memory at a high sampling rate. An expansion of this event-trigger concept is to use specific tapping motions on device 100 as a patient trigger instead of or in conjunction with the button previously described. The use and detection of multiple types of tapping sequences may provide better resolution and accuracy into what exactly the patient was feeling, instead of relying on the patient to manually record their symptom and duration in a trigger log after the fact. An example of such added resolution is to indicate the severity of the symptom by the number of sequential taps.

[0110] Alternatively, in other embodiments, optical sensors may be used to distinguish between device motion and patient body motion. Further, in additional embodiments, the device may not require a button or trigger. In still more embodiments, suitable devices described herein this section or elsewhere in the specification may also be used.

[0111] Another optional data channel that may be added to physiological monitoring device 100 is a channel for detecting flex and/or bend of device 100. In various embodiments, for example, device 100 may include a strain gauge, piezoelectric sensor or optical sensor to detect motion artifact in device 100 itself and thus help to distinguish between motion artifact and cardiac rhythm data. Yet another optional data channel for device 100 may be a channel for detecting heart rate. For example, a pulse oximeter, microphone or stethoscope may provide heart rate information. Redundant heart rate data may facilitate discrimination of ECG signals from artifact. This is particularly useful in cases where arrhythmia such as Supraventricular Tachycardia is interrupted by artifact, and decisions must be made whether the episode was actually multiple shorter episodes or one sustained episode. Another data channel may be included for detecting ambient electrical noise. For example, device 100 may include an antenna for picking up electromagnetic interference. Detection of electromagnetic interference may facilitate discrimination of electrical noise from real ECG signals. Any of the above-described data channels may be stored to support future noise discrimination or applied for immediate determination of clinical validity in real-time.

[0112] With reference now to the embodiments of Figures 3A and 3B, flexible body 110 is shown in greater detail. As illustrated in Figure 3A, flexible body 110 may include wings 130, 131, a thin border 133 (or “rim” or “edge”) around at least part of each wing 130, 131, electrode traces 311, 312, and a hinge portion 132 (or “shoulder”) at or near a junction of each wing 130, 131 with housing 115. Also shown in Figure 3A is upper gasket 370, which is not

considered part of flexible body 110 for this description, but which facilitates attachment of flexible body 110 to housing 115.

[0113] Hinge portions 132 are relatively thin, even more flexible portions of flexible body 110. They allow flexible body 110 to flex freely at the area where it is joined to housing 115. This flexibility enhances comfort, since when the patient moves, housing 115 can freely lift off of the patient's skin. Electrode traces 311, 312 are also very thin and flexible, to allow for patient movement without signal distortion. Borders 133 are portions of flexible body 110 that is thinner than immediately adjacent portions and that provide for a smooth transition from flexible body 110 to a patient's skin, thus preventing edge-lift and penetration of dirt or debris below flexible body 110.

[0114] As shown in greater detail in Figure 3B, flexible body 110 may include multiple layers. As mentioned previously, in some embodiments, upper gasket 370 and lower gasket 360 are not considered part of flexible body 110 for the purposes of this description but are shown for completeness of description. This distinction is for ease of description only, however, and should not be interpreted to limit the scope of the described embodiments. Flexible body 110 may include a top substrate layer 300, a bottom substrate layer 330, an adhesive layer 340, and flexible electrodes 350. Top and bottom substrate layers 300, 330 may be made of any suitable, flexible material, such as one or more flexible polymers. Suitable flexible polymers can include, but are not limited to, polyurethane, polyethylene, polyester, polypropylene, nylon, teflon and carbon impregnated vinyl. The material of substrate layers 300, 330 may be selected based on desired characteristics. For example, the material of substrate layers 300, 330 may be selected for flexibility, resilience, durability, breathability, moisture transpiration, adhesion and/or the like. In one embodiment, for example, top substrate layer 300 may be made of polyurethane, and bottom substrate layer 330 may be made of polyethylene or alternatively polyester. In other embodiments, substrate layers 300, 330 may be made of the same material. In yet another embodiment, substrate layer 330 may contain a plurality of perforations in the area over adhesive layer 340 to provide for even more breathability and moisture transpiration. In various embodiments, physiological monitoring device 100 may be worn continuously by a patient for as many as 14-21 days or more, without removal during the time of wear and with device 100 being worn during showering, exercising and the like. Thus, the material(s) used and the thickness and configuration of substrate layers 300, 330 affect the function of physiological monitoring device 100. In some embodiments,

the material of substrate layers 300, 330 acts as an electric static discharge (ESD) barrier to prevent arcing.

[0115] Typically, top and bottom substrate layers 300, 330 are attached to one another via adhesive placed on one or both layers 300, 330. For example, the adhesive or bonding substance between substrate layers 300, 330 may be an acrylic-based, rubber-based, or silicone-based adhesive. In other alternative embodiments, flexible body 110 may include more than two layers of flexible material.

[0116] In addition to the choice of material(s), the dimensions, such as thickness, length and width, of substrate layers 300, 330 may be selected based on desired characteristics of flexible body 110. For example, in various embodiments, the thickness of substrate layers 300, 330 may be selected to give flexible body 110 an overall thickness of between about 0.1 mm to about 1.0 mm. According to various embodiments, flexible body 110 may also have a length of between about 7 cm and 15 cm and a width of about 3 cm and about 6 cm. Generally, flexible body 110 will have a length sufficient to provide a necessary amount of separation between electrodes 350. For example, in one embodiment a distance from the center of one electrode 350 to the center of the other electrode 350 should be at least about 6.0 cm and more preferably at least about 8.5 cm. This separation distance may vary, depending on the application. In some embodiments, substrate layers 300, 330 may all have the same thickness. Alternatively, the two substrate layers 300, 330 may have different thicknesses.

[0117] As mentioned above, hinge portions 132 allow the rigid body 115 to lift away from the patient while flexible body 110 remains adhered to the skin. The functionality of hinge portions 132 is critical in allowing the device to remain adhered to the patient throughout various activities that may stretch and compress the skin. Furthermore, hinge portions 132 allow for significantly improved comfort while wearing the device. Generally, hinge portions 132 will be sufficiently wide enough to provide adequate lift of rigid body 115 without creating too large of a peel force on flexible body 110. For example, in various embodiments, the width of hinge portion 132 should be at least about 0.25 cm and more preferably at least about 0.75 cm.

[0118] Additionally, the shape or footprint of flexible body 110 may be selected based on desired characteristics. As seen in Figure 3A, wings 130, 131 and borders 133 may have rounded edges that give flexible body 110 an overall “peanut” shape. However, wings 130, 131 can be formed in any number of different shapes such as rectangles, ovals, loops, or strips. In the

embodiment shown in Figures 3A and 3B, the footprint top substrate layer 300 is larger than the footprint of bottom substrate layer 330, with the extension of top substrate layer 300 forming borders 133. Thus, borders 133 are made of the same polyurethane material that top layer 300 is made of. Borders 133 are thinner than an adjacent portion of each wing 130, 131, since they include only top layer 300. The thinner, highly compliant rim and/or border 133 will likely enhance adherence of physiologic monitoring device 100 to a patient, as it provides a transition from an adjacent, slightly thicker portion of wings 130, 131 to the patient's skin and thus helps prevent the edge of device 100 from peeling up off the skin. Border 133 may also help prevent the collection of dirt and other debris under flexible body 110, which may help promote adherence to the skin and also enhance the aesthetics of device 100. In alternative embodiments, the footprint of substrate layers 300, 330 may be the same, thus eliminating borders 133.

[0119] While the illustrated embodiments of Figures 1A-3B include only two wings 130, 131, which extend from housing 115 in approximately opposite directions (for example, at a 180-degree angle relative to each other), other configurations are possible in alternative embodiments. For example, in some embodiments, wings 130, 131 may be arranged in an asymmetrical orientation relative to one another and/or one or more additional wings may be included. As long as sufficient electrode spacing is provided to permit physiological signal monitoring, and as long as wings 130, 131 are configured to provide extended attachment to the skin, any suitable configuration and number of wings 130, 131 and electrode traces 311, 312 may be used. The embodiments described above have proven to be advantageous for adherence, patient comfort and accuracy of collected heart rhythm data, but in alternative embodiments it may be possible to implement alternative configurations.

[0120] Adhesive layer 340 is an adhesive that is applied to two portions of the bottom surface of bottom substrate layer 330, each portion corresponding to one of wings 130, 131. Adhesive layer 340 thus does not extend along the portion of bottom substrate layer 330 upon which housing 115 is mounted. Adhesive layer 340 may be made of any suitable adhesive, although certain adhesives have been found to be advantageous for providing long term adhesion to patient skin with relative comfort and lack of skin irritation. For example, in one embodiment, adhesive layer 340 is a hydrocolloid adhesive. In another embodiment, the adhesive layer 340 is comprised of a hydrocolloid adhesive that contains naturally-derived or synthetic absorbent materials which take up moisture from the skin during perspiration.

[0121] With reference now to Figure 3B, each of the two portions of adhesive layer 340 includes a hole, into which one of electrodes 350 fits. Electrodes 350 are made of flexible material to further provide for overall conformability of flexible body 110. In one embodiment, for example, flexible electrodes 350 may be made of a hydrogel electrode 350. Electrodes 350 generally provide conformal, non-irritating contact with the skin to provide enhanced electrical connection with the skin and reduce motion artifact. In some embodiments, hydrogel electrodes 350 may be punched into adhesive layer 340, thus forming the holes and filling them with hydrogel electrodes 350. In one alternative embodiment, electrodes 350 and adhesive 340 may be replaced with an adhesive layer made of a conductive material, such that the entire adhesive layer on the underside of each wing 130, 131 acts as an electrode. Such an adhesive layer may include a hybrid adhesive/conductive substance or adhesive substance mixed with conductive elements or particles. For example, in one embodiment, such an adhesive layer may be a hybrid of a hydrogel and a hydrocolloid adhesive. Housing 115 of Figure 1A also protects the electronics and power source contained in housing 115, enhances the ability of a patient to provide an input related to a perceived cardiac event, and allows for simple manufacturing and reusability of at least some of the contents of housing 115. These and other features of physiological monitoring device 100 are described in greater detail below.

[0122] As discussed above, in some embodiments, adhesive layer 340 may cover a portion of the underside of lower substrate layer 330, such that at least a portion of the bottom side of flexible body 110 does not include adhesive layer 340. As seen in Figure 3A, hinges 132 may be formed in the flexible body 110 as portions of each wing 130, 131 on which adhesive layer 340 is not applied. Hinge portions 132 are generally located at or near the junction of flexible body 110 with housing 115, and thus provide for flexing of device 100 to accommodate patient movement. In some embodiments, hinge portions 132 may have a width that is less than that of adjacent portions of wings 130, 131, thus giving device 100 its “peanut” shape mentioned above. As shown in Figure 8, as a subject moves, device 100 flexes along with patient movement. Device flexion may be severe and is likely to occur many times during long term monitoring. Hinge portions 132 may allow for dynamic conformability to the subject, while the rigidity of housing 115 may allow housing 115 to pop up off the patient’s skin during device flexion, thus preventing peeling of the device 100 off of the skin at its edge.

[0123] Flexible body 110 further includes two electrode traces 311, 312 sandwiched between upper substrate layer 300 and lower substrate layer 330. Each electrode trace 311, 312 may include an electrode interface portion 310 and an electrocardiogram circuit interface portion 313. As illustrated in the embodiments of Figures 3C and 3D, ECG circuit interface portions 313 are in physical contact with spring fingers 237 and provide electrical communication with PCBA 120 when device 100 or zoomed-in device portion 101 is assembled. Electrode interface portions 310 contact hydrogel electrodes 350. Thus, electrode traces 311, 312 transmit cardiac rhythm signals (and/or other physiological data in various embodiments) from electrodes 350 to PCBA 120.

[0124] The material and thickness of electrode traces 311, 312 are important for providing a desired combination of flexibility, durability and signal transmission. For example, in one embodiment, electrode traces 311, 312 may include a combination of silver (Ag) and silver chloride (AgCl). The silver and silver chloride may be disposed in layers. For example, one embodiment of electrode traces 311, 312 may include a top layer of silver, a middle layer of carbon impregnated vinyl, and a bottom (patient-facing) layer of silver chloride. In another embodiment, both top and bottom layers of electrode traces 311, 312 may be made of silver chloride. In one embodiment, the top and bottom layers may be applied to the middle layer in the form of silver ink and silver chloride ink, respectively. In an alternative embodiment, each electrode trace may include only two layers, such as a top layer of silver and a bottom layer of silver chloride. In various embodiments, the material of a bottom layer of each electrode trace 311, 312, such as AgCl, may be selected to match the chemistry of the hydrogel electrodes 350 and create a half-cell with the body of the subject.

[0125] The thickness of the electrode traces 311, 312 may be selected to optimize any of a number of desirable properties. For example, in some embodiments, at least one of the layers of electrode traces 311, 312 can be of a sufficient thickness to minimize or slow depletion of the material from an anode/cathode effect over time. Additionally, the thickness may be selected for a desired flexibility, durability and/or signal transmission quality.

[0126] As mentioned above, in some embodiments, top gasket 370 and bottom gasket 360 may be attached upper substrate 300 and lower substrate 330 of flexible body 110. Gaskets 360, 370 may be made of any suitable material, such as urethane, which provides a water tight seal between the upper housing member 140 and lower housing member 145 of housing 115. In one

embodiment, top gasket 370 and/or bottom gasket 360 may include an adhesive surface. Figure 3E depicts yet another embodiment where top gasket 370 includes tabs 371 that protrude away from the profile of top housing 140 while still being adhered to upper substrate 300. The tabs 371 cover a portion of electrode traces 311, 312 and provide a strain relief for the traces at the point of highest stress where the flexible body meets the housing.

[0127] With reference now to the embodiment of Figure 4, upper housing member 140 and lower housing member 145 of housing 115 are shown in greater detail. Upper and lower housing members 140, 145 may be configured, when coupled together with gaskets 360, 370 in between, to form a watertight enclosure for containing PCBA 120, battery holder 150, batteries 160 and any other components contained within housing 115. Housing members 140, 145 may be made of any suitable material to protect internal components, such as water resistant plastic. In one embodiment, upper housing member 140 may include a rigid sidewall and/or hook 440, a light pipe 410 to transmit visual information from the LEDs on the PCBA through the housing member, a slightly flexible top surface 420, and an inner trigger member 430 extending inward from top surface 420. Top surface 420 is configured to be depressed by a patient when the patient perceives what he or she believes to be an arrhythmia or other cardiac event. When depressed, top surface 420 depresses inner trigger member 430, which contacts and activates trigger input 210 of PCBA 120. Additionally, as discussed previously, top surface 420 may have a concave shape (concavity facing the inside of housing 115) to accommodate the shape of a finger. It is believed that the design of upper housing member 140 isolates activation of the trigger input 210 from electrodes 350, thereby minimizing artifact in the data recording.

[0128] With continued reference to Figure 4, lower housing member 145 may be configured to detachably connect with upper housing member 140 in such a way that housing members 140, 145 may be easily attached and detached for reusability of at least some of the component parts of monitoring device 100. In some embodiments, a bottom surface 445 (patient facing surface) of lower housing member 145 may include multiple dimples 450 (or “bumps,” “protrusions” or the like), which will contact the patient’s skin during use. Dimples 450 may allow for air flow between bottom surface 445 and the patient’s skin, thus preventing a seal from forming between bottom surface 445 and the skin. It is believed that dimples 450 improve comfort and help prevent a perception in currently available devices in which the patient feels as if monitoring device 100 is falling off when it housing 115 lifts off the skin and breaks a seal with the skin. In

yet another embodiment the bottom surface 445 of lower housing member 145 may include multiple divots (recesses instead of protrusions) to prevent a seal from forming.

[0129] Referring now to the embodiment of Figure 5A, battery holder 150 is shown in greater detail. Battery holder 150 may be made of plastic or other suitable material, is configured to be mounted to PCBA 120 and subsequently attached to housing 115, and is capable of holding two batteries 160 (Figure 1B). In alternative embodiments, battery holder 150 may be configured to hold one battery or more than two batteries. A plurality of protrusions 152 provide a stable platform for batteries 160 to be positioned a fixed distance above the surface of PCBA 120, avoiding unwanted contact with sensitive electronic components yet providing for adequate compression of spring contacts 235 (Figure 5B). Protrusions 153 lock batteries 160 into position and resist the upward force on the batteries from spring contacts 235. Battery holder 150 also positions batteries appropriately 160 to provide for adequate compression of spring contacts 236. Use of battery holder 150 in conjunction with spring contacts 235 and 236 allows for batteries 160 to be electrically connected to PCBA 120 while still having additional electronic components between batteries 160 and PCBA 120 and maintain a very compact assembly. Battery holder 150 may include a flexible hook 510 which engages a corresponding rigid hook 440 of upper housing member 140. Under normal assembly conditions the flexible hook 510 remains securely mated with rigid hook 440. For disassembly, flexible hook 510 can be pushed and bent using an appropriate tool passed through top housing 140 causing it to disengage from rigid hook 440 and subsequently allow top housing 140 to be removed.

[0130] With reference now to the embodiments of Figure 6A and 6B, physiological monitoring device 100 is shown in side view cross-section. As shown in 6A, physiological monitoring device 100 may include flexible body 110 coupled with housing 115. Flexible body 110 may include top substrate layer 300, bottom substrate layer 330, adhesive layer 340 and electrodes 350. Electrode traces 311, 312 are also typically part of flexible body 110 and are embedded between top substrate layer 300 and bottom substrate layer 330, but they are not shown in Figure 6. Flexible body 110 forms two wings 130, 131, extending to either side of housing 115, and a border 133 surrounding at least part of each wing 130, 131. Housing 115 may include an upper housing member 140 coupled with a lower housing member 145 such that it sandwiches a portion of flexible body 110 in between and provides a watertight, sealed compartment for PCBA 120. Upper housing member 140 may include inner trigger member 430, and PCBA may include

patient trigger member 210. As discussed previously, lower housing member 145 may include multiple dimples 450 or divots to enhance the comfort of the monitoring device 100.

[0131] It is desirable that PCBA 120 is sufficiently rigid to prevent bending and introducing unwanted artifact into the signal. In certain embodiments, an additional mechanism to reduce and prevent unwanted bending of PCBA 120 may be used. This mechanism is shown in Figure 6B. Support post 460 is integral to lower housing 145 and is positioned directly under patient trigger input 210. During patient symptom triggering, upper housing member 140 is depressed, engaging inner trigger mechanism 430 and transmitting a force through patient trigger input 210 into PCBA 120. The force is further transmitted through PCBA 120 and into support post 460 without creating a bending moment, thus avoiding unwanted artifact.

[0132] Referring to Figure 7, in some embodiments, physiological monitoring device 100 may include one or more additional, optional features. For example, in one embodiment, monitoring device 100 may include a removable liner 810, a top label 820, a device identifier 830 and a bottom label 840. Liner 810 may be applied over a top surface of flexible member and/or body 110 to aid in the application of device 100 to the subject. As is described in further detail below, liner 810 may help support borders 133 of flexible body 110, as well as wings 130, 131, during removal of one or more adhesive covers (not shown) that cover adhesive surface 340 before use. Liner 810 may be relative rigid and/or firm, to help support flexible body 110 during removal of adhesive covers. In various embodiments, for example, liner 810 may be made of cardboard, thick paper, plastic or the like. Liner 810 typically includes an adhesive on one side for adhering to the top surface of wings 130, 131 of flexible body 110.

[0133] Labels 820, 840 may be any suitable labels and may include produce name(s), manufacturer name(s), logo(s), design(s) and/or the like. They may be removable or permanently attached upper housing member 140 and/or lower housing member 145, although typically they will be permanently attached, to avoid unregulated reuse and/or resale of the device by an unregistered user. Device identifier 830 may be a barcode sticker, computer readable chip, RFID, or the like. Device identifier 830 may be permanently or removably attached to PCBA 120, flexible body 110 or the like. In some embodiments, it may be beneficial to have device identifier 830 stay with PCBA 120.

[0134] Referring now to the embodiments of Figures 8A and 8B, physiological monitoring device 100 generally includes hinge portions 132 at or near the juncture of each wing

130, 131 with housing 115. Additionally, each wing 130, 131 is typically adhered to the patient via adhesive layers 340, while rigid body 115 is not adhered to the patient and is thus free to “float” (for example, move up and down) over the patient’s skin during movement and change of patient position. In other words, when the patient’s chest contracts, housing pops up or floats over the skin, thus minimizing stress on device 100, enhancing comfort, and reducing the tendency of wings 130, 131 to peel off of the skin. The advantage provided by the combination of the floating rigid body 115 and the adhered wings 130, 131 is illustrated in Figures 8A and 8B. In Figure 8A, a patient is sleeping, and in Figure 8B, a patient is playing golf. In both examples, monitoring device 100 is squeezed together by the patient’s body, causing housing 115 to float above the skin as wings 130, 131 move closer together. This advantage of a floating, non-attached portion of a physiological monitoring device is described in further detail in U.S. Patent 8,560,046, which was previously incorporated by reference.

[0135] Referring now to Figures 9A-9F, one embodiment of a method for applying physiological monitoring device 100 to the skin of a human subject is described. In this embodiment, before the first step shown in Figure 9A, the patient’s skin may be prepared, typically by shaving a small portion of the skin on the left chest where device 100 will be placed and then abrading and/or cleaning the shaved portion. As shown in Figure 9A, once the patient’s skin is prepared, a first step of applying device 100 may include removing one or both of two adhesive covers 600 from adhesive layers 340 on the bottom surface of device 100, thus exposing adhesive layers 340. As illustrated in Figure 9B, the next step may be to apply device 100 to the skin, such that adhesive layer 340 adheres to the skin in a desired location. In some embodiments, one adhesive cover 600 may be removed, the uncovered adhesive layer 340 may be applied to the skin, and then the second adhesive cover 600 may be removed, and the second adhesive layer 340 may be applied to the skin. Alternatively, both adhesive covers 600 may be removed before applying device 100 to the skin. While adhesive covers 600 are being removed, liner 810 acts as a support for flexible body 110, provides the physician or other user with something to hold onto, and prevents flexible body 110 and borders 133 of flexible body 110 from folding in on themselves, forming wrinkles, and so forth. As described above, liner 810 may be made of a relatively stiff, firm material to provide support for flexible body 110 during application of device 100 to the skin. Referring to Figure 9C, after device 100 has been applied to the skin, pressure may be applied to

flexible body 110 to press it down onto the chest to help ensure adherence of device 100 to the skin.

[0136] In a next step, referring to Figure 9D, liner 810 is removed from (for example, peeled off of) the top surface of flexible body 110. As shown in Figure 9E, once liner 810 is removed, pressure may again be applied to flexible body 110 to help ensure it is adhered to the skin. Finally, as shown in Figure 9F, upper housing member 140 may be pressed to turn on physiological monitoring device 100. This described method is only one embodiment. In alternative embodiments, one or more steps may be skipped and/or one or more additional steps may be added.

[0137] In certain embodiments, when a desired monitoring period has ended, such as about 14 to 21 days in some cases, a patient (or physician, nurse or the like) may remove physiological monitoring device 100 from the patient's skin, place device 100 in a prepaid mailing pouch, and mail device 100 to a data processing facility. At this facility, device 100 may be partially or completely disassembled, PCBA 120 may be removed, and stored physiological data, such as continuous heart rhythm information, may be downloaded from device 100. The data may then be analyzed by any suitable method and then provided to a physician in the form of a report. The physician may then discuss the report with the patient. PCBA 120 and/or other portions of device 100, such as housing 115, may be reused in the manufacture of subsequent devices for the same or other patients. Because device 100 is built up as a combination of several removably coupled parts, various parts may be reused for the same embodiment or different embodiments of device 100. For example, PCBA 120 may be used first in an adult cardiac rhythm monitor and then may be used a second time to construct a monitor for sleep apnea. The same PCBA 120 may additionally or alternatively be used with a differently sized flexible body 110 to construct a pediatric cardiac monitor. Thus, at least some of the component parts of device 100 may be interchangeable and reusable.

[0138] In further embodiments described in greater detail below, the monitoring data may be transmitted wirelessly or through other communication mediums to be analyzed, rather than requiring physical shipment of the device for analysis and reporting.

[0139] Advantageously, physiological monitoring device 100 may provide long term adhesion to the skin. The combination of the configuration of flexible and conformal body 110, the watertight, low profile configuration of housing 115, and the interface between the two allows

device 100 to compensate for stress caused as the skin of the subject stretches and bends. As a result, device 100 may be worn continuously, without removal, on a patient for as many as 14 to 21 days or more. In some cases, device 100 may be worn for greater or less time, but 14 to 21 days may often be a desirable amount of time for collecting heart rhythm data and/or other physiological signal data from a patient.

[0140] One or more of the various components of the physiological monitoring device 100 may be alternatively configured or substituted with embodiments of components disclosed elsewhere herein. For example, in some embodiments, the electrodes 350 and/or flexible body 110 may be configured to deliver one or more therapeutic drugs to the patient's skin, such as via a drug eluting adhesive or other suitable delivery systems. The one or more therapeutic agents may be configured to combat skin irritation, itchiness, and/or bacterial growth; may be configured to induce or block histamine release; and/or may comprise anesthetic qualities, any of which may improve patient compliance and/or prolong the duration of wear of the physiological monitoring device 100. The therapeutic agents may serve alternative or additional therapeutic purposes as well. In some embodiments, the therapeutic agents may be incorporated directly into the adhesive layer 340. For example, the therapeutic agents may be mixed into a hydrocolloid solution during fabrication of the adhesive layer 340. The therapeutic agents may be configured to elute from the adhesive layer 340 into contact with the patient's skin. The adhesive layer 340 can be configured to provide controlled release of the drug. For instance, the adhesive layer 340 may be configured to release the drug gradually and/or at a substantially constant rate over a period of time (e.g., over about: 1 week, 2 weeks, 3 weeks, 4 weeks, 5 weeks, 6 weeks, 7 weeks, 8 weeks, 9 weeks, 10 weeks, etc.). The adhesive layer 340 may comprise perforations and/or a microporous structure configured to facilitate diffusion of the one or more therapeutic agents through the thickness of the adhesive layer 340. In some embodiments, the therapeutic agents may be incorporated into one or more overlaying support layers of the flexible body 110, such as the top substrate layer 300 and/or the bottom substrate layer 330. The support layers of the flexible body 110 may comprise pockets or containers configured to store the one or more therapeutic agents. The pockets may be in fluid communication with the adhesive layer 340 through perforations formed in the substrate layer or through pores or channels formed in the substrate layers. In some embodiments, the one or more therapeutic agents may diffuse through the adhesive layer 340 to reach the skin. In some embodiments, the perforations in the substrate layers may extend through the adhesive layer 340

to the surface of the patient's skin. In some embodiments, the electrodes 350 or flexible body 110 may be configured to include antimicrobial agents to inhibit the growth of microorganisms. The agents may include coatings or embedded ingredients in the adhesive or electrode gel materials. These antimicrobial agents may be configured for release gradually and/or at a substantially constant rate over a period of time (e.g., over about: 1 day, 3 days, 5 days, 1 week, 2 weeks, 3 weeks, 4 weeks, 5 weeks, 6 weeks, 7 weeks, 8 weeks, 9 weeks, 10 weeks, 1 month, 3 months, 5 months, 1 year, 3 years, 5 years, etc.). The adhesive layer 340 may comprise perforations and/or a microporous structure configured to facilitate diffusion of the one or more therapeutic agents through the thickness of the adhesive layer 340. Alternately, the antimicrobial properties may be intrinsic to the structure of the adhesive, gels or any substrate or support layer. In other embodiments, the electrodes 350 or flexible body 110 may be configured to release deodorant or perfume components to limit odor arising from long-term wear. Similar to therapeutic and antimicrobial agents described above, the components could be configured to release over time and/or diffuse through the thickness of the adhesive or gel layers.

[0141] Figures 10A-10C schematically illustrate alternative examples of trace layer 609. The trace layer 609 may comprise an electrical trace 611, 612 for each electrode 350 (such as shown in Figure 3B) of the physiological monitoring device 100. The electrical traces 611, 612 may be disposed on (e.g., printed onto) a non-conductive insulating layer 613. In some embodiments, the insulating layer 613 may comprise a polyester, such as polyethylene terephthalate (PET) and/or another non-conductive polymer. One or more of the electrical traces 611, 612 may be disposed on the same insulating layer 613. The insulating layer 613 may be configured to maintain a separation between the electrical traces 611, 612 that are coupled to distinct electrodes 350. The electrical traces 611, 612 may extend from the electrodes 350 into the housing 115 to make electrical contact with the PCBA 120. In some embodiments, such as embodiments in which the physiological monitoring device 100 comprises two opposite wings 130, 131 arranged generally collinear with one another, the electrical traces 611, 612 may extend generally collinearly along a direction defining a longitudinal axis of the device. A transverse axis may be defined substantially perpendicular to the longitudinal axis. The longitudinal axis and/or the transverse axis may substantially bisect the housing 115 of the physiological monitoring device 100.

[0142] Each trace 611, 612 may extend from an electrode contact area configured to contact an electrode 350 along a connecting portion of the trace layer 609 to a housing area configured to be received within the housing 115 (e.g., between an upper housing 140 and a lower housing 145, such as shown above in Figure 7 and below in Figures 12-13B). The housing area of the trace layer 609 may have an area generally configured to match the perimeter of the upper housing 140 and lower housing 145 where the housings meet (or as described below in relation to the embodiments of Figures 12A-15I, such as 640 and 645). For instance, the trace layer 609 may comprise a generally circular housing area. The trace layer 609 may have a plurality of holes 616 extending between upper and lower surfaces of the trace layer 609. The holes 616 may allow mechanical elements (e.g., posts as described elsewhere herein) to pass through, such as mechanical elements which couple or mate the upper housing 140 and the lower housing 145. The holes 616 may be disposed generally along a perimeter of the housing area of the trace layer 609. The holes 616 may extend through only the insulating layer 613 and not the electrical traces 611, 612. At least some of the holes 616 may be configured in dimension to substantially match the size of one or more mechanical mating elements (e.g., posts) such that passage of the one or more mechanical mating elements through the holes 616 may help stabilize the orientation of the trace layer 609 and/or may help secure the trace layer 609 to the housing 115. The housing area of the trace layer 609 may comprise a large central hole through which components in the upper housing 140 may directly contact components in the lower housing 145 (or as described below in relation to the embodiments of Figures 12A-15I, such as 640 and 645). The housing area of the electrical traces 611, 612 may be disposed on opposite sides of the insulating layer 613 within the housing area of the trace layer 609. The trace layer 609 may extend generally along the longitudinal axis between the electrode contact areas. The connecting portions of the trace layer 609 between the electrode contact areas and the housing areas may comprise a width along the transverse direction less than that of the electrode contact areas and/or the housing areas of the trace layer 609.

