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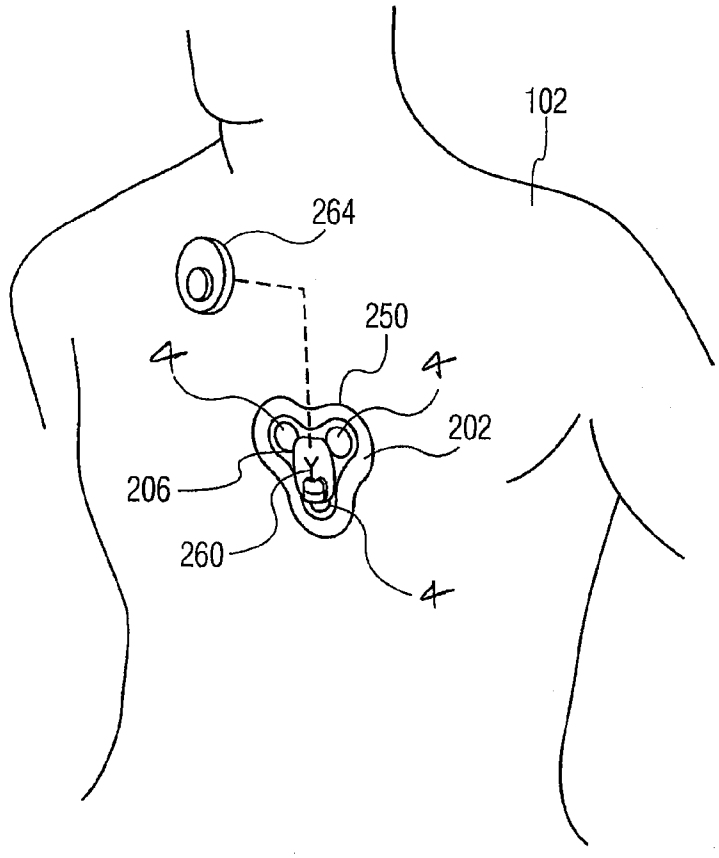

(57) Abstract: A cardiac monitoring and recording device for recording patient ECG by monitoring patient motion, and storing at least a portion of the recorded patient ECG in response to determining the occurrence of a triggering event, such as a fainting episode, based on the patient motion.

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CARDIAC MONITORING AND RECORDING DEVICE HAVING MOTION ACTIVATED TRIGGER

This application claims the benefit of United States provisional patent application number 60/748,916, filed December 8, 2005.

The present invention relates generally to medical monitoring and recording systems, and more specifically, to cardiac monitoring and recording systems having a motion sensor for monitoring patient motion and from which an output is provided that is monitored for a motion activated trigger, such as a fainting episode.

For a number of years, cardiac patients have been evaluated using portable cardiac monitoring/recording devices. A patient wears medical sensors, typically electrodes, that are connected to a portable recording device carried by the patient which records electrocardiograph ("ECG") signals detected by the sensors. An example of a cardiac monitoring/recording device is a "Holter" electrocardiograph that is used to record patient ECG over a period of time, such as 24 hours, so that a record of heart activity over an extended time period can be obtained.

Another example of a cardiac monitoring/recording device is a "loop recorder." These devices record ECG in a first-in first-out fashion and can be configured to retain varying amounts of ECG. Outpatients with suspected cardiac arrhythmias are presently monitored using patient activated or automatic loop recorders. When a patient feels symptomatic, they are instructed to press a button on the loop recorder which preserves the recorded ECG according to the preselected parameters. The preserved ECG can be reviewed at a later time by a physician. Automatically activated devices provide some level of ECG analysis and will "trigger" the preservation of ECG without patient intervention. These devices are manufactured by several vendors, for example, Bramar, Instromedics, and GE, and have been the standard of care for several decades.

Conventional cardiac monitoring/recording devices, however, suffer from drawbacks. For example, with respect to patient activated loop recorders, a patient who is suffering from syncope or pre-syncope may be unable to activate the recorder. The fainting or near fainting episode and the subsequent recovery typically leave the patient disoriented

and possibly unable to follow the procedure necessary to activate the device (*i.e.*, push a button) and preserve the ECG that is present at the onset of the symptoms. In cases where the etiology of the syncope is not cardiogenic, the preserved ECG will show normal sinus rhythm but the health care professional cannot know for sure when the syncope occurred. Since the preserved ECG segments are typically short (100 seconds), it is possible that the patient is unable to press the activation button on the device before the 100 second window passes and the causal ECG is lost. Because fainting leaves a patient disoriented, they rarely are able to reconstruct a timeline precise enough to assure their physician that they did indeed activate the loop recorder within the 100 second window, thus making it nearly impossible to be certain that what was captured included the cardiac rhythm that precipitated the fainting episode.

Should a patient be prescribed an automatically activated loop recorder, there is still uncertainty since the loop recorder will not activate in the presence of a normal sinus rhythm. This means that if a patient faints and the loop recorder does not activate (which would be the expected behavior during non-cardiogenic syncope), the physician has no choice but to rely on the accuracy of the recorder's arrhythmia analysis algorithm and in the absence of actual ECG make an assumption that the fainting was not cardiogenic in origin. To complicate the matter, automatic analysis of ECG in an ambulatory patient is exceptionally difficult due to the presence of motion induced artifact. While the analysis algorithms are of high quality, they are all compromised by this artifact noise and thus are prone to false positives and false negatives.

Although previously described with respect to loop recorders, the drawbacks are also applicable to other cardiac monitoring/recording devices, such as Holter electrocardiographs. For example, unless a patient is capable of manually activating the device to identify occurrence of a fainting episode, a physician may be unable to determine whether syncope is cardiogenic from a continuously recorded ECG that does not reveal any abnormalities in a normal sinus rhythm. Additionally, automatically identifying occurrence of a fainting episode in a Holter electrocardiograph suffers from the same drawbacks as for a loop recorder.

In accordance with the principles of the present invention a cardiac monitor is provides which has a motion sensor, an electrocardiogram (ECG) recording circuit, a data storage circuit and a processor. The motion sensor is operable to detect patient motion and generate an output indicative of patient motion and the ECG recording circuit is operable to record patient ECG. The processor is coupled to the motion sensor, ECG recording circuit and the data storage circuit, and is operable to monitor the output of the motion sensor and process at least one of the output of the motion sensor and the patient ECG in response to determining the occurrence of a triggering event based on the output of the motion sensor.

In an example of the invention described below a cardiac monitoring system is provided having electrodes adapted to detect patient electrocardiogram and a motion sensor operable to detect patient motion and generate an output indicative of patient motion. A loop recorder coupled to the electrodes is operable to continuously record a time period of patient ECG and is further operable to monitor the output of the motion sensor and store the recorded time period of patient ECG in response to determining the occurrence of a fainting episode from the output of the motion sensor.

Another aspect of the invention provides a method for recording patient ECG including recording patient ECG, monitoring patient motion, and storing at least a portion of the recorded patient ECG in response to determining the occurrence of a triggering event based on the patient motion.

In the drawings:

Figure 1 is a block diagram of a cardiac monitoring and recording system according to an embodiment of the present invention.

Figure 2 is a flow diagram of a process according to an embodiment of the present invention.

Figure 3 is a flow diagram of a process according to an embodiment of the present invention.

Figures 4A and 4B are flow diagrams of fainting episode processes according to embodiments of the present invention.

Figure 5 is schematic representation of a cardiac monitoring and recording system in which an embodiment of the present invention is implemented.

Figures 6A and 6B are schematic representations of a cardiac monitoring and recording system including a medical sensor according to embodiments of the present invention.

Figure 7 is an exploded isometric diagram of the medical sensor of Figure 6.

Figure 8 is a plan view of the medical sensor of Figure 6.

Figures 9A and 9B are plan views of a pattern of conductive material according to an embodiment of the present invention for an electrode layer of the medical sensor of Figure 6.

Figures 10A and 10B are plan views of a pattern of conductive material according to another embodiment of the present invention for an electrode layer of the medical sensor of Figure 2.

Figures 11A and 11B illustrate an electrode layer with four electrodes.

Figures 12A, 12B, and 12C illustrate an electrode layer with an integral, separately bonded motion sensor.

Figure 13 illustrates a monitor/recorder device for a patient-worn sensor which has a motion sensor integral to the device.

Certain details are set forth below to provide a sufficient understanding of the invention. However, it will be clear to one skilled in the art that the invention may be practiced without these particular details. Moreover, the particular embodiments of the present invention described herein are provided by way of example and should not be used to limit the scope of the invention to these particular embodiments.

Figure 1 illustrates a block diagram of a cardiac monitoring/recording device 10 according to an embodiment of the invention. The cardiac monitoring/recording device 10 includes an ECG electrode interface 14 for coupling ECG electrodes 4 and providing electrical signals to an analog-to-digital converter (ADC) 16 for converting the analog signals detected by the ECG electrodes 4 into digital data representing the detected signals. The digital data is provided to a processor 18 that records the data by storing the data in data

storage 12 for later retrieval. The data storage 12 represents conventional storage media that store data, for example, volatile and non-volatile devices including semiconductor memory, disk memory, magnetic memory, and other recording media as well.

