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(54) **METHOD OF SIGNAL ENHANCEMENT FOR ECG DEVICES**

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See application file for complete search history.

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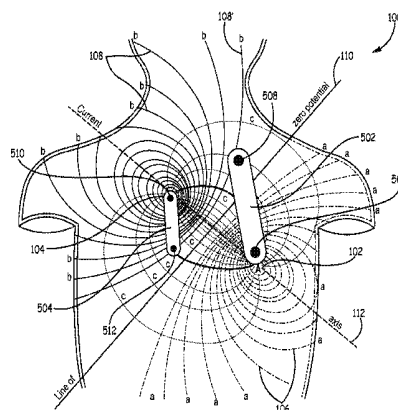
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(57) **ABSTRACT**

An embodiment of the invention comprises a method of monitoring cardiac electrical activity with two or more ECG devices and computing an enhanced cardiac electrical signal from the cardiac electrical signals obtained from the two or more ECG devices. Electrodes of the two or more ECG devices are positioned in a manner to provide an electrical potential difference that is large enough to give useful information about a given ECG signal. The method further includes recommending addition of a supplemental ECG device when it is determined that the one or more of the existing ECG devices are inadequate for providing cardiac electrical data that identifies a specific cardiac event.

4 Claims, 6 Drawing Sheets



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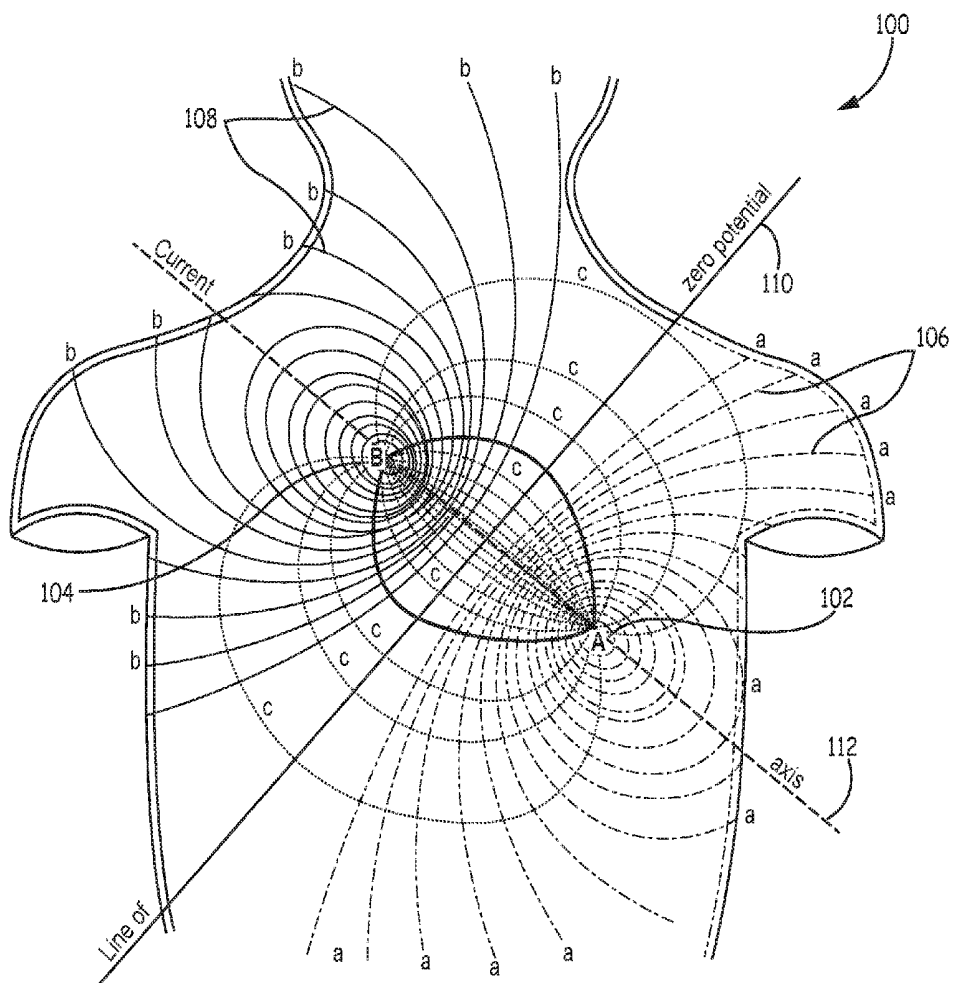