[0143] The electrical traces 611, 612 may be disposed (e.g., printed and/or applied in any suitable manner) on one or both sides (top and bottom) of the insulating layer 613. The electrical traces 611, 612 may comprise any of the conductive materials discussed elsewhere herein. For instance, in some embodiments, the electrical traces 611, 612 may comprise a layer of silver (Ag) printed on the insulating layer 613. In embodiments, the electrode interface portion 310 of the electrical traces 611, 612 may comprise a layer of silver chloride (AgCl) in addition to or

alternatively to the layer of silver or other conductive material generally used for the traces 611, 612, as described elsewhere herein. In some embodiments, the layer of silver chloride or other electrode interface material may be printed over the top of the layer of silver or other conductive layer of the electrical traces 611, 612. Silver may provide a more isotropic conductance than silver chloride, which may provide better lateral conductance in an x- and y- directions but worse vertical conductance along a z-direction (transverse to the longitudinal and lateral axes). In some embodiments, the electrical traces 611, 612 may be disposed primarily on one side of the insulating layer 613 (e.g., the bottom side or patient-facing side). For instance, the electrode interface portion 310 and portions of the traces 611, 612 along the connecting portion of the trace layer 609 may be disposed on only a single side, but the electrocardiogram circuit interface portion 313 of the traces 611, 612 may be positioned on the opposite side of the trace layer 609. Positioning the electrode interface portion 310 and electrocardiogram circuit interface portion 313 on opposite sides of the trace layer 609 may allow for facile interfacing between the electrical traces 611, 612 and PCBA 120, which may be positioned opposite the trace layer 609 from the patient's skin to minimize the amount of space occupied by the housing 115 between the patient and the trace layer 609. In certain embodiments, the trace layer 609 may comprise one or more vias 619 formed in through holes of the trace layer 609 that extend through the insulating later 613. The through holes may be formed through the conductive material electrical traces 611, 612 and filled with the same and/or a different conductive material to form the vias 619 which conduct electric signals from one side of the trace layer 609 to the other. The vias 619 may simplify the design and construction of the trace layer 609 by avoiding the use of bends in metal components. In some embodiments, conductive rivets may be used in addition to or alternatively to the conductive vias 619. The electrocardiogram circuit interface portion 313 of the traces 611, 612 may comprise relatively larger surface areas than the traces 611, 612 along the connecting portion of the trace layer 609 in order to provide sufficient contact area for electrical contacts to electrically couple the traces 611, 612 to the PCBA 120.

[0144] As shown in Figure 10B, in some embodiments, one or more resistors 614 may be disposed within the electrical traces 611, 612. The resistors 614 may comprise a conductive material of increased resistance over the conductive material(s) (e.g., silver and/or silver chloride) used to generally conduct electricity between the electrodes 350 and the PCBA 120. For example, the resistors 614 may comprise carbon and/or increased amounts of carbon as compared to the

electrical traces 611, 612. In some embodiments, the resistors may have a resistance that is at least approximately about: 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, or 100 kilohms ($k\Omega$). The material of the resistor 614 may be selected to reduce or minimize “popcorn” noise or $1/f$ noise. As shown in Figures 10A-10C, the resistors 614 may intersect the conductive path of the electrical traces 611, 612 between the electrode interface portion 310 and the electrocardiogram interface portion 313 such that they are disposed in-line with the conductive material of the electrical traces 611, 612. The resistors 614 may be disposed on a housing portion of the trace layer 609 such that they are enclosed within the housing 115. The resistors 614 may be disposed (e.g., printed) onto the substrate layer 613 in the same manner or a different manner from the conductive material of the electrical traces 611, 612. The resistors 614 may replace resistors that would otherwise be disposed on the PCBA 120, thereby potentially providing space-saving advantages. In some embodiments, the resistors 614 may be used to reduce the current that travels along the electrical circuit formed by the body and the interfacing electrodes 350. The resistors 614 may act as a safety feature that allows the physiological monitoring device 100 to be suitable for use with a patient.

[0145] Returning to Figure 10A, in some embodiments, the electrode interface portions 310 may comprise a central aperture 617. The central aperture 617 may be generally circular or any suitable shape, for example an oval, square, triangle, rectangle, or suitable polygonal shape. The central aperture 617 may provide for improved moisture management. For example, moisture trapped between the electrode 350 and the skin of the patient may be able to transpire through the electrode (e.g., a hydrogel electrode) and evaporate through the central aperture 617 and/or transpire through breathable substrate layers positioned over central layer. Improving moisture management may inhibit delamination and increase the duration of wear of the physiological monitoring device allowing for longer use. In some embodiment, the trace layer 609 may comprise a plurality of central apertures 617 positioned over the top surface of the electrode 350. The cumulative surface area of the one or more central apertures and/or vias 619 may be balanced relative to the surface area of the electrode 350 to prevent dry-out of hydrogel electrodes 350 and/or to attenuate fluctuations in conductivity that may occur as the electrode delaminates from the skin, since the metal is more conductive than the hydrogel. In some embodiments, no substrate layers may be positioned over the trace layer 609 or any overlying substrate layers may comprise corresponding apertures positioned over the central aperture 617 such that at least a portion of the upper surface of the electrode 350 is exposed to the ambient environment. In some embodiments,

the diameter of the central aperture 617 may be somewhat smaller than an outer diameter of the electrode 350 such that the trace layer 609 is seated on top of a top surface of the electrode 350. An electrical connection may be formed between an upper surface of the electrode and a lower surface of the trace layer 609 via the electrode interface portion 310 of the electrical trace 611, 612. In some embodiments, the diameter of the central aperture 617 substantially matches the outer diameter of the electrode 350 such that the electrode 350 may be received within the central aperture 617. An electrical connection may be formed between lateral edges of the conductive traces 611, 612 and the lateral sides of the electrode 350 in addition or alternatively to interactions between other portions and surfaces. In some embodiments, the electrode 350 (e.g., a hydrogel electrode or any suitable electrode) may be formed in situ within the central aperture and/or swelled within the central aperture 617. The electrode 350 may be swelled to have a diameter slightly larger than the diameter of the central aperture 617 such that a compressive force induces sufficient contact between the trace layer 609 and the electrode 350.

[0146] Figure 10A illustrates an example of a trace layer 609. Figure 10B depicts a close-up of the inset A in Figure 10A. As shown in Figure 10A, the connecting portions of the trace layer 609 may substantially bisect the hydrogel electrode 350 and/or the electrode interface portion 310 of the traces 611, 612. The electrical traces 611, 612 may be substantially linear along the connecting portion of the trace layer 609 as shown in Figure 10A. In some embodiments, one or more of the electrical traces 611, 612 may comprise a plurality of bends. The plurality of bends may produce a zig-zag or accordion-like configuration which allows the one or more of the electrical traces 611, 612 to better absorb tensile and/or compressive strains along the longitudinal axis. Figure 10C illustrates another example of a trace layer 609. The trace layer 609 may not be symmetrical about the transverse and/or the longitudinal axis as shown in Figure 10C. In some embodiments, the electrode interface portion 310 of one trace 611 may be configured to be positioned higher up on the patient's body than the electrode interface portion 310 of the other trace 612. The electrode interface portions 310 may extend away from the portion of the traces 611, 612 along the connecting portion of the trace layer 609 in lateral directions parallel to the transverse axis. The electrode interface portions 310 may extend away from the connecting portions in opposite directions. In some embodiments, the entire trace 611 may be configured to be positioned higher up on the patient's body than the opposing trace 612 as shown in Figure 10C. The connecting portions of the trace layer 609 may be substantially parallel but may be offset

along the transverse axis such that the connecting portions are not collinear. In some embodiments, both the connecting portions may be offset and the electrode interface portions 310 of the different traces 611, 612 may extend in opposite directions as shown in Figure 10C. The lateral offsetting of the electrodes 350 along the transverse axis may be configured to appropriately position the electrodes as shown in Figures 9A-9F while allowing the transverse axis to remain parallel to the height of a patient.

[0147] In some embodiments, the electrode interface portions 310 of one or more of the traces 611, 612 may be configured as a closed loop of the trace layer 609 which extends 360 degrees to enclose the central aperture 617. The trace layer 609 along the loop may comprise a substantially uniform width which may be the same width as the trace layer 609 along the connecting portion. In certain embodiments, the width may be nonuniform. The electrical trace 611, 612 may extend along the entire circumference of the loop or may extend only partially along the loop such that the electrical trace 611, 612 does not form a closed loop with itself.

[0148] In some embodiments, the physiological monitoring device 100 may comprise a battery terminal connector 650 configured to physically connect the two opposite terminals of a battery. Figures 11A-11E schematically depict two examples of a battery terminal connector 650. Figure 11B depicts an inner surface of a battery terminal connector 650 configured to contact the battery terminals and Figure 11A depicts an outer surface of the battery terminal connector 650 opposite the surface depicted in Figure 11B. Figure 11D depicts an inner surface of another example of a battery terminal connector 650 configured to contact the battery terminals and Figure 11C depicts an outer surface of the battery terminal connector 650 opposite the surface depicted in Figure 11D. Figure 11E illustrates a side view of a battery 160 to which a battery terminal connector 650 has been coupled (e.g., adhered). The battery terminal connector 650 may be configured to electrically connect to each of the terminals of a battery 160 and to functionally reposition electrical access to the battery terminals. The battery terminal connector 650 may be configured to connect the terminals of a coin-style battery or a battery comprising opposing top and bottom sides in which one terminal is positioned on the top side and the opposite terminal is positioned on the bottom side. In certain embodiments, the battery terminal connector 650 may be configured to position electrical access to both terminals of the battery on a single side of the battery (e.g., the top side) in order to simplify the electrical coupling of each terminal to the PCBA 120. Accordingly, the battery terminal connector 650 may comprise a first portion 655 (e.g., a

bottom portion), a top portion 657 (e.g., a top portion), and a connecting portion 656 joining the first portion 655 and the second portion 657. At least the connecting portion 656 of the battery terminal connector 650 may be sufficiently flexible such that the connecting portion 656 may bend, fold, or wrap around a lateral side of the battery 160 between top and bottom surfaces of the battery 160.

[0149] The battery terminal connector 650 may comprise an insulating layer 651 and two conductive battery traces 652, 653. Each of the battery traces 652, 653 may be configured to contact one of the two battery terminals. The insulating layer 651 may be configured to maintain a separation between the two battery traces 652, 653, thereby insulating the battery traces 652, 653 from one another. The insulating layer 651 may be configured to prevent at least one of the battery traces 652, 653 from contacting the battery terminal electrically coupled to the other battery trace. The insulating layer 651 may be formed of a non-conductive material. For instance, the insulating layer 651 may comprise a polyethylene such as polyethylene terephthalate (PET) or other suitable non-conductive polymers. The battery traces 652, 653 may be formed of a highly conductive material configured to electronically connect the battery terminals to the circuitry of the physiological monitoring device 100. For instance, the battery traces 652, 653 may comprise silver or copper (e.g., tin-plated copper foil). At least portions of the inner surface of the battery terminal connector 650 may be adhered to the battery terminals using a conductive adhesive (e.g., a conductive acrylic adhesive) configured to electrically couple each of the battery terminals to one of the battery traces 652, 653.

[0150] The battery terminal connector 650 may comprise any suitable arrangement of the battery traces 652, 653 and the insulating layer 651. In various embodiments, one of the battery traces 652 may extend from a first side of the battery (e.g., a bottom side) to the second side of the battery (e.g., the top side). The first battery trace 652 may be exposed on the inner surface of the battery terminal connector 650 on the first side of the battery 160 and exposed on only the outer surface of the battery terminal connector 650 on the second side of the battery 160. The second battery trace 653 may be disposed on only the second side of the battery 160. The second battery trace 653 may be exposed on both the inner surface and the outer surface of the battery terminal connector 650 on the second side of the battery 160. The PCBA 120 may be configured to form electrical contacts with both of the battery traces 652, 653 on the outer surface of the battery terminal connector 650 as described elsewhere herein. The insulating layer 651 may be disposed

on at least the second side of the battery 160 to separate the battery traces 652, 653 on the second side of the battery 160 and to insulate the first battery trace 652 from the battery terminal on the second side of the battery 160. In embodiments, the insulating layer 651 may be disposed on the inner surface of the battery terminal connector 650 along the connecting portion 656 and/or along at least portions of the first side of the battery 160 (e.g., the bottom portion). The insulating layer 651 may be disposed on the outer surface of the battery terminal connector 650 along the connecting portion 656 and/or the first side of the battery 160 (e.g., the bottom portion).

[0151] Returning to Figures 11A-11B, in some embodiments, the second battery trace 653 may be disposed (e.g., printed or via other suitable means) on the outer surface of the battery terminal connector 650 but may comprise an extension 654 extending beyond an edge of the insulating layer 651 such that the battery terminal on the second side of the battery 160 may electrically contact the extension 654 of the second battery trace 653 and the electric current may be transferred to the outer surface of the battery terminal connector 650 via the extension 654. In some embodiments, as shown in Figures 11C-11D, the second battery trace 653 may be disposed (e.g., printed) on the inner surface and the outer surface of the battery terminal connector 650. The second battery trace 653 may sandwich a portion of the insulating layer 651. The battery terminal connector 650 may comprise through holes filled with conductive material to form vias electrically connecting the second battery trace 653 on the inner surface and the outer surface of the battery terminal connector such that electrical current may be transferred from the second side of the battery through the battery terminal connector 650 to an outer surface of the battery terminal connector 650. In some embodiments, vias may also electrically connect the first battery trace 652 between an inner surface and an outer surface of the battery terminal connector 650. Conductive rivets may be used in addition to or alternatively to the conductive vias disclosed herein. Figures 11F through 11I depict an example of a battery terminal connector 650 configured to contact the battery terminals. Figure 11F depicts the outer surface of the battery terminal connector 650 prior to application of non-conductive coverlay and/or layer 658 (as shown in Figures 11H), while Figure 11G depicts the inner surface of the battery terminal connector 650 prior to addition of adhesive 660 (as shown in Figure 11I). In some embodiments, a second non-conductive layer 658 may cover the first battery trace 652 and the connecting portion 656 on the outside surface of the battery terminal connector 650. In certain embodiments, the battery terminal connector 650 may have at least one protruding tab 659 to positionally fix the battery terminal connector and battery

assembly inside of the device housing. There may be one, two, three, four, or more protruding tabs. One of skill in the art will understand that the protruding tabs may be shaped in any suitable manner, such as a curved shape or an angular shape.

[0152] Figures 12A-12G illustrate multi-perspective views of another example of an upper housing 640. Figure 12A depicts a partially exploded view of the upper housing 640. In some embodiments, the upper housing 640 may have a circular, ovoid, obround, rectangular, square, or any other suitable profile shape in the horizontal plane. The upper housing 640 may comprise a flexible upper frame 642 and a rigid shell 643. Figure 12B shows a perspective view of the flexible upper frame 642. Figure 12C shows a side view of the flexible upper frame 642. Figure 12D shows a top view of the flexible upper frame 642. The rigid shell 643 may be more rigid than the flexible upper frame 642. For example, the rigid shell 643 may be formed from a hard plastic (e.g., a polycarbonate such as MakrolonTM) and the flexible upper frame 642 may be formed from a softer rubber (e.g., SantopreneTM). The upper housing 640 may comprise a button 644 forming at least a portion of a top surface of the upper housing 640 and enclosing the internal components of the housing 615 from above. The button 644 may be a separate piece that is assembled with the flexible upper frame 642 and rigid shell 643 to form the upper housing 640, as shown in Figure 12A. The button 644 may be relatively rigid relative to the flexible upper frame 642. In some embodiments, the button 644 may be formed from the same material as the rigid shell 643. The button 644 may be securely attached to the flexible upper frame 642 by any suitable means (e.g., using adhesive, detents, snap fits, etc.) such that the button 644 is configured as “floating” button over the internal space of the upper housing 640. In some embodiments, the flexible upper frame 642 may be overmolded over at least a portion of the upper and lower surfaces of the button 644. Overmolding may be used to secure the button 644 to the rigid shell 643. In some embodiments, the button 644 may be entirely encased within the flexible upper frame 642.

[0153] The rigid shell 643 may form a lateral surface of the upper housing 640 (e.g., a circumference), as shown in Figure 12A. The rigid shell 643 may form an outer annular portion or an outer perimeter of a top surface of the upper housing 640, as shown in Figure 12A. The flexible upper frame 642 may be overmolded to the rigid shell 643. The flexible upper frame 642 may join the rigid shell 643 to the button 644 as described elsewhere herein. The flexible upper frame 642 may fill an annular gap in a top surface of the upper housing 640 between the outer perimeter formed by the rigid shell 643 and the button 644 forming a flexible border to the button 644. The

flexible upper frame 642 may be configured to be biased in a manner that allows the button 644 to be depressed in a downward direction relative to the rigid shell 643 to actuate trigger 210. In some embodiments, the lower surface of the button 644 may be shaped to have a convex surface or other protrusion configured to actuate the trigger input 210. In some embodiments, a protrusion (e.g., an upside down dome, pillar, or any suitable shape) may be attached to a lower surface of the button 644. The protrusion may accentuate the trigger actuation such that less strain is required to actuate the trigger input 210. The protrusion may be made of metal and/or plastic.

[0154] In some embodiments, the button 644 may be configured as a cantilever button rather than a floating button, in which a cantilever arm connects the button 644 to a lateral side (e.g., an inner diameter) of the rigid shell 643. The cantilever arm may be concealed by the flexible upper frame 642 such that the button 644 nonetheless externally appears as a floating button. In some embodiments, the button 644 may not be a floating button but may be integral with or directly joined to the rigid shell 643. The button 644 may be semi-rigid but comprise sufficient flexibility such that the button 644 can be elastically deformed. The button 644 may comprise a raised and/or convex configuration (e.g., a dome-like configuration) when unbiased. The button 644 may be configured such that the shape of the button 644 can be elastically deformed to actuate the trigger input 210. For instance, a dome may be at least partially inverted at or near an apex of the dome, such that the center of the domed button 644 extends downward within the space enclosed by the upper housing 640 to actuate the trigger input 210. In some embodiments, upon reaching a threshold strain, the dome may snap or buckle into an inverted configuration in which less pressure is required to continue depressing the dome. The buckling or snapping effect may be configured to provide a useful tactile indication of trigger 210 actuation. In some embodiments, upon release of pressure, the dome may snap back to its unbiased configuration. In some embodiments, the domed button 644 may include a conductive material or be coated in a conductive surface, and the domed body may make direct contact with electrical terminals on the PCBA 120 to actuate a trigger input without need for an additional trigger input button 210 on the PCBA. In certain embodiments, the button 644 may be rigid, but is attached to an elastically deformable snap dome that makes contact direct contact with electrical terminals on the PCBA 120 while providing tactile feedback to the user. In some embodiments, the semi-rigid button 644 may be snapped into the rigid shell 643 such as through a lip seal (the button 644 may be attached over an o-ring). In some embodiments, the button 644 may be ultrasonically welded or sealed onto the rigid shell 643. In

some embodiments, the button 644 may be formed as a thinned out portion of the upper surface of the rigid shell 643. In some embodiments, the button 644 may be formed from a soft material, such as a thermoplastic elastomer, configured to fold, flex, and/or rebound. The button 644 may comprise a hard external surface piece mounted onto the softer material for the user to press and/or a hard internal surface piece mounted onto the softer material for contacting the trigger input 210. In some embodiments, the softer material for contacting the trigger input may include a soft conductive piece (such as a conductive foam pill) enabling trigger input by shorting pads or traces on the PCBA without requiring an explicit button component on the PCBA. In some embodiments, the button 644 may be configured similar to a computer keyboard button. For instance, the button 644 may be configured to sit on one or more support members that surround the trigger input 210 and hold the button 644 over the trigger input 210 in a biased non-contacting position. In some embodiments, the electrical signal indicating button depression may be depressed through to the printed circuit board, through a flex circuit attached to the button or through electrical traces applied to the rigid shell 643. These electrical traces may be applied via laser direct structuring, plating to a platable substrate applied in a secondary mold process, or printing via aerosol jet, inkjet or screen printing of conductive materials.

[0155] The flexible upper frame 642 may comprise an upper rim 642a configured to interface with the top surface of the rigid shell 643, as described elsewhere herein, and a lower rim 642b. The lower rim 642b may comprise a larger diameter than the upper rim 642a. The upper rim 642a and/or the lower rim 642b may comprise annular (e.g., ring-shaped) configurations. The lower rim 642b may be configured to interface with the lower surface of the lateral sidewall of the rigid shell 643 (e.g., via overmolding or a snap fit). An inner diameter of the lower rim 642b may be configured to interface with an outer diameter of the PCBA 120 (e.g., via a snap fit). The lower rim 642b may functionally couple the PCBA 120 to the rigid shell 643. In some embodiments, the lower rim 642b may be approximately the same rigidity as the upper rim 642a. In some embodiments, the lower rim 642b may be more rigid than the upper rim 642a. The upper rim 642a may be joined to the lower rim 642b by one or more vertical ribs 642c. A plurality of ribs 642c may be spaced (e.g., substantially uniformly) around the periphery of the upper housing 640. The ribs 642c may help retain the PCBA 120 within the upper housing. In some embodiments, the PCBA 120 may be configured with grooves in the peripheral edge of the PCBA 120 to at least partially receive one or more of the ribs 642c. The ribs 642c may at least partially conform to the

shape of the PCBA 120. The ribs 642c may help absorb shock that would otherwise be transmitted to the PCBA 120 and could, for instance, potentially cause motion artifacts. Some of the ribs 642c may not join the upper rim 642a and the lower rim 642b. Some of the ribs 642c may extend upward from the bottom rim 642b but do not attach to the upper rim 642a, as shown in Figures 12B-12D. Some of the ribs 642c may extend downward from the upper rim 642a but do not attach to the lower rim 642b. In some embodiments, only a single rib 642c connects the upper rim 642a and the lower rim 642b, as shown in Figures 12B-12D. In some embodiments, the upper rim may not connect to the lower rim, or one of the two rings may be omitted entirely.

[0156] In some embodiments, one or more connecting ribs 642c may be circumferentially positioned substantially opposite the trigger input 210. The one or more connecting ribs and/or frames 642 may act as a fulcrum or pivot point about which the upper rim 642a and the button 644 are depressed. The fulcrum-like arrangement may allow deeper depression of the button 644 on the side of the PCBA 120 comprising the trigger input 210. In some embodiments, one or more fulcrum posts may extend upward (e.g., from the PCBA 120) vertically beneath the button 644. The fulcrum posts may be spaced around a periphery beneath the lower surface of the button 644. The fulcrum posts may have a height shorter than that of the trigger input 210. The fulcrum posts may act as fulcrums and facilitate biasing the lower surface of the button 644 toward the trigger input 210 as the button 644 is depressed if the lower surface of the button 644 contacts the fulcrum post. The fulcrum posts may be particularly useful if the trigger input is positioned off-center of the button 644 (e.g., on a periphery of the PCBA 120). In some embodiments, the upper rim 642a of the flexible upper frame 642 may be filled to form a continuous area such that the upper frame 642 may comprise an upper surface flush with the upper surface of the rigid shell 643 and covering a central portion of the top surface of the upper housing 640. In some embodiments, the button 644 may be formed as an integral portion of the flexible upper frame 642 and may be approximately the same or even less rigid as the remainder of the flexible upper frame 642. In some embodiments, a button 644 (which may be flexible or rigid) may be coupled to an upper surface of the flexible upper frame 644 (e.g., underneath the upper surface). The button 644 may be attached to the upper surface of the upper frame 642 (which may be flexible or rigid) via a snap-fit, barb-fit, adhesive, suction force, etc. In some embodiments, in order to minimize the potential for PCBA flex during application of force on the input trigger by the button, the upper housing 640 may include a stop feature that limits the travel of the button

644 to minimize stress to the board. Such a stop feature could also be implemented as a component on the PCBA, for example as a non-active molded component that is press-fit on the PCBA or an active components such as an antenna that is soldered to the board but has a deliberate extension to enable limiting the button's travel.

[0157] Figure 12E depicts a perspective view of an inner surface of the upper housing 640. In some embodiments, the upper housing 640 may comprise downward extending columns 641 configured for securing or helping to secure the upper housing 640 to a lower housing 645. The columns 641 may be spaced (e.g., substantially uniformly) around a periphery of the upper housing 640. The columns 641 may have channels configured to receive and retain posts 646 extending from a lower housing 645 as described elsewhere herein (e.g., via a press fit or an interference fit). The columns 641 may be formed as part of the rigid shell 643. The columns 641 may be formed integrally with the rigid shell 643. The columns 641 may be positioned inward of the lower rim 642b of the flexible upper frame and/or housing 640. One or more of the columns 641 may be merged together with an inner diameter of the rigid shell 643, as shown in Figure 12E. One or more of the columns 641 may be spaced inward from the inner diameter of the rigid shell 643. The columns 641 may extend to a height above that of the inner diameter of the upper housing 640 as shown in Figure 12E, to approximately the same height of the inner diameter of the upper housing 640, or below the height of the inner diameter of the upper housing 640. The flexible upper frame 642 may extend to a height above that of the inner diameter of the rigid shell 643, to approximately the same height of the inner diameter of the rigid shell 643, or below the height of the inner diameter of the rigid shell 643 as shown in Figure 12E. In certain embodiments, and as described above, button 644 may flex as an integrated part of the housing and/or shell 643. In such an embodiment, upper rim 642a is no longer necessary. A window may be added to button 644 covered in a thin layer of semi-transparent material to allow for light transmission from an underlying LED.

[0158] As shown in Figure 12F, top 714 and bottom 716 portions of the housing may be positioned above and below the flexible body 718. As shown in Figure 6D2, in embodiments, a gasket 719 may be positioned between the upper housing 714 and lower housing 716, co-molded into one or more of the housings. The gasket may compress down on the adhesive assembly and a ridged interface (shown below in Figure 12G) or another gasket on the opposite housing to provide waterproofing to the internal electronics hardware. As depicted in Figure 12G, a ridge 721 may be

positioned on an upper edge of the lower housing 716, the ridge 721 configured to press into the adhesive layer and/or the gasket 719. One of skill in the art will understand that the ridge 721 may be of any suitable shape, for example such as an edged ridge as depicted in Figure 721. In some examples, the ridge may be rounded, square, and/or polygonal. In certain examples, the height of the ridge may be about 0.01mm to 0.5mm, about 0.05mm to 0.4mm, about 0.1mm to 0.3mm, about 0.1mm to 0.2mm, or about 0.15mm such as about 0.13mm.

[0159] Figures 13A-13B illustrate multi-perspective views of another example of a lower housing 645. The lower housing 645 may be configured to engage upper housing 640. Figure 13A depicts a perspective view of the lower housing 645 and Figure 13B depicts a side view of the lower housing 645. In some embodiments, the lower housing 645 may comprise a plurality of posts 646 extending upward from the main body of the lower housing 645 beyond an upper peripheral edge configured to meet a lower peripheral edge of the upper housing 640. The posts 646 may be configured to extend into the internal space enclosed by the upper housing 640. In other embodiments, the posts 646 may not extend beyond the upper peripheral edge of the lower housing 645. In some embodiments, the posts 646 may be configured to pass through the holes 616 in the trace layer 609 and may help secure the trace layer 609 to the lower housing 645 as described elsewhere herein. The plurality of posts 646 may be configured to be received within and to mate with an equal number of columns 641 positioned opposite the posts 646 in the upper housing 640. For example, the plurality of posts 646 may be configured to form a press-fit or an interference fit with the plurality of columns 641 such that the posts 646 and columns 641 are configured to secure or lock together the upper housing 640 and the lower housing 645. The engagement between the posts 646 and columns 641 may resist separation forces between the upper housing 640 and the lower housing 645. Separation forces may be induced by the spring 665 described elsewhere herein, counterforces from compression of gaskets between the upper and lower housings 640, 645 to form a water tight seal, the transference of force from the upper housing 640 to the lower housing 645 during actuation of the trigger 210, etc. In some embodiments, some or all of the posts 646 may be arranged on the upper housing 640 and some or all of the columns 641 may be arranged on the lower housing 645. In some embodiments, the lower housing 645 may comprise one or more buckle columns configured to contact a bottom surface of the PCBA 120 (or a spring contact spacer as described elsewhere herein). The buckle columns may be configured to trap the PCBA 120 in firm contact against the upper housing 640, subsume the tolerance in the

PCBA 120 thickness, and/or provide additional rigidity for inducing a firm tactile response against the button 644 pressing forces. In embodiments, the lower housing 645 may be joined with the upper housing 645 through alternate processes, such as ultrasonic welding, potentially removing the need for press fit posts.

[0160] In some embodiments, the housing 115 may comprise a spring 665 configured to provide a consistent force bias the internal components enclosed by the housing 115 into contact with each other. The spring 665 may generally bias the components toward the top and/or the bottom of the housing 115. The spring 665 may absorb the tolerance stack of the internal components and maintain a substantially consistent biasing and vertical positioning or spacing between the components regardless of minor variations in the size of the various internal components or fit with respect to each other. The spring 665 may bias the PCBA 120 into contact with hard stops formed in the upper housing 640 such that the PCBA is able to provide a counterforce to resist the button pressing force and allow actuation of the input trigger 210. In some embodiments, the spring 665 may be a wave spring although other configurations of springs (e.g., a coil spring) may be used. In some embodiments, the spring 665 may be replaced by an elastomeric foam which may provide dampening properties in addition to the abovementioned properties. Figures 14A-14B illustrate orthogonal side views of an example of a wave spring 665. The wave spring 665 may be configured to be seated substantially along the internal diameter of the housing 115. In some embodiments, the spring 665 may be configured to be seated in the bottom of the lower housing 145 and to bias the internal components upward toward the upper housing 140, as described elsewhere herein.