A motion sensor 22 is included in the cardiac monitoring/recording device 10 to detect patient movement and provide output signals to the processor 18. The motion sensor 16 can be implemented using known motion sensors, for example, an accelerometer or force sensor. The motion sensor 16 preferably detects motion in at least one axis of motion, although motion sensors capable of multiple-axis detection can be used as well. A user interface 20 is coupled to the processor 18 to allow a user to interact with the cardiac monitoring/recording device 10. For example, the user interface 20 includes a switch or button that can be manually triggered by a patient upon detecting a fainting episode. Additionally, the user interface 20 can include electrical terminals from which recorded ECG and motion detection information is retrieved from the data storage 12. Other types of user interfaces can be includes in the user interface 20 as well, for example, a wireless interface that is adapted to transmit the data stored in the data storage 12 wirelessly.

As will be explained in more detail below, the processor 18 is programmed to monitor the output of the motion sensor 22. Figure 2 illustrates a process 30 for one embodiment of the invention in which the processor 18 is programmed to monitor the output of the motion sensor 22 and record the output along with detected ECG signals at steps 32-36. The ECG and the output of the motion sensor 22 are stored as data in the data storage 12. The data stored can be retrieved through the user interface 20 for evaluation. Recording the output of the motion sensor at step 36 allows for identifying a fainting episode and corresponding timing of the fainting episode relative to the recorded ECG at step 32. For example, the recorded ECG and the output of the motion detector can be displayed on a common time scale and an evaluator can review the recorded motion sensor information for visual "signatures" identifying the occurrence of a fainting episode. The timing of the fainting episode can be compared to the recorded ECG to determine if there are any changes in normal sinus rhythm in time proximity to the fainting episode, suggesting that syncope is cardiogenic.

Figure 3 illustrates a process 40 according to another embodiment of the present invention. In addition to recording the ECG at step 42, the processor 18 is programmed to monitor the output of the motion sensor 22 at step 44 and identify the occurrence of a fainting episode at step 46. A fainting episode may be indicated by an output from the motion sensor 22 that is consistent with the patient fainting, for example, an output indicating a sudden change in direction of motion or force followed by inactivity. An output consistent with abruptly coming to rest, such as when a fainting patient comes to rest on the ground, can also be part of the analysis for determining the occurrence of a fainting episode at step 46. In an embodiment using an accelerometer capable of measuring acceleration in at least one specific axis of motion, an output consistent with falling to the ground can be used for identifying the occurrence of a fainting episode. The processor 18 can be programmed to detect other "signatures" for fainting episodes as well. Other information can be considered in addition to the output of the motion sensor 22. For example, the ECG can be monitored for abnormal rhythm in addition to an output of the motion sensor 22 that is consistent with fainting. In response to determining the occurrence of a fainting episode from at least the output of the motion sensor 22 at step 46, the processor can perform or initiate a fainting episode process at step 48.

Figure 4A illustrates a fainting episode process 50 according to an embodiment of the present invention. The fainting episode process 50 can be used for step 48 of process 40. In response to the processor 18 determining the occurrence of a fainting episode, the processor 18 stores information at step 52 that identifies the time at which the fainting episode occurs relative to the ECG. In this manner, when the ECG is reviewed, the fainting episode can be identified and correlated to any changes in a normal sinus rhythm. The fainting episode process 50 can be used in Holter electrocardiographs that continuously record ECG information. In comparison to the process 30 illustrated in Figure 2, a separate motion sensor channel for the output of the motion sensor 22 is not necessary because the timing of the fainting episode is stored rather than continuously recording the output of the motion sensor 22. However, the process 50 can be performed in addition to the process 30, and used to confirm the occurrence of fainting episodes as detected by the processor 18.

That is, the continuous output of the motion sensor 22 may suggest the occurrence of a fainting episode, however, those that are marked by the processor 18 in accordance with processes 40 and 50 are confirmed as fainting episodes.

Figure 4B illustrates a fainting episode process 60 according to another embodiment of the present invention. In response to the processor 18 determining the occurrence of a fainting episode, a portion of the recorded ECG relative to the occurrence of the fainting episode event is selected at step 62 and the selected portion of the recorded ECG is stored in data storage 12 at step 64. For example, in one embodiment the portion of the recorded ECG that is stored in the data storage 12 is ECG information for a 100 second time period that is centered around the occurrence of the fainting episode to provide 50 seconds of ECG information prior to the fainting episode and 50 seconds of ECG information following the fainting episode for review. The 100 seconds of ECG information previously described is provided by way of example. Different lengths of ECG information and different relative timing to the fainting episode can be stored as well.

The fainting episode process 60 is suited for use with loop recorder-type cardiac monitoring/recording devices that continuously record ECG information but retain a limited time period of ECG information before recording over the previously recorded ECG information. With these types of cardiac monitoring/recording devices, the ECG information for the limited time period is selectively stored in data storage. In the fainting episode process 60, retained ECG information is stored in the data storage in response to the processor 18 determining the occurrence of a fainting episode from the output of the motion sensor. In this way, the ECG information recorded during the occurrence of a fainting episode can be reviewed at a later time for changes in the ECG from a normal sinus rhythm corresponding to the fainting episode.

The fainting episode process 60 can be combined with other fainting episode processes as well. For example, the processor 18 can be programmed to perform processes 50 and 60 together in order to trigger storage of recorded ECG information and also store information identifying the time at which the fainting episode occurred relative to the stored ECG information in response to a fainting episode. In this manner, the stored ECG

information and the timing of the fainting episode relative to the ECG information can be reviewed.

Figure 5 illustrates a patient 102 wearing a Holter electrocardiograph. Medical sensors in the form of electrodes 4 are attached to the patient 102 and are electrically coupled to a recorder 110 through wires 105 and connector 106. The recorder 110 includes a cardiac monitoring/recording device according to an embodiment of the present invention, such as cardiac monitoring/recording device 10 illustrated in Figure 1. For clarity of illustration the number and placement of electrodes shown in Figure 5 may differ from an actual patient configuration. The recorder 110 is typically worn by the patient 102 using a belt 108, or other means, such as being carried over the shoulder. The electrodes 104 detect electrical signals that are indicative of patient biological information and the recorder 110 records the electrical signals for later download and analysis.

The recorder 110 further includes a motion sensor having an output that is monitored by a processor, as previously described. In one embodiment, the processor is further programmed to record the output of the motion sensor along with the ECG information. In another embodiment, the processor is programmed to determine whether a fainting episode is detected from at least the output of the motion sensor. In response to detecting a fainting episode, a fainting episode process according to an embodiment of the invention is executed, for example, fainting episode processes 40 and 50 illustrated in Figures 3 and 4. In other embodiments, a plurality of fainting episode processes are executed concurrently by the processor.

Figure 6A illustrates a cardiac monitoring/recording system according to an embodiment of the present invention positioned on a patient 102. The cardiac monitoring/recording system of Figure 6A includes a medical sensor 200 and a monitor/recorder 110. As will be described in more detail below, a medical sensor 200 includes a plurality of electrodes 204 for sensing, among other things, the patient's cardiac rhythm as well as a motion sensor 206 that detects patient movement and translates the patient motion into electrical signals that are provided to the monitor/recorder 110. The monitor/recorder 110 includes a cardiac monitoring/ recording device according to an

embodiment of the present invention, for example, the cardiac monitoring/recording device 10 shown in Figure 1. In one embodiment, the monitor/recorder 110 includes a motion sensor having an output that is monitored by a processor, as previously described. The processor is programmed to perform processes according to embodiments of the present invention, for example, the processes 30, 40, 50, and 60.

In one embodiment, the medical sensor 200 further includes a motion sensor 206 integrated in the medical sensor with the electrodes 204. Electrical signals detected and generated by the medical sensor 200 are provided to the monitor/recorder 110 through cable 220 and connector 222. The processor in the monitor/recorder 110 can monitor the output of the motion sensor 206 in addition to or alternatively to a motion sensor included in the monitor/recorder 110. The cable 220 is connected to the medical sensor 200 through connector 210. The medical sensor 200 is adhesively attached to the patient 102 by a flexible retention seal 202. Preferably, the retention seal and adhesive are formed from materials that allow the medical sensor 200 to remain adhered to the patient 102 while in motion and during activity. Such materials are known to those ordinarily skilled in the art, and consequently, in the interest of brevity, a more detailed description of such materials will not be provided herein.

As shown in Figure 6A, the medical sensor 200 is relatively compact and does not use a plurality of wires for connecting to the monitor/recorder 110, as with the conventional configuration of electrodes shown in Figure 5. Additionally, the medical sensor 200 includes a motion sensor 206 formed proximate the electrode 204, and is preferably integrated in the medical sensor 200. The information obtained by the motion sensor 206 can be used by the monitor/recorder 110 to gauge patient health. For example, the information can provide an indication if the patient is conscious or unconscious, breathing or not breathing, walking or still. As previously discussed, the output of the motion sensor 206 can be monitored by a processor and recorded and/or analyzed for occurrence of a fainting episode. Additionally, the patient motion data can also be correlated with the ECG waveform to analyze whether to administer cardiopulmonary resuscitation ("CPR") or defibrillation.

Figure 6B illustrates a cardiac monitoring/recording system according to another embodiment of the present invention positioned on the patient 102. The cardiac monitoring/recording system includes a medical sensor 250 and a monitor/recorder device 264. The monitor/recorder includes a cardiac monitoring/recording device according to an embodiment of the present invention. The medical sensor 250 is similar to the medical sensor 200 in that it includes a plurality of electrodes 204 and a motion sensor 206, and is adhesively attached to the patient 102 by a retention seal 202. As with the medical sensor 200, the motion sensor 206 is preferably integrated in the medical sensor 250 with the electrodes 204. In contrast to the medical sensor 200, however, the medical sensor 250 includes a clip 260 that can be used to removably attach the miniature monitor/recorder device 264. The clip 260 is formed with conductive traces that are connected to the miniature monitor/recorder device 264 when it is clipped into place, thereby allowing electrical signals detected and generated by the medical sensor 250 to be provided to the monitor/recorder device 264. As with the medical sensor 200, the medical sensor 250 is relatively compact and does not have a plurality of wires extending across the torso of the patient 102. Additionally, having a miniature monitor/recorder device 264 clipped to the medical sensor 250 provides a compact medical monitor/recorder system 264 that can be readily worn by the patient 102 and avoids many of the difficulties associated with conventional monitor/recorder systems and electrode configurations.

