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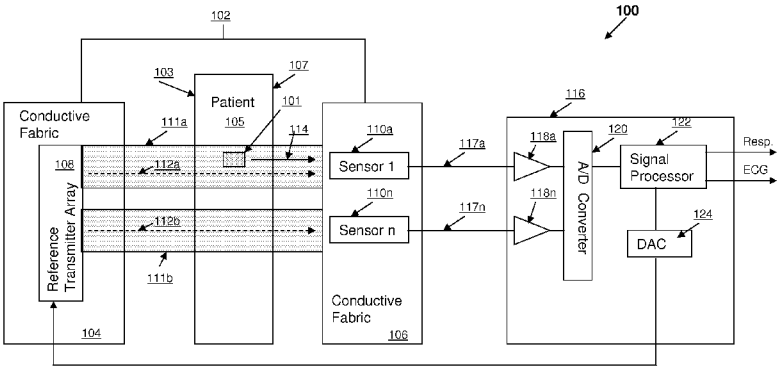

Fig 1A

(57) Abstract: A system and method for determining at least one patient parameter using electrophysiological signals from the patient is provided. The system includes a housing and a reference transmitter array. The reference transmitter array emits at least one reference signal having a predetermined frequency content. The reference transmitter is retained in a predetermined position by the housing on a first side of the patient's body. At least one sensor senses a composite signal including at least one signal generated by the patient's body and a modified reference signal, the modified reference signal being the reference signal received on the second side of the patient's body and including noise, the sensor being retained in a predetermined position by said housing on a second side of the patient's body opposite the first side. A signal processor is electrically coupled to the reference transmitter array and the at least one sensor. The signal processor controls the reference transmitter array to emit the at least one reference signal and receives the composite signal from the at least one sensor and filters the composite signal to remove the reference signal and noise therefrom to produce a first signal of interest for use in determining a first patient parameter.

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Apparatus and Method for Measuring Electrophysiological Signals Using Dry Electrodes

Field of the Invention

This invention concerns an apparatus and method for patient monitoring devices and, more specifically, for measuring electrophysiological signals from a patient using dry electrodes.

Background of the Invention

In the course of providing healthcare to patients, it is necessary to monitor vital statistics and other patient parameters. A plurality of different patient monitoring devices may selectively monitor the electrical impulses generated by a patient. These devices employ at least one electrode positioned on the patient's skin at particular locations. The monitoring device may be connected to the patient by a plurality of electrodes that monitor the electrical impulses associated with the patient. In order for the monitoring device to effectively monitor the electrical impulses of the patient, the electrodes conventionally include a conductive gel that is embedded in an adhesive pad. Thus, these electrodes are known as "wet electrodes". Wires from the monitor are selectively connected to respective electrodes in order to communicate voltages detected thereby to the monitoring device and provide a healthcare practitioner with data regarding a physiological condition of the patient. Exemplary types of patient monitoring devices able to monitor electrical impulses from a patient include Electrocardiogram (ECG) monitors and Electroencephalogram (EEG) monitors. However, certain drawbacks are associated with sensing electrophysiological signals using gel-based electrodes. In particular, gel-based electrodes dry out after a period of time and need to be changed in order to ensure that signal quality is at a sufficient level to determine the associated patient physiological parameter. Additionally, applying gel-based electrodes requires proper skin preparation to ensure proper connection to the patient thereby requiring additional time and expense by a healthcare practitioner when applying wet electrodes.

One manner of attempting to overcome the deficiencies of wet electrodes is to employ an electrode that is able to sense electrophysiological signals from a patient using a "dry electrode" because it does not require a conductive gel

between the electrode and the patient's skin. The term "dry electrode" may also be referred to as a contact-less electrode because the electrode does not need to be in direct contact with the skin of the patient in order to sense the physiological signal from the patient. These dry electrodes are able to sense the electrical field potential of the patient's body and perform a differential analysis to derive a patient parameter therefrom. Thus, the dry electrodes may appear to be preferable because they are not affected by any of the drawbacks associated with conductive gel and patient preparation associated therewith. However, dry electrodes are extremely sensitive to patient movement and ambient noise which may negatively impact the signal sensed thereby. In view of their sensitivity, using conventional dry electrodes has been unable able to yield a diagnostic quality signal representing a patient parameter. Therefore, it is desirable to produce a patient monitoring apparatus and system that enables sensing and determining diagnostic quality patient parameter data for use by a healthcare professional. A system according to invention principles addresses deficiencies of known systems.

Summary of the Invention

In one embodiment, a system for determining at least one patient parameter using electrophysiological signals from the patient is provided. The system includes a housing and a reference transmitter array. The reference transmitter array emits at least one reference signal having a predetermined frequency content. The reference transmitter is retained in a predetermined position by the housing on a first side of the patient's body. At least one sensor senses a composite signal including at least one signal generated by the patient's body and a modified reference signal, the modified reference signal being the reference signal received on the second side of the patient's body and including noise, the sensor being retained in a predetermined position by said housing on a second side of the patient's body opposite the first side. A signal processor is electrically coupled to the reference transmitter array and the at least one sensor. The signal processor controls the reference transmitter array to emit the at least one reference signal and receives the composite signal from the at least one sensor and filters the composite signal to remove the reference signal and noise therefrom to produce a first signal of interest for use in determining a first patient parameter.

In another embodiment, a method for determining at least one patient parameter using electrophysiological signals from the patient is provided. The method includes controlling, by a signal processor, a reference transmitter array to transmit at least one reference signal and emitting the at least one reference signal having predetermined frequency content by the reference transmitter array, the reference transmitter being retained in a predetermined position by the housing on a first side of the patient's body. At least one sensor positioned on a second side of the patient's body senses a composite signal including at least one signal generated by the patient's body and a modified reference signal, the modified reference signal being the reference signal received on the second side of the patient's body and including noise, the at least one sensor being retained in a predetermined position by said housing on a second side of the patient's body opposite the first side. The composite signal is received from the at least one sensor and filtered to remove the reference signal and noise therefrom to produce a first signal of interest for use in determining a first patient parameter.