[0161] Figures 15A-15I illustrate multiple views of another example of a physiological monitoring device 600. The physiological monitoring device 600 may comprise one or more of the components described elsewhere herein. The physiological monitoring device 600 may comprise a housing 615 comprising an upper housing 640 and a lower housing 645 which are configured to mate together sandwiching a flexible body 610 between the upper housing 640 and the lower housing 645. The flexible body 610 may comprise the trace layer 609 and one or more substrate layers forming the wings of the physiological monitoring device 600. The wings may comprise adhesive layers 340 and electrodes 350 as described elsewhere herein. The rigid body and/or housing 615 may enclose a PCBA 120, a flexible upper frame 642, a battery 160, a battery

terminal connector 650, a portion of the trace layer 609, a spring contact spacer 632, and a spring 665.

[0162] Figure 15A depicts a perspective view of an embodiment of the physiological monitoring device 600. Figure 15B depicts an exploded view of the physiological monitoring device 600. Figure 15C depicts a side view of the housing 615 in which the rigid shell 643 and button 644 of the upper housing 640 has been removed. Figure 15D depicts a side view of the housing 615 as shown in Figure 15C with flexible upper frame 642 additionally being removed. Figure 15E depicts a side view of the housing 615 as shown in Figure 15D with the lower housing 645 additionally being removed. Figure 15F depicts a side view of the housing 615 as shown in Figure 15E with the battery 160 and spring 665 additionally being removed. Figure 15G depicts a sectional view of the housing as shown in Figure with the section taken between the circuit board 120 and the spring contact spacer 632. Figure 15H depicts a sectional view of the housing as shown in Figure 15G with the spring contact spacer 632 additionally being removed. Figure 15I depicts a side view of the housing 615 as shown in Figure 15H additionally including the PCBA 120.

[0163] The upper housing 640 and the lower housing 645 may sandwich the flexible body 610 as described elsewhere herein. In some embodiments, the flexible body 610 may comprise one or more apertures 332 through extending through one or more of the substrate layers to provide breathability and moisture management and/or to facilitate drug delivery to the skin of the surface, as described elsewhere herein. An upper gasket layers 360 and/or a lower gasket layer 370 (not shown) may be provided on opposite sides of the flexible body 610 (not shown). The gasket layers 360, 370 may be adhesive for adhering to the flexible body 610. A compressible seal may be formed above and/or below the flexible body 610. In some implementations, a compressive seal may be formed with the flexible upper frame 642. The battery 160 may be positioned below the flexible body 610 comprising the trace layer 609. The PCBA 120 may be positioned above the flexible body 610 comprising the trace layer 609. A battery terminal connector 650 may be adhered or otherwise coupled to the battery 160 such that first and second battery traces 652, 653 are exposed on an outer surface of the battery terminal connector 650 on a top side of the battery 160. The first and second battery traces 652, 653 may be exposed to the internal volume of the upper housing 640 through a large central opening in the housing area of the trace layer 609 as shown in Figure 15H.

[0164] Electrical contact between the PCBA 120 and the first and second battery traces 652, 653 and/or electrical contact between the PCBA 120 and the electrocardiogram interface portions 313 of the electrical traces 611, 612 may be established by spring contacts 637, depicted in Figures 15G- 15I. The spring contacts 637 may be coupled to the bottom surface of the PCBA 120 as seen in Figure 15I. The housing 615 may comprise a spring contact spacer 632 positioned below the PCBA 120 (not shown in Figure 15I). In some embodiments, the spring contact spacer 632 may be rigidly affixed (e.g., adhered) to the bottom of the PCBA 120. In embodiments, the spring contact spacer may be attached or integrated into the flexible body 610. In some embodiments, the spring contact spacer may be integrated into the battery terminal connector. The spring contact spacer 632 may comprise a flat body and a plurality of downward extending legs 633. The legs 633 may be configured to be seated against a top surface and/or a lateral surface of the battery 160, as shown in Figure 15E, such that the spring contact spacer 632 maintains a minimum separation distance between the battery 160 and the PCBA 120 and provides sufficient space for the spring contacts 637. The spring contact spacer 632 may comprise one or more holes 634 through which the spring contacts 637 may extend downward from the bottom surface of the PCBA 120, as depicted in Figure 15G. The lower housing 645 may comprise a spring 665, as described elsewhere herein positioned below the battery 160 as shown in Figure 15E. The spring 665 may bias the battery 160 upward and may bias the first and second battery traces 652, 653 into physical and electrical contact with corresponding spring contacts 637. The electrocardiogram interface portions 313 of the traces 611, 612 may be seated on a top side of the battery 160 such that biasing the battery 160 upward also biases the electrocardiogram interface portions 313 of the traces 611, 612 into physical and electrical contact with corresponding spring contacts 637. The substantially consistent spacing between the traces and the PCBA 120 provided by the spring 665 and the spring contact spacer 632 may reduce, minimize, or eliminate noise in the electrical signal caused by fluctuating degrees of electrical contact between the spring contacts 637 and the traces. The assembly may comprise at least one spring contact 637 for each of the first battery trace 652, second battery trace 653, first electrical trace 611, and second electrical trace 612. The assembly may comprise more than one spring contacts 637 for some or all of the traces. The spring contacts 637 may be configured under compression induced by the arrangement of the various components, including spring 665, to establish an electrical pathway between each of the traces and the PCBA 120. The compressive contact between the spring contacts 637 and the traces may be maintained

even under nominal changes in the separation distances between the traces and the PCBA 120 (e.g., caused by movement) since the spring contacts 637 may extend further downward if the separation distance increases and the biasing corresponding decreases. In some embodiments, the first and second battery traces 652, 653 may be configured to be positioned on an opposite side of the housing 615 from the first and second electrical traces 611, 612 as shown in Figure 15H. In other embodiments, the spring contacts may be configured to carry electrical signals from battery or electrocardiogram signals by contacting electrical traces applied to the upper housing 640 or the bottom housing 645. These electrical traces may be applied to the housings through the use of laser direct structuring, plating to a platable substrate applied in a secondary mold process, or printing via aerosol jet, inkjet or screen printing of conductive materials. In other embodiments, RF antennas for wireless communication (such as Bluetooth) could be configured through the use of such electrical traces in the top housing 640 or bottom housing 645.

[0165] Figures 16A-16D depict multiple views of an embodiment of a physiological monitoring device 800, similar to the physiological monitoring devices depicted in Figures 10A-15I, such as Figure 15A. Here, the physiological monitoring device includes a central housing 802, comprising an upper housing 802 and a lower housing 806 sandwiched over flexible substrate 810. One of skill in the art will understand that the housing may be constructed from any suitable material disclosed herein, such as a rigid polymer or a soft, flexible polymer. In some embodiments, the housing may include an indicator 808, which may be in any suitable shape such as an oval, a circle, a square, or a rectangle. The indicator may comprise an LED light source (not shown) or any suitable light source, which may be overlain by a transparent or translucent viewing layer positioned against the inner surface of the upper housing. The viewing layer may be constructed from thermoplastic polyurethane or any suitable material. The indicator may be used to indicate a status of the physiological monitoring device such as the battery life of the physiological monitoring device. In some embodiments, the indicator may indicate whether the physiological monitoring device is collecting data, transmitting data, paused, experiencing an error, or analyzing data. The indicator may display any suitable color, for example red, amber, or green.

[0166] Extending outward from the housing are a plurality of wings 812. One of skill in the art will understand that although two wings are depicted here, other embodiments of the physiological monitoring device 800 may include more than two wings. As explained elsewhere

in the specification, the wings may be shaped in such a way to improve adhesion to the skin and retention of the physiological monitoring device against the skin. In embodiments, the wings may be asymmetric, with a greater portion of one wing (an upper lobe) 814 lying above the longitudinal line and a greater portion of another wing lying (a lower lobe) 816 below the longitudinal line, thereby allowing the physiological monitoring device to be positioned diagonally over the heart such that the lower lobe is positioned lower than the heart when a patient is in a standing position.

[0167] Extending outward from the housing and contained on or within the wings are electrode traces 818, similar to the electrode traces described elsewhere in the specification, such as with respect to Figures 10A-10C and Figure 15A. As explained elsewhere in the specification, the electrode traces may be printed directly on a flexible substrate which may be part of a multi-layer flexible assembly 820. Additional printed lines 822 may surround the electrode trace 818 for visual enhancement of the physiological monitoring device, however said printed lines 822 may be printed on a different layer than the flexible substrate on which the electrode traces are printed. The printed lines may be printed such that they blend with the shape of the electrode trace. As explained elsewhere in the specification, the electrode trace may encircle a series of breathing holes 824 which allow for air passage to an underlying hydrogel. In embodiments, there may be one, two, three, four, or more breathing holes. As explained elsewhere in the specification, apertures 826 may extend through one or more layers of the physiological monitoring device to provide breathability and moisture management. In embodiments, an adhesive border layer 828 may extend outward from the wings, thereby allowing for improved adhesion. Figure 16B depicts the underside of the physiological monitoring device 800 depicted in Figure 16A. Here, lower housing 806 is clearly visible as are the electrode traces 818 and printed lines 822 extending outward from the housing. Figures 16C and 16D depict the physiological monitoring device 800 of Figures 16A-16B, here including an externally facing top liner 826 and skin facing patient release liner 828 overlying the wings and surrounding the housing 802. Such release liners serve to protect the physiological monitoring device 800 during storage, in particular to protect the adhesive surfaces of the physiological monitoring device. In embodiments, the liners may be shaped such that two sides meet to form an opening for the housing to extend vertically past the liners.

[0168] In some implementations, an abrader may be used to abrade the skin of the patient prior to adhesion of the physiological monitoring device 100, 600, 800 (such as described

elsewhere in the specification) to the patient. The abrader may be used to remove a top layer of skin from the patient to improve long-term adhesion of the physiological monitoring device 100, 600 and/or signal quality from the physiological monitoring device 100, 600. Figures 17A and 17B schematically illustrate cross-sectional views of two examples of an abrader 700. The abrader 700 may comprise a housing 702. The housing 702 may serve as a handle by which the patient or another person can hold and operate the abrader 700. In some embodiments, additional elements, such as an elongated handle for example, may extend from or otherwise be coupled to the housing 702. The abrader 700 may comprise a substantially flat abrading surface 704 for abrading the skin. The abrading surface 704 may comprise a generally large surface area. The abrading surface 704 may comprise a rough surface and/or protrusions for abrading the skin. In some embodiments, the housing 702 may entirely or substantially circumferentially surround the abrading surface 704, as depicted in Figures 17A and 17B. The housing 702 may substantially enclose the abrading surface 704 during the abrasion procedure. The abrading surface 704 may be coupled to the housing 702 via a compressible member or biasing element 706. In some embodiments, the compressible member 706 may be a spring as shown in Figure 17A. In some embodiments, the compressible member 706 may be a compressible foam as depicted in Figure 17B. The abrading surface 704 may be configured to protrude beyond a bottom surface of the housing 702 in an unbiased configuration.

[0169] The amount of abrasion may depend on the amount of pressure applied to the abrader 700. Higher degrees of pressure may result in increased friction between the abrader 700 and the skin of the patient resulting in more severe abrasion. Too much pressure may result in patient discomfort or pain during and/or after the abrasion procedure. Too little pressure may result in inadequate abrasion. The compressible element 706 may help the user tune the amount of pressure that is applied to the abrader 700. The abrader 700 may be configured such that exertion of a pressure beyond a threshold of necessary pressure sufficiently biases the compressible element 706 to an extent such that the abrasion surface is withdrawn into the housing 702 and can no longer contact the skin. In some embodiments, the abrader 700 may be finely tuned such that when the bottom of the housing 702 is pressed into contact with the skin it deforms the skin encircled by the housing 702 to an extent that the abrading surface 704 is still able to make contact with the skin. The compressible element 706 may provide a tuned amount of force at this level of compression to achieve a desirable degree of abrasion. In some implementations, a desirable amount of abrasion

may be achieved when the abrading surface 704 is fully protruding from the housing 702 such that the housing does not come into substantial contact with the skin. In some embodiments, an indicator can be used to indicate to the user that a desired (e.g., a sufficient) amount of pressure has been achieved. For example, the foam compressible member 706 may be formed from an open-cell foam having an internal color and an external color, distinct from the internal color. The foam may be configured to be visible to the user. For instance, the housing may comprise an annular configuration surrounding the foam compressible member 706 such that the foam compressible member 706 is visible from the top during the abrasion procedure, as depicted in Figure 17B. The internal color of the foam may be visible when the compressible member 706 is in an unbiased configuration. The compressible member 706 may be configured such that upon achieving a threshold degree of compression, the open cells are compressed or closed sufficiently enough that the internal color becomes no longer visible to the user. The color change in the foam may serve as a visual indicator the user that sufficient pressure has been achieved. The visibility of the internal color may indicate to the user that he or she should exert more pressure.

[0170] In various alternative embodiments, the shape of a particular physiological monitoring device may vary. The shape, footprint, perimeter or boundary of the device may be circular, an oval, triangular, a compound curve or the like, for example. In some embodiments, the compound curve may include one or more concave curves and one or more convex curves. The convex shapes may be separated by a concave portion. The concave portion may be between the convex portion on the housing and the convex portion on the electrodes. In some embodiments, the concave portion may correspond at least partially with a hinge, hinge region or area of reduced thickness between the body and a wing.

[0171] While described in the context of a heart monitor, the device improvements described herein are not so limited. The improvements described in this application may be applied to any of a wide variety of physiological data monitoring, recording and/or transmitting devices. The improved adhesion design features may also be applied to devices useful in the electronically controlled and/or time released delivery of pharmacological agents or blood testing, such as glucose monitors or other blood testing devices. As such, the description, characteristics and functionality of the components described herein may be modified as needed to include the specific components of a particular application such as electronics, antenna, power supplies or charging connections, data ports or connections for down loading or off-loading information from the

device, adding or offloading fluids from the device, monitoring or sensing elements such as electrodes, probes or sensors or any other component or components needed in the device specific function. In addition, or alternatively, devices described herein may be used to detect, record, or transmit signals or information related to signals generated by a body including but not limited to one or more of ECG, EEG and/or EMG. In certain embodiments, additional data channels can be included to collect additional data, for example, device motion, device flex or bend, heart rate and/or ambient electrical or acoustic noise.

[0172] The physiological monitors described above and elsewhere in the specification may further be combined with methods and systems of data processing and transmission that improve the collection of data from the monitor. Further, the methods and systems described below may improve the performance of the monitors by enabling timely transmission of clinical information while maintaining the high patient compliance and ease-of-use of the monitor described above. For example, the methods and systems of data processing and transmission described herein this section or elsewhere in the specification may serve to extend the battery life of the monitor, improve the accuracy of the monitor, and/or provide other improvements and advantages as described herein this section or elsewhere in the specification.

Device Monitoring and Clinical Analysis Platform

[0173] The systems and methods described in detail below, may selectively extract, transmit, and analyze electrocardiographic signal data and other physiological data from a wearable physiological monitor, such as is described above. The systems and methods described below can improve the performance of a wearable physiological monitor that simultaneously records and transmits data through multiple means. For example, selective transmission of extracted data allows for decreased power consumption because the wearable patch is not required to transmit all recorded data. By sending extracted data, much of the analysis may be performed away from the wearable device without requiring full on-board rhythm analysis, which can also be highly power consumptive, reducing battery life. Further, remote analysis without the power constraints inherent to a wearable device may allow for greater sensitivity and accuracy in analysis of the data. Decreased power consumption serves to improve patient compliance because it prolongs the time period between or even eliminates the need for device replacement, battery changes or battery recharging during the monitoring cycle. By decreasing battery consumption,

longer monitoring times may be enabled without device replacement, for example, at least one week, at least two weeks, at least three weeks, or more than three weeks.

[0174] Figure 18 depicts a general overview of an embodiment of a system 900 for inferring cardiac rhythm information from an R-R interval time series 902, as may be generated by a continuous heart rate monitoring device 904. The R-R interval time series 902 inputted to the system may include a series of measurements of the timing interval between successive heartbeats. Typically, each interval represents the time period between two successive R peaks as identified from an ECG signal. R peaks are part of the QRS complex, a combination of three graphical deflections typically seen on an ECG, representing the depolarization of the left and right ventricles of a mammal's heart. The R peak is generally the tallest and most visible upward deflection on an ECG, and thus makes for an appropriate reference point. However, in further embodiments, any characteristic ECG fiducial point (such as the QRS complex onset or offset) may be used in place of the R peak to provide an estimate of the R-R interval time series. As described above in relation to Figures 1 through 9 and throughout the specification, the physical characteristics of the monitoring device are constructed in such a way as to improve signal fidelity, therefore the high signal fidelity allows for a high level of confidence in accurately extracting R-R peak data.

[0175] The R-R interval time series 902 data may be extracted from or received from a dedicated heart rate monitor such as a heart rate chest strap or heart rate watch, or a wearable health or fitness device 906, 908 that incorporates heart rate sensing functionality. Alternatively, the R-R interval time series 902 may be derived from a wearable patch 904 designed to measure an ECG signal (for instance, by locating the R peaks in the ECG using a QRS detection algorithm). Furthermore, the R-R interval time series 902 may be estimated from an alternative physiological signal such as that obtained from photoplethysmography (PPG). In this scenario, the peak-to-peak interval time series determined from the PPG signal may be used as an accurate estimate of the R-R interval time series.

[0176] In one aspect, a cardiac rhythm inference system 910 is implemented as a cloud service or server-based system that exposes an application programming interface (API) enabling R-R interval time series data or other signal data to be transmitted to the system (for instance, via HTTP) and the resulting cardiac rhythm information to be returned to the calling software. The R-R interval time series data 902 or other signal data may be transmitted to the cloud service directly from the heart-rate monitoring device itself, or indirectly via a smartphone 912, tablet or other

internet-enabled communication device 914 that can receive data from the heart rate monitoring device in either a wireless or wired manner. In addition, the R-R interval time series data 902 or other signals may be transmitted from a server 916 that stores the data for a number of users.

[0177] In some embodiments, a cardiac rhythm inference system 910 is provided through a software library that can be incorporated into a standalone application for installation and use on a smartphone, tablet or personal computer. The library may provide identical functionality to that of the inference service, but with R-R interval time series data 902 or other signal data transmitted directly through a functional call, as opposed to through a web service API.

[0178] In certain embodiments, a cardiac rhythm inference system may accept a plurality of R-R interval time series measured from devices of a given user 918, in addition to an individual R-R interval time series 902. In this scenario, the system computes the frequency and duration of each of the cardiac rhythm types inferred from the collection of time series data. These results may then be used to estimate confidence statistics for each type of cardiac rhythm based on the frequency and duration of occurrence of that rhythm across the various time series. In addition, the rhythm confidence statistics may be updated in a sequential manner for each separate call of the inference service. Furthermore, in some embodiments, the cardiac rhythm information inferred by the system may be provided back to the calling software only in the event that the confidence score for a given rhythm type exceeds a pre-determined threshold value.

[0179] In particular embodiments, a cardiac rhythm inference system 910 may accept additional sources of data, generally described as alternate sensor channels, in addition to R-R interval time series data, to enhance the accuracy and/or value of the inferred results. One additional source of data includes user activity time series data, such as that measured by a 3-axis accelerometer concurrently with the R-R interval time series measurements. In addition, the system may accept other relevant metadata that may help to improve the accuracy of the rhythm analysis, such as user age, gender, indication for monitoring, pre-existing medical conditions, medication information, medical history and the like, and also information on the specific day and time range for each time series submitted to the system. Furthermore, the measurement device might also provide some measure of beat detection confidence, for example, for each R-Peak or for sequential time periods. This confidence measure would be based on analysis the recorded signal that, in typical embodiments, would not be recorded due to storage space and battery energy requirements. Finally, in the particular case that the R-R interval time series data are derived from

an ECG signal, the system may accept additional signal features computed from the ECG. These features may include a time series of intra-beat interval measurements (such as the QT or PR interval, or QRS duration), or a time series of signal statistics such as the mean, median, standard deviation or sum of the ECG signal sample values within a given time period.

[0180] The various aspects described above could be used either individually or in combination to provide an application providing insights into an individual's health, stress, sleep, fitness and/or other qualities.

[0181] Some embodiments concern a system for selective transmission of electrocardiographic signal data from a wearable medical sensor. Current wearable sensors, such as the iRhythm ZioPatch™ 904, and further described above in relation to Figures 1-9, are capable of recording a single-lead electrocardiogram (ECG) signal for up to two weeks on a single battery charge. In many situations however, it is desirable for the sensor to be able to transmit, in real-time or near real-time, specific sections of the recorded ECG signal with clinical relevance to a computer device, such as either a smartphone 912 or an internet-connected gateway device 914 for subsequent processing and analysis. In this way, the patient or their physician can be provided with potentially valuable diagnostic ECG information during the period that the patient wears the sensor.

[0182] As described above, a significant challenge with this approach is to manage the battery life of the wearable sensor without requiring replacement or recharging, both of which reduce user compliance. Each transmission of an ECG from the sensor to a smartphone or local gateway device (using, for example, Bluetooth Low Energy) results in a subsequent reduction in the total charge stored in the sensor battery. Some embodiments of the present disclosure, particularly those of Figures 17 to 24 address this issue through the use of a novel hardware and software combination to enable the selective transmission of clinically relevant sections of ECG from a wearable sensor.

[0183] In certain embodiments, the wearable sensor incorporates either a software, hardware or hybrid QRS detector that produces a real-time estimate of each R-peak location in the ECG. The R-peak location data is then used to compute an R-R interval time series that is subsequently transmitted to a smartphone or gateway device according to a predefined schedule (for example, once per hour). In addition, a time stamp is also transmitted which stores the onset time for the R-R interval time series relative to the start of the ECG recording. Since the R-R

interval time series for a given section of ECG is significantly smaller (in terms of bytes occupied) than the ECG signal itself, it can be transmitted with considerably less impact on battery life.

[0184] In some embodiments of a second stage of the system, the R-R interval time series together with the onset time stamp is subsequently transmitted by the smartphone or gateway device to a server. On the server, the R-R interval time series is used to infer a list of the most probable heart rhythms, together with their onset and offset times, during the period represented by the time series data. The list of inferred heart rhythms is then filtered according to specific criteria, such that only rhythms matching the given criteria are retained after filtering. A measure of confidence may also be used to assist in filtering the events in a manner that might improve the Positive Predictivity of detection.

[0185] In certain embodiments of a third stage of the system, for each rhythm in the filtered rhythm set, the server transmits to the smartphone or gateway device the onset and offset time for that specific rhythm. In the event that the inferred rhythm duration exceeds a pre-defined maximum duration, the onset and offset times may be adjusted such that the resulting duration is less than the maximum permissible duration. The onset and offset times received by the gateway are then subsequently transmitted to the wearable sensor, which in turn transmits the section of the recorded ECG signal between the onset and offset times back to the gateway. This section of ECG is then transmitted to the server where it can be analyzed and used to provide diagnostic information to the patient or their physician.

[0186] In some embodiments, the system fundamentally allows a device worn for up to about: 14, 21, or 30 days or beyond without battery recharging or replacement (both activities that reduce patient compliance and, therefore, diagnostic value) to provide timely communication of asymptomatic arrhythmia events. This development is motivated by technology constraints: in order to enable a small, wearable device that does not require battery change or recharging while providing continuous arrhythmia analysis with high accuracy, it is desirable to limit the complexity of analysis performed on-board. Similarly, streaming of all of the recorded ECG data to an off-board analysis algorithm may not be practical without imposing greater power requirements. This motivates a more creative “triage” approach where selected features of the recorded ECG signal, including but not limited to R-R intervals, are sent for every beat, allowing a customized algorithm to locate a number (for example, 10) of 90-second events to request from the device in full

resolution to support comprehensive analysis, for example, a resolution capable of supporting clinical diagnosis.

[0187] In other embodiments, the system would provide the ability to detect asymptomatic arrhythmias in a timely manner on a wearable, adhesively affixed device that does not require frequent recharging or replacement. This would be used to enhance the value of some current clinical offerings, which only provide clinical insight after the recording is completed and returned for analysis.

[0188] In certain embodiments, the system would allow actionable clinical insight to be derived from data collected on low-cost, easy-to-use consumer wearable devices that are otherwise only focused on fitness and wellness. For example, the technology could be used to create a very effective, low-cost screening tool capable of detecting the presence of Atrial Fibrillation in the at-large population. By using such a tool, not only would patients in need of care be found more easily, but it may be done earlier and more cost effectively, which lead to better outcomes – namely, through reducing stroke risk by identifying AF more quickly.

[0189] In particular embodiments, the system may provide the service through a downloadable application that, after receiving customer consent for data access and payment approval, would initiate access and analysis of heart beat data stored from wearable devices, either stored locally in a mobile device or in an online repository. This data pull and analysis would happen through an Algorithm API, and would result in a clinical finding being sent back to the application to be provided to the user. If the data was sufficient to support a “screening oriented” finding, for example, “Likely presence of an irregular rhythm was detected”, the application would direct them to a cardiologist where a more diagnostically focused offering, for example, the ZIO® Service, could be provided to support clinical diagnosis and treatment. In further embodiments, as also described elsewhere in the specification, the system may trigger an alarm if a particular measurement and/or analysis indicates that an alarm is needed.

[0190] Further examples of additional scenarios of clinical value may include coupling ambulatory arrhythmia monitoring with a blood-alcohol monitor to study the interaction of AF and lifestyle factors. For example, ambulatory arrhythmia monitoring could be coupled with a blood-glucose monitor to study the impact of Hypoglycemia on arrhythmias. Alternatively, ambulatory arrhythmia monitoring could be coupled with a respiratory rate and/or volume monitor to study the interaction of sleep apnea and breathing disorders. Further, there could be evaluation of the

high rates of supraventricular ectopic beats as a potential precursor for AF (for example, 720 SVEs in 24-hour period).

Extraction, Transmission, and Processing Systems

[0191] Figure 19 is a schematic illustration of an embodiment of a system and method 1000 for a wearable medical sensor 1002 with transmission capabilities, similar to the system and/or method described above in relation to Figure 19. In some embodiments, sensor 1002, which may be any type of sensor or monitor described herein this section or elsewhere in the specification, continuously senses an ECG or comparable biological signal 1004 and continuously records an ECG or comparable biological signal 1004. In certain embodiments, the sensing and/or recording steps may be performed intermittently. The collected signal 1004 may then be continuously extracted into one or more features 1006, representing example features A, B, and C. The features are not intended to be samplings of different temporal sections of the signal, instead (as will be described in greater detail below) the different features may correspond to different types or pieces of data such as R-peak locations or R-peak amplitudes. The features of the ECG or comparable biological signal are extracted to facilitate analysis of the signal 1004 remotely. In certain embodiments, features are extracted on a windowed basis, with the window size varying for example between 1 hour or multiple hours to a few seconds. In certain embodiments, the window may be at most: about .1 second, about 1 second, about 2 seconds, about 3 seconds, about 5 seconds, about 10 seconds, about 30 seconds, about 1 minute, about 5 minutes, about 30 minutes, about 1 hour, about 2 hours, about 4 hours, or more than 4 hours. The extraction windows may be separated by various amounts of time if they are repeated. For example, the extraction windows may be separated by at least: about 30 seconds, about 1 minute, about 5 minutes, about 30 minutes, about 1 hour, about 3 hours, about 6 hours, about 12 hours, about 24 hours, about 48 hours, or more than three days. In certain embodiments, the windowing sizes may vary depending on the feature extracted. Feature extraction may be limited to one type or various types of features, and features chosen for extraction may vary depending on the nature of the signal observed.

[0192] A wide variety of different types of ECG or comparable biological signal features may be extracted. For example, R-peak locations may be extracted. In certain embodiments, the R-peak locations are extracted via various methods such as: a Pan-Tompkins algorithm (Pan and Tompkins, 1985), providing a real-time QRS complex detection algorithm

employing a series of digital filtering steps and adaptive thresholding, or an analog R-peak detection circuit comprising an R-peak detector consisting of a bandpass filter, a comparator circuit, and dynamic gain adjustment to locate R-peaks. The RR-intervals may be calculated from peak locations and used as the primary feature for rhythm discrimination. In embodiments, an R-peak overflow flag may be extracted. If more than a certain number of R-peaks were detected during a given time window such that not all data can be transmitted, a flag may be raised by the firmware. Such an extraction may be used to eliminate noisy segments from analysis, on the basis that extremely short intervals of R-R are not physiologically possible. With similar motivation, an R-peak underflow flag may be extracted to indicate an unrealistically long interval between successive R peaks, provided appropriate considerations for asystole are made in this evaluation. In an alternative implementation with the same goal, the lack of presence of R peaks in a prolonged interval could be associated with a confidence measure, which would describe the likelihood that the interval was clinical or artifact.

[0193] In general, the word “module,” as used herein, refers to logic embodied in hardware or firmware, or to a collection of software instructions, possibly having entry and exit points, written in a programming language, such as, for example, Python, Java, Lua, C and/or C++. A software module may be compiled and linked into an executable program, installed in a dynamic link library, or may be written in an interpreted programming language such as, for example, BASIC, Perl, or Python. It will be appreciated that software modules may be callable from other modules or from themselves, and/or may be invoked in response to detected events or interrupts. Software modules configured for execution on computing devices may be provided on a computer readable medium, such as a compact disc, digital video disc, flash drive, or any other tangible medium. Such software code may be stored, partially or fully, on a memory device of the executing computing device, such as the computing system 13000, for execution by the computing device. Software instructions may be embedded in firmware, such as an EPROM. It will be further appreciated that hardware modules may be comprised of connected logic units, such as gates and flip-flops, and/or may be comprised of programmable units, such as programmable gate arrays or processors. The block diagrams disclosed herein may be implemented as modules. The modules described herein may be implemented as software modules, but may be represented in hardware or firmware. Generally, the modules described herein refer to logical modules that may be

combined with other modules or divided into sub-modules despite their physical organization or storage.