In another embodiment, the miniature monitor/recorder device 264 includes a motion sensor, alternatively or in addition to the motion sensor 206, that detects patient motion. Although not integrated in the medical sensor 250 with the electrodes 204, the miniature monitor/recording device 264 is firmly attached to the patient 102 by way of the clip 260. Thus, the motion sensor located in the monitor/recording device 264 more accurately detects patient motion than if located in a recorder 110 worn on the belt 108 or carried on a strap over the shoulder. A processor in the monitor/recorder device 264 is programmed to monitor the output of at least one of the motion sensors 206 and one located in the monitor/recorder device 264 and perform processes according to embodiments of the present invention, for example, the processes 30, 40, 50, and 60.

Figure 7 is an exploded isometric diagram of the medical sensors 200 and 250. An electrode layer 304 includes conductive material formed on a dielectric film. The electrodes 204 and conductive traces 306 are formed from the conductive material using conventional processes known in the art. In the embodiment shown in Figure 7, the motion sensor 206 is formed from regions of conductive material that are formed on opposite sides of the dielectric film resulting in a capacitive structure. Preferably, the conductive film has piezoelectric properties so that movement of a patient wearing the medical sensor 200/250 will be translated into electrical signals. An example of a material that can be used for the conductive material of the layer 304 is polyvinylidene fluoride ("PVDF"), a piezoelectric polymer. PVDF can be used to form flexible and light weight conductive material for the layer 304. The motion sensor can alternatively be made of other piezoelectric materials such as diced or composite PZT ceramic.

A frame 308 is included in the medical sensor 200/250 to provide structural support. The frame 308 is flexible and resilient, allowing the medical sensor 200/250 to bend as the patient moves. An example of a suitable material for the frame 308 is silicone. The frame 308 includes holes 310 which are aligned with the electrodes 204 that are formed on the layer 304. An adhesive material can be applied to the frame 308 on the side opposite of the layer 304 so that when the medical sensor 200/250 is applied to the patient 102 the frame 308 as well as the retention seal 202 are adhesive. Hydrogel 312 is included to provide a conductive coupling medium with the patient when the medical sensor 200/250 is attached. The hydrogel 312 is positioned in the holes 310 and are in contact with the electrodes 204. As a result, when the medical sensor 200/250 is placed on a patient, an electrical connection between the electrodes 204 and the patient are formed.

The layer 304, frame 308, and hydrogel 312 are adhered to the adhesive side of the retention seal 202. A hole 314 in the retention seal 202 allows the conductive traces 306 of the layer 304 to be contacted by the connector 210 for the medical sensor 200 or by the clip 260 for the medical sensor 250. The connector 210/clip 260 is attached to the retention seal 202 using an adhesive, or other process that provides the connector 210/260 to remain electrically coupled to the conductive traces 306 and firmly affixed. A release liner 316 is

used to prevent the medical sensor 200/250 from being adhered prior to use and is removed when the medical sensor 200/250 is attached to the patient 102. Although not shown in Figures 6A, 6B and 7, the medical sensor 200/250 can also be configured to have a connector, such as a clip connector, that is removably connected so that the medical sensor 200/250 can be first placed on the patient 102 and then connected to the cable 220.

Figure 8 illustrates the medical sensor 200/250 as viewed from the adhesive side of the retention seal 202 and frame 308 after the release liner 316 has been removed. As shown in Figure 8, the electrodes 204 are arranged in a triangular configuration. The regions of conductive film that are used for the motion sensor 206 (not shown in Figure 8) can be generally disposed in the triangular region formed by the arrangement of electrodes 204. By virtue of the piezoelectric properties of the conductive material used in forming the motion sensor 206 and the flexible and resilient nature of the medical sensor 200/250, as the patient 102 moves, likely causing the medical sensor 200/250 to bend and deflect, electrical signals will be generated. As previously discussed, the electrical signals can be used as an indicator of patient health. For example, if motion is sensed, there is a likelihood that the patient is active, and is not in cardiac arrest or has fainted. Additionally, when related to the patient's cardiac rhythm, the sensed motion can serve as a quality indicator of the monitored and recorded cardiac signals.

Figures 9A and 9B illustrate patterns of conductive material formed on a dielectric film for the electrode layer 304 according to an embodiment of the present invention. Figure 9A illustrates a pattern for a first side of the layer 304 and Figure 9B illustrates a pattern for a second opposite side of the layer 304. The first side includes conductive regions representing the electrodes 204 and the motion sensor 206. The second side includes a conductive region 206' (the second capacitive plate) for the motion sensor 206 and conductive regions for the conductive traces 306. The motion sensor 206, as previously discussed, is formed from two or more conductive regions formed in a capacitor arrangement. With this structure, the motion sensor 206 as shown in Figures 9A and 9B translates motion (due to stretching, bending and deflection of the conductive regions on the first and second sides) into electrical signals. The conductive traces 306 are configured with

printed through-hole vias to provide electrical coupling from the electrodes 204 and the motion sensor region 206 formed on the first side to a generally central region 504 on the second side, from which electrical connections can be made through the hole 314 to the connector 210/clip 260. One of the conductive traces 306' is formed to provide coupling from the motion sensor region 206 on the first side of layer 304 to the generally central region 504 on the second side. The conductive region 206' and traces 306, 306' can be coupled to the connector 210 (Figure 6A) or to the clip 260 (Figure 6B), or to another coupling mechanism.

Figures 10A and 10B illustrates patterns of conductive material formed on a dielectric film for the electrode layer 304 according to another embodiment of the present invention. Figure 10A illustrates a pattern for a first side of the layer 304 and Figure 10B illustrates a pattern for a second opposite side of the layer 304. The first side includes conductive regions representing the electrodes 204 and the motion sensor 206. The second side includes a conductive region for the motion sensor 206 and for the conductive traces 306. The regions of conductive material on the first and second sides for the motion sensor 206 are arranged to provide a capacitor structure. The conductive traces 306 are configured to provide electrical coupling by means of printed or plated through-hole vias from the electrodes 204 and motion sensor 206 formed on the first side to a generally central region 504 on the second side. One of the conductive traces 306 is formed to provide coupling to the motion sensor 206 in the generally central region 504 on the second side.

As with the patterns of Figures 9A and 9B, the patterns of Figures 10A and 10B provide electrodes 204 that are arranged in a triangular configuration, and the conductive traces 306 provide coupling to the electrodes and the motion sensor 206 to a generally central region. In contrast to the patterns of Figures 9A and 9B, however, the patterns of Figures 10A and 10B for the regions of conductive material on the first and second sides for the motion sensor 206 generally cover a larger region of the layer 304, namely, a region from the perimeter of the layer 304 to the central region 504. Using the same conductive material for the patterns of Figures 9A, 9B and Figures 10A, 10B will provide motion sensors 206 having different levels of sensitivity due to the difference in the area of the capacitive regions.

Generally, the motion sensor 206 formed using the patterns of Figures 10A, 10B is more sensitive than one formed using the patterns of Figures 9A, 9B. As illustrated by the two patterns for the motion sensor 206, the level of sensitivity of the motion sensor 206 can be adjusted based on the size of the regions of conductive material on the first and second sides of the layer 304 that are used to form the motion sensor 206. In one embodiment, the sensitivity of the motion sensor is sufficient to detect cardiac pulses of the patient wearing the medical sensor. Although adjusting the sensitivity of the motion sensor 206 by adjusting the size of the regions of conductive material has been described herein, other known techniques can be used as well. The particular technique employed may depend on the type of motion sensor used.

Figures 11A and 11B illustrate first and second sides, respectively, of another example of an electrode layer 304 of the present invention. In this example the layer 304 has the motion sensor 206 and three patient electrodes previously discussed. In addition this example has a fourth patient electrode 204' centrally located on the first side of the layer 304 as shown in Figure 11A. As can be seen in Figure 11B, the traces 306, 306' and motion sensor region 206' surround the central region 504 of the second side of the electrode layer, from which connections can be made to other electrical conductors or components of the wearable patient monitor.

Figures 12A, 12B, and 12C illustrate another example of an electrode layer 304 of the present invention. In this example the layer 304 has four patient electrodes 204 as discussed above. However the motion sensor 406, rather than utilizing the layer 304 material for the capacitive dielectric, is a separate unit with its own dielectric separate from that of layer 304. As shown in Figure 12C, the separate motion sensor 406 is placed in this example on the second side of the layer 304 and laminated or bonded in place as shown in Figure 12B. From its location on the second side of the layer 304 connections can be made from the motion sensor extension traces 2,4 to other conductors or components of the patient monitor. Figure 13 is an exploded view of a monitor/recorder device 264 with an integral motion sensor 14. The device 264 has a clamshell case of two halves 82 and 84. On the lower edge of the case half 82 is a connector 86 that connects to a mating connector of the connector

210/clip 260.. The electrical components of the device are located on a printed circuit assembly 80, including in this example the piezoelectric motion sensor 14. A battery 40 is located between the printed circuit assembly and the case half 84. The piezoelectric motion sensor 14 may be located on the printed circuit assembly 80 as shown in this illustration, or may be attached to a case half 82 or 84 to take advantage of the acoustic properties of the case and better transmit motion of the patient to the sensor 14.