FIG. 1

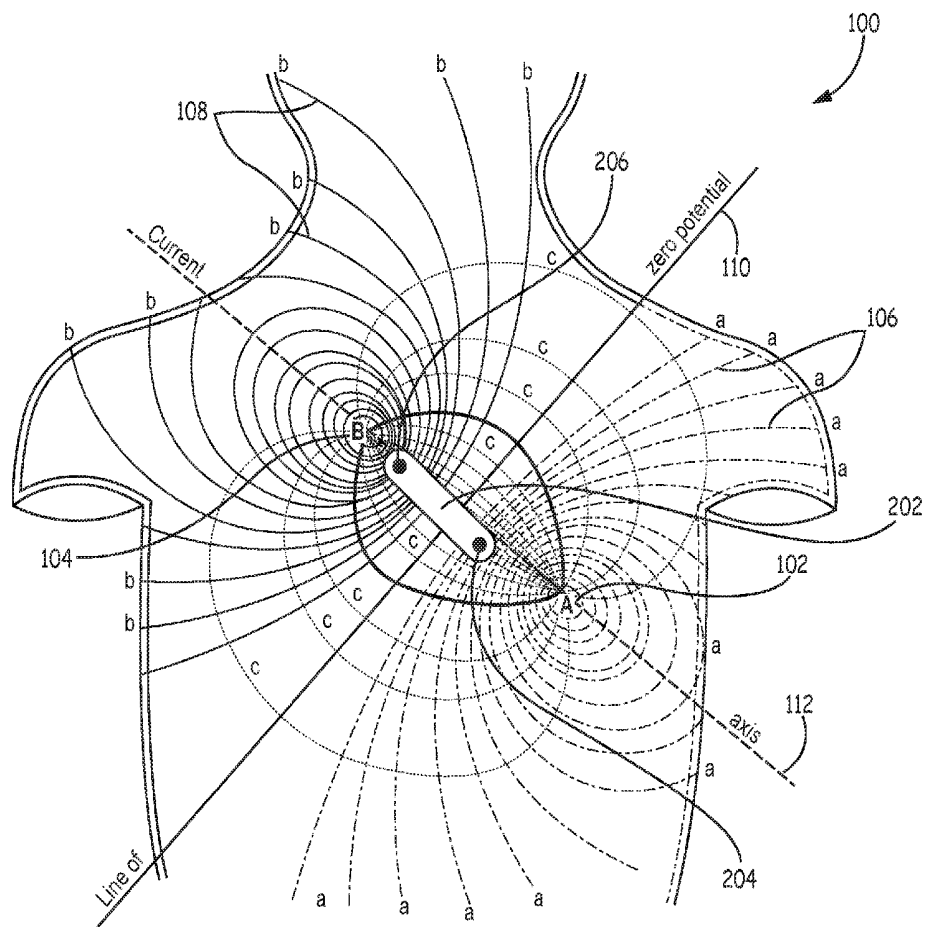


FIG. 2

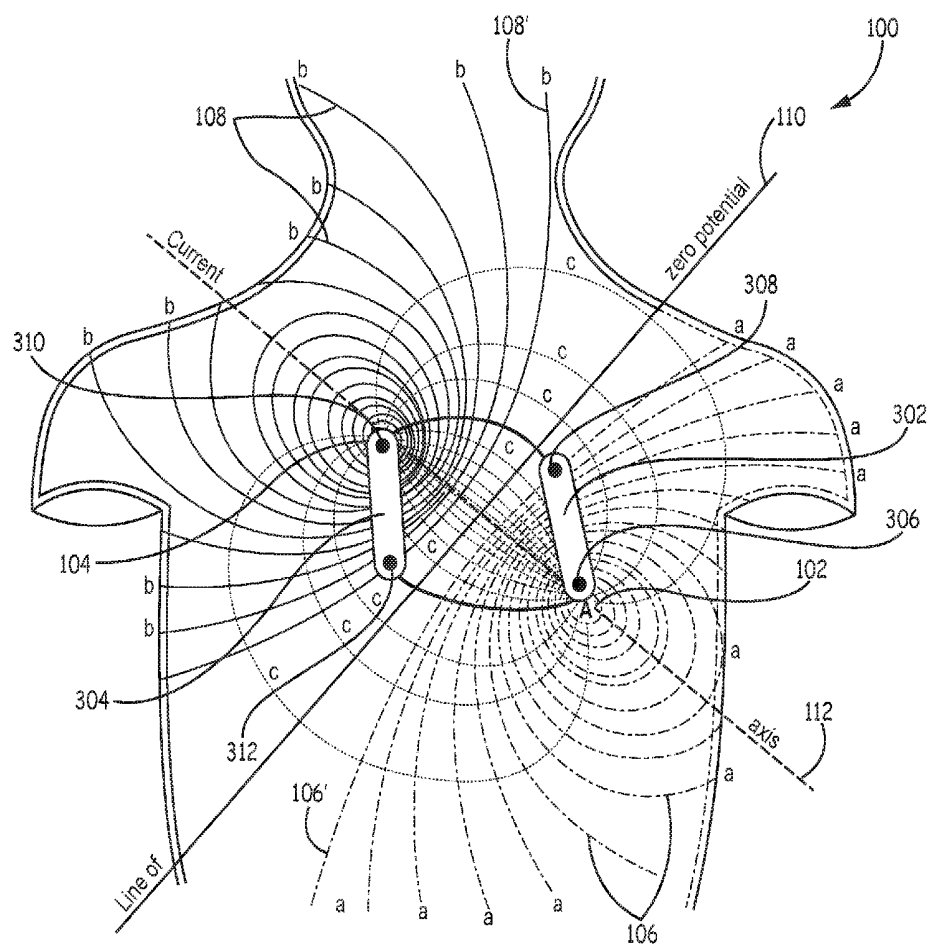


FIG. 3

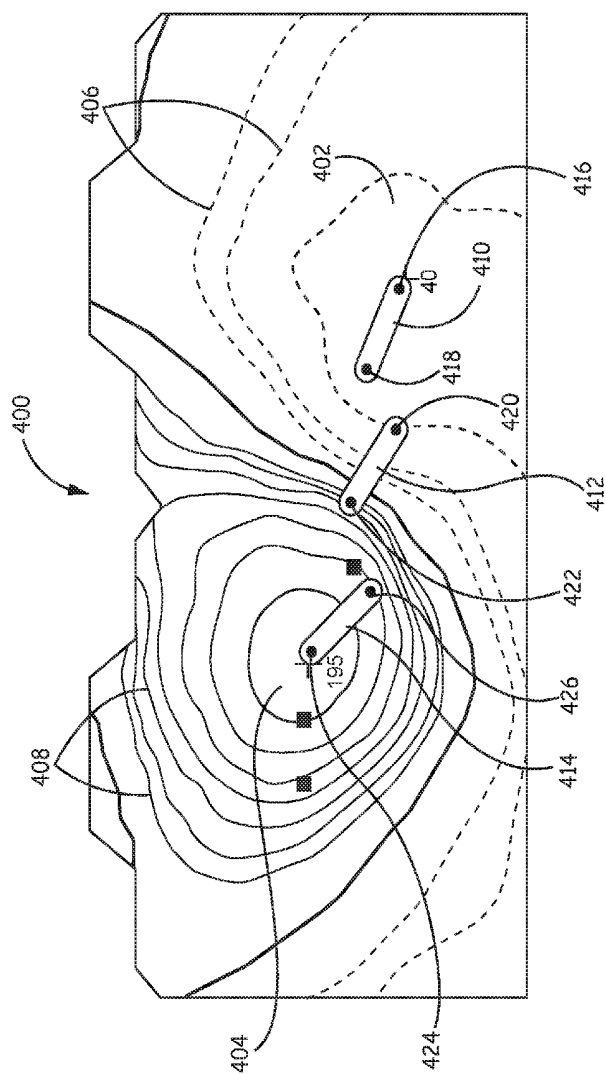


FIG. 4

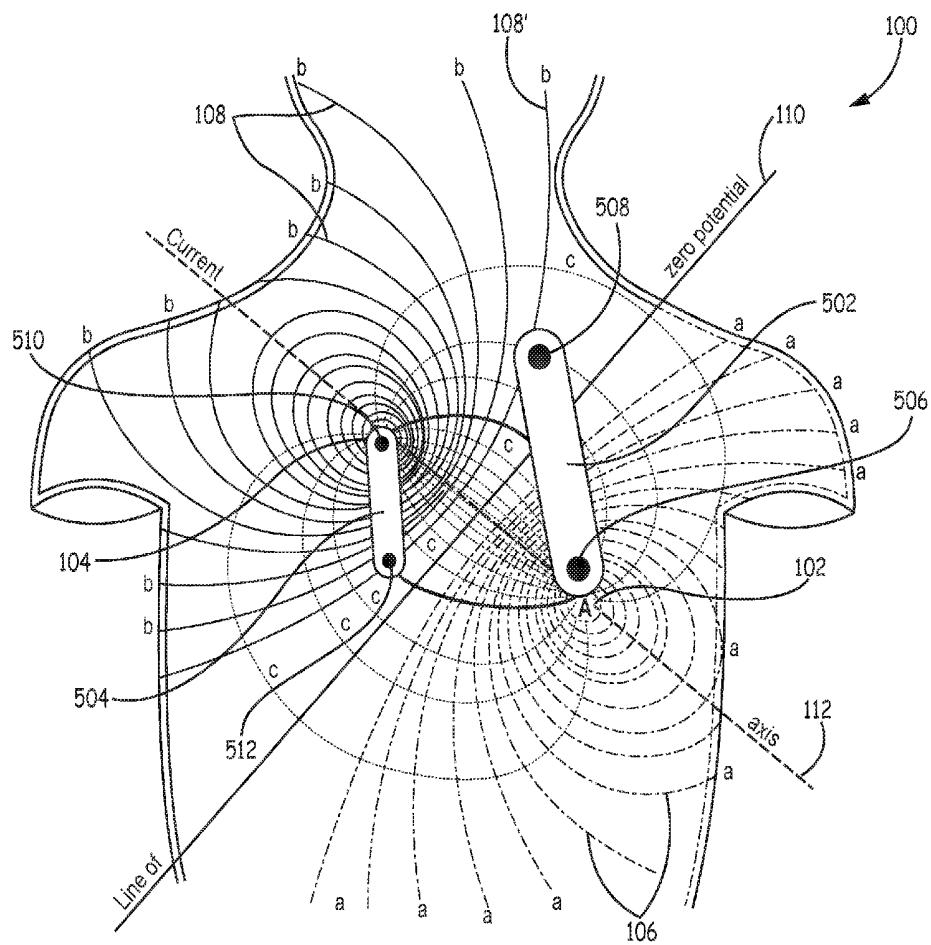


FIG. 5

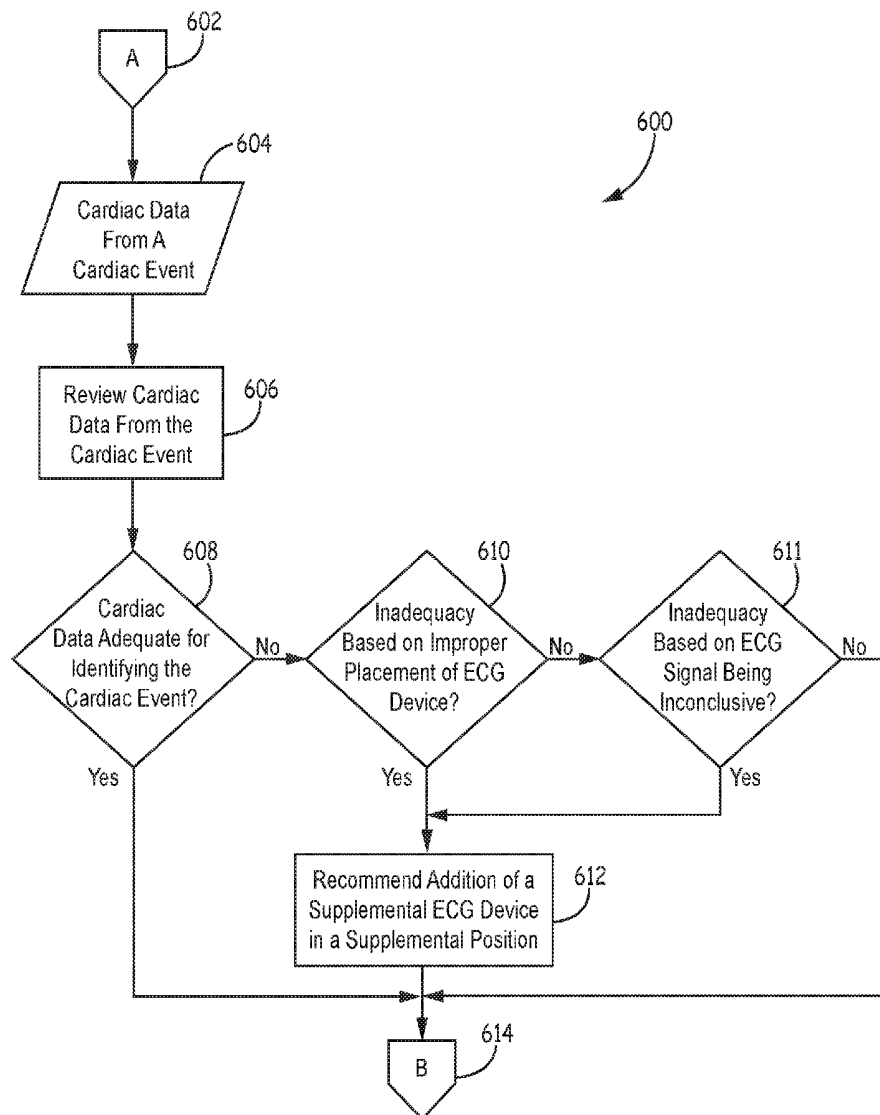


FIG. 6

1

METHOD OF SIGNAL ENHANCEMENT FOR ECG DEVICES

RELATED APPLICATION

This application is a divisional of U.S. patent application Ser. No. 13/099,065, filed May 2, 2011 entitled "METHOD OF SIGNAL ENHANCEMENT FOR ECG DEVICES", herein incorporated by reference in its entirety.