[0194] Each of the processes, methods, and algorithms described in the preceding sections may be embodied in, and fully or partially automated by, code modules executed by one or more computer systems or computer processors comprising computer hardware. The code modules may be stored on any type of non-transitory computer-readable medium or computer storage device, such as hard drives, solid state memory, optical disc, and/or the like. The systems and modules may also be transmitted as generated data signals (for example, as part of a carrier wave or other analog or digital propagated signal) on a variety of computer-readable transmission mediums, including wireless-based and wired/cable-based mediums, and may take a variety of forms (for example, as part of a single or multiplexed analog signal, or as multiple discrete digital packets or frames). The processes and algorithms may be implemented partially or wholly in application-specific circuitry. The results of the disclosed processes and process steps may be stored, persistently or otherwise, in any type of non-transitory computer storage such as, for example, volatile or non-volatile storage.

[0195] The various features and processes described above may be used independently of one another, or may be combined in various ways. All possible combinations and subcombinations are intended to fall within the scope of this disclosure. In addition, certain method or process blocks may be omitted in some implementations. The methods and processes described herein are also not limited to any particular sequence, and the blocks or states relating thereto can be performed in other sequences that are appropriate. For example, described blocks or states may be performed in an order other than that specifically disclosed, or multiple blocks or states may be combined in a single block or state. The example blocks or states may be performed in serial, in parallel, or in some other manner. Blocks or states may be added to or removed from the disclosed example embodiments. The example systems and components described herein may be configured differently than described. For example, elements may be added to, removed from, or rearranged compared to the disclosed example embodiments.

[0196] Conditional language, such as, among others, “can,” “could,” “might,” or “may,” unless specifically stated otherwise, or otherwise understood within the context as used, is generally intended to convey that certain embodiments include, while other embodiments do not include, certain features, elements and/or steps. Thus, such conditional language is not generally

intended to imply that features, elements and/or steps are in any way required for one or more embodiments or that one or more embodiments necessarily include logic for deciding, with or without user input or prompting, whether these features, elements and/or steps are included or are to be performed in any particular embodiment. The term “including” means “included but not limited to.” The term “or” means “and/or.”

[0197] Any process descriptions, elements, or blocks in the flow or block diagrams described herein and/or depicted in the attached figures should be understood as potentially representing modules, segments, or portions of code which include one or more executable instructions for implementing specific logical functions or steps in the process. Alternate implementations are included within the scope of the embodiments described herein in which elements or functions may be deleted, executed out of order from that shown or discussed, including substantially concurrently or in reverse order, depending on the functionality involved, as would be understood by those skilled in the art.

[0198] All of the methods and processes described above may be at least partially embodied in, and partially or fully automated via, software code modules executed by one or more computers. For example, the methods described herein may be performed by the computing system and/or any other suitable computing device. The methods may be executed on the computing devices in response to execution of software instructions or other executable code read from a tangible computer readable medium. A tangible computer readable medium is a data storage device that can store data that is readable by a computer system. Examples of computer readable mediums include read-only memory, random-access memory, other volatile or non-volatile memory devices, CD-ROMs, magnetic tape, flash drives, and optical data storage devices.

[0199] It should be emphasized that many variations and modifications may be made to the above-described embodiments, the elements of which are to be understood as being among other acceptable examples. All such modifications and variations are intended to be included herein within the scope of this disclosure. The foregoing description details certain embodiments. It will be appreciated, however, that no matter how detailed the foregoing appears in text, the systems and methods can be practiced in many ways. For example, a feature of one embodiment may be used with a feature in a different embodiment. As is also stated above, it should be noted that the use of particular terminology when describing certain features or aspects of the systems and methods should not be taken to imply that the terminology is being re-defined herein to be

restricted to including any specific characteristics of the features or aspects of the systems and methods with which that terminology is associated.

[0200] Various embodiments of a physiological monitoring device, methods, and systems are disclosed herein. These various embodiments may be used alone or in combination, and various changes to individual features of the embodiments may be altered, without departing from the scope of the invention. For example, the order of various method steps may in some instances be changed, and/or one or more optional features may be added to or eliminated from a described device. Therefore, the description of the embodiments provided above should not be interpreted as unduly limiting the scope of the invention as it is set forth in the claims.

[0201] Various modifications to the implementations described in this disclosure may be made, and the generic principles defined herein may be applied to other implementations without departing from the spirit or scope of this disclosure. Thus, the scope of the disclosure is not intended to be limited to the implementations shown herein, but are to be accorded the widest scope consistent with this disclosure, the principles and the novel features disclosed herein.

[0202] Certain features that are described in this specification in the context of separate embodiments also can be implemented in combination in a single embodiment. Conversely, various features that are described in the context of a single embodiment also can be implemented in multiple embodiments separately or in any suitable subcombination. Moreover, although features may be described above as acting in certain combinations and even initially claimed as such, one or more features from a claimed combination can in some cases be excised from the combination, and the claimed combination may be directed to a subcombination or variation of a subcombination.

[0203] Similarly, while operations are depicted in the drawings in a particular order, such operations need not be performed in the particular order shown or in sequential order, or that all illustrated operations be performed, to achieve desirable results. Further, the drawings may schematically depict one more example processes in the form of a flow diagram. However, other operations that are not depicted can be incorporated in the example processes that are schematically illustrated. For example, one or more additional operations can be performed before, after, simultaneously, or between any of the illustrated operations. Moreover, the separation of various system components in the embodiments described above should not be interpreted as requiring such separation in all embodiments. Additionally, other embodiments are within the scope of the

following claims. In some cases, the actions recited in the claims can be performed in a different order and still achieve desirable results.

[0204] The reference in this specification to any prior publication (or information derived from it), or to any matter which is known, is not, and should not be taken as an acknowledgment or admission or any form of suggestion that the prior publication (or information derived from it) or known matter forms part of the common general knowledge in the field of endeavour to which this specification relates.

[0205] Throughout this specification and claims which follow, unless the context requires otherwise, the word “comprise”, and variations such as “comprises” or “comprising”, will be understood to imply the inclusion of a stated integer or group of integers or steps but not the exclusion of any other integer or group of integers.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. An electronic device for monitoring physiological signals in a user, the device comprising:

a housing enclosing a circuit board, the housing further comprising a rigid shell surrounding a flexible frame and forming a peripheral exterior of at least a portion of the housing, wherein a button is formed within an opening of the flexible frame, the button being configured to be manually depressed by the user into the flexible frame; and

an electrode configured to detect physiological signals of the user when the electrode is engaged with a surface of the user.

2. The electronic device of Claim 1, further comprising a flexible wing extending from the housing.

3. The electronic device of any one of the previous claims, further comprising a trace layer coupled to the flexible wing and configured to transmit electrical signals from the electrode to the circuit board, the trace layer comprising a polymeric body extending from a first contact region positioned adjacent the electrode to a second contact region positioned adjacent the circuit board.

4. The electronic device of Claim 3, wherein the trace layer comprises a conductive material disposed on a first side of the polymeric body, the conductive material having a first conductance, and a resistor disposed on the first side of the polymeric body intersecting the conductive material between the first and second contact regions, the resistor having a second conductance.

5. The electronic device of Claim 4, wherein the first conductance is greater than the second conductance such that the resistor applies a resistance between the first and second contact regions.

6. The electronic device of Claim 4, wherein the trace layer comprises one or more vias extending through the polymeric body of the trace layer and filled with a conductive material, the one or more vias electrically connecting the conductive material disposed on the first side of the polymeric body and a conductive material disposed on a second side of the polymeric body opposite the first side.

7. The electronic device of Claim 6, wherein the vias are positioned at the second contact region.

8. The electronic device of Claim 4, wherein the first contact region comprises a hole through a center of the first contact region to allow moisture to transpire from a hydrogel through a flexible wing.

9. The electronic device of Claim 4, wherein the first contact region is positioned over the electrode.

10. The electronic device of Claim 4, wherein the first contact region comprises a hole surrounding the electrode such that the electrode is arranged concentrically inside the hole, the electrode configured to electrically connect to a circumference of the hole.

11. The electronic device of Claim 4, wherein the first contact region is positioned on a bottom side of the trace layer and the second contact region is positioned on a top side of the trace layer.

12. An electronic device for monitoring physiological signals in a user, the device comprising:

a housing, the housing comprising:

a rigid shell forming a peripheral exterior of at least a portion of the housing,

a flexible frame surrounded at least partially by the rigid shell, and

a button is formed within an opening of the flexible frame, the button being configured to be manually depressed by the user into the flexible frame; and

an electrode configured to detect physiological signals of the user when the electrode is engaged with a surface of the user.

13. The electronic device of Claim 12, the device comprising:

an adhesive layer coupled to a bottom surface of a flexible wing of the electronic device for adhering the electronic device to the user,

wherein the flexible wing and/or the adhesive layer comprises a therapeutic agent for delivery to the surface of the user, the adhesive layer being configured to allow the therapeutic agent to be eluted through the adhesive layer to the surface of the user.

14. The electronic device of Claim 13, wherein the adhesive layer comprises a hydrocolloid.

15. The electronic device of any one of Claims 13-14, wherein the therapeutic agent is configured to reduce skin irritation, reduce itchiness, reduce bacterial growth, induce histamine release, and/or provide an anesthetic effect.

16. The electronic device of any one of Claims 13-15, wherein the therapeutic agent is dissolved into the adhesive layer.

17. The electronic device of any one of Claims 13-15, wherein the therapeutic agent is contained within a plurality of pockets disposed within one or more substrate layers of the flexible wing.

18. The electronic device of Claim 17, wherein one or more substrate layers of the flexible wing comprises pores configured to help transport the therapeutic agent through the flexible wing.

19. The electronic device of any one of Claims 13-18, wherein the adhesive layer comprises one or more pores configured to help transport the therapeutic agent through the adhesive layer to the surface of the user.

20. An electronic device for monitoring physiological signals in a user, the device comprising:

a housing, the housing comprising:

a rigid shell forming a peripheral exterior of at least a portion of the housing,

a flexible frame disposed within a central opening of the rigid shell, and

a button disposed on a top surface of the flexible frame, the button being configured to be manually depressed by the user into the flexible frame; and

a sensor configured to detect physiological signals of the user when the sensor is engaged with a surface of the user.

21. The electronic device of Claim 20, wherein the flexible frame is overmolded to the rigid shell.

22. The electronic device of any one of Claims 20-21, wherein the button is a rigid element and the flexible frame joins the button to the rigid shell, the flexible frame forming a flexible border around the button such that the button is a floating button and pressing the button causes the flexible frame to flex.

23. The electronic device of any one of Claims 20-22, wherein the housing further comprises: a top housing coupled to a bottom housing, and a column extending downward from the top housing and a post extending upward from the bottom housing, the post being received in

the column or the column being received in the post, wherein the column and post are press-fit together and configured to resist internal forces within the housing that promote separating the top housing from the bottom housing.

24. The electronic device of any one of Claims 20-23, further comprising a spring positioned between a bottom surface of the bottom housing and a circuit board of the electronic device, the spring configured to subsume tolerance stack within the housing.

25. The electronic device of Claim 24, wherein the housing encloses a battery and the spring is further configured to bias traces electrically connected to battery terminals and a trace electrically coupled to the sensor into electrical contact with the circuit board.

26. The electronic device of Claim 25, wherein the electrical contact is made via a plurality of spring contacts.

27. The electronic device of Claim 24, wherein the spring is a wave spring.

28. The electronic device of any one of Claims 20-27, further comprising a spacer positioned between the circuit board and a battery, the spacer being configured to maintain the battery at a constant separation distance from the circuit board.

29. The electronic device of any one of Claims 20-28, further comprising foam positioned between a bottom surface of the housing and the circuit board, the foam configured to subsume tolerance stack within the housing.

30. The electronic device of any one of Claims 20-29, wherein the circuit board comprising a trigger input configured to be manually actuated by a user for indicating a trigger event, the opening being positioned over the trigger input, and the button being configured to be manually depressed to actuate the trigger input.

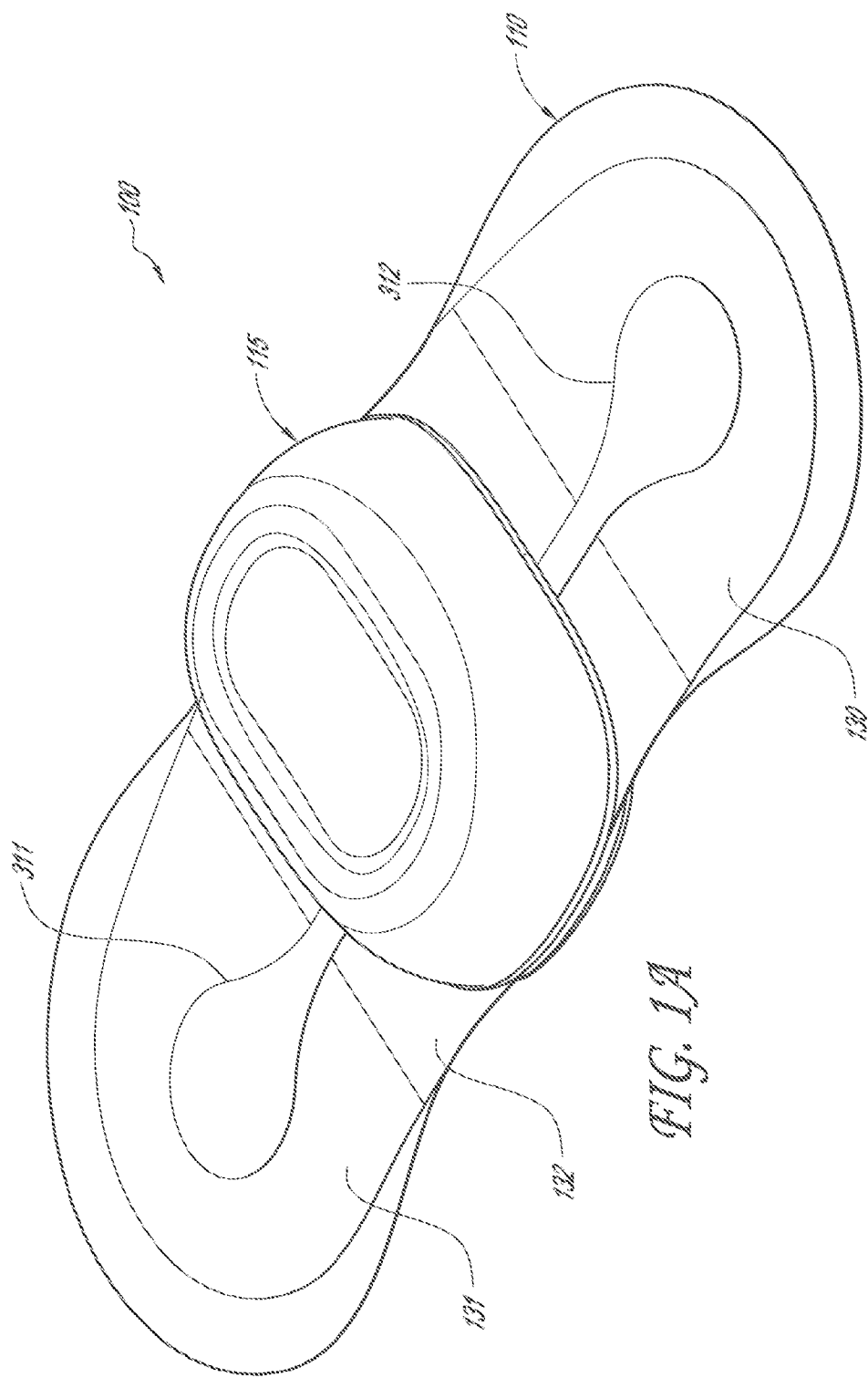


FIG. 1A

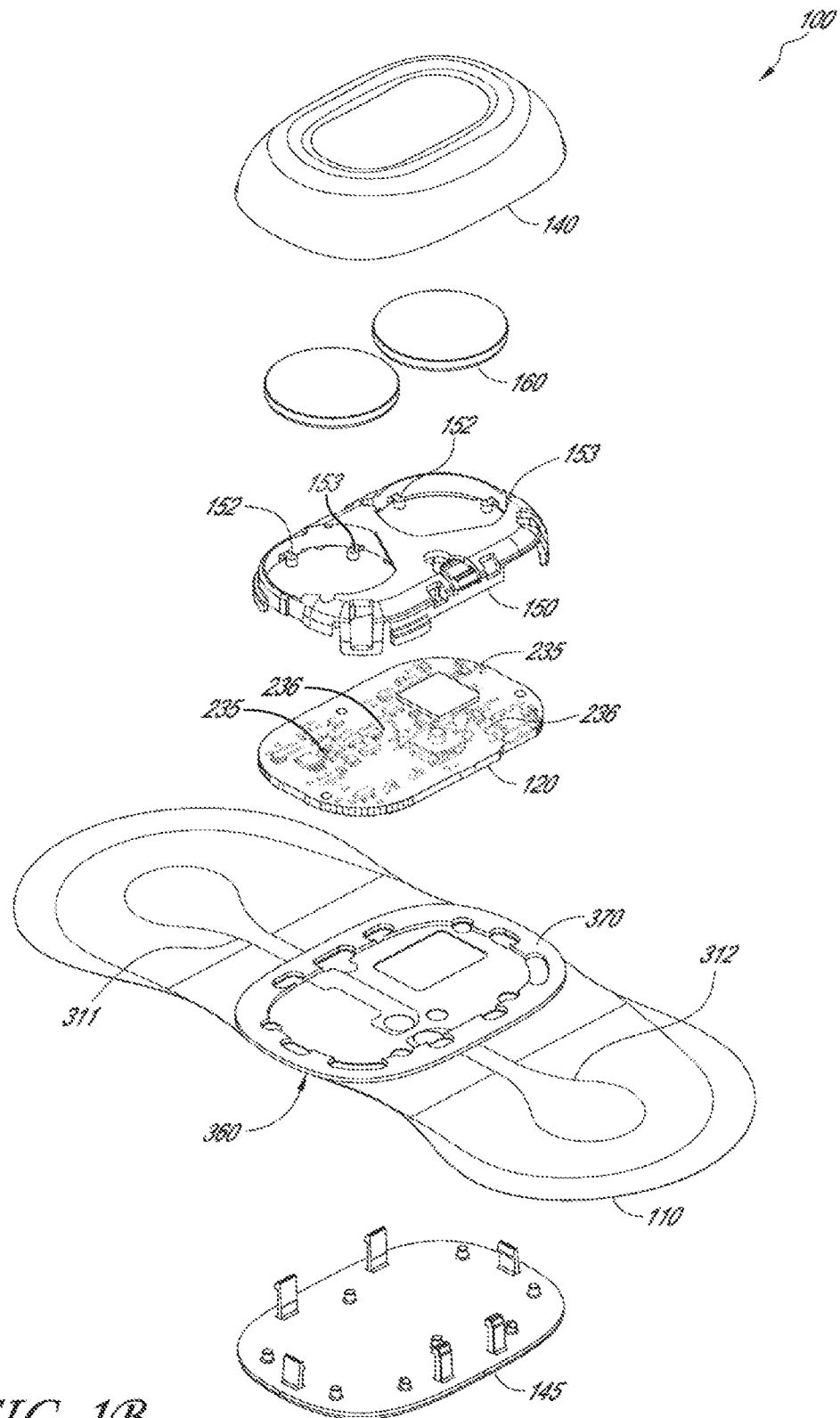
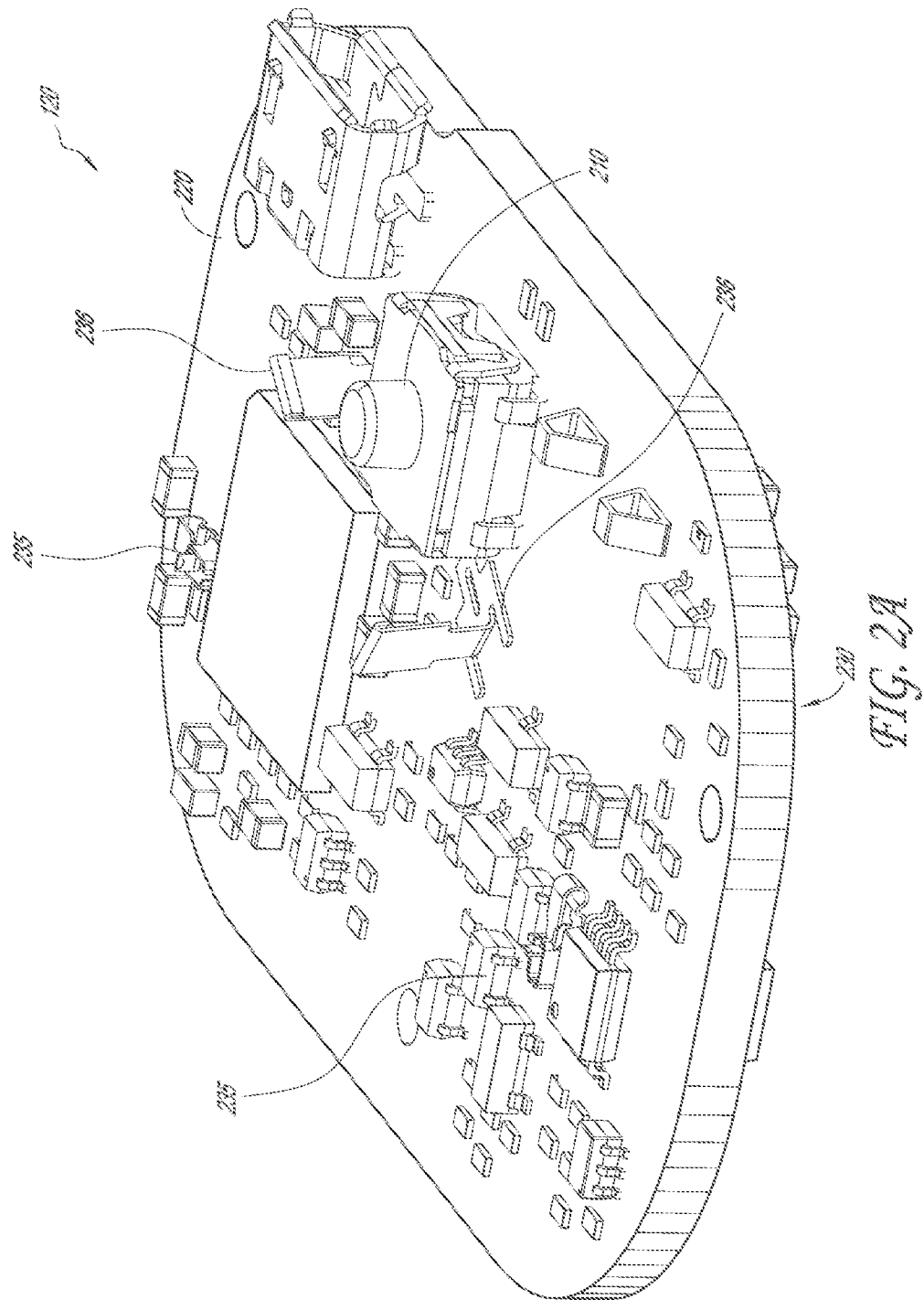


FIG. 1B



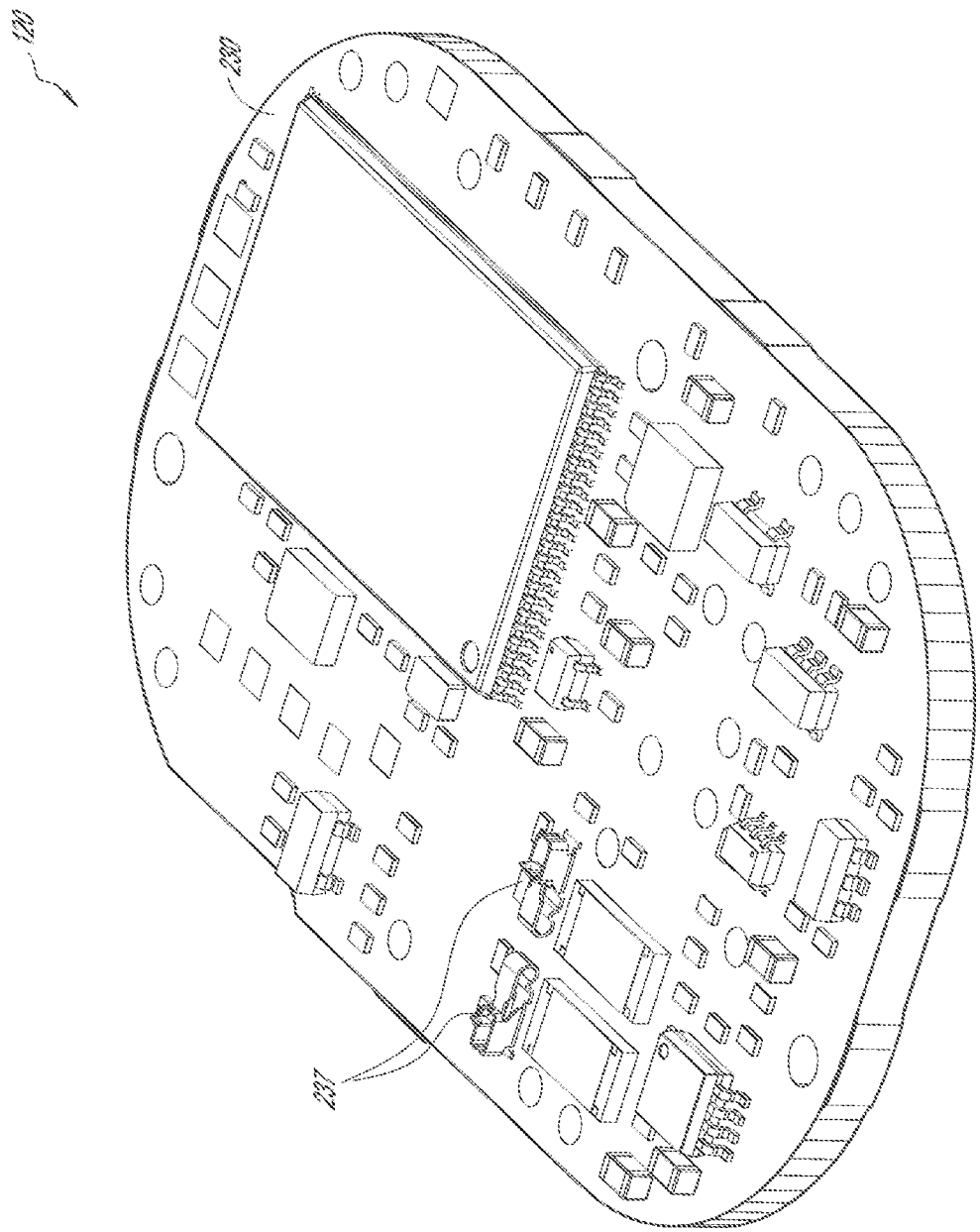
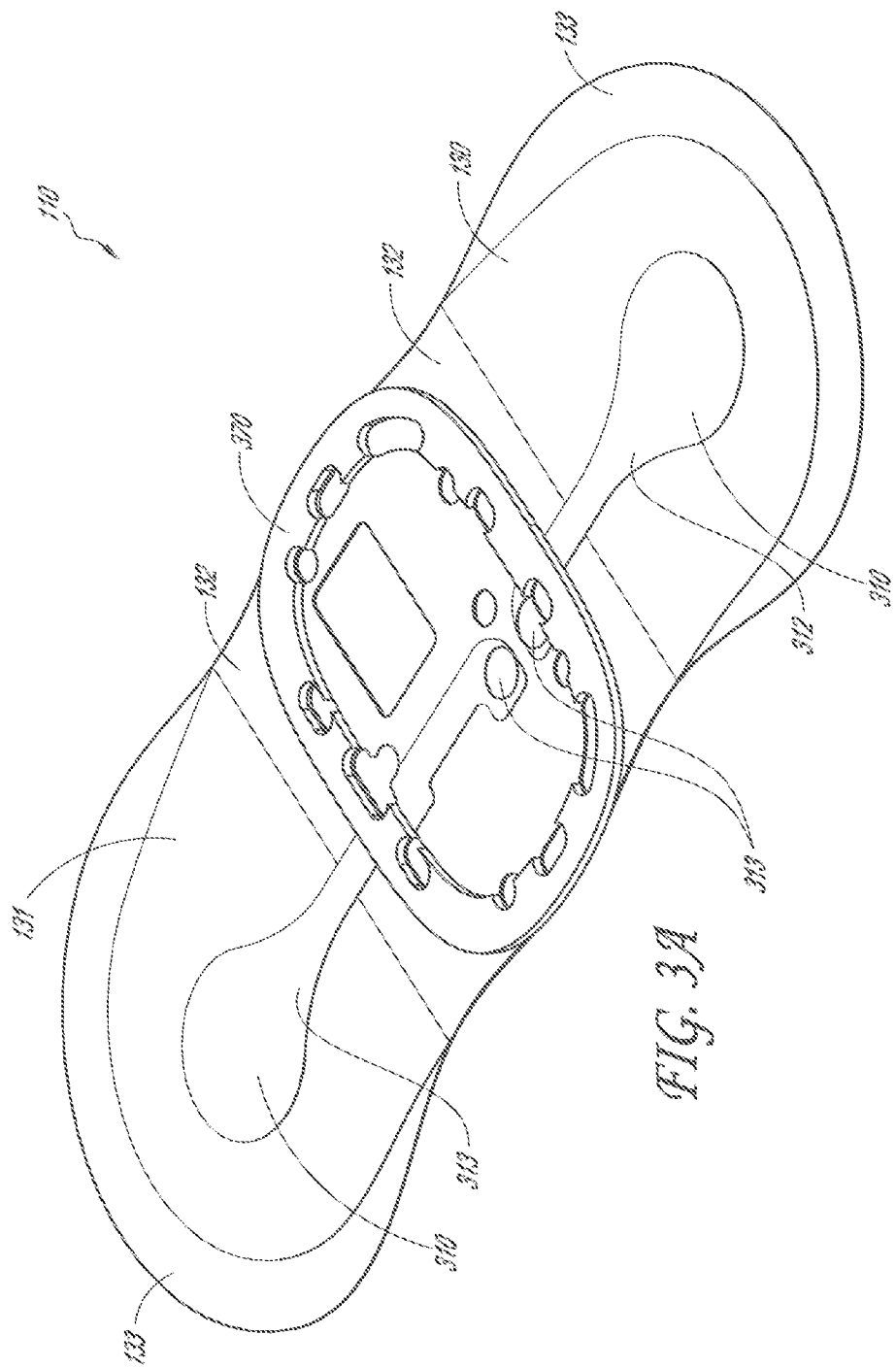