From the foregoing it will be appreciated that, although specific embodiments of the invention have been described herein for purposes of illustration, various modifications may be made without deviating from the spirit and scope of the invention. Accordingly, the invention is not limited except as by the appended claims.

WHAT IS CLAIMED IS:

1. A cardiac monitor, comprising:

a motion sensor operable to detect patient motion and generate an output indicative of patient motion;

an electrocardiogram (ECG) recording circuit operable to record patient ECG;

a data storage circuit operable to store data representing the output of the motion sensor and patient ECG; and

a processor coupled to the motion sensor, ECG recording circuit and the data storage circuit, the processor operable to monitor the output of the motion sensor and process at least one of the output of the motion sensor and the patient ECG in response to determining the occurrence of a triggering event based on the output of the motion sensor.

2. The cardiac monitor of claim 1 wherein the processor which is operable to process at least one of the output of the motion sensor and the patient ECG in response to determining the occurrence of a triggering event based on the output of the motion sensor comprises a processor operable to process at least one of the output of the motion sensor and the patient ECG in response to determining a fainting episode from the output of the motion sensor.

3. The cardiac monitor of claim 2 wherein the processor which is operable to process at least one of the output of the motion sensor and the patient ECG in response to determining the occurrence of a fainting episode from the output of the motion sensor comprises a processor operable to store data in the data storage circuit indicative of the time at which the triggering event occurred relative to the ECG in response to determining a fainting episode from the output of the motion sensor.

4. The cardiac monitor of claim 3 wherein the cardiac monitor comprises a Holter cardiograph.

5. The cardiac monitor of claim 2 wherein the processor which is operable to process at least one of the output of the motion sensor and the patient ECG in response to determining the occurrence of a fainting episode from the output of the motion sensor comprises a processor operable to store data representing a time period of recorded patient ECG in the data storage circuit in response to determining a fainting episode from the output of the motion sensor.

6. The cardiac monitor of claim 5 wherein the processor which is operable to store data representing a time period of recorded patient ECG in the data storage circuit comprises a processor operable to store data representing a time period having time before and after the occurrence of the fainting episode.

7. The cardiac monitor of claim 5 wherein the cardiac monitor comprises a loop recorder.

8. The cardiac monitor of claim 1, further comprising a user interface coupled to the processor and operable to provide data stored in the data storage circuit external the cardiac monitor.

9. The cardiac monitor of claim 1, further comprising a motion sensor recording circuit coupled to the processor and the motion sensor, the motion sensor recording circuit operable to continuously record the output of the motion sensor.

10. The cardiac monitoring system of claim 1 wherein the motion sensor comprises a piezoelectric motion sensor located on a printed circuit assembly that includes the processor.

11. The cardiac monitoring system of claim 1 wherein the motion sensor comprises an accelerometer.

12. A cardiac monitoring system, comprising:

electrodes adapted to detect patient electrocardiogram;

a motion sensor operable to detect patient motion and generate an output indicative of patient motion; and

a loop recorder coupled to the electrodes and operable to continuously record a time period of patient ECG and further operable to monitor the output of the motion sensor and store the recorded time period of patient ECG in response to determining the occurrence of a fainting episode from the output of the motion sensor.

13. The cardiac monitoring system of claim 12 wherein the motion sensor comprises a motion sensor included in the loop recorder.

14. The cardiac monitoring system of claim 13 wherein the motion sensor included in the loop recorder comprises a piezoelectric motion sensor located on a printed circuit assembly.

15. The cardiac monitoring system of claim 12 wherein the motion sensor comprises a motion sensor integrated with the electrodes.

16. The cardiac monitoring system of claim 15 wherein the electrodes and motion sensor are integrated in an adhesive medical sensor having at least three electrodes.

17. The cardiac monitoring system of claim 12 wherein the loop recorder comprises a loop recorder configured to be detachably attached to a clip mounted on the electrodes.

18. A method for recording patient ECG, comprising:

recording patient ECG;

monitoring patient motion; and

storing at least a portion of the recorded patient ECG in response to determining the occurrence of a triggering event based on the patient motion.

19. The method of claim 18 wherein storing at least a portion of the recorded patient ECG in response to determining the occurrence of a triggering event based on the patient motion comprises storing at least a portion of the recorded patient ECG in response to determining a fainting episode from the patient motion.

20. The method of claim 19, further comprising storing data indicative of the timing of the fainting episode relative to the patient ECG.

21. The method of claim 18 wherein monitoring patient motion comprises monitoring the output of a motion sensor operable to detect patient motion.

22. The method of claim 18, further comprising continuously recording patient ECG and storing data representing the continuous recording of patient ECG.

23. The method of claim 18 wherein storing at least a portion of the recorded patient ECG in response to determining the occurrence of a triggering event based on the patient motion comprises storing a time period of recorded patient ECG having time periods before and after the occurrence of the triggering event.

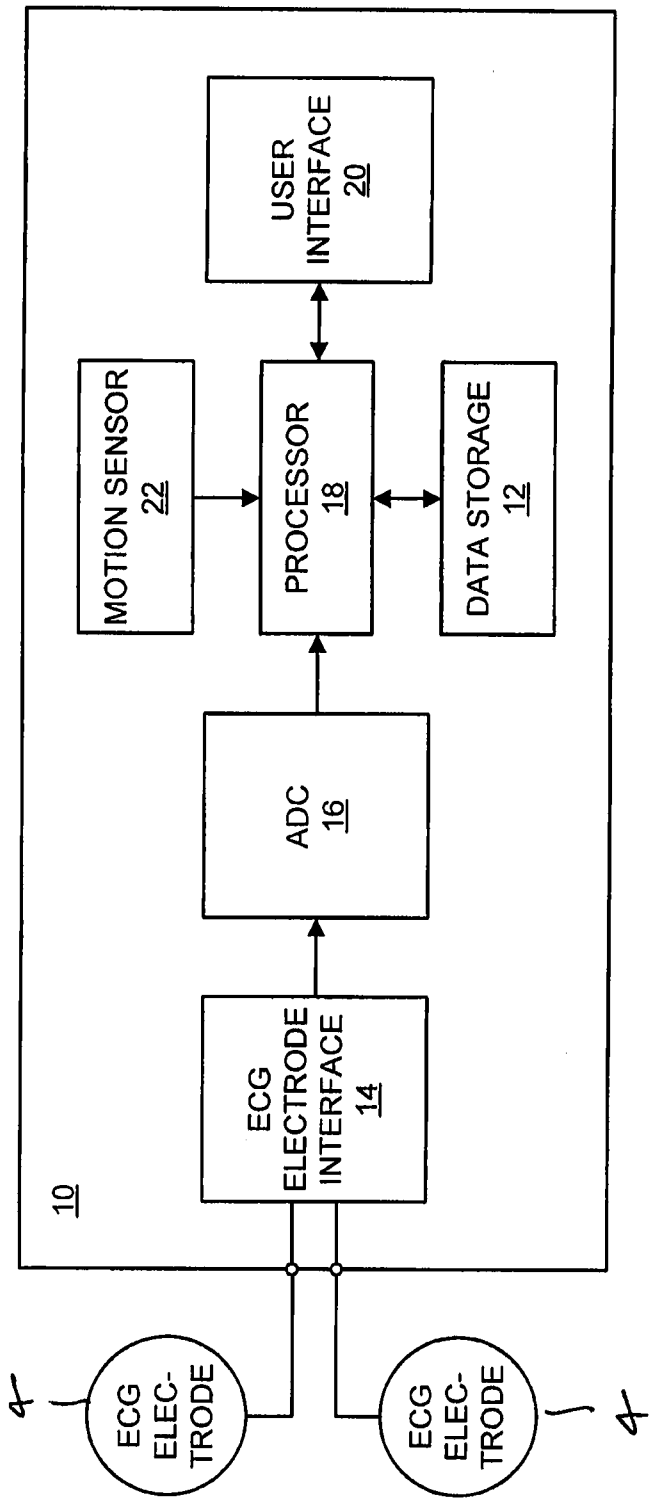

10
ECG ELECTRODE INTERFACE 14
ADC 16
PROCESSOR 18
MOTION SENSOR 22
DATA STORAGE 12
USER INTERFACE 20
ECG ELEC-TRODE
ECG ELEC-TRODE
4
4