FIELD

The present invention relates to a method of providing enhanced cardiac electrical signals.

BACKGROUND

Devices for monitoring cardiac events (e.g., arrhythmia, myocardial infarction, etc.) and the cardiac electrical activity are well known in the art. These include external devices generally known as Electro-Cardiograms (ECG) wherein a plurality of electrodes are positioned at predetermined locations on a patient's body for monitoring the electrical waves corresponding to the various states of the heart. ECG devices that can be subcutaneously implanted in a patient are also well known and widely used.

Subcutaneous devices having integrated electrodes used for monitoring cardiac electrical activity are restricted in size to ensure that the electrodes are sufficiently spaced apart for providing an electrical potential difference that is large enough to give useful information about a given ECG signal. However, there is an ever increasing desire for miniaturization for ease of surgically implanting and/or replacing the device with minimally invasive procedures, and also for lending comfort to the patient after a device has been implanted. As can be appreciated, decreasing the size of a subcutaneous device also decreases the distance between the device's integrated electrodes. This then decreases the amplitude of the cardiac electrical signal measured by the electrodes, along with likely decreasing the signal-to-noise ratio.

SUMMARY

An embodiment of the invention comprises a method of monitoring cardiac electrical activity with at least two subcutaneous devices. The first of the two subcutaneous devices includes a first pair of electrodes wherein the first electrode of the first pair of electrodes is positioned near a location of maximum electrical potential (relative to the second electrode), and the second electrode of the first pair of electrodes is positioned along a first equipotential line extending from the location of maximum electrical potential. Similarly, the second of the two subcutaneous devices includes a second pair of electrodes wherein the first electrode of the second pair of electrodes is positioned near a location of minimum electrical potential (relative to the second electrode), and the second electrode of the second pair of electrodes is positioned along a second equipotential line extending from the location of minimum electrical potential. The first and the second subcutaneous devices measure a first and a second cardiac electrical signal. The first cardiac electrical signal represents an electrical potential between the first and the second electrode of the first pair of electrodes, and the second cardiac electrical signal represents an electrical potential between the first and the second electrode of the second pair of electrodes. The first

2

and the second cardiac electrical signals are stored in a memory of the respective first and second subcutaneous devices and are transmitted to an external device (i.e., a device that has not been subcutaneously implanted) when requested to do so by the external device. In some embodiments, the external device is a device that a patient uses to draw cardiac electrical data from the implanted devices and to transmit such data to a separate device at a clinic. In some embodiments, the external device is a device at a clinic that receives cardiac electrical data from a patient device (or from the implanted devices themselves). The external device is configured for computing an enhanced cardiac electrical signal that represents a larger electrical potential difference than would be provided by either of the first or second subcutaneous devices alone. In accordance with an embodiment of the invention, the enhanced cardiac electrical signal is also computed as a linear or nonlinear combination of the first and the second cardiac electrical signals (e.g., an arithmetic sum of such signals) by way of a synchronization mechanism.

A method, in accordance with an embodiment of the invention, includes adding a second, third or more ECG devices. This can include recommending implantation of a supplemental subcutaneous device (e.g., when it is determined that the received cardiac electrical data does not enable a physician to identify the cardiac event that prompted the patient to request the data from the implanted device(s)). This could be because the electrodes of the existing ECG device(s) are not positioned properly to provide accurate cardiac electrical data regarding the first predetermined ECG signal. This could be because the cardiac electrical data regarding the first predetermined ECG signal, though accurately provided, does not provide sufficient diagnostic information explain the cardiac event. Adding a supplemental ECG device can address any inaccuracies or insufficiencies in electrode positioning and/or position electrodes to gather information regarding a second (or subsequent) predetermined ECG signal.

Generally, embodiments of the present invention pertain to generating an enhanced cardiac electrical signal by combining the cardiac electrical signals measured by at least two ECG devices. In some embodiments, one or more of the ECG devices can be external (e.g., to provide increased simplicity, ease of implementation, convenience, etc.). In preferred embodiments, the ECG devices can be subcutaneous. Some particularly advantageous embodiments are able to accommodate the decreasing size of subcutaneous devices for monitoring cardiac electrical activity.

The component that computes the enhanced cardiac electrical signal can vary in different embodiments. For example, in some embodiments, the first ECG device can provide the first cardiac electrical signal to an external device, and the second ECG device can also provide the second cardiac electrical signal to the external device, which can compute the enhanced cardiac electrical signal. In another example, the first ECG device can provide the first cardiac electrical signal to the second ECG device, and the second ECG device can provide both the first and second cardiac electrical signals to an external device, which can compute the enhanced cardiac electrical signal. In yet another example, the first ECG device can provide the first cardiac electrical signal to the second ECG device, and the second ECG device can compute the enhanced cardiac electrical signal.

BRIEF DESCRIPTION OF THE DRAWINGS

The following drawings are illustrative of particular embodiments of the present invention and therefore do not

limit the scope of the invention. The drawings are not to scale (unless so stated) and are intended for use in conjunction with the explanations in the following detailed description. Embodiments of the present invention will hereinafter be described in conjunction with the appended drawings, wherein like numerals denote like elements.

FIG. 1 is an illustration of a body surface potential map;

FIG. 2 is an illustration of a prior art subcutaneous device for monitoring cardiac electrical signals;

FIG. 3 is an illustration of at least two subcutaneous devices for enhancing cardiac electrical signals;

FIG. 4 is an illustration of at least three subcutaneous devices for enhancing cardiac electrical signals;

FIG. 5 is an illustration of a supplemental subcutaneous device implanted for enhancing cardiac electrical signals; and

FIG. 6 is a flowchart of a method for adding a supplemental ECG device for enhancing cardiac electrical signals.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The following detailed description is exemplary in nature and is not intended to limit the scope, applicability, or configuration of the invention in any way. Rather, the following description provides some practical illustrations for implementing exemplary embodiments of the present invention. Examples of constructions, materials, dimensions, and manufacturing processes are provided for selected elements, and all other elements employ that which is known to those of ordinary skill in the field of the invention. Those skilled in the art will recognize that many of the noted examples have a variety of suitable alternatives.