FIG. 2B



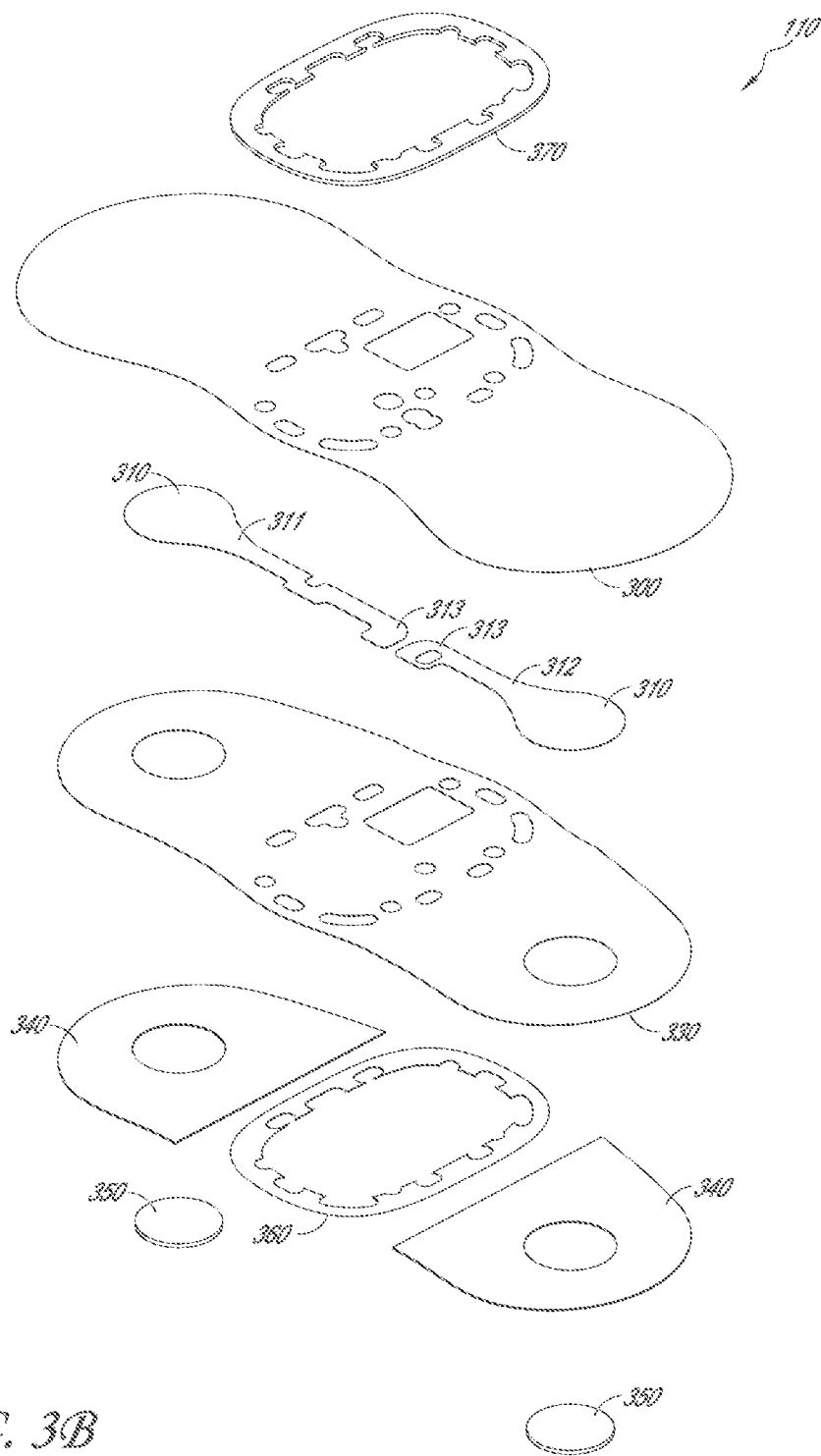
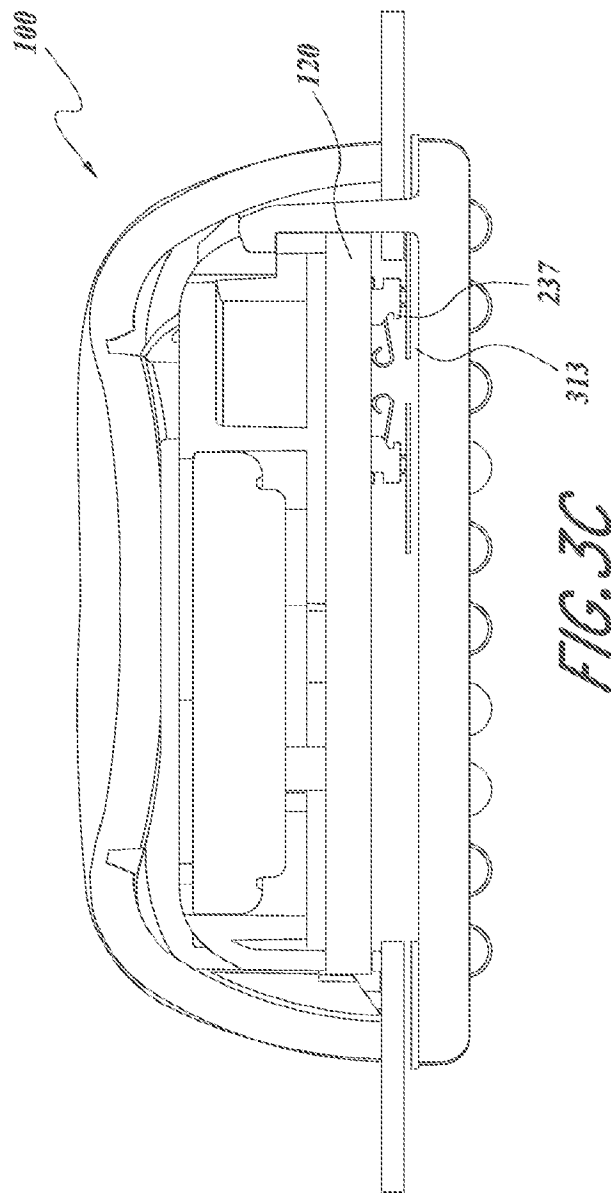
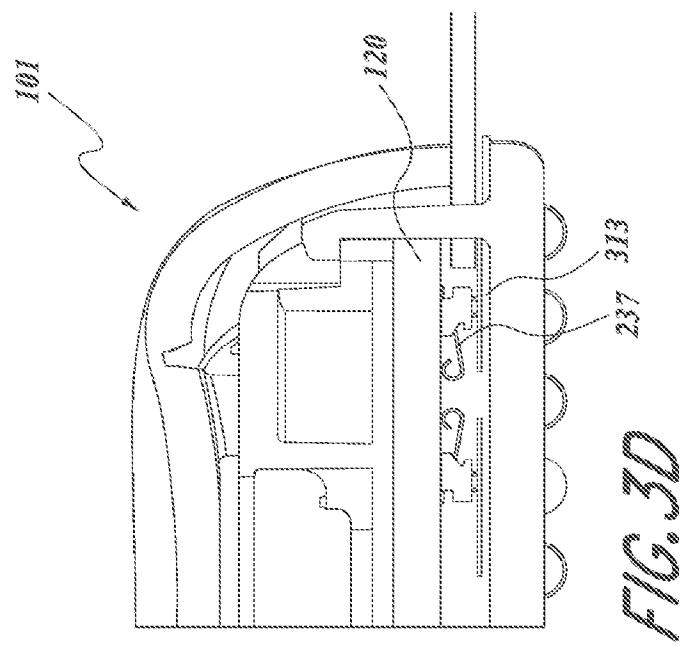


FIG. 3B





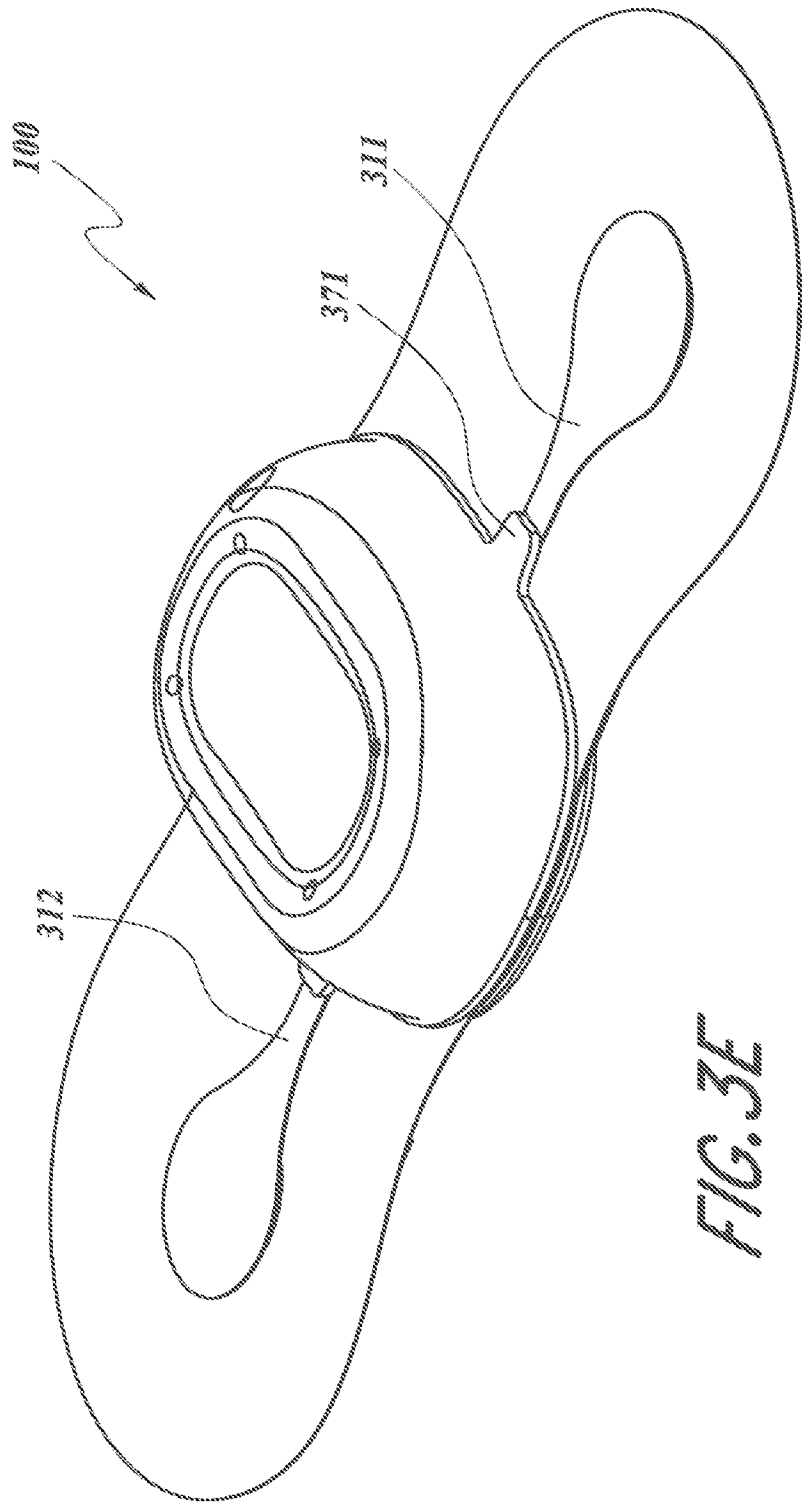


FIG. 3E

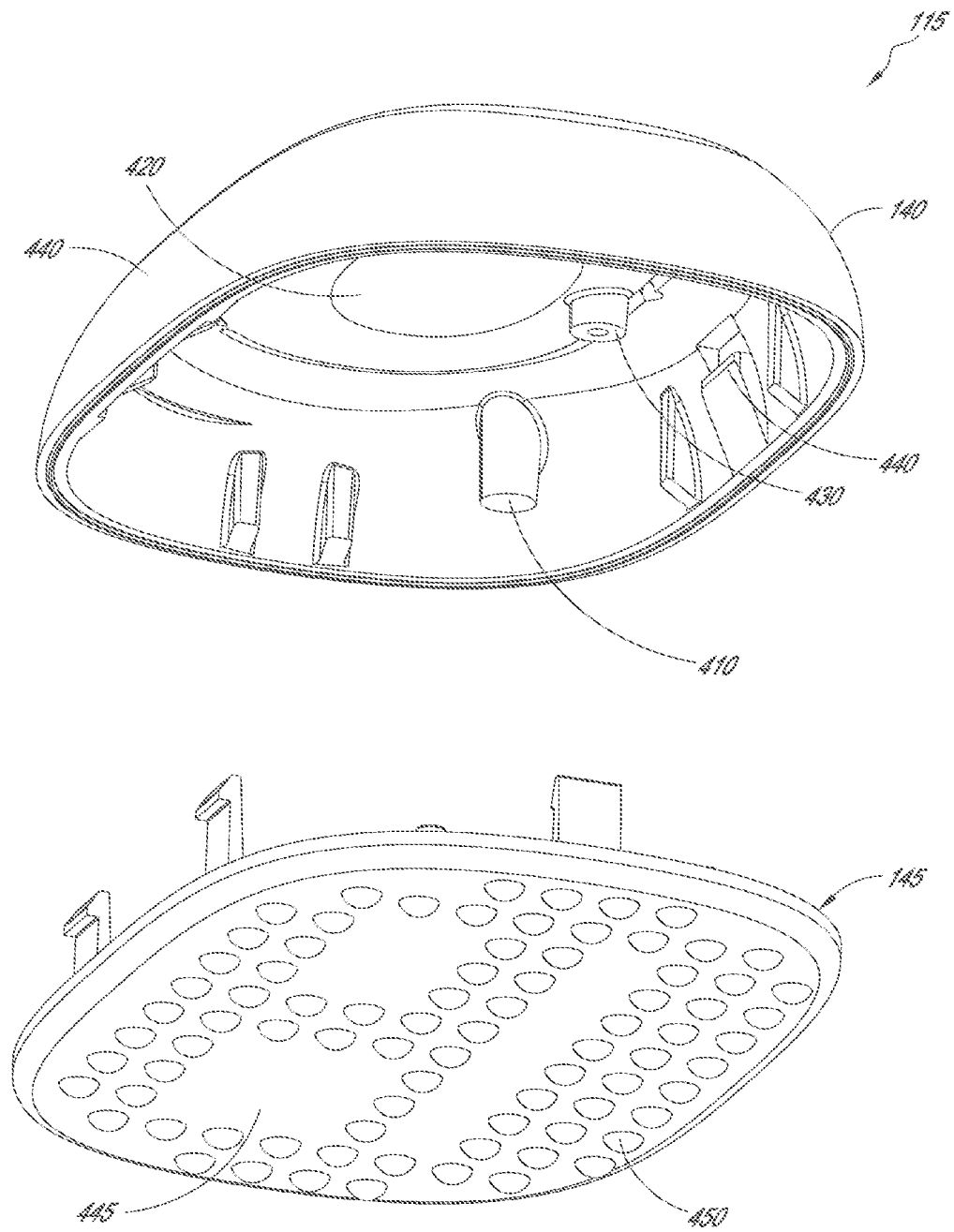
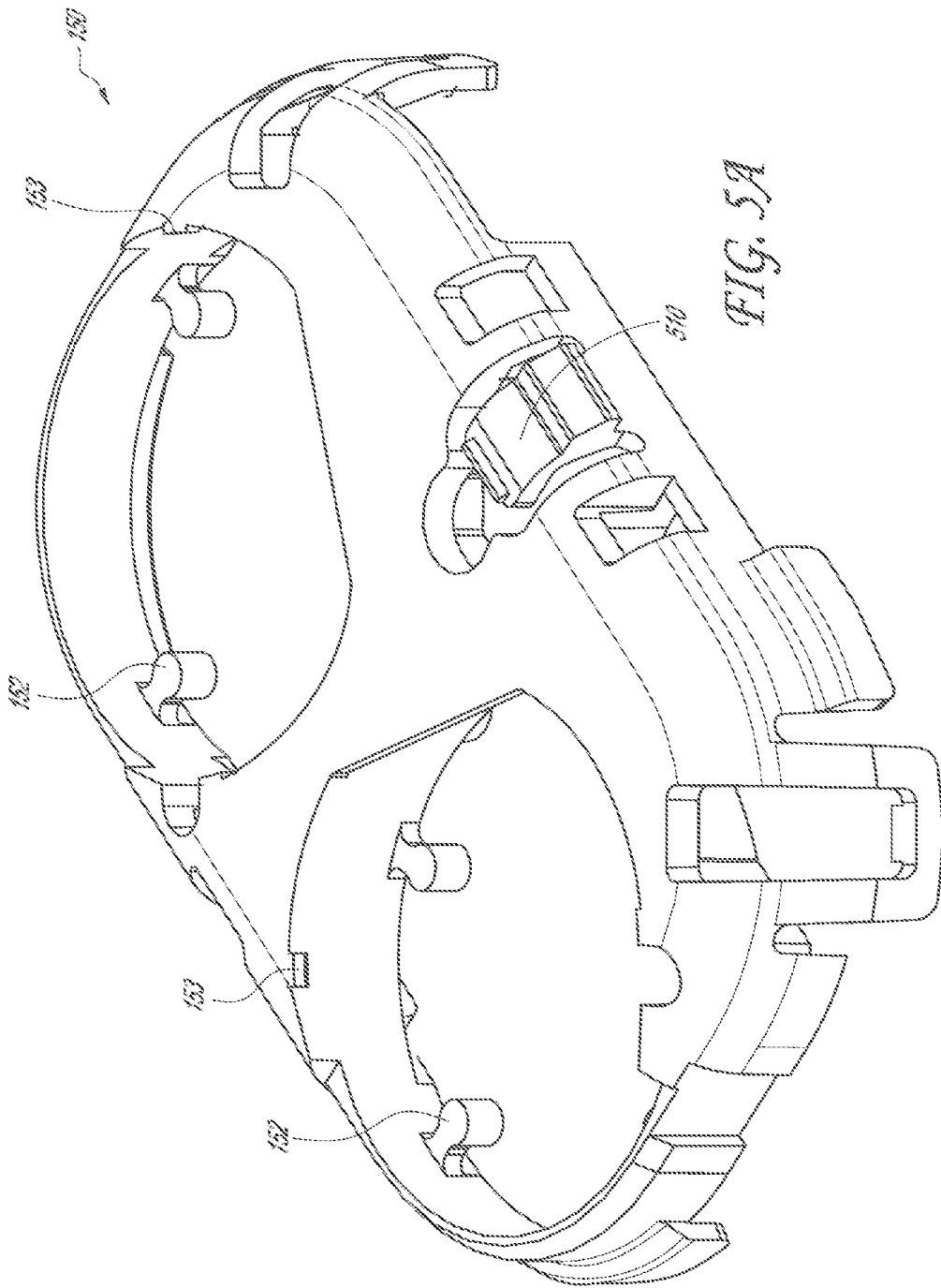


FIG. 4



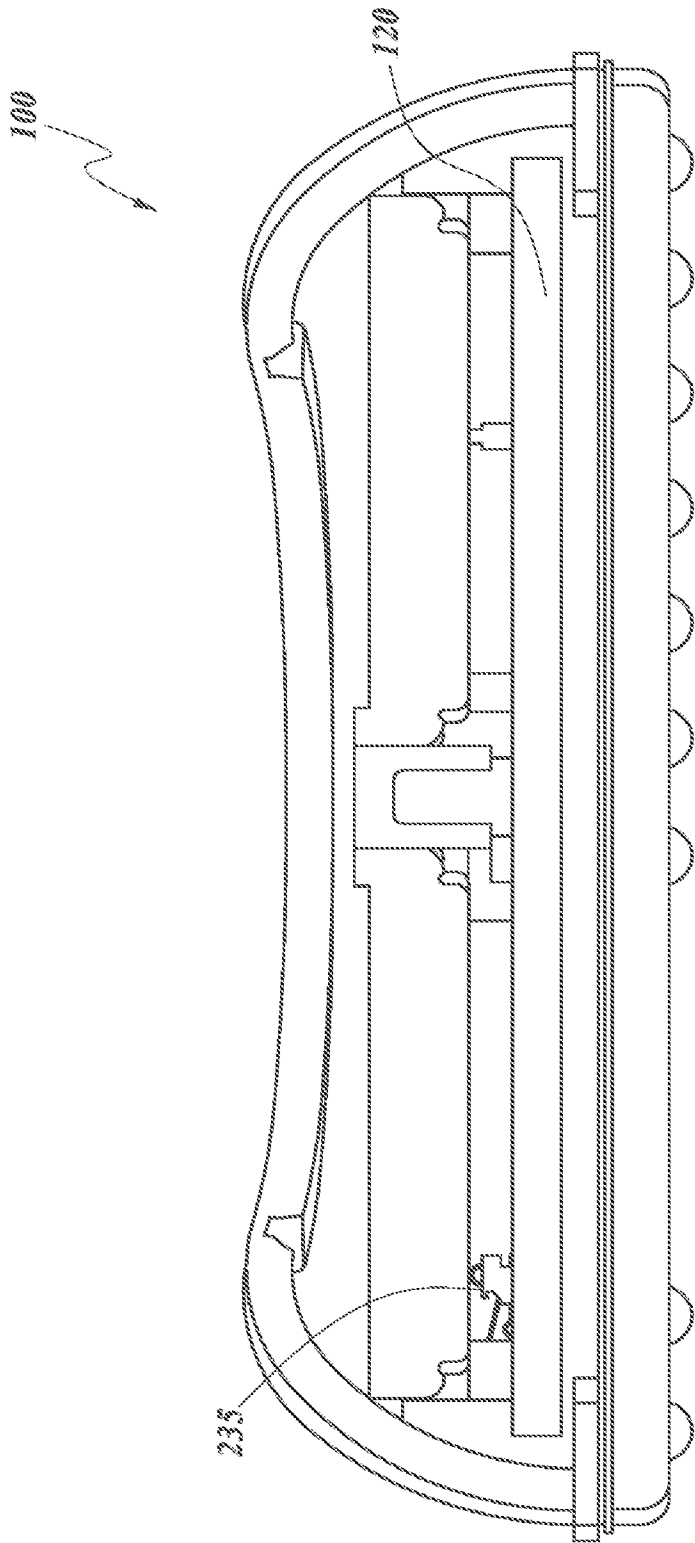
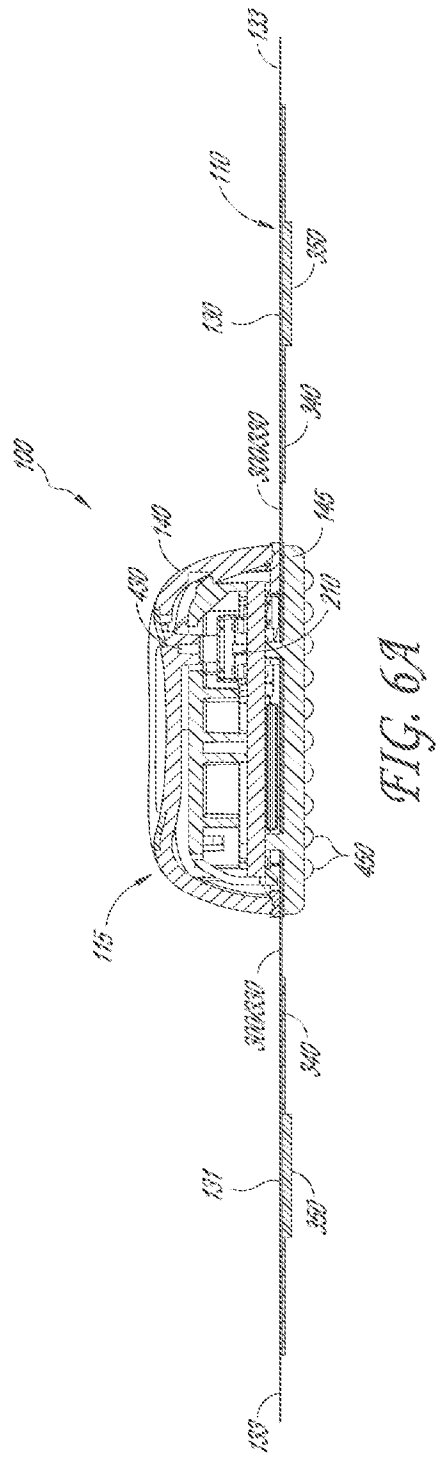
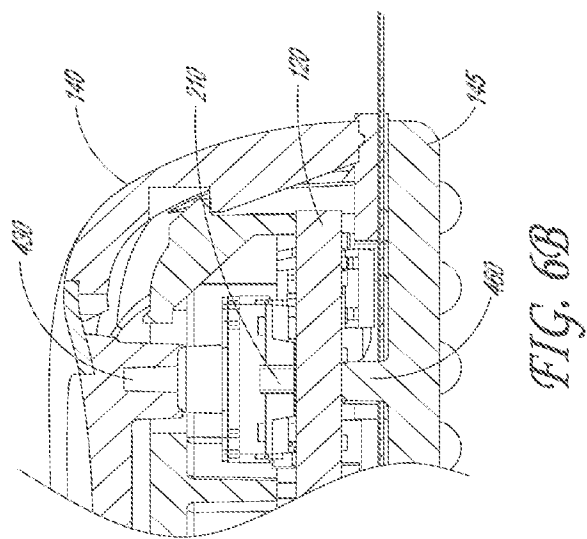