Fig. 1

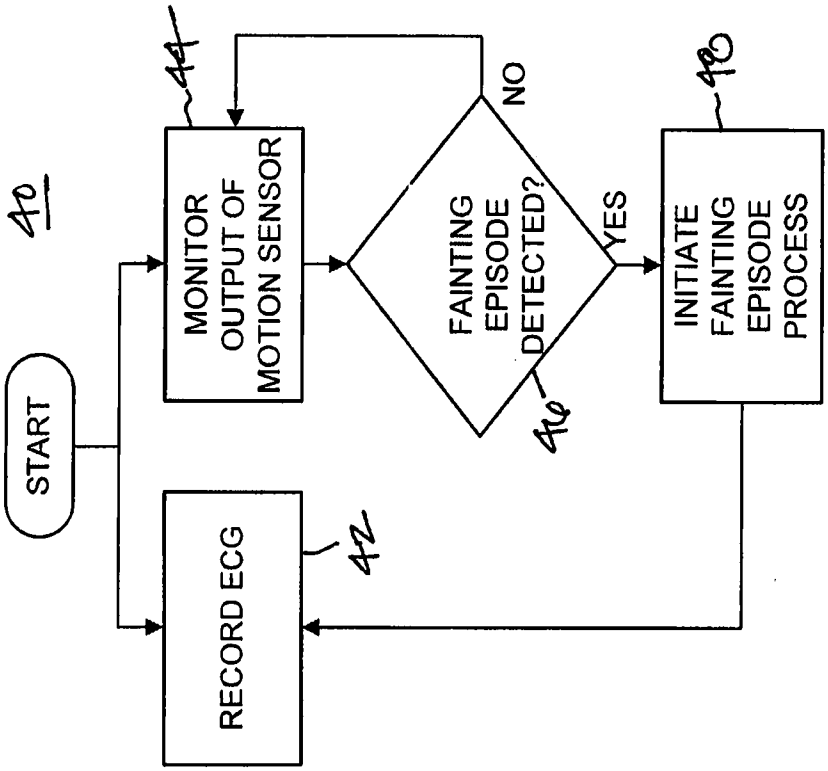
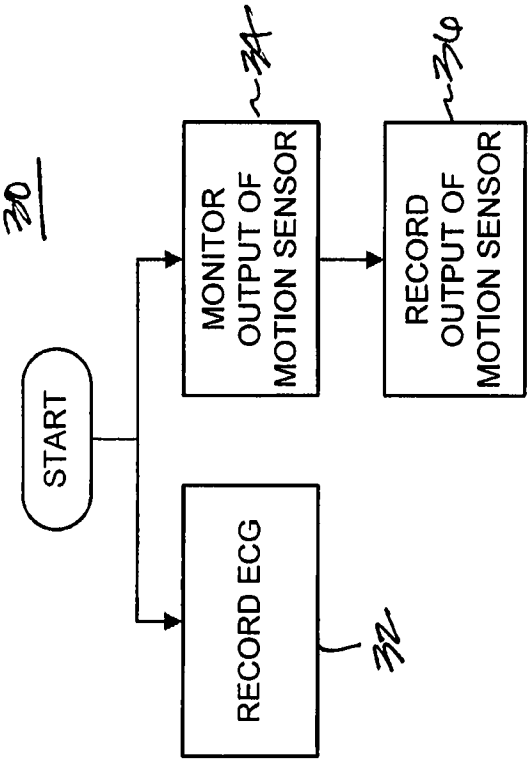

40
START
MONITOR OUTPUT OF MOTION SENSOR
44
FAINTING EPISODE DETECTED?
NO
YES
46
INITIATE FAINTING EPISODE PROCESS
48
RECORD ECG
42

Fig. 3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START
MONITOR OUTPUT OF MOTION SENSOR
34
RECORD OUTPUT OF MOTION SENSOR
36
RECORD ECG
32

Fig. 2

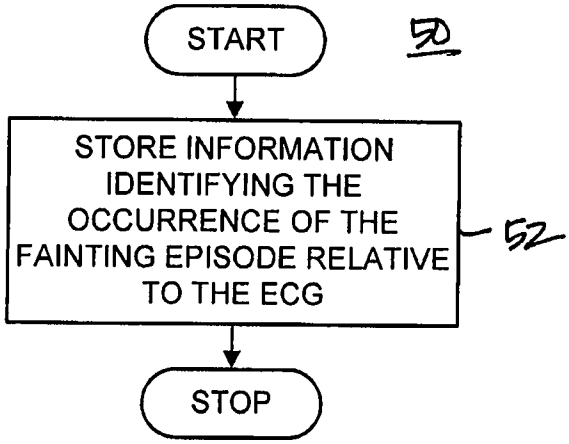

START
50
STORE INFORMATION IDENTIFYING THE OCCURRENCE OF THE FAINTING EPISODE RELATIVE TO THE ECG
52
STOP

Fig. 4A

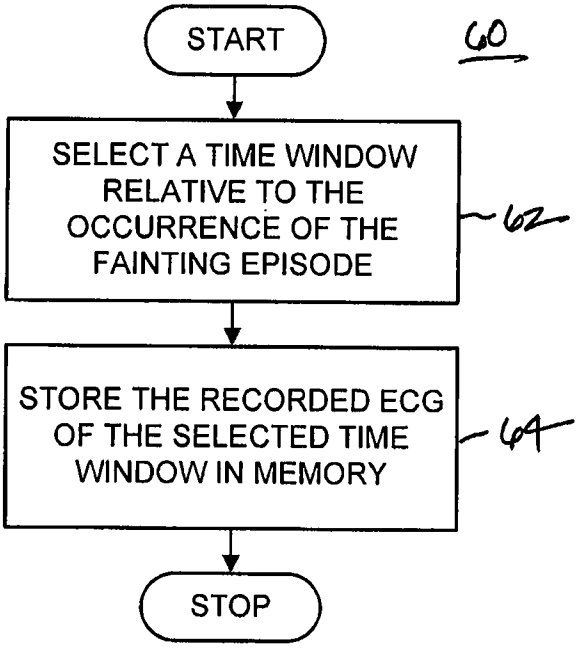

START
60
SELECT A TIME WINDOW RELATIVE TO THE OCCURRENCE OF THE FAINTING EPISODE
62
STORE THE RECORDED ECG OF THE SELECTED TIME WINDOW IN MEMORY
64
STOP