FIG. 1 is an illustration of a body surface potential map 100 on a human chest in accordance with a dipolar model of a cardiac current generator. As shown, potential map 100 includes location 102 of maximum electrical potential and location 104 of minimum electrical potential. The change in electrical potential from one of maximum electrical potential at location 102 to one of minimum electrical potential at location 104 is represented by equipotential lines 106 and 108, also labeled as “a” and “b”, respectively. The potential change or voltage between point 102 and any point on one of the equipotential lines 106 is the same. As equipotential lines 106 and 108 extend from locations 102 and 104 of maximum and minimum electrical potential, respectively, there exists a “line of zero potential” 110. Additionally, the difference in the electrical potential between locations 102 and 104 of maximum and minimum electrical potential, respectively, results in the largest potential change or voltage between any two locations on the patient’s torso.

FIG. 2 illustrates the location or positioning of an subcutaneous device 202 for monitoring cardiac electrical activity of a patient. In FIG. 2, subcutaneous device 202 is shown superimposed on the body surface potential map 100. Subcutaneous device 202 comprises a pair of electrodes 204 and 206 positioned near longitudinally opposing ends of subcutaneous device 202. In accordance with methods well known in the art for implanting a cardiac monitoring device, each electrode 204 and 206 of the pair of electrodes of subcutaneous device 202 is respectively positioned generally near locations 102 and 104 of maximum and minimum electrical potential. In this way, the difference in measured potential between electrode 204 and electrode 206 can provide important information about the body surface potential map 100 and the patient’s cardiac condition.

Because prior art devices such as device 202 are implanted subcutaneously in a patient, it is desirable to make such devices as small as possible for ease of surgically implanting and/or replacing the device with minimally invasive procedures, and also for lending comfort to the patient after the device has been implanted. However, in order to robustly monitor and record cardiac electrical activity, it is highly desirable to have a large ECG signal, preferably with electrodes placed at the maximum and minimum electrical potentials at locations 102 and 104, respectively. As can be seen, decreasing the length of a device such as subcutaneous devices 202 will also decrease the longitudinal distance between electrodes 204 and 206, thereby decreasing the amplitude of the ECG signal. Accordingly, the cardiac electrical activity monitored and/or recorded by such a smaller device may not be sufficiently robust or meaningful for diagnosis purposes. Furthermore, smaller devices provide less margin for error in placement, with any misalignment or incorrect placement of any one or both electrodes 204 and 206 being further magnified and potentially resulting in cardiac electrical data that is not sufficiently robust or meaningful for diagnosis purposes.

These and other shortcomings of prior art devices such as subcutaneous device 202 and/or implantable cardiac monitoring devices smaller than prior art devices are addressed by embodiments of the instant invention.

FIG. 3 illustrates the location or positioning of at least two subcutaneous devices 302 and 304 for monitoring and/or recording cardiac electrical activity, wherein each one of the two devices 302 and 304 is smaller than prior art devices such as subcutaneous device 202 of FIG. 2. In FIG. 3, the two subcutaneous devices 302 and 304 are shown superimposed on the body surface potential map 100. First subcutaneous device 302 comprises a first pair of electrodes 306 and 308 positioned near longitudinally opposing ends of first subcutaneous device 302. As shown, first subcutaneous device 302 is implanted such that first electrode 306 of the first pair of electrodes is positioned near location 102 of maximum electrical potential for a first predetermined ECG signal (relative to second electrode 308). Also as shown, second electrode 308 of the first pair of electrodes is positioned along a first equipotential line 106’ extending from location 102 of maximum electrical potential for the first predetermined ECG signal. As such, first subcutaneous device 302 will provide a first cardiac electrical signal measured as the electrical potential between its electrodes 306 and 308. Similarly, second subcutaneous device 304 comprises a second pair of electrodes 310 and 312 positioned near longitudinally opposing ends of second subcutaneous device 304. As shown, second subcutaneous device 304 is implanted such that first electrode 310 of the second pair of electrodes is positioned near location 104 of minimum electrical potential for the first predetermined ECG signal (relative to second electrode 312). Also as shown, second electrode 312 of the second pair of electrodes is positioned along a second equipotential line 108’ extending from location 104 of minimum electrical potential for the first predetermined ECG signal. As such, second subcutaneous device 304 will provide a second cardiac electrical signal measured as the electrical potential between its electrodes 310 and 312. Then, as is discussed in greater detail below, in accordance with an embodiment of the invention, an enhanced cardiac electrical signal is computed as a linear or nonlinear combination of the first and the second cardiac electrical signals (e.g., an arithmetic sum of such signals). A

synchronization mechanism can be provided between the two subcutaneous devices 302 and 304 to enable combination of the signals.

Also in accordance with an embodiment of the invention, an external device requests and receives the first and the second cardiac electrical signals, respectively, from the first and the second subcutaneous devices 302 and 304. This sequence is often initiated by a patient who has just experienced a cardiac event. He/she then typically instructs the external device to make such a request of the implanted devices. The external device then transmits the first and the second cardiac electrical signals it received from the first and the second subcutaneous devices 302 and 304, respectively, (in raw form or after processing) to another device (e.g., located at a clinic) which is configured for computing an enhanced cardiac electrical signal. In many such embodiments, the enhanced cardiac electrical signal represents a difference in electrical potential that is greater than the electrical potential difference between electrodes 306 and 308 or between electrodes 306 and 308.

The initial request for the cardiac electrical signal(s) from the device(s) can come from a several sources. For example, as alluded to above, the patient can initiate the request (e.g., while or after experiencing a cardiac event). In another example, the request can be initiated automatically according to a predetermined schedule of time intervals. In yet another example, the request can be initiated automatically by a diagnostic algorithm.

In an embodiment of the invention, first subcutaneous device 302 is configured for measuring a plurality of the first cardiac electrical signals over a pre-specified period of time and storing the measured plurality of the first cardiac electrical signals in a memory of the first subcutaneous device 302. Similarly, second subcutaneous device 304 is configured for measuring a plurality of the second cardiac electrical signals over a pre-specified period of time and storing the measured plurality of the second cardiac electrical signals in a memory of the second subcutaneous device 304. The plurality of the first and the second cardiac electrical signals respectively stored in the memory of the first and the second subcutaneous devices 302 and 304 are transmitted to the external device upon receiving a request from the external device.