Brief Description of the Drawings

Figure 1A depicts an exemplary block diagram of the dry electrode measurement system according to invention principles;

Figure 1B depicts exemplary waveforms representing the signals sensed by the dry electrode measurement system according to invention principles;

Figure 1C depicts an exemplary waveform representing the frequency spectrum of the system according to invention principles;

Figure 2 depicts a cross-sectional block diagram of the positioning of the dry electrode measurement system on the body of a patient according to invention principles;

Figure 3 depicts an exemplary block diagram of the dry electrode measurement system for use in measuring ECG data from a patient according to invention principles;

Figure 4 depicts a diagram of an exemplary sensor for use with the dry electrode measurement system according to invention principles;

Figure 5 depicts an exemplary block diagram of signals being measured by the dry electrode measurement system according to invention principles;

Figure 6 depicts a block diagram of the dry electrode measurement system including a plurality of waveforms representing signals generated and measured by the system;

Figure 7 depicts a plurality of waveforms representing signals generated and measured by the dry electrode measurement system according to invention principles;

Figure 8 depicts a block diagram of the dry electrode measurement system including a plurality of waveforms representing signals generated and measured by the system;

Figure 8B depicts an exemplary block diagram of the signal processor of the dry electrode measurement system according to invention principles;

Figure 9 depicts a plurality of waveforms representing signals generated and measured by the dry electrode measurement system according to invention principles;

Figures 10A depicts a front view of an exemplary housing for use with the dry electrode measurement system according to invention principles;

Figure 10B depicts a rear view of an exemplary housing for use with the dry electrode measurement system according to invention principles;

Figures 11A depicts a front view of an exemplary housing for use with the dry electrode measurement system according to invention principles;

Figure 11B depicts a rear view of an exemplary housing for use with the dry electrode measurement system according to invention principles;

Figure 12 depicts a side view of an exemplary housing for use with the dry electrode measurement system according to invention principles; and

Figure 13 is a flow diagram detailing operation of the dry electrode measurement system according to invention principles.

Detailed Description

An apparatus and system for measuring electrophysiological signals using at least one sensor that does not require direct contact with the skin of a patient is provided. The at least one sensor senses an electrical field potential generated by the patient and uses the data representing the sensed electrical field potential to determine at least one type of patient parameter. The electrical field potential of the patient is the signal of interest being sensed by the at least one sensor. One

skilled in the art of electrical field transmission will understand that the electrical field emitted by the source within the patient is emitted in all directions (360 degrees in all planes) from the source and any discussion that follows referencing a particular electrical field in a particular direction does so for purpose of clarity and ease of understanding with respect to the sensors charged with sensing the electrical field from the source but does not mean that other electrical fields in other directions cease to be emitted. Thus, the at least one sensor may be a dry electrode that advantageously senses the electrical field potential of the patient by being placed on or near the patient without needing conducting gel positioned between the sensor and the patient. The apparatus also includes a reference transmitter array positioned on a side of the body opposite the at least one sensor. The reference transmitter array advantageously generates and transmits at least one reference signal having a predetermined frequency content through the body of the patient. The predetermined frequency content may include one of (a) a signal having a single frequency associated therewith and (b) a signal having a plurality of different frequencies associated therewith. As used herein, the term reference transmitter array and reference transmitter may be used interchangeably depending on the particular embodiment being discussed. In one embodiment, the reference transmitter array may include a single reference transmitter. In another embodiment, the reference transmitter array may include at least two reference transmitters. The at least one sensor senses a composite signal including the reference signal and the signal of interest. The composite signal may also include any noise within the system. The noise may be an artifact generated by at least one of patient motion or sensor motion as well as any external environmental electrical fields. The composite signal sensed by the at least one sensor is provided to a patient monitoring device (or a front end for a patient monitoring device) which filters the reference signal and any noise therefrom to extract only the signal of interest. The reference transmitter advantageously characterizes the common mode noise (e.g. external electrical fields) as well as the motion of the patient. By characterizing noise, the patient monitoring device to effectively compensate for any of (a) the natural motion of the human body during breathing; (b) undesired motion of the at least one sensor; and (c) any external electrical fields in order to extract a high quality signal of interest. In one embodiment, the signal of interest may be an ECG signal for the patient and the at least one sensor may be dry ECG

electrodes positioned in a conventional ECG electrode arrangement on the body of the patient.

In another embodiment, the at least one sensor may also be used to selectively sense a second signal of interest representing a second different patient parameter. In this embodiment, upon receipt of the composite signal comprising the reference signal and a first signal of interest, the patient monitoring device may automatically determine data representing patient motion. In this manner, the patient monitoring device may advantageously extract the second signal of interest by removing both the reference signal and the first signal of interest. Thus, the second signal of interest may represent the change in motion of the patient. Data representing the change in motion of the patient may be used to determine a second different patient parameter. For example, in this embodiment, the second signal of interest may represent the respiration of the patient. Thus, the composite signal sensed by the at least one sensor advantageously includes the reference signal at the predetermined frequency content; the change in electrical field potential representing the ECG for the patient as well as motion data representing the inhalation and exhalation of the patient (e.g. the change in size of the thoracic cavity). Data representing patient respiration may be derived by filtering the composite signal and by demodulating the reference signal to extract respiration data from the composite signal.