Fig. 4B

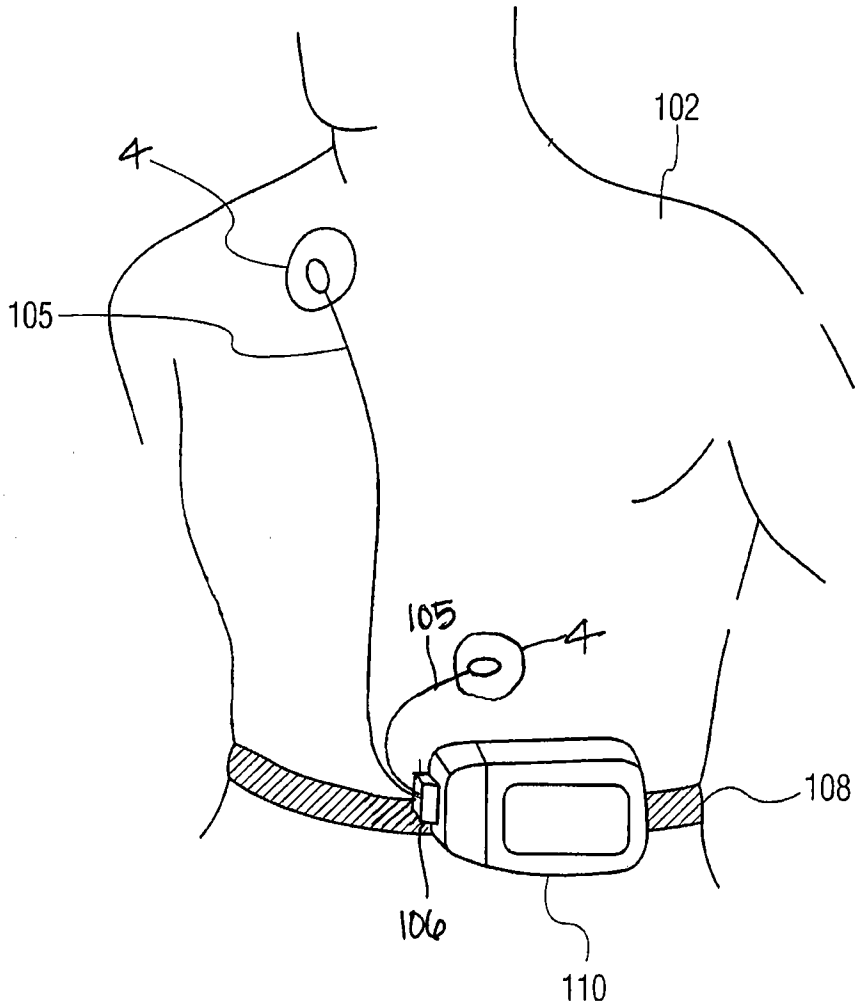


Fig. 5

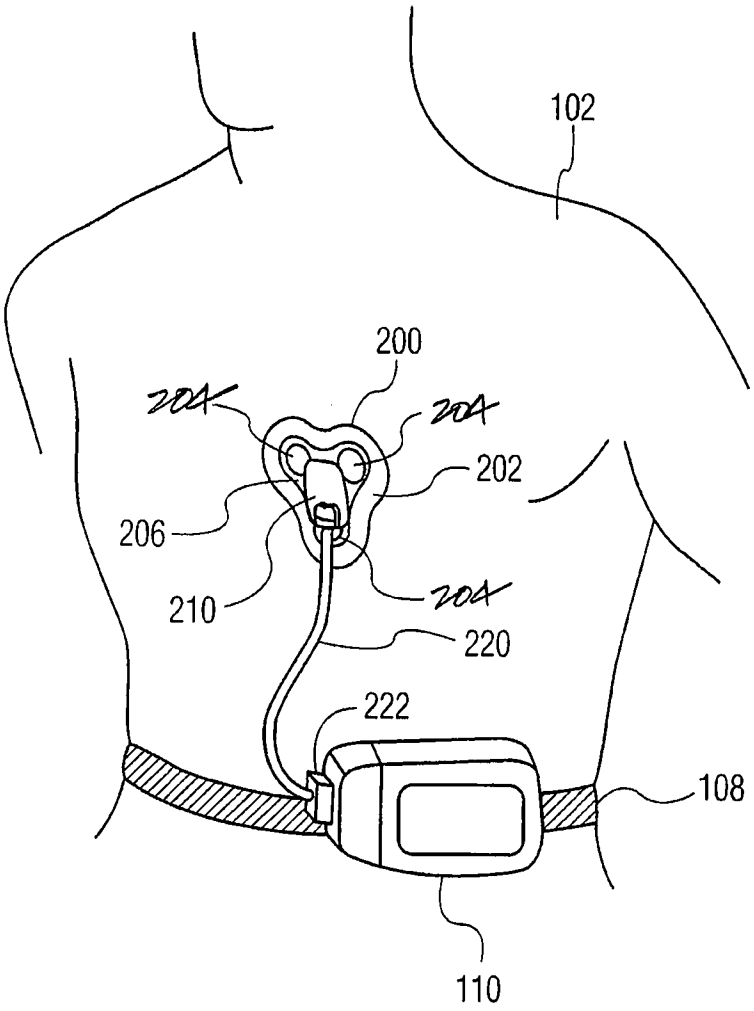


Fig. 6A

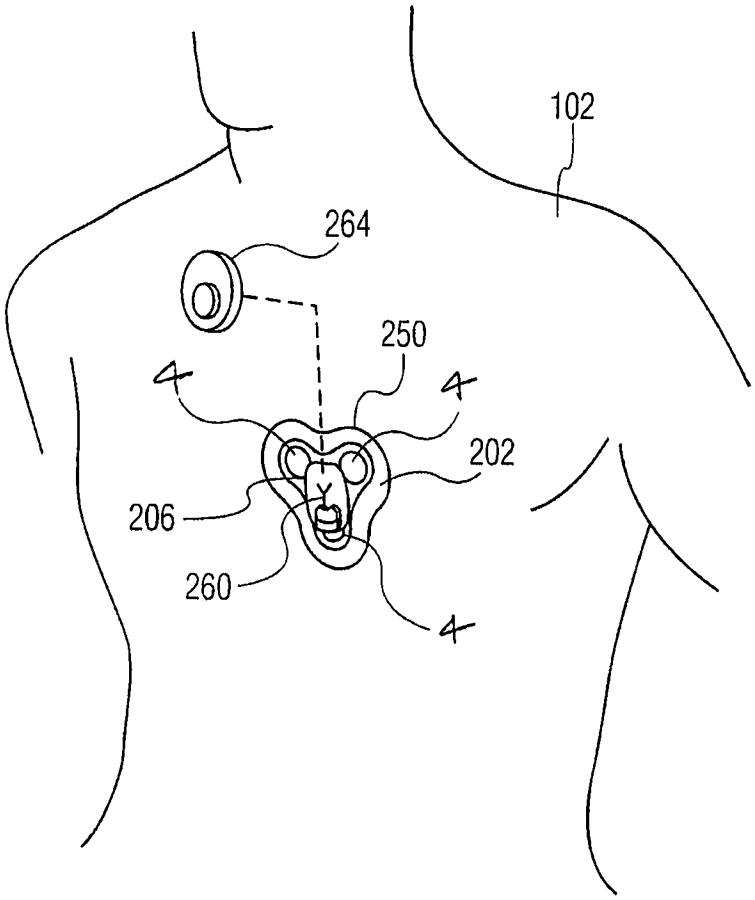
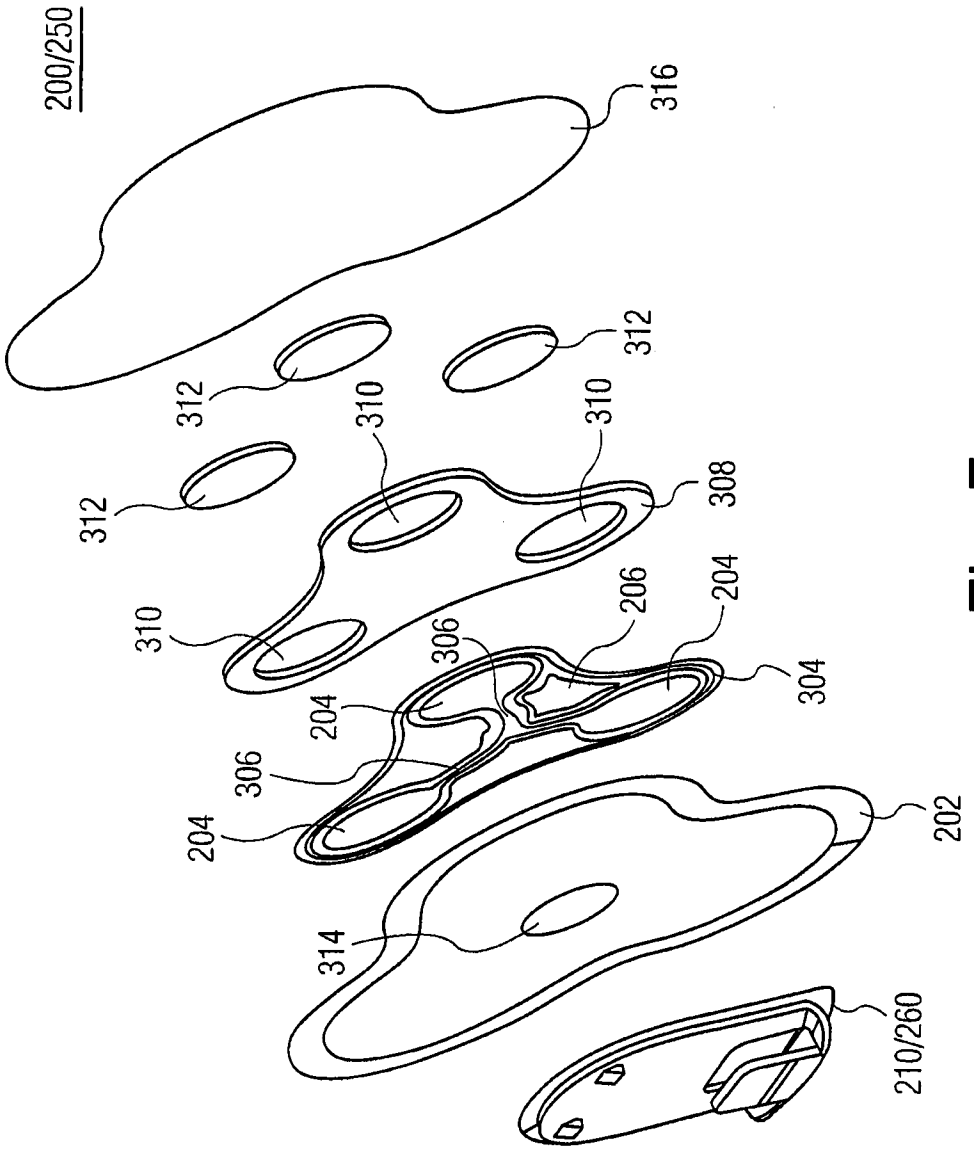