In an embodiment of the invention, the plurality of the first cardiac electrical signals measured by the first subcutaneous device 302 span a first period of time encompassing a pre-specified period of time both before and after receiving the request, from the external device, to transmit the plurality of the first cardiac electrical signals. Similarly, the plurality of the second cardiac electrical signals measured by the second subcutaneous device 304 span a first period of time encompassing a pre-specified period of time both before and after receiving the request, from the external device, to transmit the plurality of the second cardiac electrical signals. In this way, when a patient experiences a cardiac event, he/she can initiate transmission of cardiac electrical data to a clinic device for analysis, and the transmitted data can be from just before the cardiac event and just after the cardiac event, thereby giving the physician a clear picture of the predetermined ECG signal throughout the cardiac event.

As described in the foregoing, the enhanced cardiac electrical signal, in an embodiment of the invention, is computed as an arithmetic sum (or other a linear or nonlinear combination) of the first cardiac electrical signal and the second cardiac electrical signal. Also as described in the foregoing, and also in accordance with an embodiment of

the invention, the first cardiac electrical signal is measured by the first subcutaneous device 302 as the difference in the electrical potential between its corresponding first and second electrodes 306 and 308 of the first pair of electrodes. Similarly, the second cardiac electrical signal is measured by the second subcutaneous device 304 as the difference in the electrical potential between its corresponding first and second electrodes 310 and 312 of the second pair of electrodes. For example, if V_{306} and V_{308} , respectively, are the electrical potentials measured by the first and the second electrodes 306 and 308 of the first pair of electrodes of the first subcutaneous device 302, then the first cardiac electrical signal measured by the first subcutaneous device 302 is $V_{302} = V_{306} - V_{308}$. Similarly, if V_{310} and V_{312} , respectively, are the electrical potentials measured by the first and the second electrodes 310 and 312 of the second pair of electrodes of the second subcutaneous device 304, then the second cardiac electrical signal measured by the second subcutaneous device 304 is $V_{304} = V_{312} - V_{310}$. Accordingly, in some embodiments, the enhanced cardiac electrical signal between the locations 102 and 104 of maximum and minimum potentials, respectively, can be computed as

$$V_{EN} = V_{302} + V_{304} = (V_{306} - V_{308}) + (V_{312} - V_{310}) = V_{306} - V_{308} + V_{312} - V_{310}$$

As can be seen, by locating the second electrode 308 of the first pair of electrodes of the first subcutaneous device 302 on an equipotential line that is near the equipotential line of the second electrode 312 of the second pair of electrodes of the second subcutaneous device 304, the electrical potentials V_{308} and V_{312} will be very similar or essentially equal. Accordingly, $V_{EN} = V_{306} - V_{310}$. In some instances in which the first electrode 306 of the first pair of electrodes of the first subcutaneous device 302 is positioned proximate the location 102 of maximum potential, the electrical potential V_{306} can approximate the maximum potential. Similarly, in instances in which the first electrode 310 of the second pair of electrodes of the second subcutaneous device 304 is positioned proximate the location 104 of minimum potential, the electrical potential V_{310} can approximate the minimum potential. Therefore, in such instances in which the enhanced cardiac electrical signal V_{EN} is computed as an arithmetic sum of the first cardiac electrical signal V_{302} measured by the first subcutaneous device 302 and the second cardiac electrical signal V_{304} measured by the second subcutaneous device 304, the enhanced cardiac electrical signal can approximate the difference in electrical potential between the locations 102 and 104 of maximum and minimum potentials, respectively.

As described in the foregoing, there exists a "line of zero potential" 110 between the locations 102 and 104 of maximum and minimum electrical potential. Accordingly, by locating both second electrodes 308 and 312 of the first and the second pair of electrodes of the first and the second subcutaneous devices 302 and 304 substantially near the "line of zero potential" 110, the electrical potentials V_{308} and V_{312} can be essentially negligible, and therefore, the enhanced cardiac electrical signal $V_{EN} = V_{306} - V_{310}$.

In some embodiments of the invention, an external device (e.g., located at a clinic) requests and receives the first and the second cardiac electrical signals, respectively, from the first and the second subcutaneous devices 302 and 304. The external device then computes an enhanced cardiac electrical signal.

FIG. 4 is an illustration of a body surface potential map 400 on a human chest in accordance with a dipolar model of a cardiac current generator (found in Horacek et al., *Optimal*

Electrocardiographic Leads for Detecting Acute Myocardial Ischemia, 34 Journal of Electrocardiology 97 (2001)). As shown, potential map 400 includes location 402 of maximum electrical potential and location 404 of minimum electrical potential for a predetermined ECG signal. The change in electrical potential from one of maximum electrical potential at location 402 to one of minimum electrical potential at location 404 is represented by equipotential lines 406 and 408, respectively. In accordance with an embodiment of the invention, FIG. 4 illustrates the location or positioning of at least three subcutaneous devices 410, 412 and 414 for monitoring and/or recording cardiac electrical activity, wherein each one of the three subcutaneous devices 410, 412 and 414 are smaller than the prior art devices such as subcutaneous device 202. First subcutaneous device 410 comprises a first pair of electrodes 416 and 418 positioned near longitudinally opposing ends of first subcutaneous device 410. As shown, first subcutaneous device 410 is implanted such that first electrode 416 of the first pair of electrodes is positioned near location 402 of maximum electrical potential for a first predetermined ECG signal (relative to the second electrode 418). Also, second electrode 418 of the first pair of electrodes can be positioned along an equipotential line (not shown) extending from location 402 of maximum electrical potential for the first predetermined ECG signal. As such, first subcutaneous device 410 will provide a first cardiac electrical signal measured as the electrical potential between its electrodes 416 and 418. Similarly, second subcutaneous device 412 comprises a second pair of electrodes 420 and 422 positioned near longitudinally opposing ends of second subcutaneous device 412. As shown, second subcutaneous device 412 is implanted such that first electrode 420 of the second pair of electrodes is positioned near equipotential line 406 for the first predetermined ECG signal. Also as shown, second electrode 422 of the second pair of electrodes is positioned along equipotential line 408 extending from location 404 of minimum electrical potential for the first predetermined ECG signal. As such, second subcutaneous device 412 will provide a second cardiac electrical signal measured as the electrical potential between its electrodes 420 and 422. Also, third subcutaneous device 414 comprises a third pair of electrodes 424 and 426 positioned near longitudinally opposing ends of third subcutaneous device 414. As shown, third subcutaneous device 414 is implanted such that first electrode 424 of the third pair of electrodes is positioned near location 404 of minimum electrical potential for a second predetermined ECG signal (relative to the second electrode 426). Also as shown, second electrode 426 of the third pair of electrodes is positioned near equipotential line 408 extending from location 404 of minimum electrical potential for the second predetermined ECG signal. As such, third subcutaneous device 414 will provide a third cardiac electrical signal measured as the electrical potential between its electrodes 424 and 426.