FIG. 5B





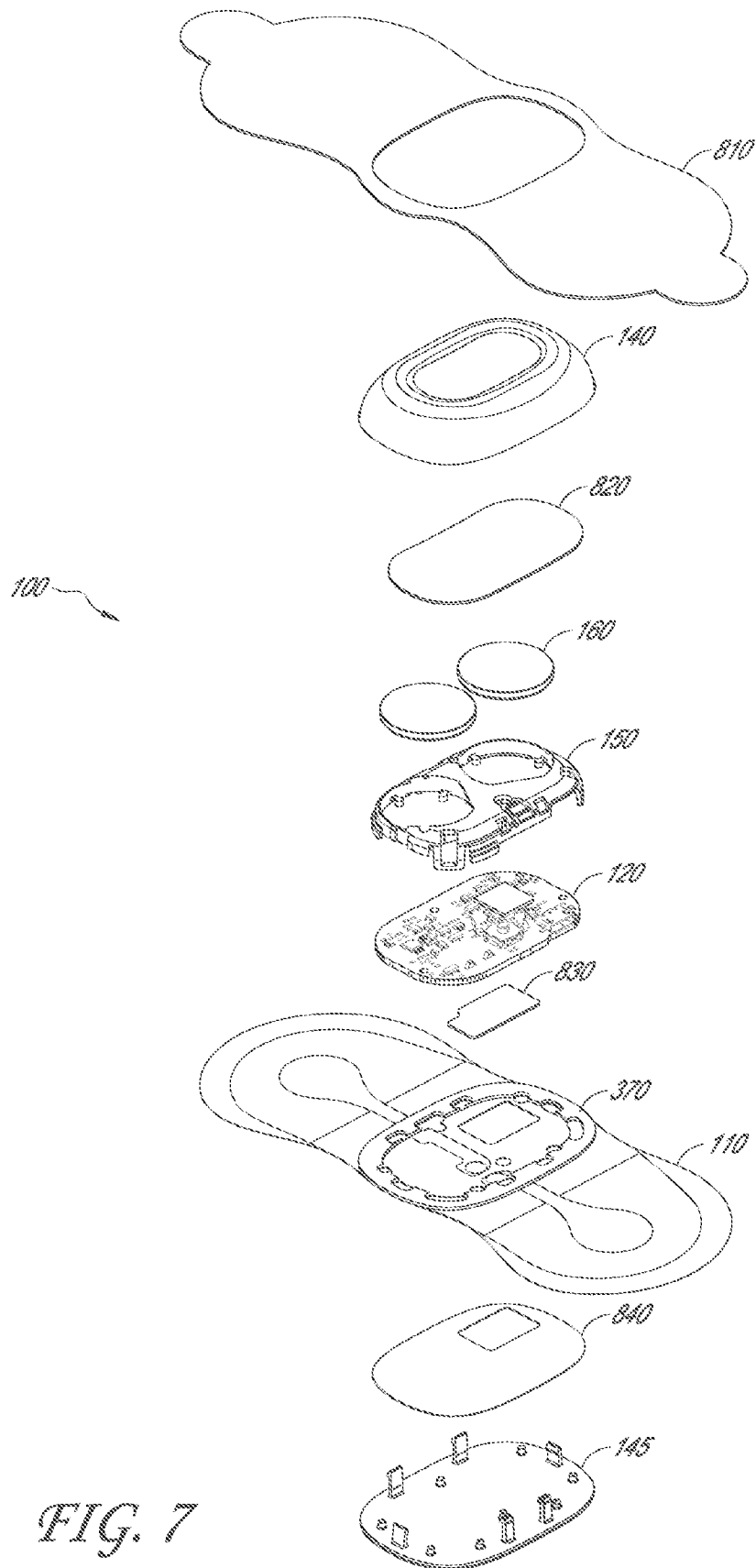


FIG. 7



FIG. 8A

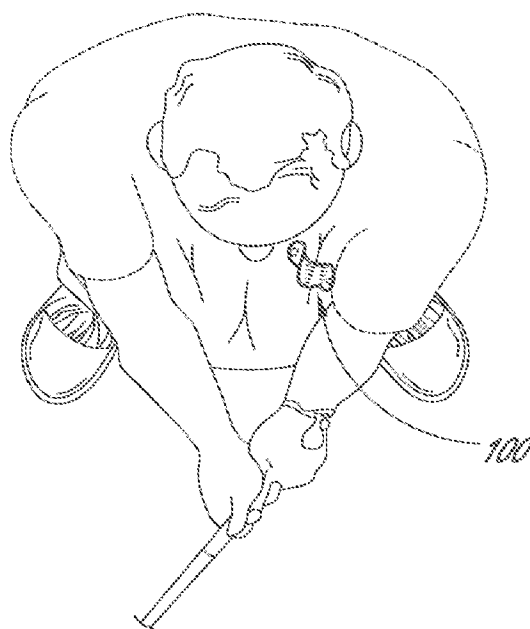


FIG. 8B

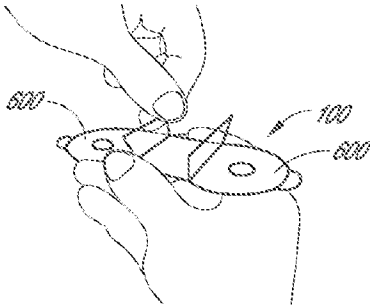


FIG. 9A

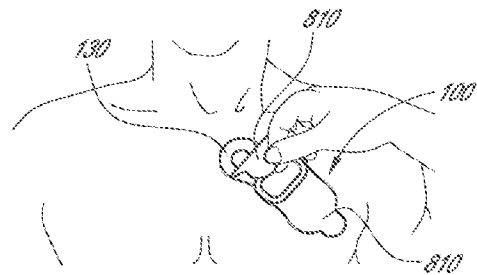


FIG. 9D

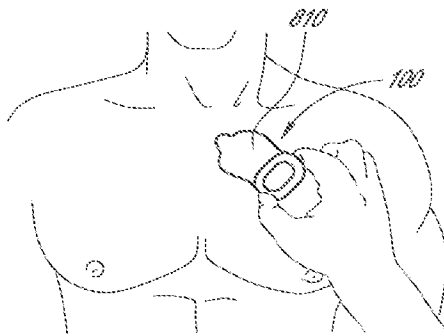


FIG. 9B

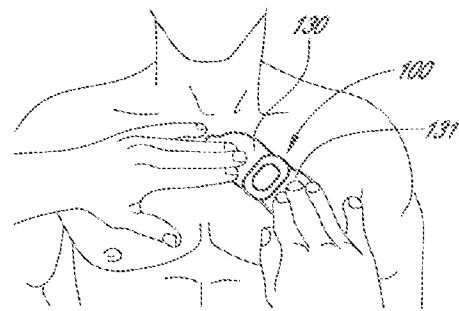


FIG. 9E

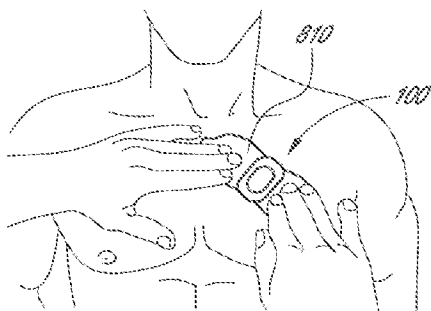


FIG. 9C

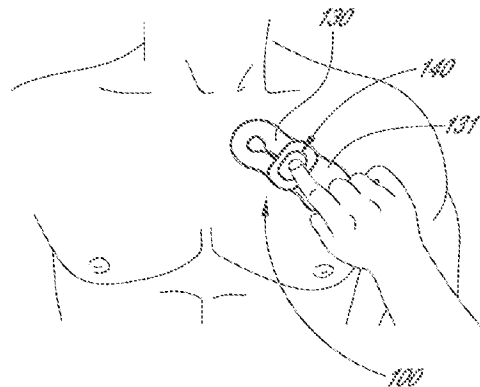
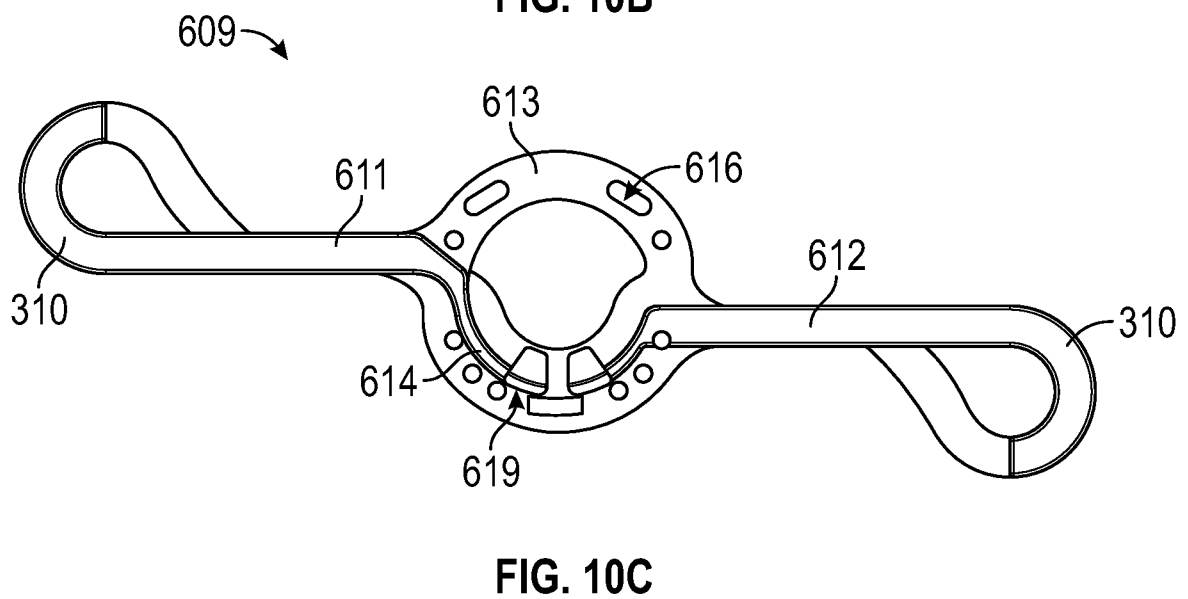
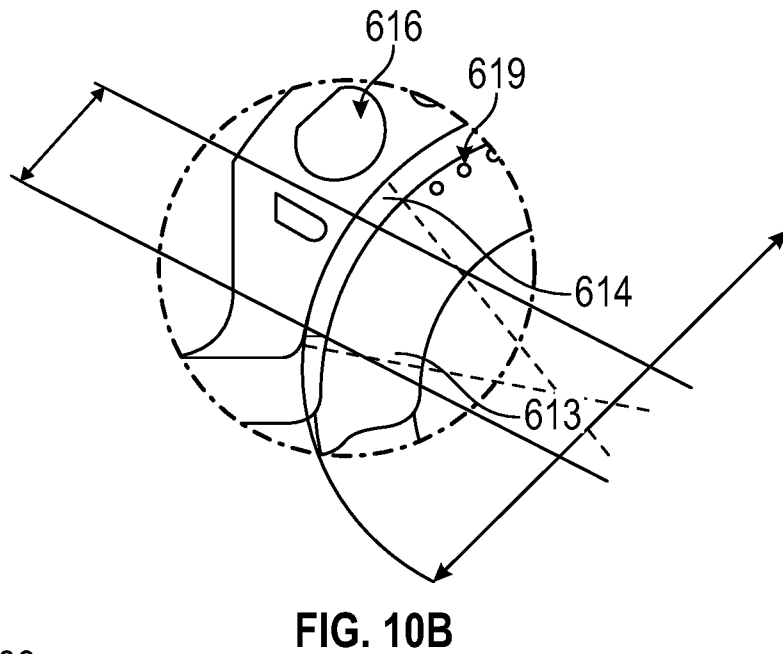
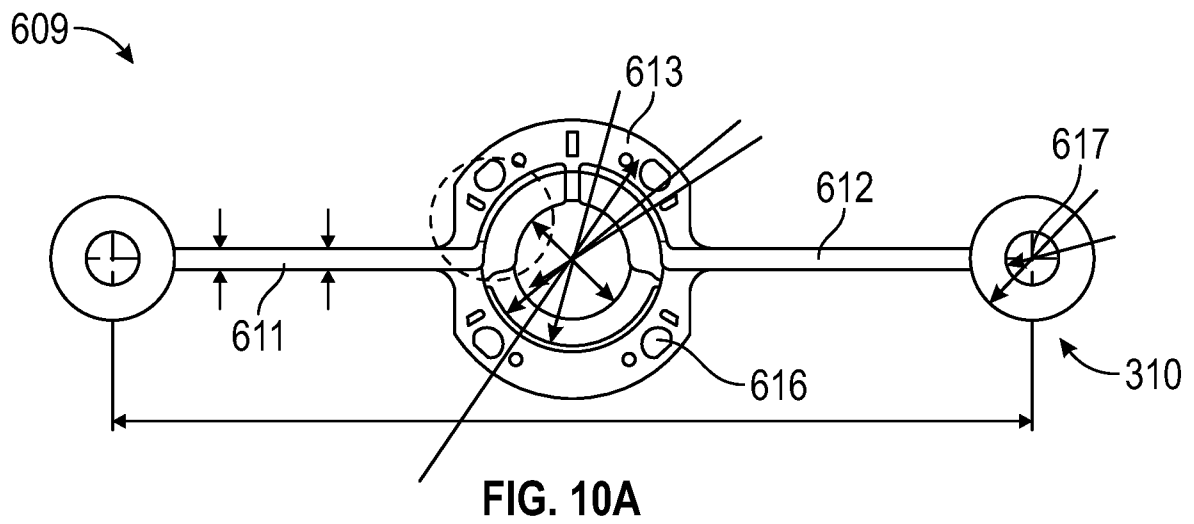


FIG. 9F



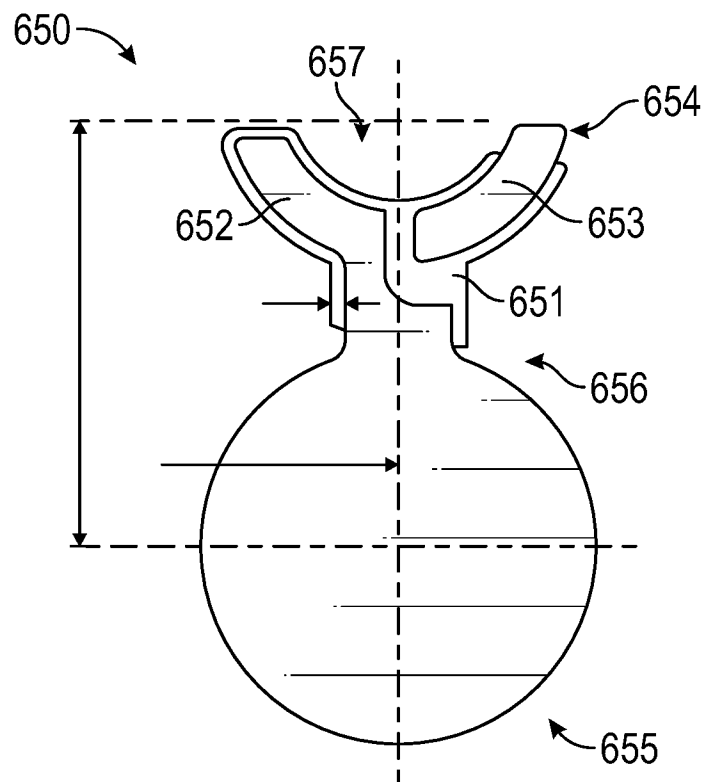


FIG. 11A

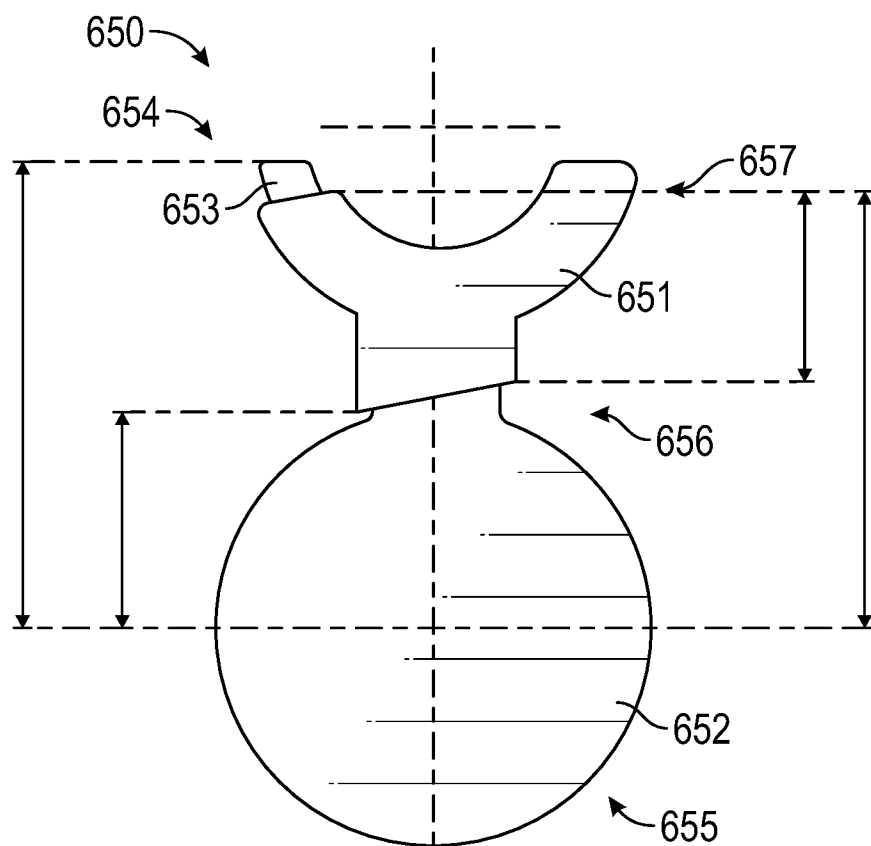


FIG. 11B

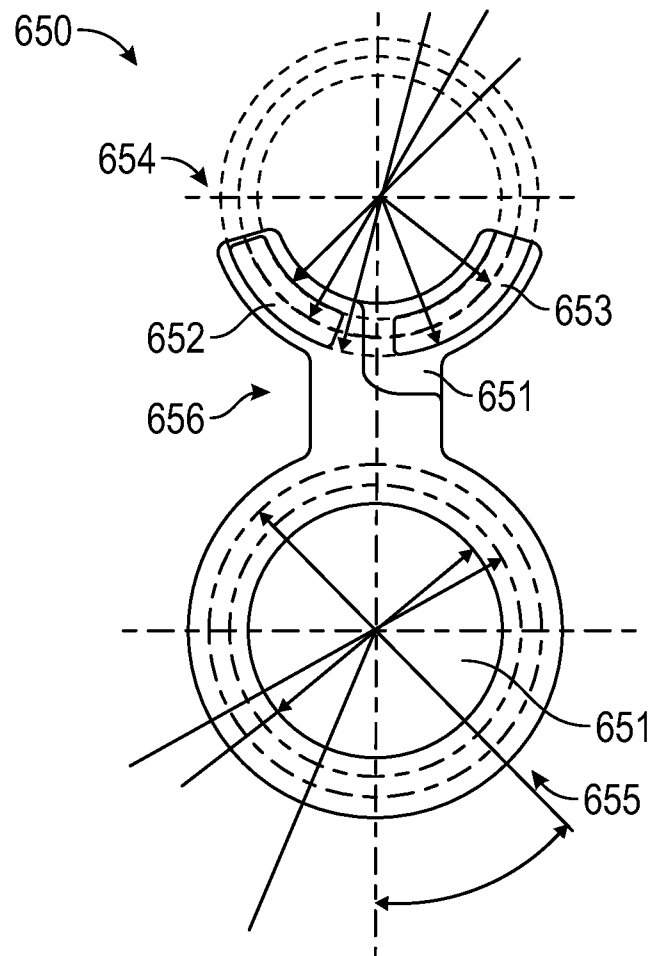


FIG. 11C

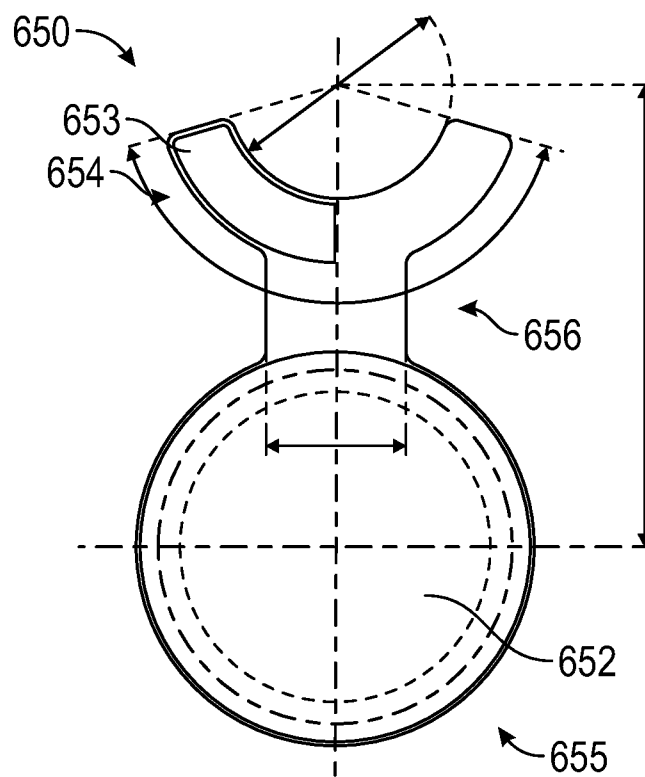


FIG. 11D

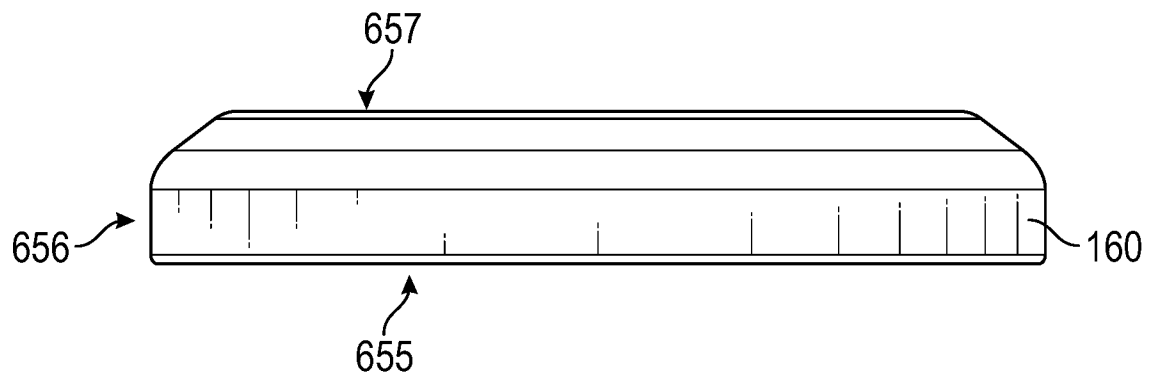
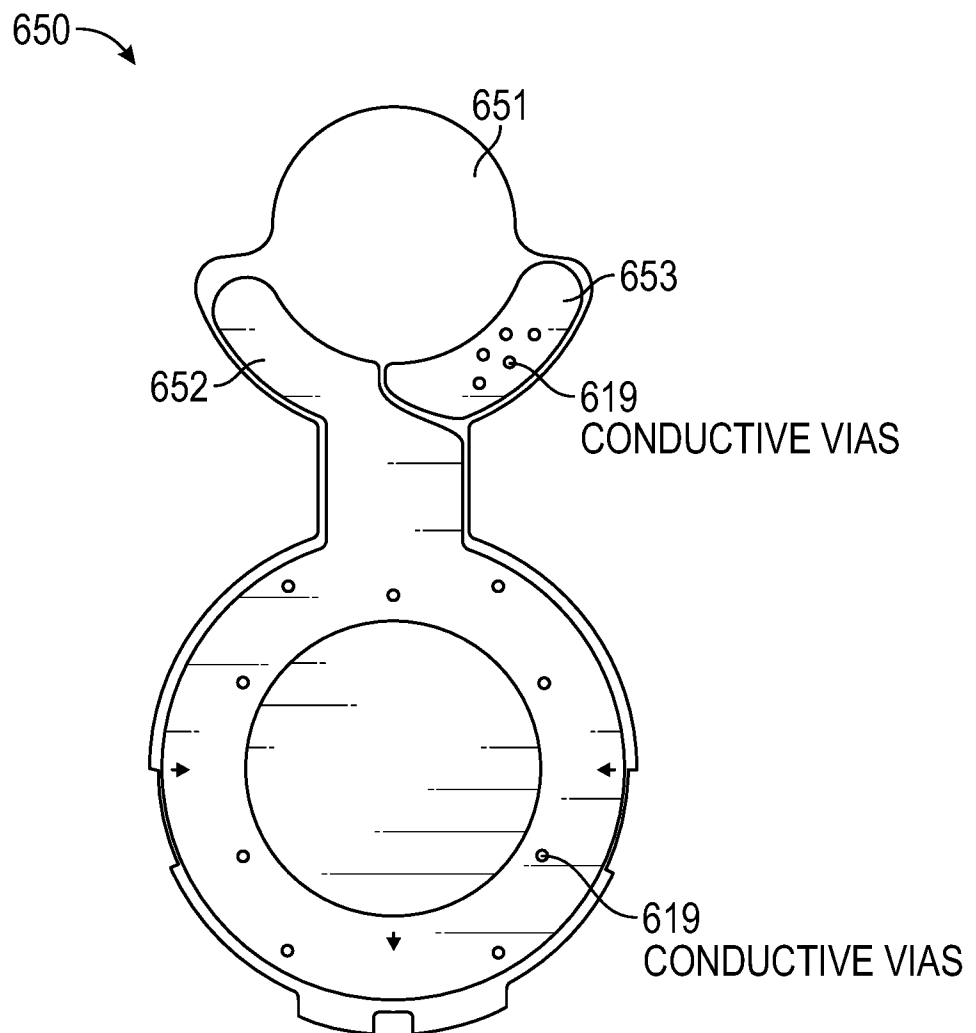
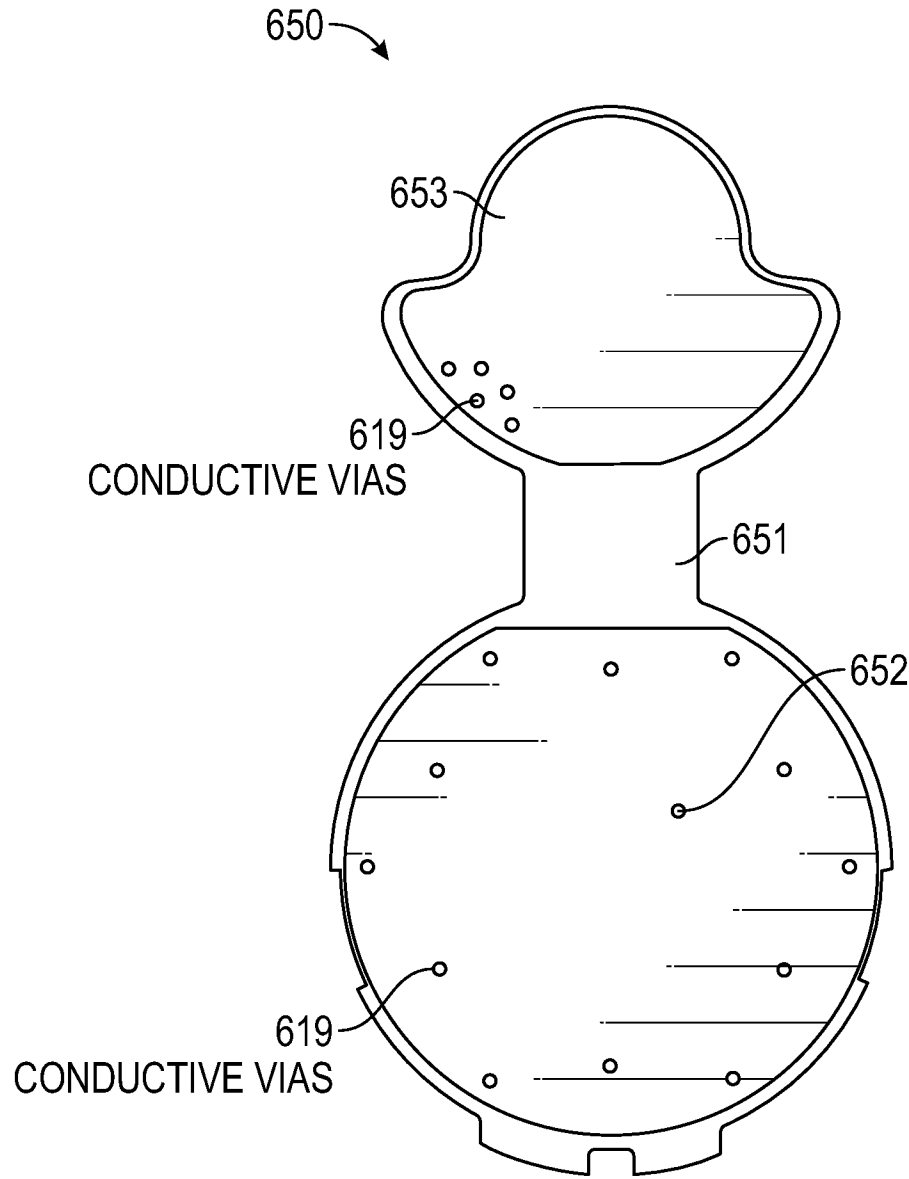