In a further embodiment, the reference transmitter array may include a plurality of reference transmitters that selectively and directionally transmit respective reference signals having the same signal characteristics (e.g. frequency, time and phase). A first reference transmitter of the array is positioned at a predetermined distance from the second reference transmitter of the array thereby allowing the respective directionally transmitted reference signals to travel through the body of the patient and minimizing cross-transmission through the patient. This embodiment may include a first set of sensors positioned at a first position on the body and a second set of sensors positioned at a predetermined distance from the first set of sensors. In this embodiment, a first reference transmitter of the array is positioned in substantial alignment with the source of the first signal of interest and the at least one sensor. The first set of sensors is positioned on the patient in substantial alignment with both the first transmitter of the array and the source of the signal of interest to sense a first composite signal

including the signal of interest generated by the patient, a noise component (e.g. patient motion, sensor motion and any external environmental electrical fields). A second set of sensors may be positioned at a distance from the first set of sensors to sense a second composite signal including the second reference signal and the noise component. By positioning the second set of sensors at a predetermined distance from the first set of sensors, the amount of the signal of interest sensed thereby is reduced thereby allowing the patient monitoring device to adaptively filter the first composite signal to derive the first signal of interest. In this embodiment, the first set of sensors is positioned on a side of the body opposite the first reference transmitter and substantially aligned with the first reference transmitter. The second set of sensors may be positioned on a side of the body opposite the first and second reference and substantially aligned with the second reference transmitter. The first composite signal and second composite signal are provided to the signal processor. The signal processor advantageously uses the second composite signal to adaptively filter the first composite signal to remove the reference signal and any noise therefrom to extract the signal of interest representing the patient parameter. The signal processor may also advantageously filter the second composite signal to remove the reference signal therefrom to generate a second signal of interest associated with a second different patient parameter. A respective example of this embodiment may include the first set of sensors positioned in a conventional ECG electrode configuration. The first set of ECG electrodes may advantageously sense the first composite signal including an ECG signal, the reference signal and noise. The second set of sensors, which may include only a single sensor, may be positioned at the lower abdomen of the patient (e.g. between the diaphragm and the navel of the patient) to avoid sensing any ECG signal from the patient while being able to sense the reference signal and noise. The placement of the noise sensor to reduce the levels of the signal of interest is a function of distance. Because electric field strength decreases at a rate equal to $1/r^2$, the second set of sensors should be positioned at a distance of at least 3 times the distance from the first set of sensors to ensure that the level of the signal of interest sensed by the second set of sensors is sufficiently reduced. For example, if the first set of sensors sensing the first composite signal that includes the signal of interest (ECG data), noise and the reference signal is one inch away from the body, the signal of interest sensed by the second set of sensors will be

sufficiently reduced to enable the adaptive filtering if the second set of sensors is at a distance of substantially three inches from the body resulting in a reduction of 90% of the signal strength of the signal of interest as compared to signal of interest in the first composite signal. Thus, if the first set of sensors is positioned on the chest, the second set of sensors is advantageously positioned proximate to the naval to reduce the amount of the signal of interest sensed by the second set of sensors. The signal processor advantageously adaptively filters the second composite signal to characterize the noise contained within the system and subtracts the characterized noise and reference signal from the first composite signal to generate ECG data. The signal processor may also advantageously filter the second composite signal to extract the noise component which maybe a second signal of interest representing patient respiration. The ECG data and respiration data may be provided to a patient monitoring device conditioned to monitor ECG data and respiration for the patient.

In another embodiment, the apparatus includes a wearable housing that is selectively positioned over a portion of a patient's body. For example, the housing may be a garment. The housing includes a plurality of positioning mechanisms that selectively receives the at least one sensor and/or a reference transmitter and maintains the at least one sensor and/or the reference transmitter at predetermined position on the body of the patient. The positioning mechanism advantageously reduces extraneous and undesired movement of both the at least one sensor and the reference transmitter in order to maintain these elements at constant positions. This is particularly advantageous because the at least one sensor is a dry electrode and any slight movement or change in position will be sensed thereby resulting in additional noise on the composite signal that would need to be compensated for in order to derive the signal of interest. This is in contrast with wet electrodes which sense the electrical signals from the patient through a direct connection with the skin. By advantageously minimizing the noise associated with movement of the electrodes, the patient monitoring device will require less computational power to extract the signal of interest from the sensed composite signal resulting in a higher quality signal of interest that may be used to determine at least one patient parameter. The housing may be formed from a conductive material that further advantageously functions as a shield for shielding the at least one sensor from external noise and interference. In this manner, the housing operates as a Faraday

cage that enables the at least one sensor to sense only the reference signal emitted by the reference transmitter and any electrophysiological signals emanating from the patient.

The system is dynamically updated each time the at least one sensor senses data representing an electrical field from the patient. This advantageously enables the patient monitoring device to automatically and mathematically characterize any distortion related to motion representing the medium through which the reference signal is travelling using the reference signal. Upon determining this function representing the medium (e.g. the patient), the patient monitoring device may use this function to remove the reference signal and any noise from the composite signal sensed by the at least one sensor to extract the signal of interest. The extracted signal of interest may be used by the patient monitoring device to determine the at least one patient parameter. Further, once the function representing the motion of the patient is determined, the patient monitoring device may advantageously calculate data representing the motion of the patient. The motion data may then be used to advantageously calculate the second signal of interest representing a second different patient parameter.

Figure 1A represents an exemplary block diagram of the system 100 according to invention principles. The system 100 includes a housing 102 that is selectively positionable on a patient 105. The housing 102 as shown herein includes a first side 104 positioned adjacent a first side 103 of the patient 105 and a second side 106 positioned on a second side 107 of the patient opposite the first side 103. The representation of two sides as shown herein and discussed hereinafter should be understood as a single housing formed from contiguous material that is positioned over and around the patient. However, the first side 104 and the second side 106 may alternatively be separate pieces that are connected together via a connection mechanism. The depiction of the first side 104 and second side 106 is shown for purposes of example only and done so to facilitate an ease of understanding of the functional operation of the system 100. In one embodiment, the first side 103 of the patient 105 may be the patient's back and the second side 107 may be the patient's chest. The housing 102 may be formed from a conductive material thereby functioning as a shield to shield the patient and any elements of the system positioned on a patient and within the housing from any

external electrical noise and interference (e.g. power line noise and electrical fields generated by any proximate electronic devices).