As described in the foregoing with reference to FIG. 3, the external device can request and receive the third cardiac electrical signal from the third subcutaneous device 414 in addition to the first and the second cardiac electrical signals from the first and the second subcutaneous devices 410 and 412. The external device then transmits the first, the second and the third cardiac electrical signals it received from the first, the second and the third subcutaneous devices 410, 412 and 414, respectively, to another device which is configured for computing an enhanced cardiac electrical signal. The enhanced cardiac electrical signal can be an arithmetic sum (or other linear or nonlinear combination) of the first,

second, and third cardiac electrical signals. This can be especially effective in approximating the potential difference between location 402 and location 404 if electrode 418 and electrode 420 are on similar (or the same) equipotential lines and if electrode 426 and electrode 422 are on similar (or the same) equipotential lines.

As with embodiments discussed above, the request for the cardiac electrical signals can be made by an external device located near the patient or at a clinic. One or more external devices can then compute the enhanced cardiac electrical signal.

As previously described, a mis-alignment or incorrect placement of any one or both electrodes of a pair of electrodes of one or more ECG devices can result in cardiac electrical data that is not sufficiently robust or meaningful for diagnosis purposes. Also, it may be determined that the one or more ECG devices already installed are inadequate for providing cardiac electrical data for a specific ECG signal and/or cardiac event or for a different ECG signal and/or cardiac event than initially desired. Accordingly, it may be desirable to add a supplemental ECG device for enhancing the cardiac electrical signals.

One such embodiment is illustrated in FIG. 5 wherein the two subcutaneous devices 502 and 504 are shown superimposed on the body surface potential map 100. First subcutaneous device 502 comprises a first pair of electrodes 506 and 508 positioned near longitudinally opposing ends of first subcutaneous device 502. As shown, first subcutaneous device 502 is implanted such that first electrode 506 of the first pair of electrodes is positioned near location 102 of maximum electrical potential for a first predetermined ECG signal (relative to the second electrode 508). Also as shown, second electrode 508 of the first pair of electrodes is positioned along equipotential line 108' extending from location 104 of minimum electrical potential for the first predetermined ECG signal. As such, first subcutaneous device 502 will provide a first cardiac electrical signal measured as the electrical potential between its electrodes 506 and 508. Upon reviewing the first cardiac electrical signal from the first subcutaneous device 502, a care giver may conclude that first subcutaneous device 502 is not correctly positioned for the first predetermined ECG signal or not able to provide adequate diagnostic information and may accordingly recommend the implantation of supplemental subcutaneous device 504. As with subcutaneous device 502, supplemental subcutaneous device 504 comprises a supplemental pair of electrodes 510 and 512 positioned near longitudinally opposing ends of supplemental subcutaneous device 504. As shown, supplemental subcutaneous device 504 is implanted such that first electrode 510 of the supplemental pair of electrodes is positioned near location 104 of minimum electrical potential for the first predetermined ECG signal (relative to the second electrode 512). Also as shown, second electrode 512 of the supplemental pair of electrodes is positioned along equipotential line 108' extending from location 104 of minimum electrical potential for the first predetermined ECG signal. As such, supplemental subcutaneous device 504 will provide a supplemental cardiac electrical signal measured as the electrical potential between its electrodes 510 and 512. Then, because the electrical potential difference between electrode 512 and electrode 508 is essentially negligible, an enhanced cardiac electrical signal can be computed as an arithmetic sum (or other linear or nonlinear combination) of the first cardiac electrical signal and the supplemental cardiac electrical signal, and the enhanced cardiac electrical signal can represent an electrical potential difference that is greater

than the electrical potential difference between electrodes **506** and **508** or electrodes **510** and **512**.

FIG. **6** is a flowchart **600** of a method for recommending addition of a supplemental ECG device (e.g., a subcutaneous device) when it is determined that the cardiac data provided by one or more existing devices does not provide adequate information regarding the patient's cardiac event. For example, the existing device(s) can be improperly positioned for providing accurate cardiac electrical data regarding a first predetermined ECG signal. In another example, it can be determined that the first predetermined ECG signal does not completely explain the patient's event, so monitoring a different/additional ECG signal can be recommended. For example, the existing device(s) can be positioned for monitoring arrhythmia, and a supplemental ECG device can be recommended for monitoring for coronary artery disease (either in addition to arrhythmia or instead of arrhythmia). As shown, the illustrative method begins at **602** wherein at block **604** the cardiac data relating to a cardiac event as represented by a first predetermined ECG signal is made available (e.g., according to one of the ways set forth elsewhere herein). The cardiac data from block **604** is reviewed by the care giver at block **606**. Then, at block **608** the care giver makes a determination whether or not the cardiac data from block **604** is adequate for identifying the cardiac event of interest. If the cardiac data from block **604** is determined to be adequate, then the method proceeds to end block **614**. If the cardiac data from block **604** is determined to be inadequate, then the method proceeds to block **610**. At block **610**, a determination is made about whether the inadequacy of the cardiac data is based on improper positioning of the existing device(s). If the inadequacy of the cardiac data is based on improper positioning of the existing device(s), the method proceeds to block **612** (which is discussed below). If the inadequacy of the cardiac data is not based on improper positioning of the existing device(s), the method proceeds to block **611**. At block **611**, a determination is made about whether the inadequacy of the cardiac data is based on the first predetermined ECG signal being inconclusive of the patient's cardiac event. If the inadequacy of the cardiac data is based on the first predetermined ECG signal being inconclusive of the patient's cardiac event, the method proceeds to block **612** (which is discussed below). If the inadequacy of the cardiac data is not based on the first predetermined ECG device being inconclusive of the patient's cardiac event, the method proceeds to block **614**.