Fig. 6B


200/250
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210/260

Fig. 7

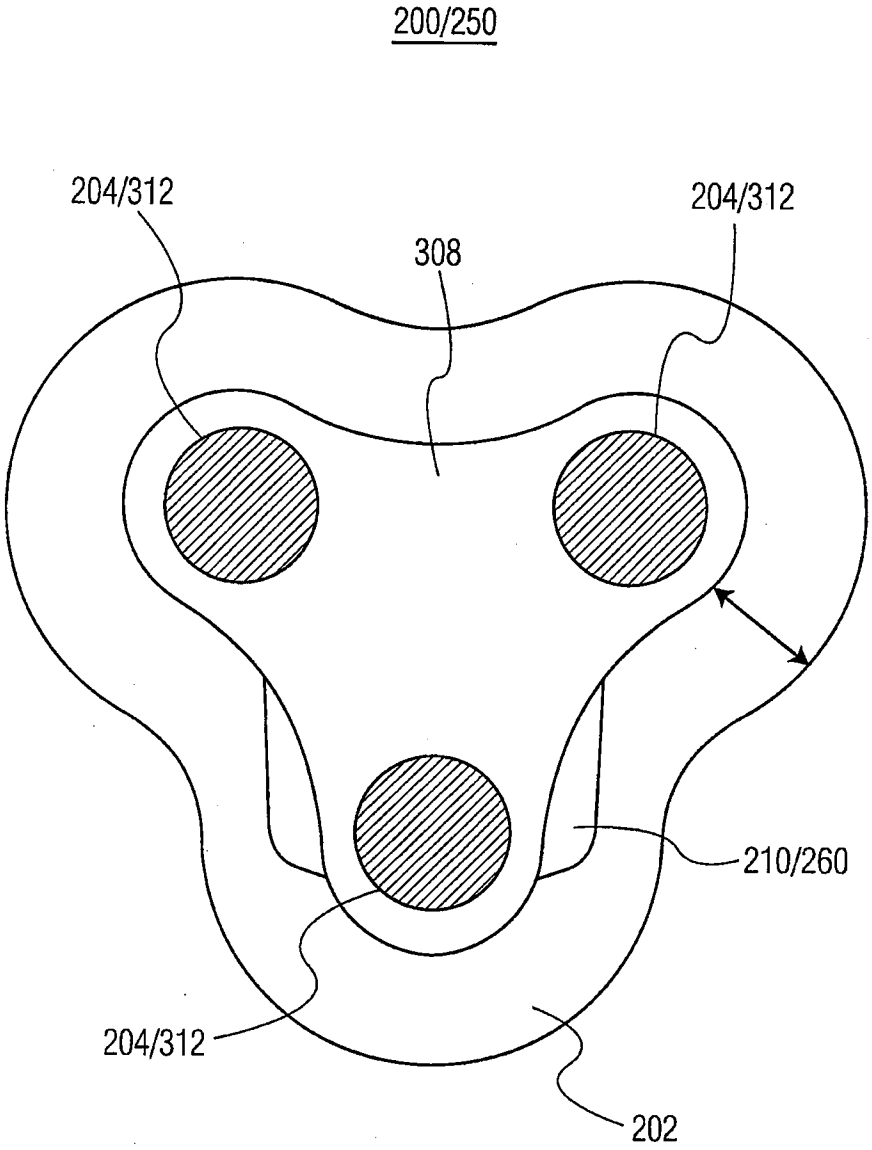

Fig. 8

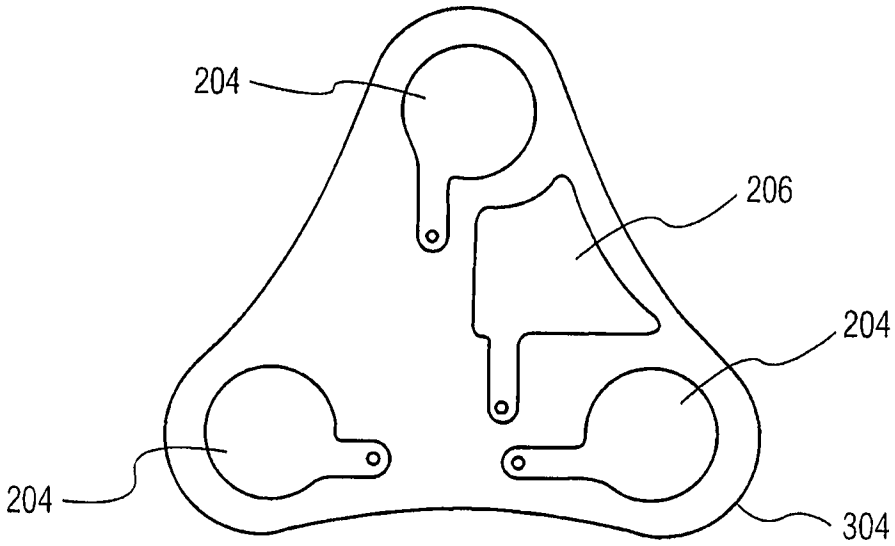

Fig. 9A

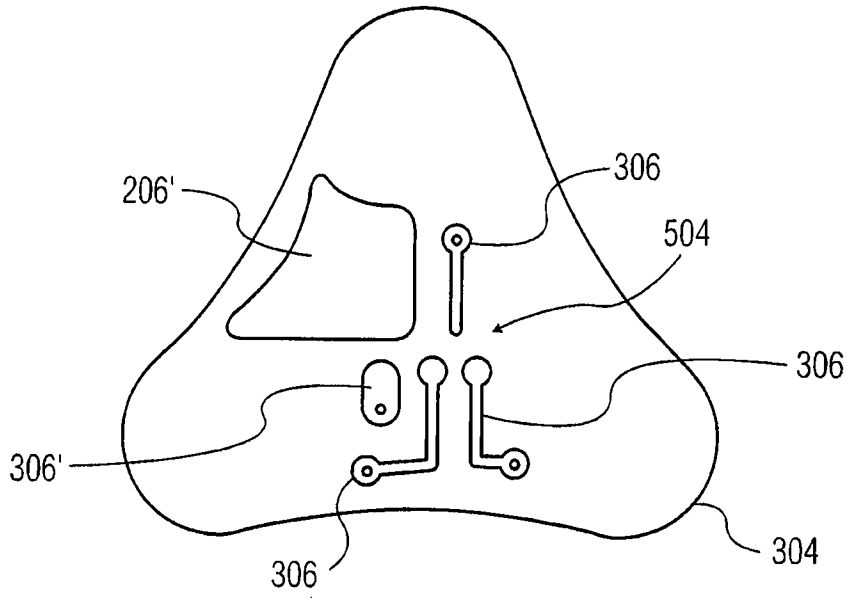

Fig. 9B

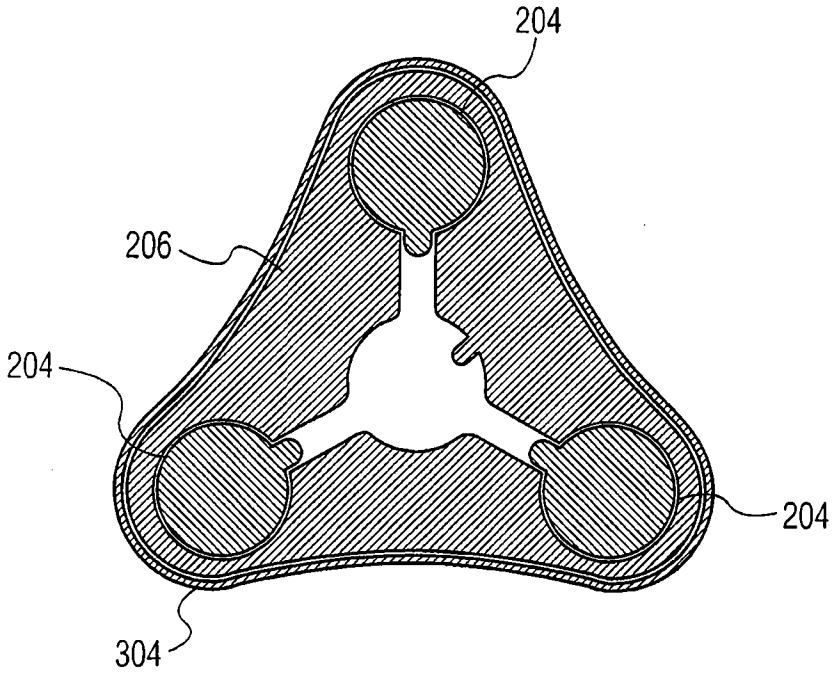

Fig. 10A

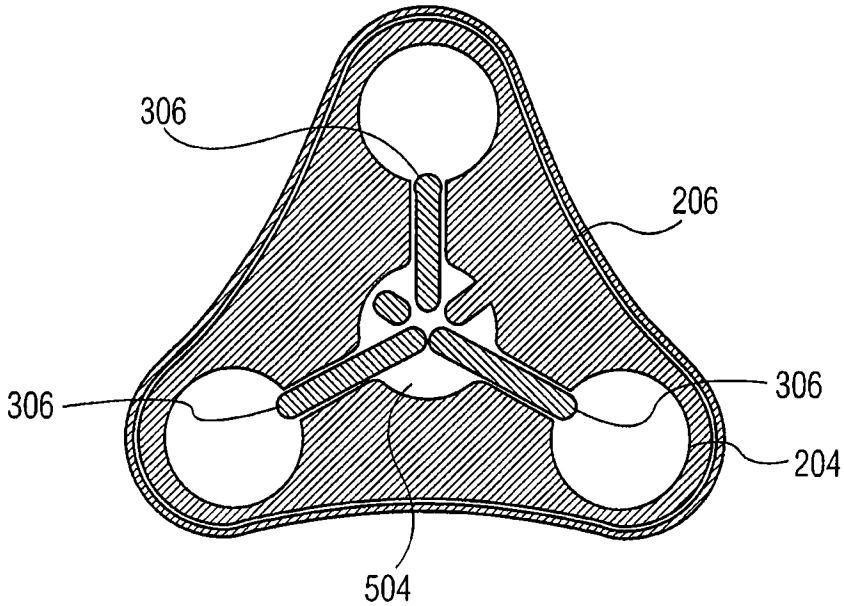