The first side of the housing 104 includes a reference transmitter array 108 that selectively transmits at least one reference signal 112 having a predetermined frequency content. The reference signal 112 is transmitted by the reference transmitter 108 in a direction through the body of the patient 105 beginning at the first side 103 of the patient and in a direction towards the second side 107 of the patient 105. As shown herein, the reference transmitter array 108 may be a directional transmitting reference array that is able to selectively transmit a first reference signal 112a along a first transmission path represented by the band labeled with reference numeral 111a and a second reference signal 112b along a second transmission path represented by the band labeled 111b. As used herein, unless specifically discussed as such, any discussion of the reference transmitter array 108 transmitting a reference signal 112 means a single reference signal being transmitted along a single transmission path.

The reference transmitter 108 may be positioned between the first side 104 of the housing and the first side 103 of the patient 105. The reference transmitter 108 is selectively controlled by a processing device 116 as will be discussed hereinafter. The processing device 116 may be a set of front end circuitry that is selectively connectable to a patient monitoring device that monitors at least one patient parameter. Alternatively, the processing device 116 may be included within a patient monitoring device. The reference signal 112 represents a baseline against which a transfer function representing motion may be calculated. The reference signal 112 may be transmitted at predetermined intervals that range substantially between 100 milliseconds and 1 second. The reference signal 112 may be at least one of an impulse or a periodic signal (e.g. square wave) that is transmitted at predetermined intervals and has a transmission path though the body 105 of the patient.

The second side 106 of the housing includes at least one sensor 110a – 110n, hereinafter referred to collectively with reference numeral 110. While the at least one sensors 110a – 110n are shown vertically positioned, this should not be construed literally. Rather, the at least one sensors 110a – 110n may be selectively positioned in any arrangement within the first side 106 of the housing 102. For example, the at least one sensors 110a – 110n may include a plurality of sensors

positioned substantially horizontally across the chest of the patient 105. The at least one sensor 110 may be a dry contact sensor that has ultra high input resistance (e.g. $5x10^{10}$ Ohms). The at least one sensor 110 may actively lower the input capacitance of a sensing element contained therein while simultaneously boosting the input resistance. The at least one sensor 110 may use a differential mode to recover data representing the surface potential of an electrical field representing a first signal of interest 114 from a patient. The signal of interest 114 is emitted from a source 101 within the patient 105 (e.g. patient's heart or patient's brain) and, while the signal of interest 114 is represented by a single arrow 114, this representation should not be taken to mean that this is the only directional path of the emitted signal of interest. Because the signal of interest 114 is an electrical field, the source 101 emits the electrical field in all directions. However, because the signal strength thereof drops off as the distance and angle from the source 101 increases, the other signal vectors have a significantly reduced amplitude at the at least one sensors 110a – 110n.

The at least one sensor 110 may be positioned between the second side 106 of the housing 102 and the second side 107 of the patient 105. The at least one sensor 110 senses the first signal of interest 114 emitted from the source 101. In addition to the at least one sensor 110 sensing the first signal of interest 114, the at least one sensor 110 also senses the reference signal 112. The at least one sensor 110 also senses any noise present within the system. The noise may include distortion associated with patient breathing, displacement or movement of the at least one sensor and any external environment electrical fields. The first signal of interest 114, the reference signal 112 and noise are combined and are transmitted as a first composite signal 117 to an input of a processing device 116.

The processing device 116 includes at least one amplifier 118a – 118n (collectively referred to using reference numeral 118) and an analog-to-digital converter 120. A signal processor 122 is electrically coupled to the converter 120. The composite signal 117 is automatically amplified and converted in a known manner for processing by the signal processor 122 to derive the first signal of interest 114 therefrom as will be discussed below. A digital to analog converter (DAC) 124 is coupled between the signal processor 122 and the reference transmitter 108. The signal processor 122 automatically controls the DAC 124 to

generate the reference signal 112 and cause the reference transmitter 108 to transmit the reference signal 112 at the predetermined intervals.

The signal processor 122 automatically controls the reference signal 112 to be generated and transmitted by the reference transmitter 108. The reference signal 112 passes through the patient's body and is used to characterize the noise within the system 100. The noise within the system may result from motion which generates artifacts that are sensed by the at least one sensor 110. Noise may also be derived from any external environmental electrical fields sensed by the at least one sensor 110. Noise associated with motion may be caused by motion associated with patient breathing that changes a distance of the at least one sensor 110 from the source 101 in the patient105. Motion within the system may also include undesired or inadvertent movement of the housing 102 or the at least one sensor 110 on the second side 107 of the patient 105 that also changes the distance of the sensor 110 from the source 101 in the patient 105. Motion in the system 100 may also refer to the undesired or inadvertent movement of the reference transmitter 108 on the first side 103 of the patient 105. Thus, the first signal of interest 114 is modulated by the reference signal 112 and any noise within the system. As used herein, the term modulation means any attenuation of any signal that is associated with a change in the medium through which the signal is passing.