As noted, if the cardiac data is inadequate for identifying or addressing the patient's cardiac event because of improper placement of the existing device or because the ECG signal is inconclusive, the method proceeds to block **612**. At block **612**, the care giver recommends addition of a supplemental ECG device (e.g., subcutaneously implanted). The supplemental ECG device can have similar characteristics as ECG devices discussed elsewhere herein. Addition of the supplemental ECG device can address the improper placement of the existing device as discussed elsewhere herein. Addition of the supplemental ECG device can involve positioning the supplemental ECG device in an optimal location for monitoring a different ECG signal.

Thus, embodiments of the invention are disclosed. Although the present invention has been described in considerable detail with reference to certain disclosed embodiments, the disclosed embodiments are presented for purposes of illustration and not limitation and other embodiments of the invention are possible. For example, though the inventive concepts discussed herein have been

described in connection with subcutaneous devices, it should be appreciated that many of the concepts can be implemented with cutaneous devices, as well as with combinations of cutaneous and subcutaneous devices. One skilled in the art will appreciate that various changes, adaptations, and modifications may be made without departing from the spirit of the invention and the scope of the appended claims.

What is claimed is:

1. A method of monitoring cardiac electrical activity, comprising:

receiving one or more cardiac electrical signals from one or more ECG devices, wherein each of said one or more ECG devices comprises a pair of electrodes positioned on longitudinally opposing ends of said one or more ECG devices, wherein

a first electrode of a first ECG device of the one or more ECG devices is positioned at a first location of either maximum or minimum electrical potential for a first predetermined ECG signal; and

each of said one or more cardiac electrical signals represents a difference in an electrical potential between the first and a second electrode of the pair of electrodes; reviewing cardiac data based on said one or more cardiac electrical signals to identify a cardiac event, and

recommending addition of a supplemental ECG device in a supplemental position if the cardiac data is determined to be inadequate for identifying the cardiac event, the supplemental ECG device comprising a supplemental pair of electrodes positioned on longitudinally opposing ends of said supplemental ECG device,

wherein the second electrode of the first ECG device is positioned along an equipotential line extending from the first location of either maximum or minimum electrical potential for the first predetermined ECG signal;

the supplemental position includes a first electrode of the supplemental pair of electrodes being positioned near a supplemental location of either minimum or maximum electrical potential for the first predetermined ECG signal and a second electrode of the supplemental pair of electrodes being positioned along an equipotential line extending from the supplemental location of either minimum or maximum electrical potential for the first predetermined ECG signal; and

an arithmetic difference in an electrical potential between the second electrode of the first ECG device and the second electrode of the supplemental pair of electrodes in the supplemental position would be essentially negligible.

2. The method of claim 1, wherein the one or more ECG devices includes a second ECG device and said one or more cardiac electrical signals is received from the first ECG device and the second ECG device.

3. The method of claim 2, wherein

the second electrode of one of the first or second ECG device is positioned along an equipotential line extending from the first location of either maximum or minimum electrical potential for the first predetermined ECG signal; and

an arithmetic difference in an electrical potential between the second electrode of the one of the first or second ECG device and the second electrode of the supplemental pair of electrodes in the supplemental position would be essentially negligible.

11

4. A method of monitoring cardiac electrical activity, comprising:

- receiving one or more cardiac electrical signals from one or more ECG devices, wherein each of said one or more ECG devices comprises a pair of electrodes positioned on longitudinally opposing ends of said one or more ECG devices, wherein
- a first electrode of a first ECG device of the one or more ECG devices is positioned at a first location of either maximum or minimum electrical potential for a first predetermined ECG signal; and
- each of said one or more cardiac electrical signals represents a difference in an electrical potential between the first and a second electrode of the pair of electrodes;
- reviewing cardiac data based on said one or more cardiac electrical signals to identify a cardiac event and determining that the cardiac data is inadequate for identifying the cardiac event because the first predetermined ECG signal is determined to be not indicative of the cardiac event;
- the first electrode of at least one of the one or more ECG devices is positioned at a second location of either maximum or minimum electrical potential for a second predetermined ECG signal;
- the second electrode of the at least one of the one or more ECG devices is positioned along an equipotential line

12

- extending from the second location of either maximum or minimum electrical potential for the second predetermined ECG signal;
- recommending addition of a supplemental ECG device in a supplemental position if the cardiac data is determined to be inadequate for identifying the cardiac event, the supplemental ECG device comprising a supplemental pair of electrodes positioned on longitudinally opposing ends of said supplemental ECG device,
- the supplemental position includes a first electrode of the supplemental pair of electrodes being positioned at a supplemental location of either minimum or maximum electrical potential for the second predetermined ECG signal and a second electrode of the supplemental pair of electrodes being positioned along an equipotential line extending from the supplemental location of either minimum or maximum electrical potential for the second predetermined ECG signal; and
- an arithmetic difference in an electrical potential between the second electrode of the at least one ECG device and the second electrode of the supplemental pair of electrodes in the supplemental position would be essentially negligible.

* * * * *

专利名称(译)	ECG设备的信号增强方法		
公开(公告)号	US9486150	公开(公告)日	2016-11-08
申请号	US14/176863	申请日	2014-02-10
[标]申请(专利权)人(译)	美敦力公司		
申请(专利权)人(译)	美敦力公司, INC.		
当前申请(专利权)人(译)	美敦力公司, INC.		
[标]发明人	SONG ZHENDGONG WANG SHENG		
发明人	SONG, ZHENDGONG WANG, SHENG		
IPC分类号	A61B5/04 A61B5/0408 A61B5/0402 A61B5/0404 A61B5/00 A61B5/042		
CPC分类号	A61B5/04085 A61B5/0404 A61B5/04012 A61B5/04028 A61B5/0006 A61B5/0422 A61B5/7221		
其他公开文献	US20140155725A1		
外部链接	Espacenet USPTO		

摘要(译)

本发明的实施例包括一种利用两个或更多个ECG设备监测心脏电活动并根据从两个或更多个ECG设备获得的心电信号计算增强的心电信号的方法。两个或更多个ECG装置的电极以某种方式定位，以提供足够大的电位差，以提供关于给定ECG信号的有用信息。该方法还包括当确定一个或多个现有ECG设备不足以提供识别特定心脏事件的心脏电数据时，建议添加补充ECG设备。