FIG. 11E

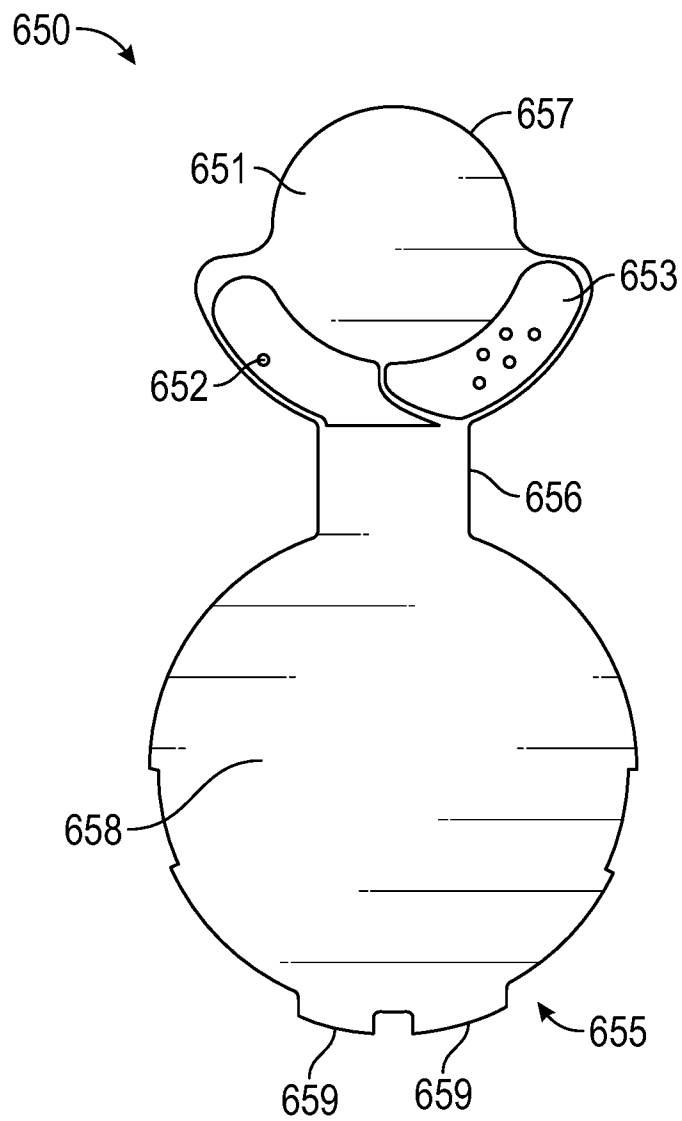


OUTER SURFACE

FIG. 11F

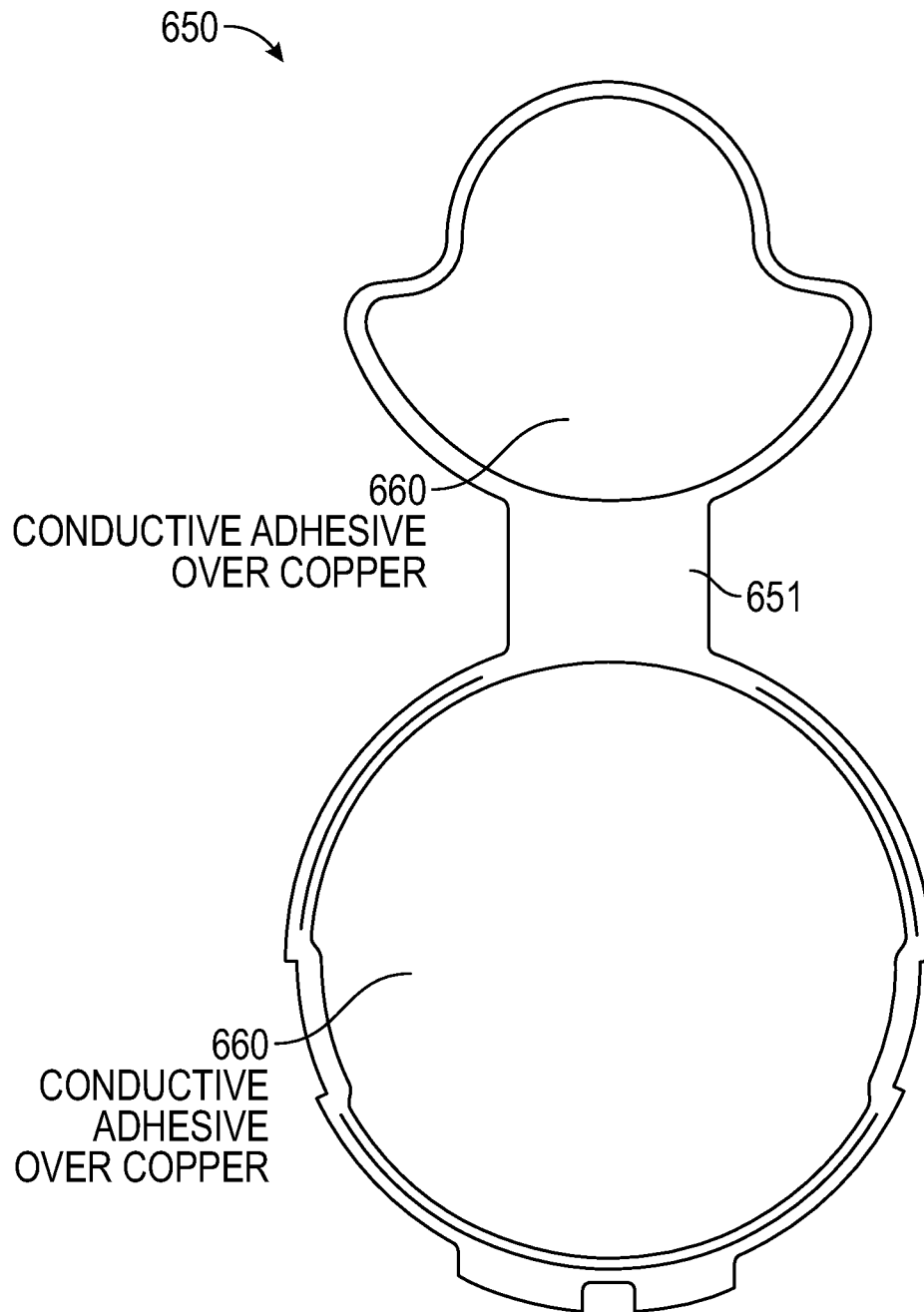


INNER SURFACE
FIG. 11G



OUTER SURFACE

FIG. 11H



INNER SURFACE

FIG. 11I

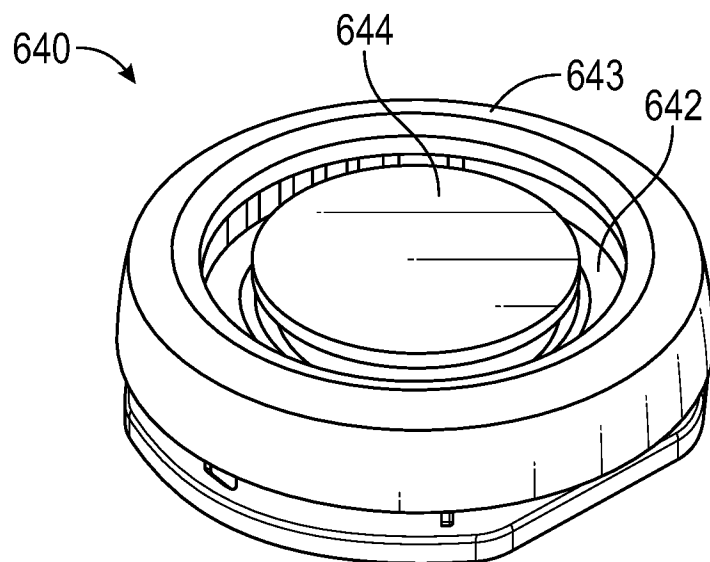


FIG. 12A

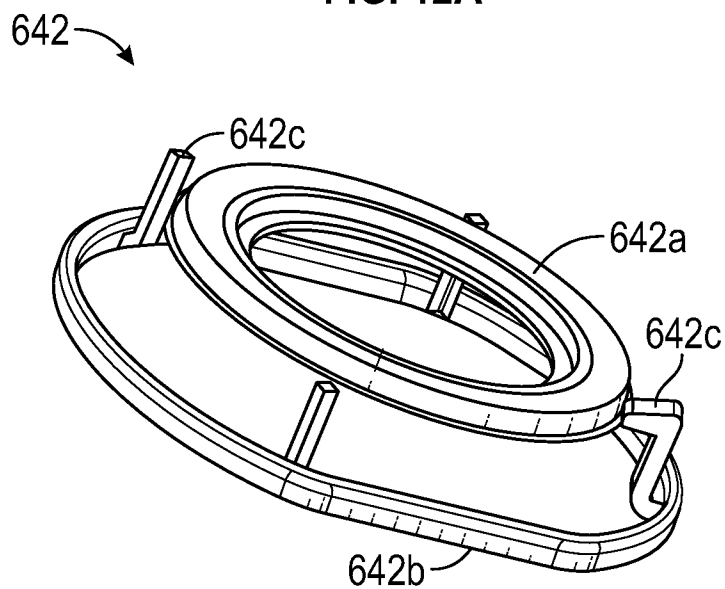


FIG. 12B

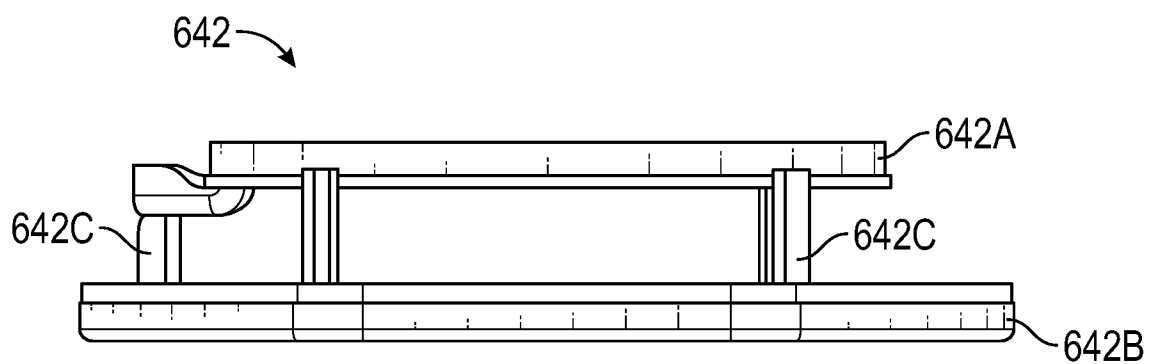


FIG. 12C

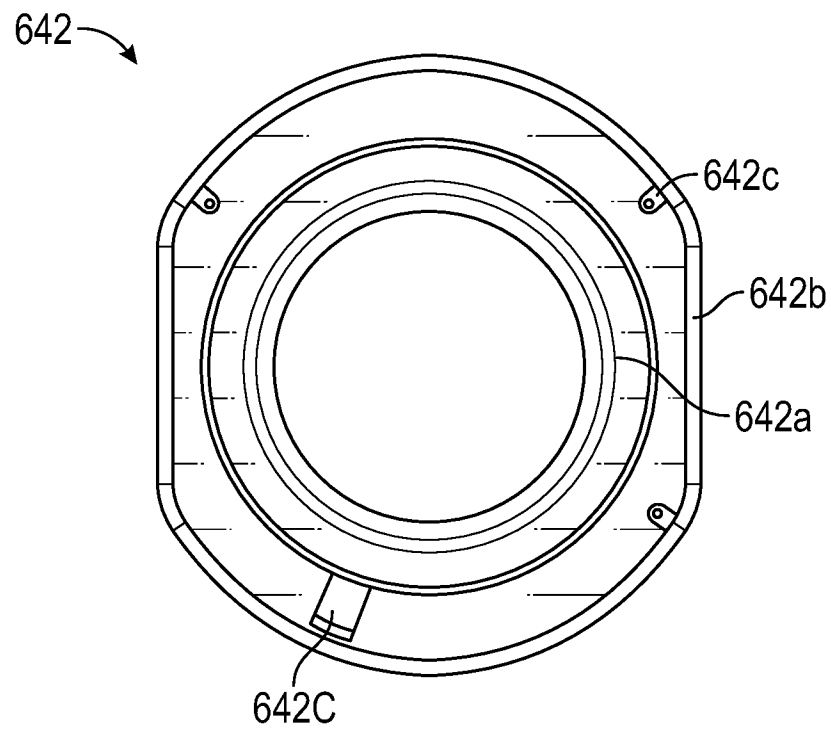


FIG. 12D

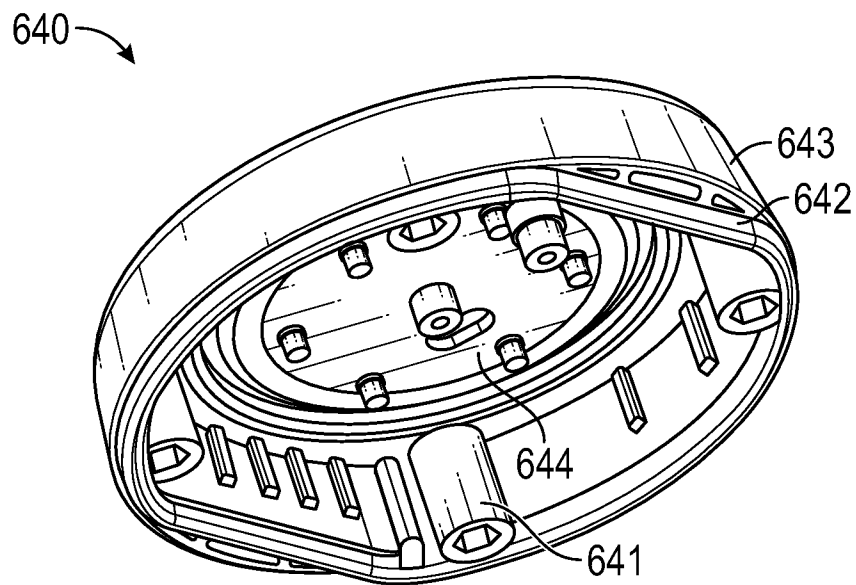


FIG. 12E

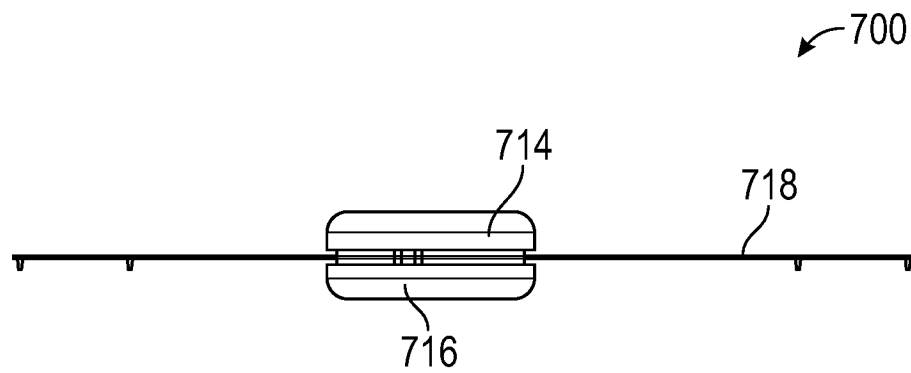


FIG. 12F

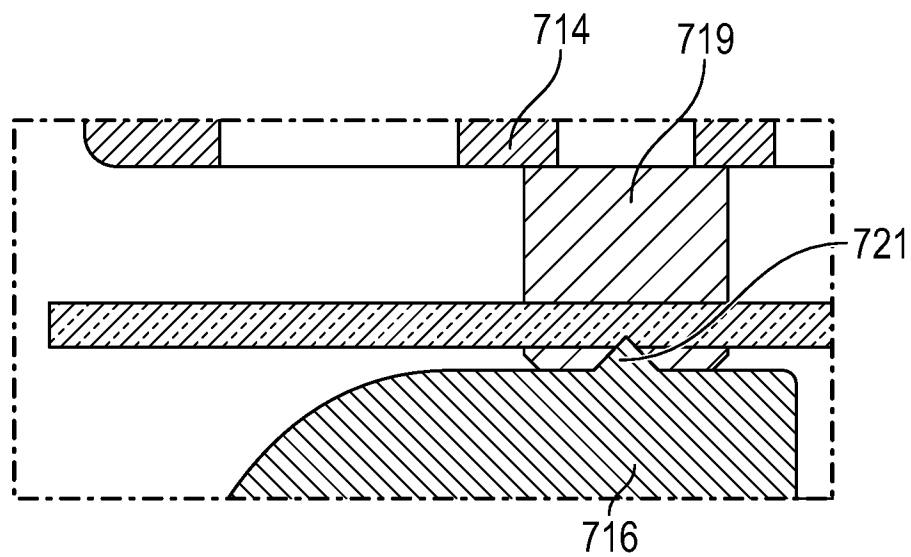


FIG. 12G

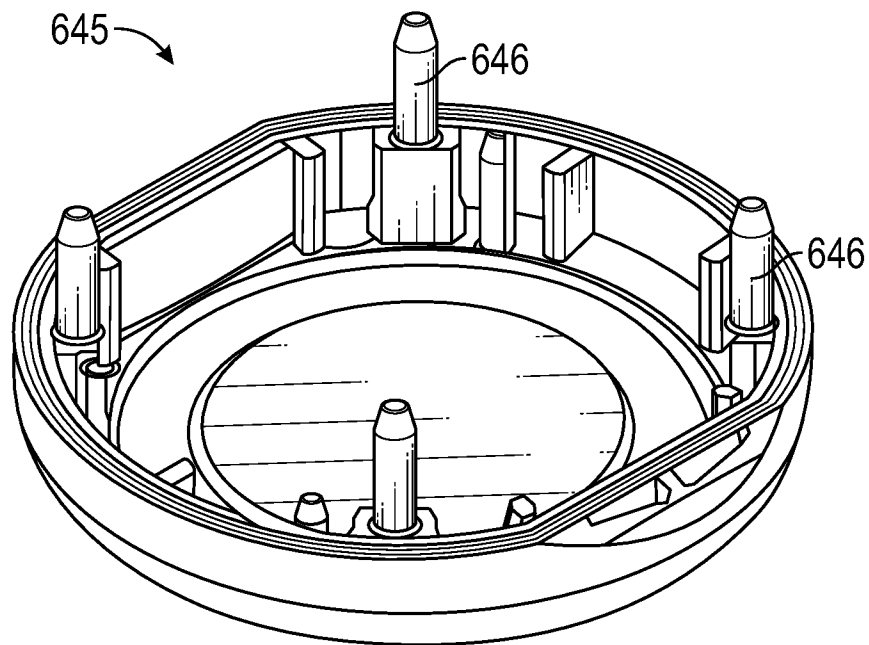


FIG. 13A

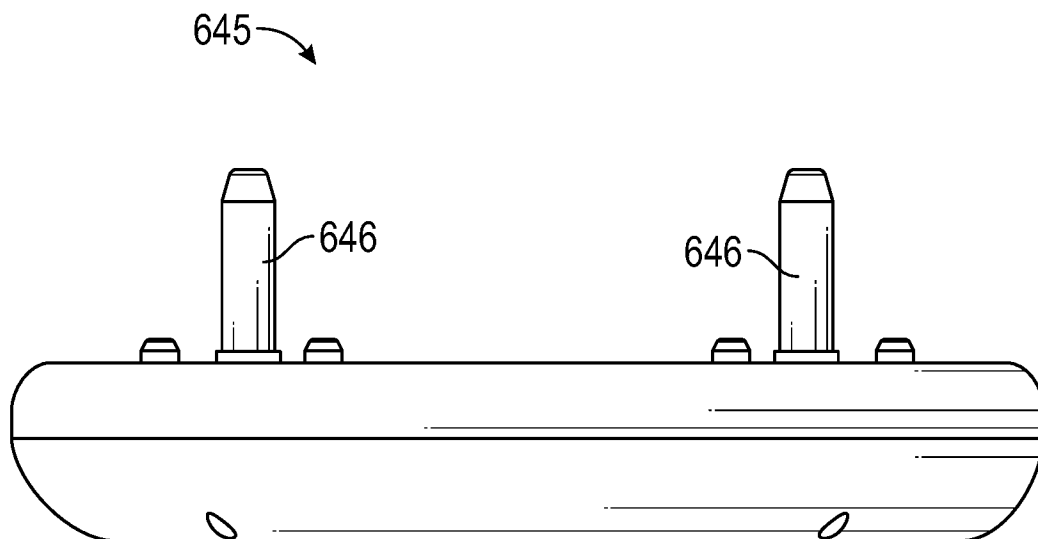


FIG. 13B

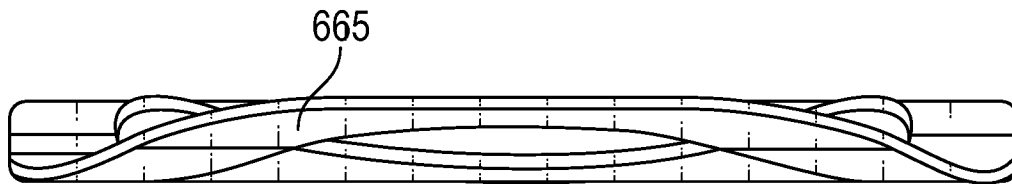


FIG. 14A

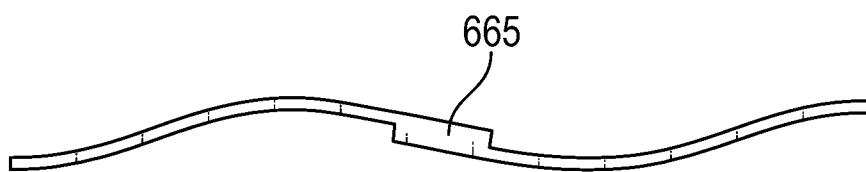


FIG. 14B

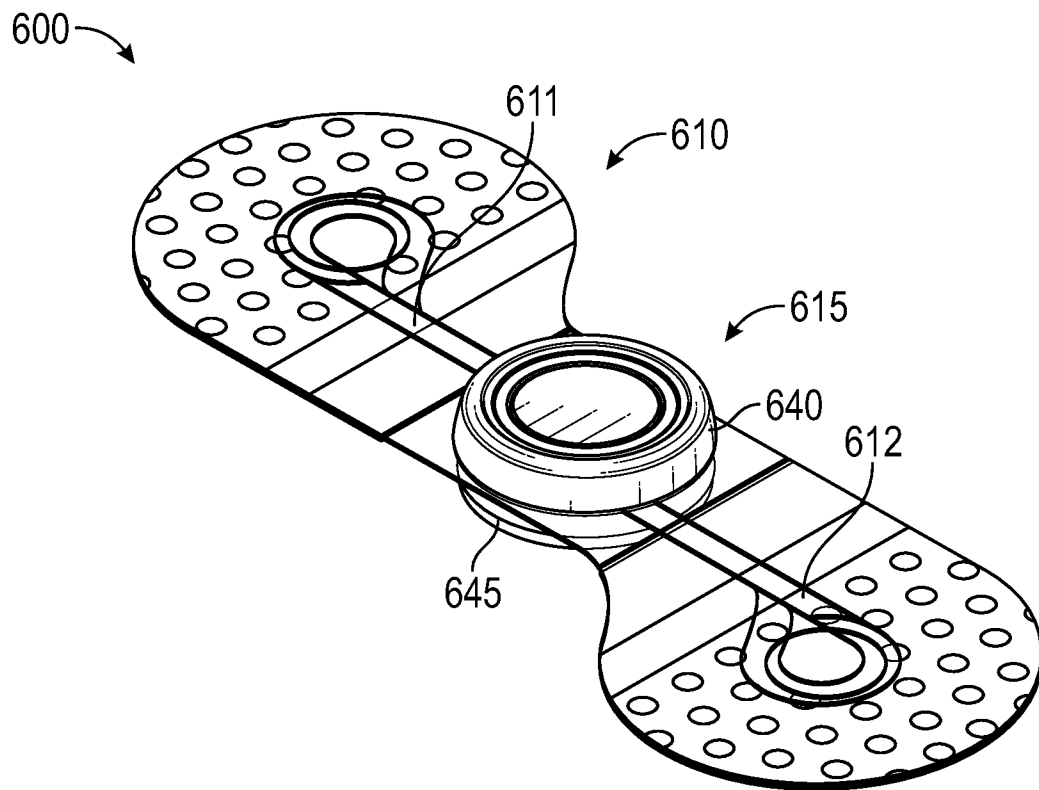


FIG. 15A