In order to determine the signal of interest 114 from the composite signal 117, the signal processor 122 automatically uses the frequency of the reference signal 112 to characterize the motion within the system 100 by calculating a function representing the medium (e.g. patient 105) through which the reference signal 112 and signal of interest 114 is traveling. In one embodiment, the function representing the medium may be calculated by demodulating the composite signal to identify the envelope thereof such as will be described below in Fig. 1B and Fig 7. Alternatively, the function representing the medium may be calculated using adaptive filtering techniques that allow the function to be calculated dynamically to automatically update and feed back into the signal processor 122 to compensate for any changes created by motion on subsequent composite signals 117 sensed by the at least one sensor 110 as described below with respect to Figures 8B and 9. Upon characterizing the motion by creating the function representing the medium 105, the signal processor 122 may automatically filter the composite signal 117 by

subtracting both the reference signal 112 and any characterized motion from the composite signal 117 in order to derive the first signal of interest 114 therefrom. The derived first signal of interest 114 may be further processed by the signal processor 122 for output by thereby for use in determining at least one patient parameter associated with the first signal of interest 114. In one embodiment, the processing device 116 is a patient monitoring device and the determination of at least one patient parameter 114 may be automatically performed in the processing device 116. In another embodiment, the processing device 116 may include front end circuitry and the processing device 116 may derive the first signal of interest 114 and communicate the first signal of interest to a patient monitoring device (not shown).

The signal processor 122 may also derive a second signal of interest from the composite signal 117. The second signal of interest may be associated with the motion of the system characterized by the signal processor 122 using the reference signal 112. The signal processor 122 may demodulate the composite signal 117 in order to identify the envelope associated with the motion of the system caused by the change in medium and subtract the identified envelope from the composite signal 117 to determine the second signal of interest. The second signal of interest may then be used to calculate a second different patient parameter associated with the motion in the system. Thus, the system 100 shown in Figure 1A advantageously enables sensing and determination of two different signals of interest that may be used to calculate and otherwise determine two different patient parameters.

In another embodiment, an alternate mechanism for determining the first and second signals of interest may be employed. In this embodiment, the reference transmitter array 108 may selectively transmit the first reference signal 112a via transmission path 111a that substantially traverses the source 101. In this embodiment, sensor 110a selectively senses the first signal of interest 114, the reference signal 112 and any noise and combines these signals into the first composite signal which is provided to a first input of the processing device 116. While Figure 1A shows a single sensor 110a sensing the first composite signal 117, one skilled in the art should understand this to represent a first group of sensors that may include more than one sensor positioned within transmission path 111a. In this embodiment, the reference transmitter array 108 also transmits

the second reference signal 112b along the second transmission path 111b for receipt by a second sensor 110n. The second sensor 110n as shown here represents a second group of sensors able to sense any signals transmitted along transmission path 111b. As shown herein, the second sensor 110n senses the second reference signal 112b and any noise present within the system to produce a second composite signal 117b that is provided to the processing device 116. In this embodiment, the first composite signal 117a is amplified by amplifier 118a, converted by the A/D converter 120 and provided to the signal processor 122. The second composite signal 117b is amplified by amplifier 118n, converted by A/D converter 120 and provided to the signal processor 122. The signal processor 122 uses the second composite signal 117b to adaptively filter the first composite signal 117a in order to compensate for the noise present thereon to derive the first signal of interest 114. Additionally, in this embodiment, the signal processor 122 may also derive the second signal of interest in a manner similar as described above. However, the demodulation may be performed on either or both the first composite signal 117a and the second composite signal 117b in order to detect the envelope of the signal that represents the motion of the patient.

In this alternate embodiment, the signal processor 122 may also simultaneously derive the signal of interest 114 using both the adaptive filtering method that uses two composite signals (117a and 117b) as well as the filtering method that uses only the first composite signal 117a. This would result in two signal of interest values which may be further processed (e.g. by averaging) to generate a composite signal of interest that would be used to determine the first patient parameter (e.g. ECG data). The derivation of two different second signals of interest may also occur to derive a composite second signal of interest for use in determining the second patient parameter (e.g. respiration data).

Figure 1B represents exemplary waveforms of the various components of the signals sensed by the at least one sensor 110 or derived from the signal sensed by the at least one sensor. As shown herein, the reference signal 112 transmitted by the reference transmitter array (108 in Fig. 1A) is a high frequency carrier signal. The frequency of the reference signal is at least 10 kilohertz but may have a frequency up to a maximum frequency able to be sensed by the at least one sensor 110 (e.g. up to 300 kHz). Data representing patient motion due to inhalation and exhalation is shown in the waveform labeled 113. This may also be

referenced as the noise component. As shown herein, the noise component in waveform 113 is shown as a sine wave for purpose of simplicity to illustrate the concept that the noise component is periodic in nature and for ease in understanding how the system of Fig. 1A may identify the envelope thereof to enable removal of the noise component from the composite signal sensed by the sensors as discussed below. However, for purpose of example only and for ease of understanding, the noise signal 113 shown herein does not include any external environmental electrical field noise or noise associated with displacement of the at least one sensor 110 on the patient. Thus, noise signal 113 represents noise associated with patient respiration. The first signal of interest 114 is shown representing ECG data emitted from the source 101 in Fig. 1A.

The reference signal 112 and noise 113 modulates the first signal of interest 114 to produce the composite signal 117 that is sensed by the at least one sensor 110. The signal processor 122 filters the composite signal using amplitude demodulation to identify the envelope of the composite signal and derive noise data 115 therefrom. Upon detecting the noise data 115 present in composite signal 117, the signal processor 122 mathematically subtracts the noise data 115 and the reference signal 112 from the composite to signal to yield the first signal of interest 114 that is used in determining the first patient parameter.

Additionally, as shown herein and for purposes of comparison, the recovered noise data 115 is plotted against the patient motion data 113 to illustrate that the recovery on noise data corresponds to the patient motion data. Thus, the signal processor 122 may use the recovered noise data 115 to determine a second patient parameter such as respiration. The corresponding peaks and valleys of the recovered noise data 115 correlate with the exhalation and inhalation of the patient and may be used to determine the rate of respiration for the patient.