Fig. 10B

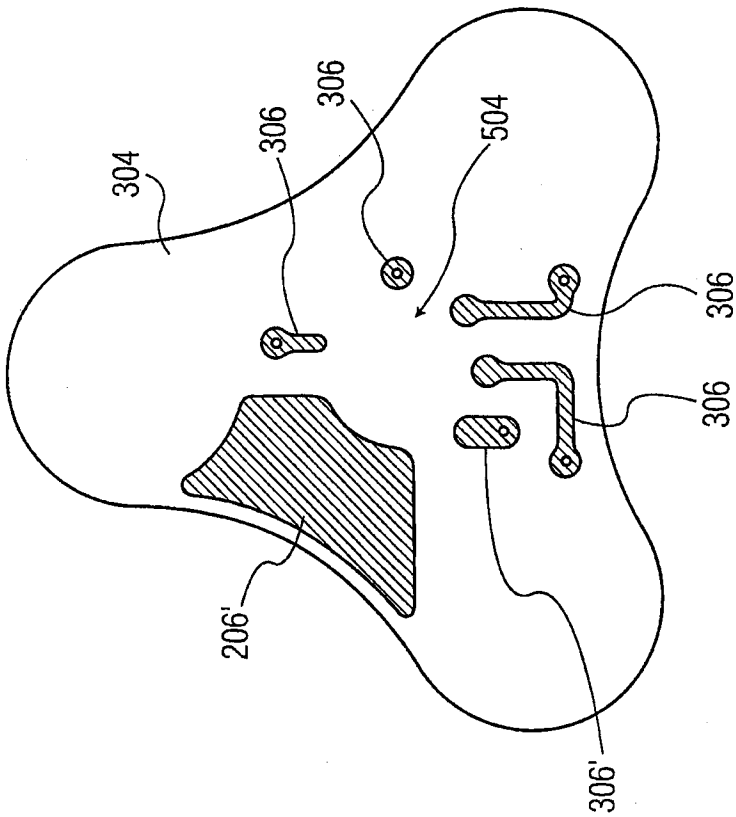

Fig. 11B

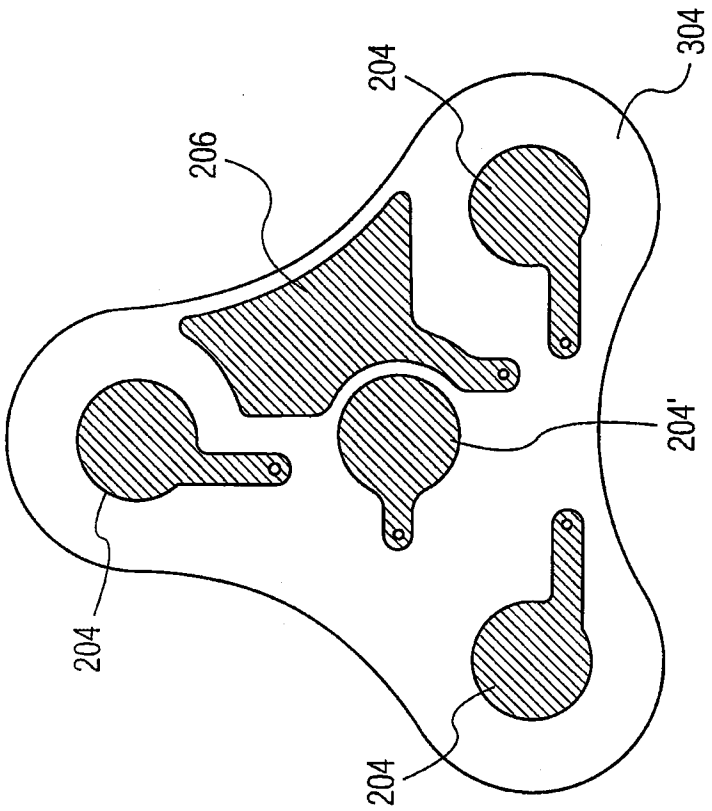

Fig. 11A

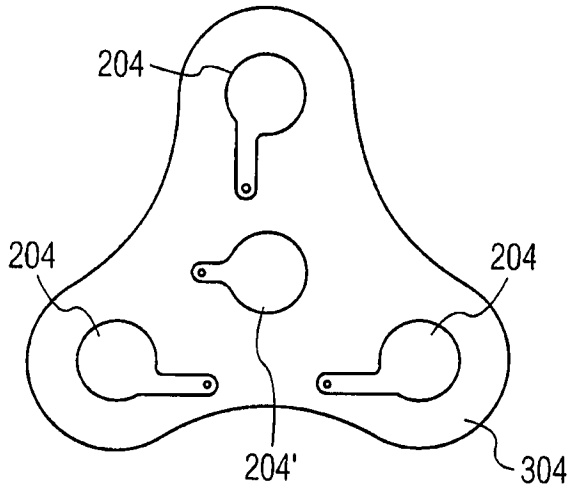

Fig. 12A

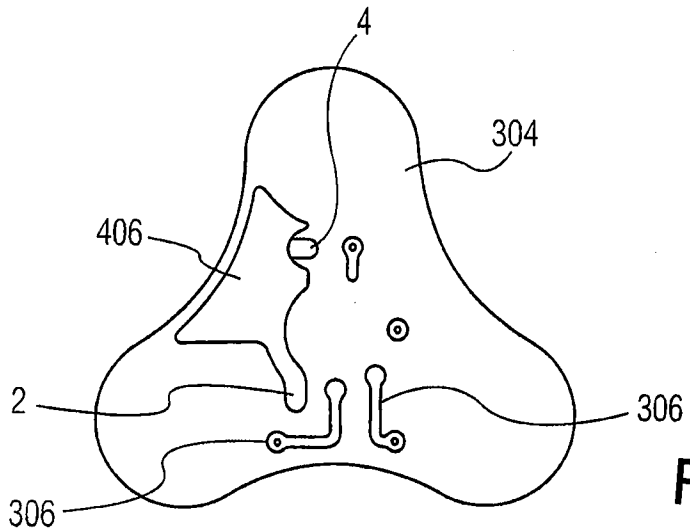

Fig. 12B

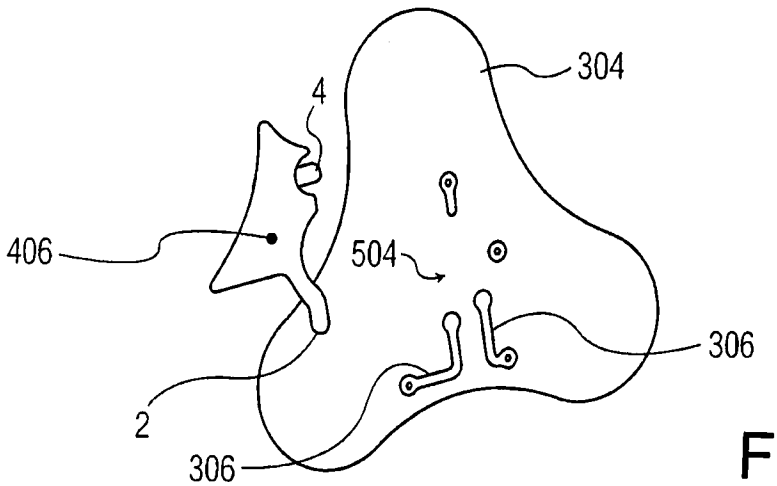

Fig. 12C

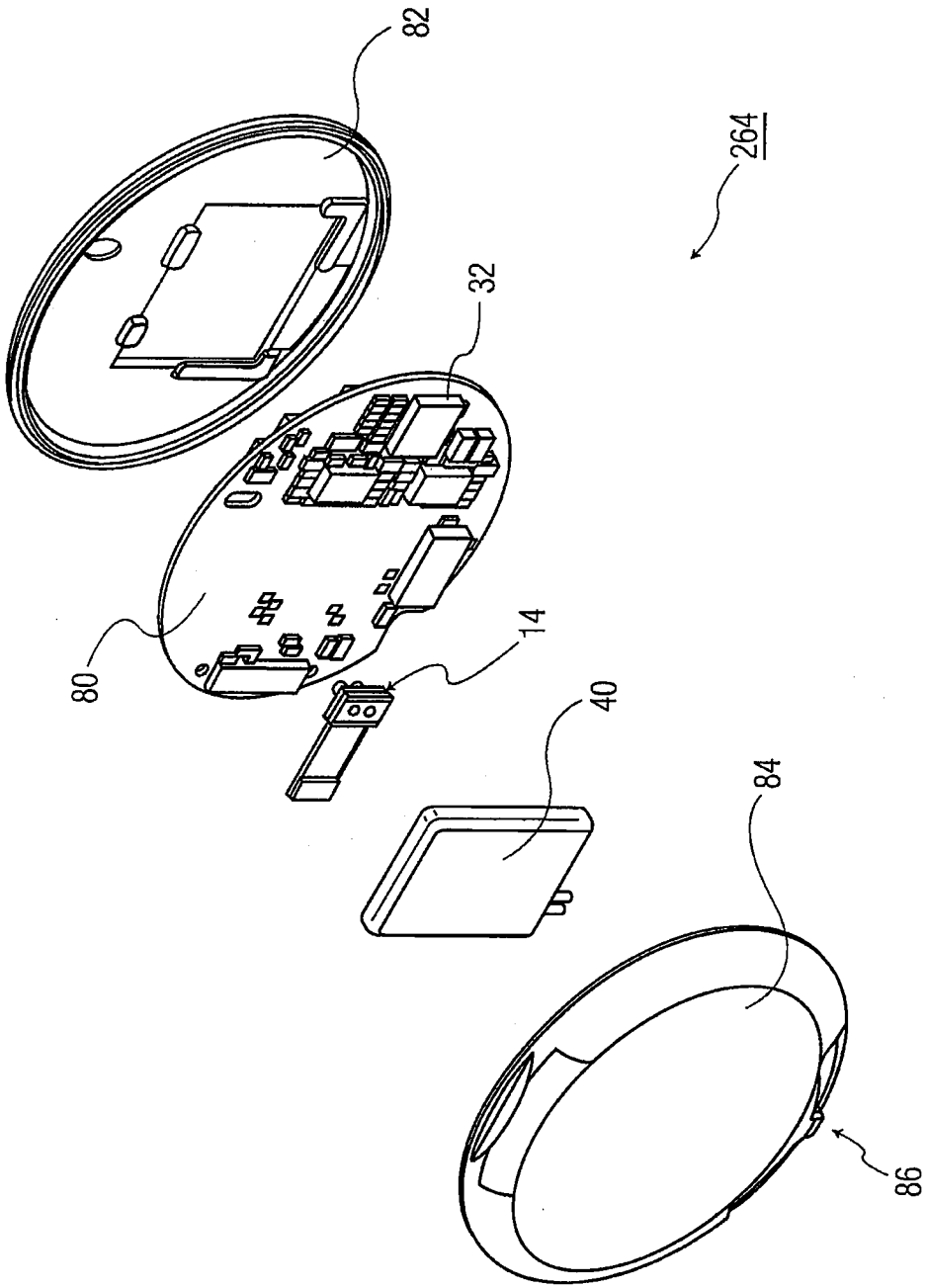

Fig. 13