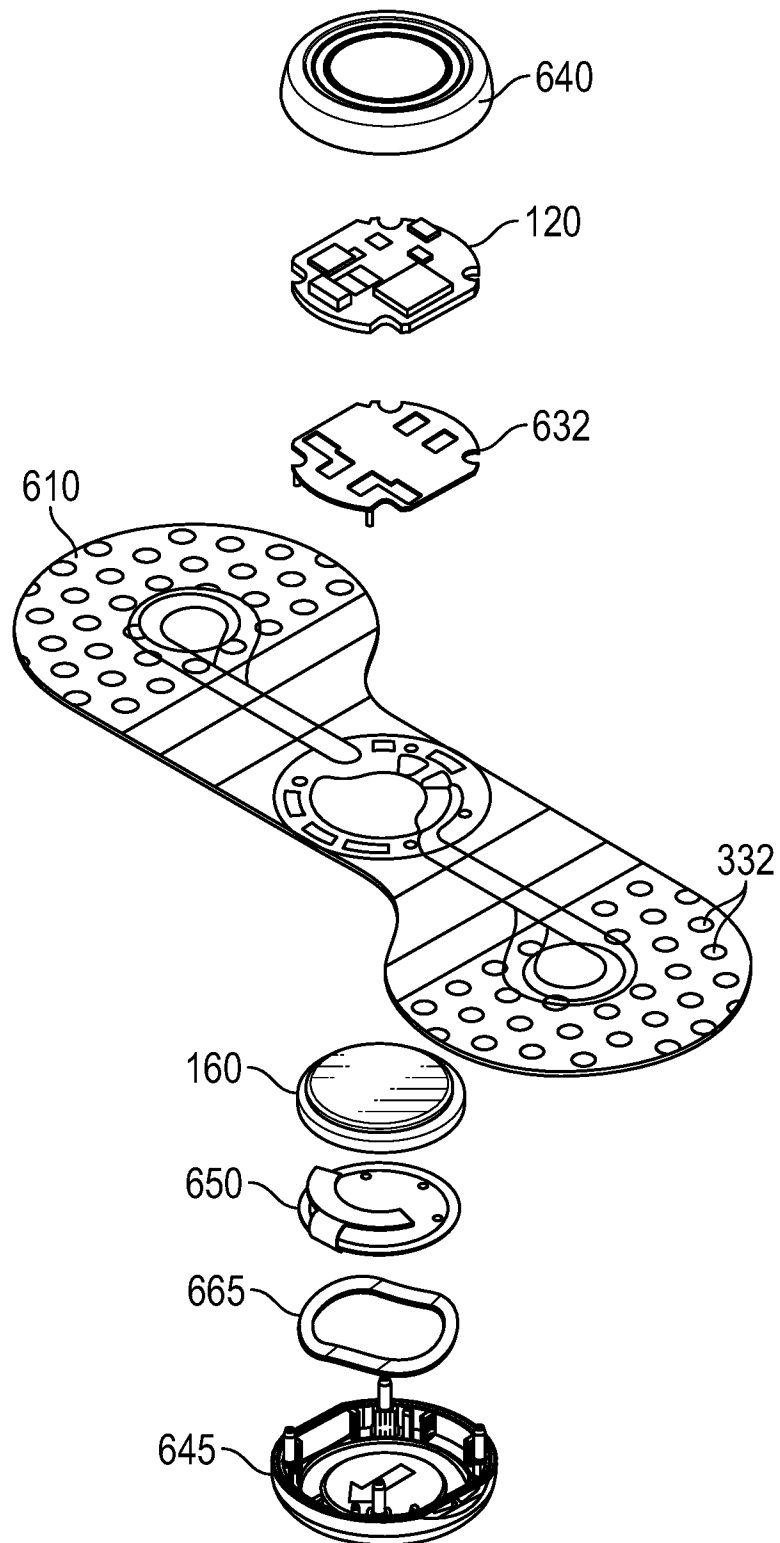


FIG. 15B

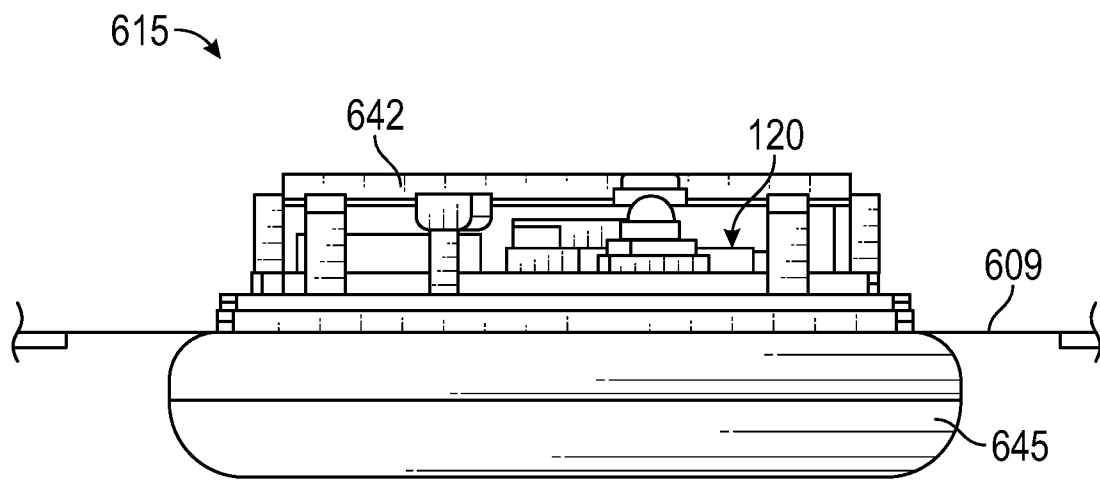


FIG. 15C

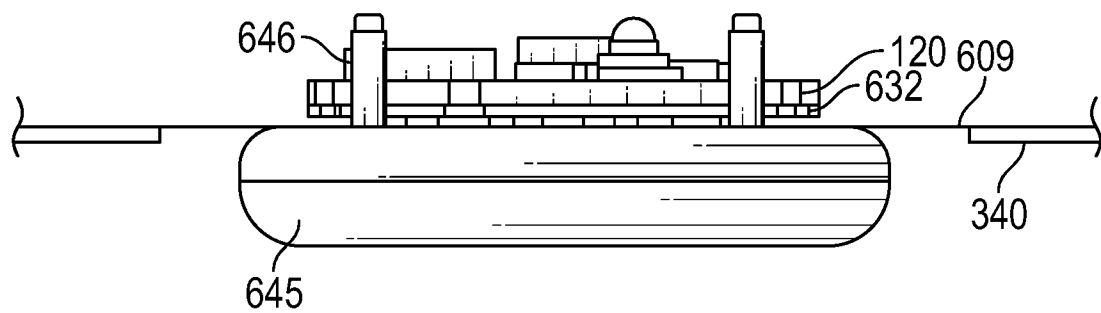


FIG. 15D

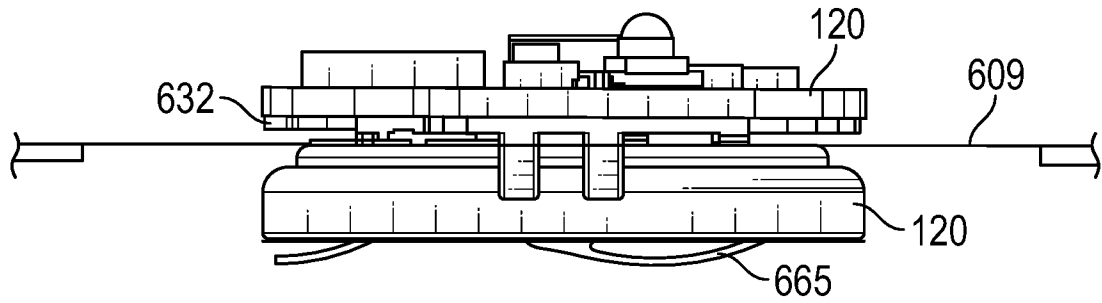


FIG. 15E

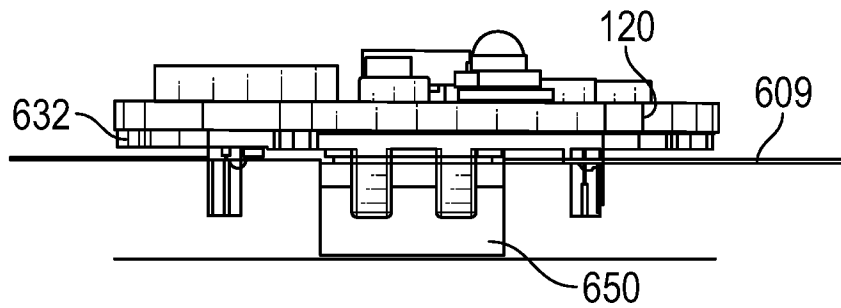


FIG. 15F

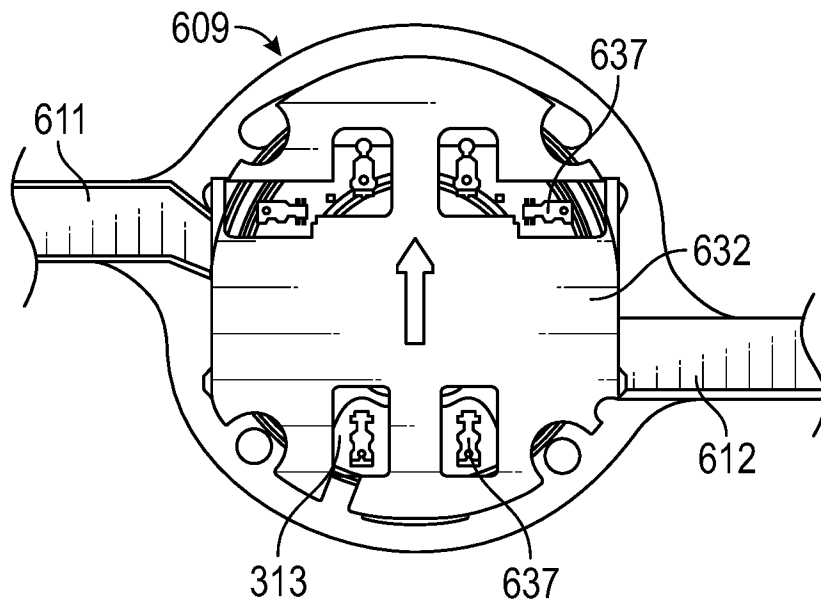


FIG. 15G

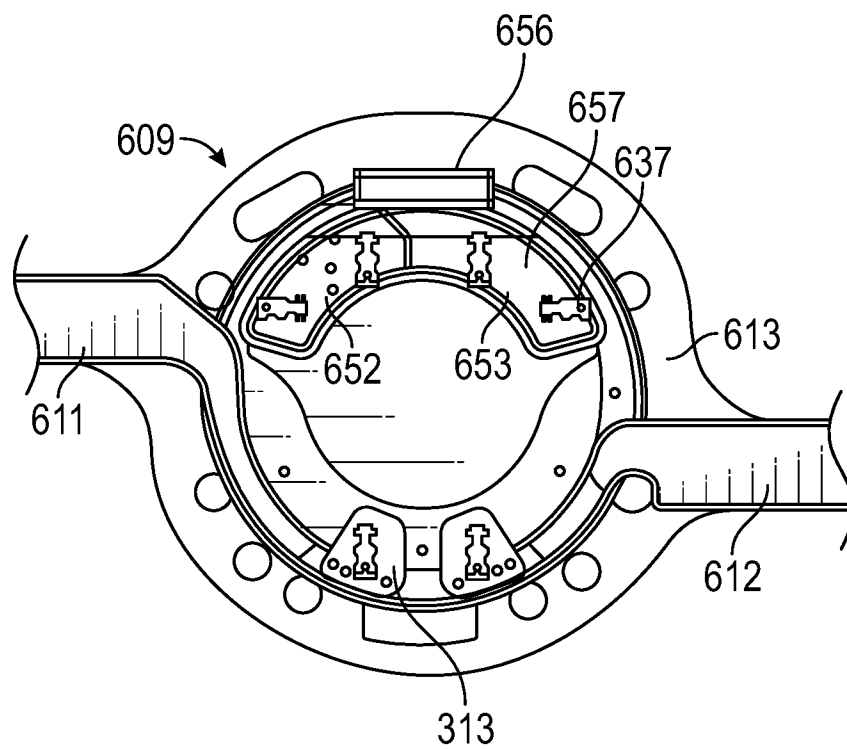


FIG. 15H

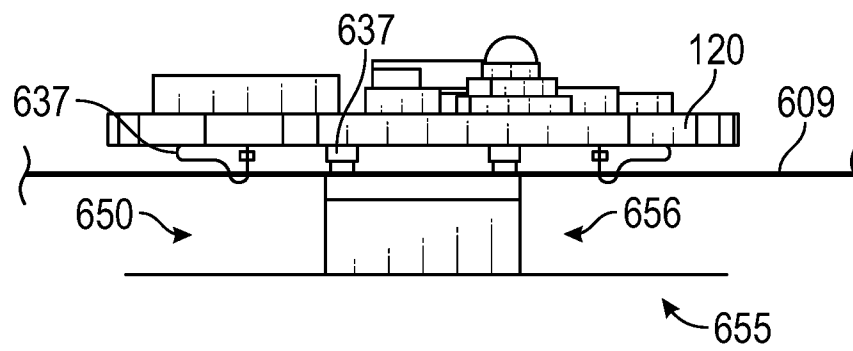


FIG. 15I

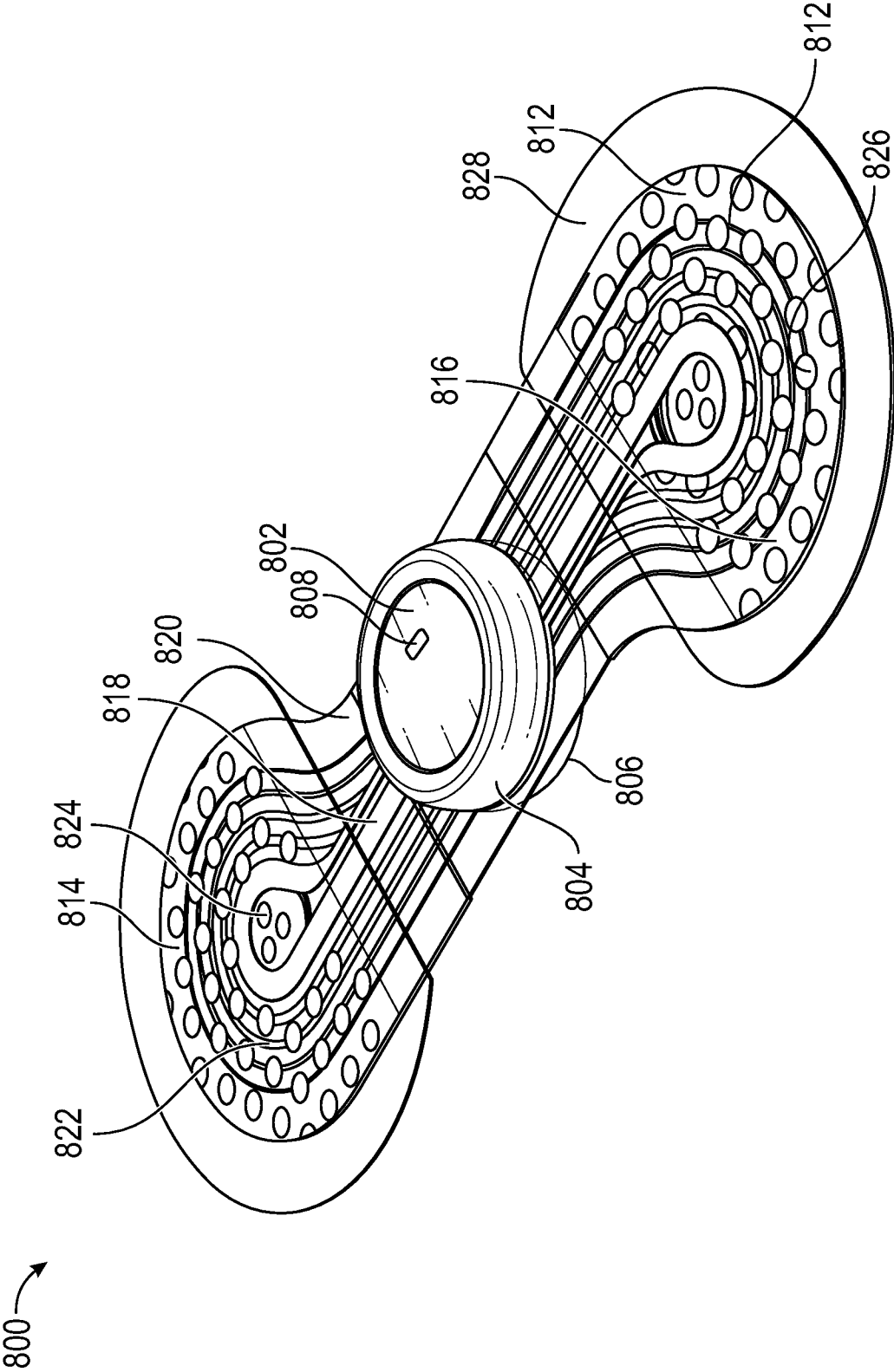


FIG. 16A

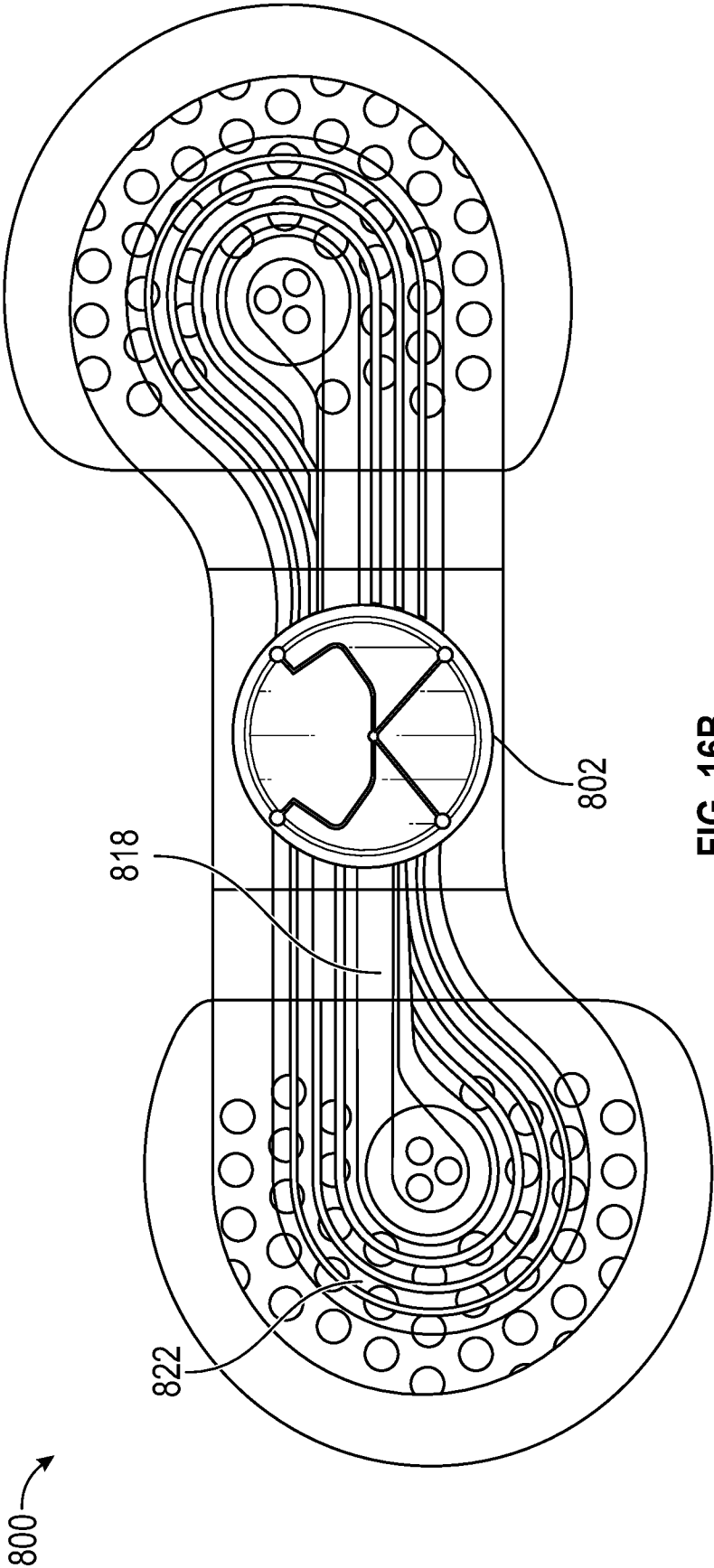


FIG. 16B

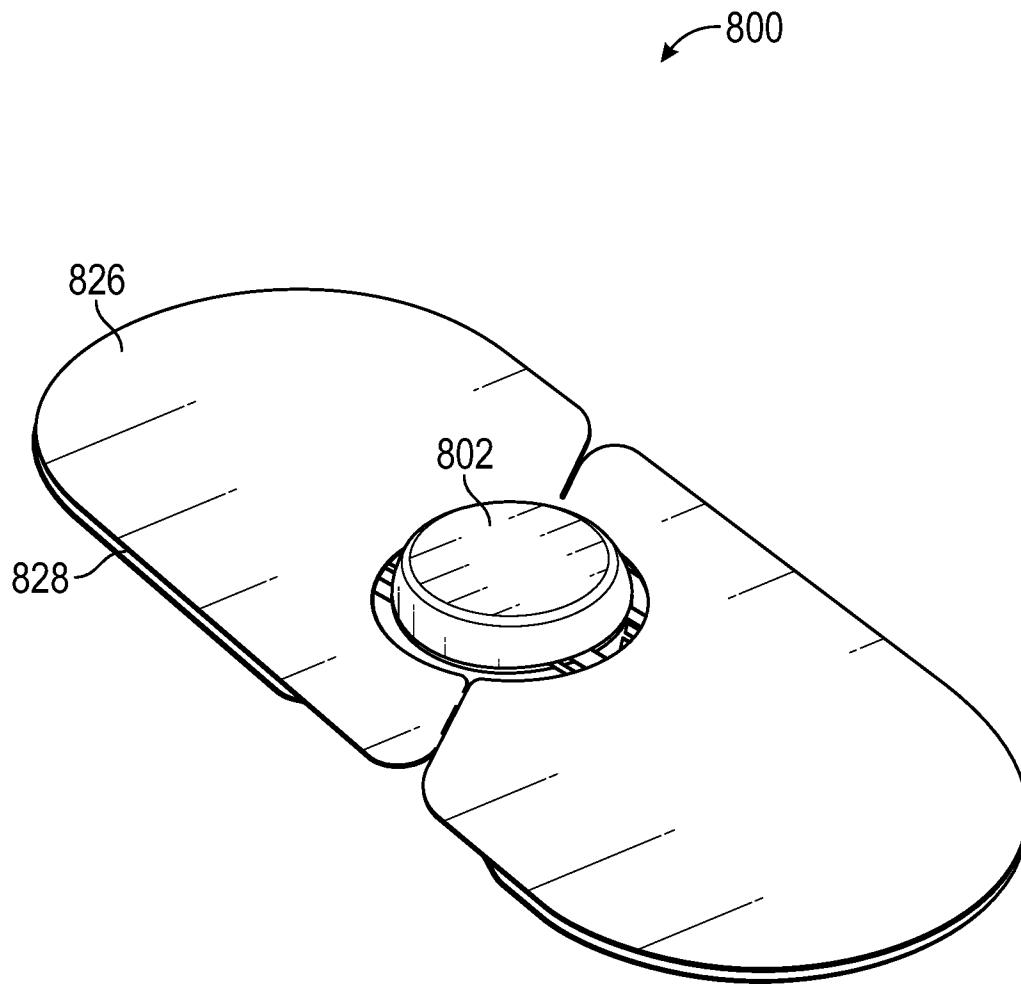


FIG. 16C

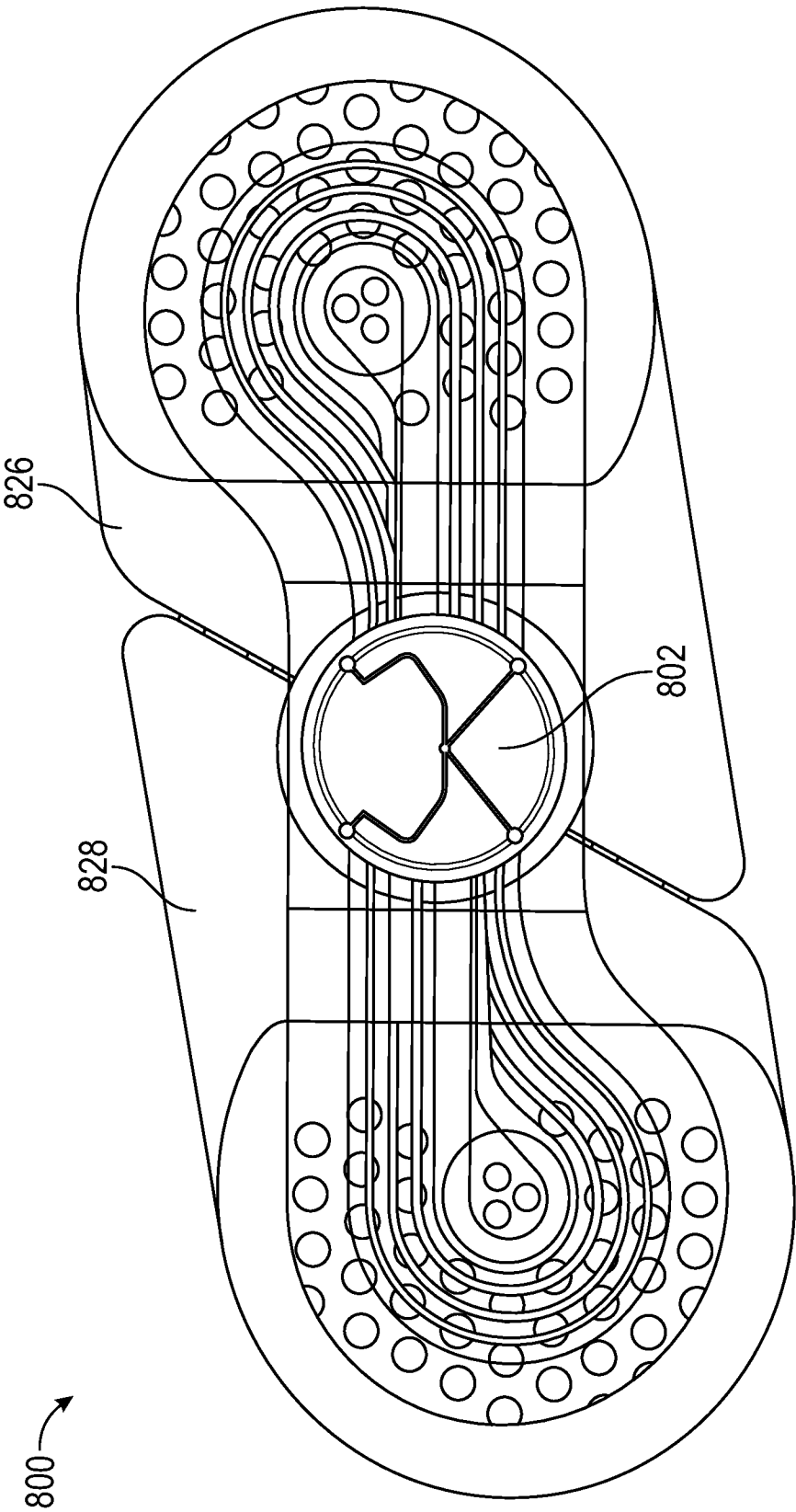


FIG. 16D

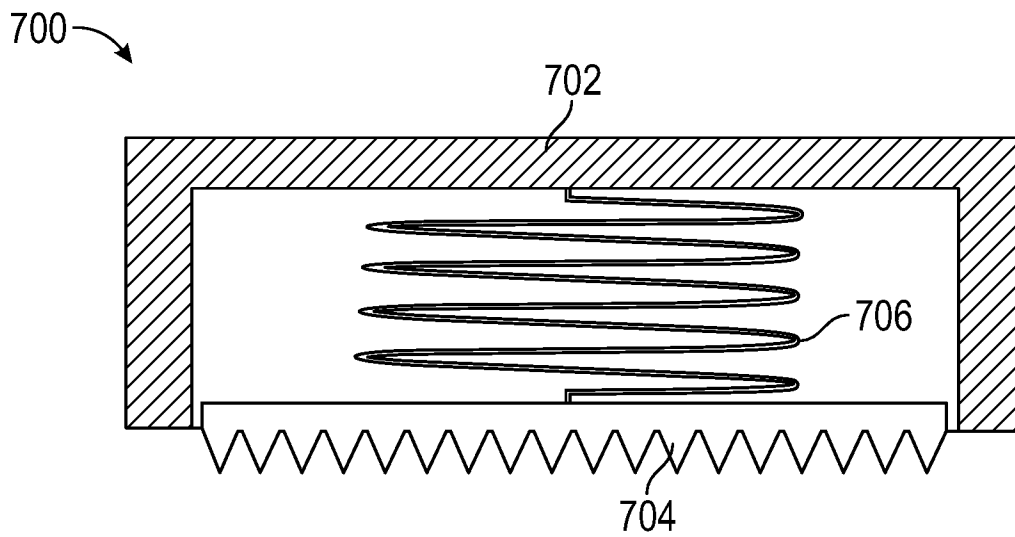


FIG. 17A

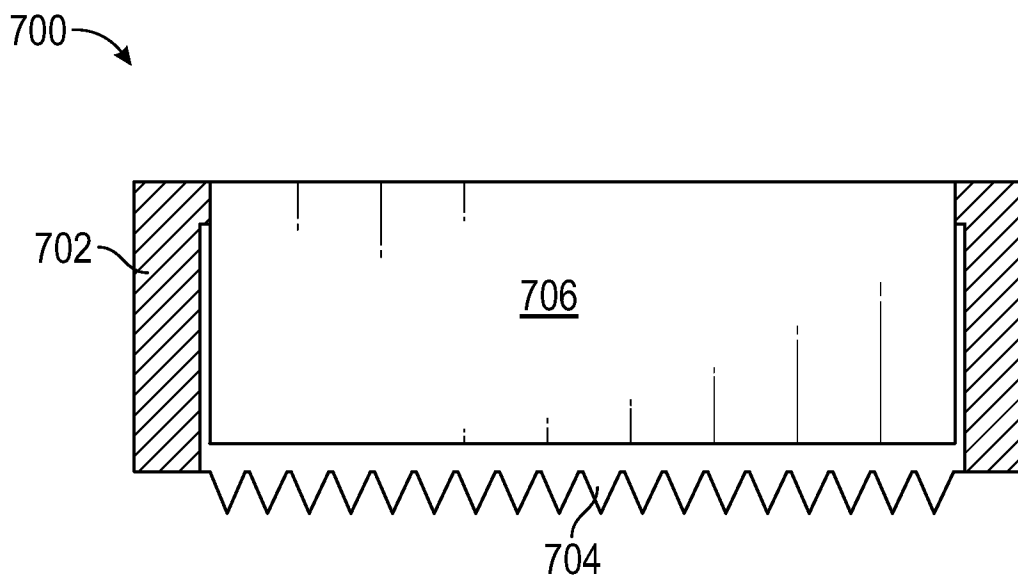


FIG. 17B

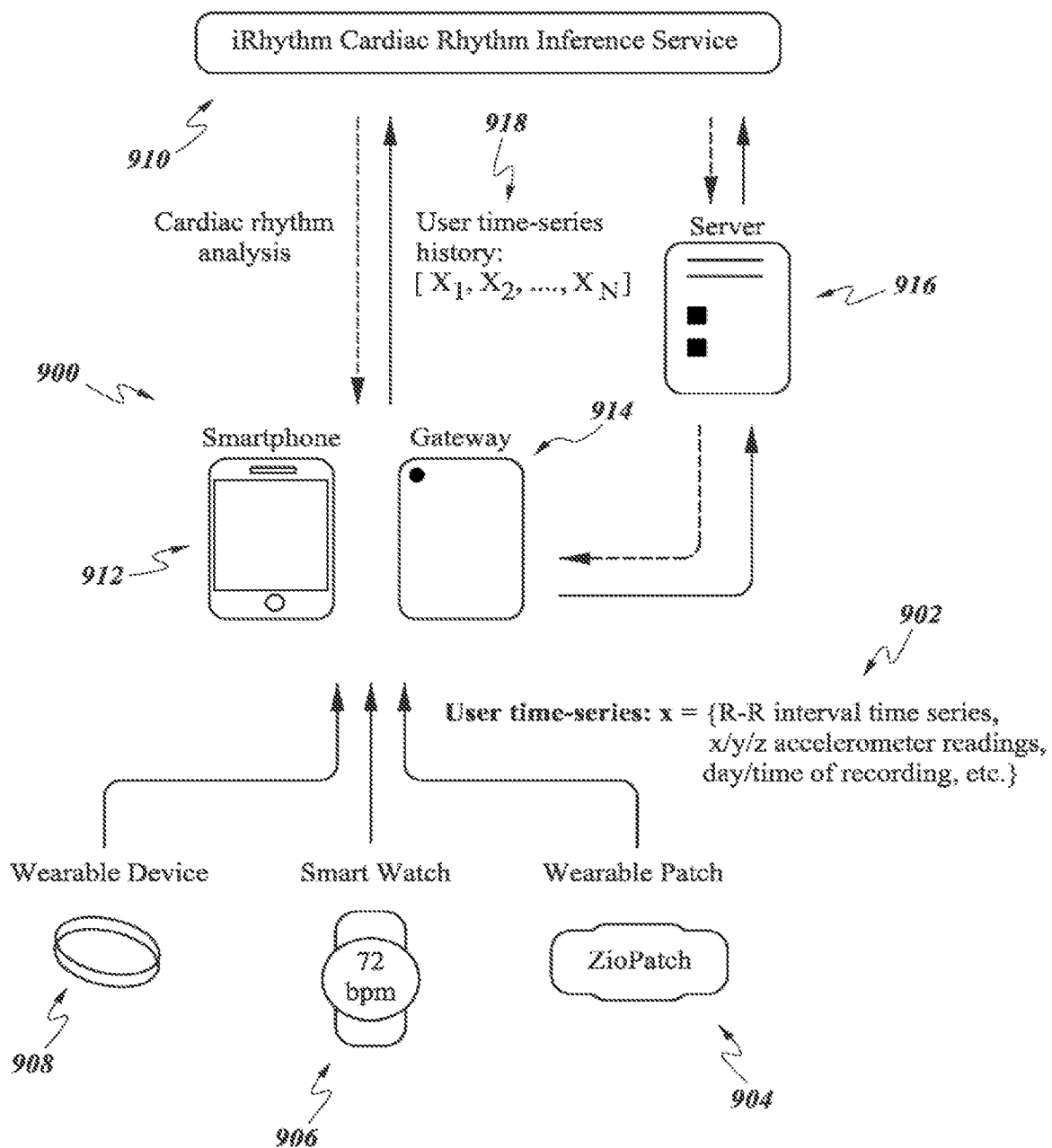


FIG. 18

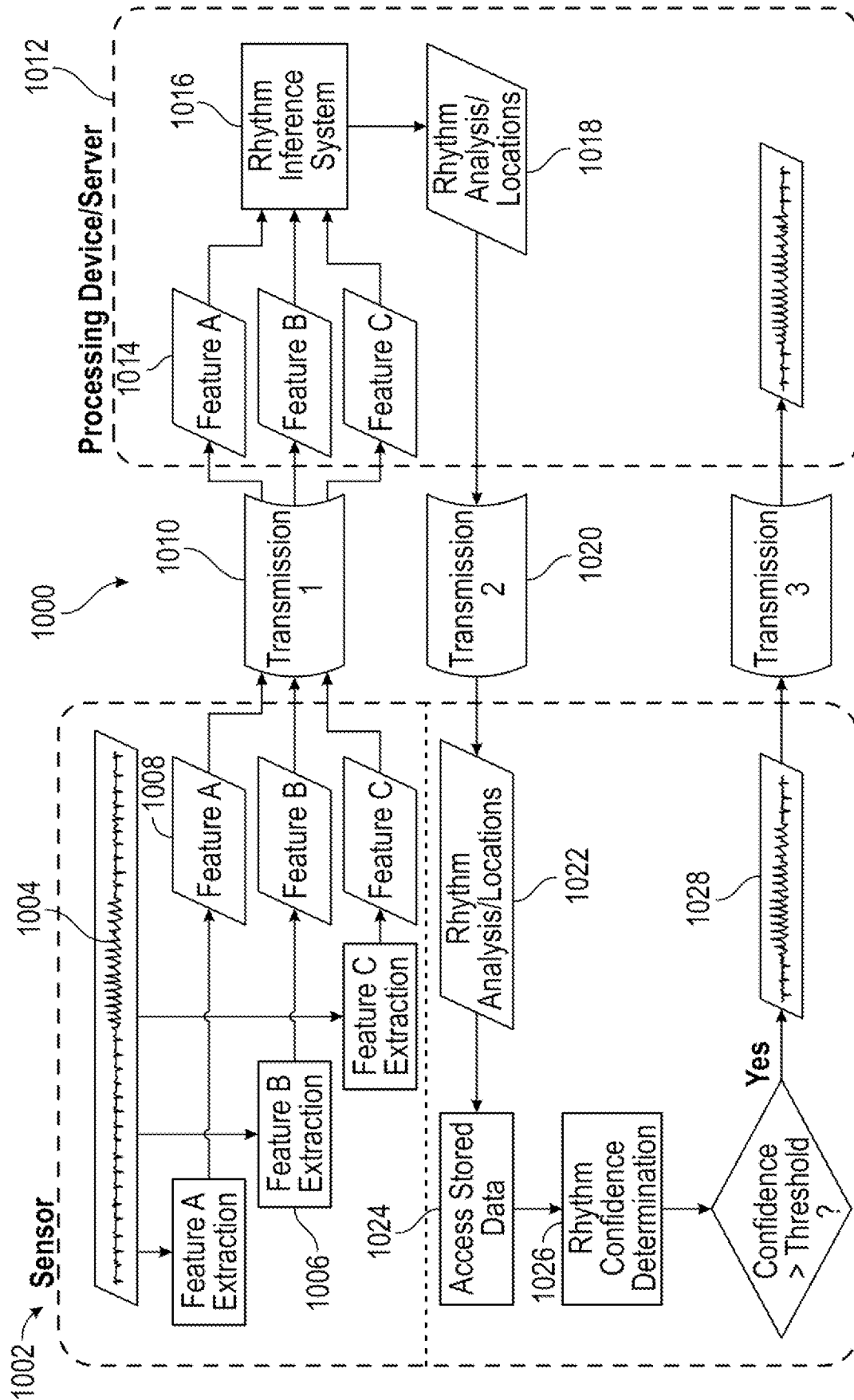


FIG. 19