Figure 1C is a spectrum chart of the system showing the amplitude and frequencies of the various signals sensed by the at least one sensor 110 in Fig. 1 . Band 150 depicts the low frequency noise associated with motion of at least one of the patient and sensors 110 as well as motion associated with respiration of the patient. Band 151 is the signal of interest (114 in Figs. 1A and 1B) representing the electrophysiological signal of the patient (e.g. ECG signal). Additionally, within band 151, there may also be periodic noise 153 such as 50Hz or 60 Hz externally generated electrical noise (e.g. power line noise). The periodic noise

153 may be filtered by signal processor 122 in Fig. 1A using standard notch filters, for example. The system further includes signals within band 152. The signals in Band 152 represent the various frequencies that may form the reference signal (112 in Fig. 1A and 1B) as well as high frequency noise present in the environment and sensed by the at least one sensor 110. As shown herein, the signals labeled 154 are a general representation of the periodic reference signal with predetermined frequency content.

Figure 2 is a cross sectional block diagram of an exemplary housing 102 positioned on the patient 105. Depiction of these elements of the system 100 is important because the transmission path of both the reference signal 112 from the reference transmitter 108 and the portion of the electrical field that represents the first signal of interest 114 is in substantially the same direction. While the fact that the electrical field generated by the source is also transmitted in all directions, including back towards the reference transmitter, those portions of the electrical field transmitted in a direction other than towards the at least one sensors 110a – 110n are not able to be used due to diminished signal strength. Moreover, the diminished signal strength does not serve to interfere with any other signals because of this diminished signal strength. As the housing 102 acts as a Faraday cage providing a shield that shields the reference transmitter 108 and the at least one electrode 110, the system is advantageously able to identify and use the transmission path of the respective signals 112 and 114 to determine the signal of interest for use in calculating at least one patient parameter therefrom. Thus, the reference transmitter 108 should remain on a side of the patient opposite the position of the at least one electrode 110 in order to allow the signal processor 122 (in Fig. 1) to properly characterize the motion of the system. As shown herein, the reference transmitter 108 is positioned between the first side 104 of the housing 102 and the first side 103 of the patient 105. In this manner the first side of the housing 102 shields the reference transmitter 108 therein and ensures that the transmission path of the reference signal (112 in Fig. 1) generated thereby flows through the patient 105 in a direction from the first side 103 to the second side 107 of the patient. In one embodiment, a first positioning mechanism 200 retains the reference transmitter 108 therein. The first positioning mechanism 200 may be a pocket or any other structure that is able to maintain the reference transmitter 108 in a constant position against the first side 103 of the patient 105. In another

embodiment, the reference transmitter 108 may be formed integrally with the first side 104 of the housing so long as the housing 102 can effectively shield the reference transmitter therein.

Furthermore, as the at least one sensor 110 is very sensitive to motion and changes in motion, the second side 106 of the housing 102 includes a plurality of sensor positioning mechanisms 204a – 204n able to retain the at least one sensor 110a – 110n therein. The sensor positioning mechanism may also include pockets that are able to maintain the sensors 110a – 110n in a substantially constant position on the second side 107 of the patient. This advantageously reduces undesired artifacts sensed by the at least one sensor 110a – 110n thereby reducing noise on the composite signal (117 in Fig. 1) and reducing an amount of processing power required by the signal processor (120 in Fig. 1) to remove the noise therefrom.

The second side 106 of the housing 102 may also include at least one channel 202a – 202n extending therethrough. The at least one channel 202a – 202n are aligned with respective sensor positioning mechanisms 204 and provide access thereto. The at least one channel 202a – 202n enables the at least one sensor to be selectively added and removed from the housing 102 as necessary.

Figure 3 is an exemplary block diagram of the dry electrode measurement system according to invention principles for use in sensing ECG signals from a patient. The system shown herein includes elements similar to those described in Figures 1 and 2, the description of which will not be repeated except to show how the individual elements are adapted to operate within an apparatus and system for sensing ECG data from a patient.

A patient 305 is represented as having the housing 302 positioned thereon. The reference transmitter 308 is positioned between a first back side 304 of the housing 302 and a back 303 of the patient 305. A plurality of sensors 310a – 310e are positioned between a second chest side 306 of the housing 302 and the chest 307 of the patient 305. In this embodiment, the sensors 310a – 310e are electrical field sensors and are used in the same manner as conventional wet electrodes used with an ECG monitoring system. For example, the first sensor 310a may be the right arm (RA) electrode in a conventional ECG electrode arrangement. The second sensor 310b may be the left arm (LA) electrode in a conventional ECG electrode arrangement. The third sensor 310c may be the left leg (LL) electrode in

a conventional ECG electrode arrangement. Thus, the first through third sensors 310a – 310c may form the primary leads from which an ECG signal may be derived. The leads are derived by taking the difference between the electric fields picked up from the sensors. Additionally, as is known in the art, ECG electrode arrangements may includes secondary (or non-primary) electrodes for deriving additional data used in determining ECG data for a patient. As shown herein, the fourth sensor 310d may be a first respective chest sensor (V1) and the fifth sensor 310e may be a second respective chest sensor (V2). The electric fields picked up from the V sensors may be used to calculate chest leads by subtracting the electric fields from the average of the three primary electric fields in the same manner that would be used using conventional electrodes. This number, configuration and positioning of electrodes is described for purposes of examples only and persons skilled in the art would understand that any of the known electrode configuration may be implemented using the present system by substituting or otherwise changing the number of electrodes and position of electrodes on the patient. Furthermore, despite the sensors 310a – 310e being appearing vertically aligned, Figure 3 is not representative of the actual placements on the human body and are simply shown to illustrate the purposes of the electrodes within the system described herein. Rather, the anatomical placement of these sensors is more accurately described as being horizontal across the chest of the patient in the known configuration.

It is important to note, that while the primary leads used in an ECG configuration typically include four leads, one of the respective primary leads functions as a neutral driver of the system in order to reduce the noise coupling to the body. However, the system according to invention principles does not require such a neutral driver because the coupled noise is subtracted by processing the reference signal from the transmitter.

The signal processor 322 in the processing device 316 causes a reference signal of a predetermined type having a predetermined frequency content (e.g. impulse, square wave, etc.) to be generated. A digital to analog converter 324 converts the generated reference signal and provides the reference signal to the reference transmitter 308 for transmitting at predetermined intervals. The reference transmitter 308 advantageously transmits the reference signal through the patient where it is sensed by the sensors 310a – 310e along with the electrical

field of the heart and noise associated with patient motion, sensor motion and/or external electrical fields. Thus, the sensors 310a – 310e sense a composite signal including the electrical field generated by the heart, the reference signal and any noise present thereon. This composite signal may be used to characterize the motion and noise within the system and allow those components to be selectively filtered to yield the signal of interest.

Each of the electrodes 310a – 310e is coupled to the processing device 316. In this embodiment, the processing device 316 is an ECG front end. The composite signal sensed by the sensors 310a – 310e are provided to the ECG front end 316 where the signals are amplified and converted from analog to digital in a known manner by respective amplifiers 318a – 318e and analog to digital converter 320. The signal processor 322 analyzes and characterizes the motion within the system using the composite signal and the reference signal. In this manner, the signal processor 322 calculates a function representative of the motion of the patient 305. Upon calculation of the function representative of the motion of the patient 305, the signal processor 322 may subtract the reference signal and data representing motion from the composite signal to yield a signal of interest representing the signal of the heart of the patient which may be used to determine ECG data for the patient. Data representing the heart signal of the patient represents the first signal of interest which may be communicated to the patient monitoring device 326 for processing in any known manner to derive an ECG waveform representative of the particular patient.

In the embodiment shown in Figure 3, the housing 302 may be coupled to a ground 325 contained in the processing device 316 to aid in eliminating patient coupled noise from the environment including line frequency. Since the front end circuit is floating, the connection to ground will cause the front end to follow the coupled potential to the shirt and therefore subtract this noise from the signal. This is shown for purposes of example only and the housing 302 does not need to be grounded in order to operate. Additionally, the housing 302 may at least one of a garment or other shirt wherein the electrodes 310a- 310e are substantially fixed to respective positions on the patient 305 by the shirt to advantageously minimize movement of the electrodes 310a – 310e with respect to the chest and heart of the patient. The housing 302 also shields the electrodes 310a – 310e from any external

electrical fields such that the electrodes 310a – 310e only sense the electrical field of the heart and reference signal.

Figure 4 is a circuit diagram representing an exemplary sensor contained within the circle labeled with reference numeral 4 in Figure 3. The exemplary sensor shown herein is the fifth sensor 310e which, in the embodiment described in Figure 3, represents a second chest electrode V2. However, the sensor being the V2 electrode is described for purposes of example only and the configuration and description of the components that form the sensor shown in Figure 4 may represent any of sensors 310a – 310e.

The sensor 310e includes an amplifier 402 coupled to a four pin connector 412 by four channels. The amplifier 402 is powered by the positive voltage supply VCC and negative voltage supply VDD channels 404 and 408, respectively. The amplifier 402 is connected to ground via channel 410. Power is provided from the processing device (316 in Fig. 3) through the connector 412 and via one of the VCC channel 404 and the VDD channel 408. The sensor 310e operates as a powered radio receiver able to sense electrical fields 410 and the power provided using channels VCC and VDD increases the sensitivity of the amplifier 402 and modifies the ability to sense available electrical fields 410. As discussed above, the electrical fields 410 may include any or both of the electrical field of the reference signal and the electrical field of the heart. The data representing the sensed electrical field communicated on signal channel 406 is received through the respective pin of the connector 412 and provided to an input amplifier 414 of the processing device (316 in Figure 3) for further processing to determine the signal of interest for use in calculating at least one patient parameter.

Figure 5 is an exemplary block diagram of the system described above in Figures 3 and 4 that shows the transmission path of the electrical fields sensed by respective sensors 310a – 310e. The signal processor 322 (see Fig. 3) automatically generates a reference signal having a predetermined frequency content and causes the reference transmitter 308 to transmit the generated reference signal at predetermined intervals. The reference signal is shown herein as dashed lines and labeled with reference numeral 502. The reference transmitter 308 is positioned between the first side 304 of the housing 302 and the back 303 of the patient. In this orientation, the first side 304 of the housing 302 shields the reference transmitter causing the transmission path of the reference signal 502 to

be in a direction through the body originating at the back 303, through the body 305 towards the chest 307 and the plurality of sensors 310a – 310e positioned thereon. While the sensors are described as being positioned on the chest of the user, one skilled in the art understands that, as these are electrical field sensors, a direct connection on or with the skin of the patient 305 using a conductive gel is not necessary.

At the same time, the patient's heart is generating an electrical field represented by the solid lines labeled with reference numeral 504. The electrical field of the heart is also being transmitted in a direction towards the chest 307 of the patient 305 for receipt by at least one of the plurality of sensors 310a – 310e. Each respective sensor 310a – 310e senses both the electrical field of the reference signal 502 and the electrical field of the heart 504 and provides these signals as a composite signal to the processing device 316 in Figure 3 for further processing in the manner discussed below.

Figure 6 is a detailed block diagram of the embodiment of the system described hereinabove with respect to Figures 3 – 5. In operation, the signal processor 322 automatically causes a reference signal of a known frequency to be generated. The reference signal is converted by the DAC 324 into an analog signal and provided to the reference transmitter 308 for transmission at predetermined intervals controlled by the signal processor 322. The reference transmitter 308 transmits the reference signal 502 in accordance with instructions from the signal processor 322. An exemplary reference signal 502 transmitted by reference transmitter 308 is represented by the waveform labeled 602. The reference signal may be a carrier signal that can be modulated by the respiratory motion of the patient. Simultaneously, the heart of the patient 305 generates an electrical field 504 that is shown in waveform 604. As both the modulated reference signal 502 and the measurable portions of the heart signal 504 are transmitted in a direction from the back (or in the case of the heart signal from the source) of the patient towards the chest of the patient, sensors 310a – 310e positioned adjacent the patient's chest are able to receive both the modulated reference signal 502 and the heart signal 504. The sensors 310a – 310e receive these signals 502, 504 as a composite signal 506. The composite signal 506 represents all signals transmitted through the body including any artifacts caused by motion (e.g. breathing or movement of the sensors) and is shown in waveform 606. Furthermore, the

sensors 310a – 310e are shielded by the conductive material (e.g. fabric) of the housing 302 thereby minimizing external noise from being sensed by the sensors 310a – 310e and being included in the composite signal 506.

The following description of signal processing will be described with reference to a composite signal 506 received on a respective one of the plurality of sensors 310a – 310e. However, one skilled in the art would understand that the following signal processing techniques may be applied to the composite signals sensed by each respective one of the plurality of sensors 310a – 310e to derive a plurality of individual signals of interest that may be used by an ECG processing algorithm in a known manner.

The composite signal 506 is received at the V2 electrode 310e. The composite signal is amplified by the electrode 310e and transmitted on the signal channel (406 in Fig. 4) to the processing device via the connector (412 in Fig. 4). The composite signal 506 as waveform 606 is amplified and converted prior to processing by the signal processor 322. In order to derive the signal of interest (e.g. the heart signal 504), the signal processor 322 automatically analyzes the composite signal to characterize any motion present within the composite signal 506 that would have resulted from a change in distance between the respective electrode 310e and the heart either as a result of respiration or dislodging of the electrode from its initial position adjacent the chest 307 of the patient 305. The reference signal 502 is modulated by noise distortion due to motion and the signal processor 322 is able to mathematically characterize the motion in the system by comparing the modulated reference signal with the original reference signal thereby enabling removal of the modulated reference signal including any artifacts caused by motion from the composite signal 506. Removal of the modulated reference signal including any motion artifacts results in a first signal of interest representing the electrical field of the heart at a respective lead in an ECG lead configuration that may then be used in conjunction with data derived from other sensors 310a – 310d to determine ECG data for the patient 305.

In another embodiment, the signal processor 322 may further advantageously determine a second patient parameter representing respiration of the patient 305. Because the reference signal is modulated by motion caused by patient respiration, the signal processor 322 may automatically demodulate the composite signal 506 using amplitude demodulation to identify the envelope of

the composite signal 506 that corresponds to the respiration of the patient. Thus, the composite signal 506 is advantageously processed a second time to extract data representing patient respiration 508 which is shown in Figure 6 as waveform 608.

Data derived from each sensor 310a – 310e and representing the heart signal for use in determining ECG data for a patient is provided as an output of the signal processor 322 to a patient monitoring device 326 that selectively uses data derived from the plurality of ECG sensors to calculate and determine ECG waveform data for the particular patient in a known manner. Additionally, data representing patient respiration 508 may also be provided as an output of the signal processor 322 for use in simultaneously monitoring ECG data and patient respiration data for the particular patient.

Figure 7 provides graphical depictions of various waveforms representing signals sensed by the sensor and which are used by the signal processor 322 when deriving heart signal data and respiration data for a particular patient. Waveform 602 represents the carrier signal or reference signal transmitted by the reference transmitter. Waveform 602 has a known frequency and is transmitted at predetermined time intervals. The frequency of the reference transmitter is at least an order of magnitude greater than the frequency of the signal of interest. For example, the frequency of the reference signal may be at least 10kHz whereas the frequency of the signal of interest may be less than 1kHz. Waveform 700 represents the motion caused by patient respiration. The motion caused by respiration as shown in waveform 700 automatically modulates (e.g. attenuates the reference signal based on changes in the medium through which the signal is passing) the reference signal 602 thereby producing a modulated reference signal waveform 702 (602+700=702). This modulated reference signal waveform 702 is received by the plurality of sensors. The number and positioning of the plurality of sensors may correspond to known ECG electrode lead combinations and arrangements. The heart of the patient generates an electrical field that is represented in waveform 604. The portion of the electrical field of the heart 604 used by the present system is the portion transmitted in a direction towards the plurality of sensors which sense all signals that are being transmitted through the patient. Thus, the sensors are able to sense a composite signal 506 including the

heart signal (604) and the modulated reference signal (702). The composite signal is represented by waveform 506 in Figure 7.

In order to extract data from the composite signal 606 for use in determining at least one patient parameter, a signal processor (322 in Fig. 6) demodulates the composite signal 506 to identify the envelope of the composite signal 506 and derive data representing patient respiration as shown in waveform 608. The demodulated respiration data 608 is subtracted from the composite signal waveform 506 and produces waveform 704 which comprises only the reference signal 602 and the heart signal 604. Thereafter, the signal processor 322 automatically subtracts the reference waveform 602 from waveform 704 in order to obtain waveform 604 that includes heart signal data. The heart signal data waveform 604 derived from respective sensors is selectively useable by a patient monitoring device to determine and monitor ECG data for the particular patient.

Figure 8A is another embodiment of the dry electrode measurement apparatus according to invention principles. This embodiment includes certain similar features and elements as those described above with respect to Figures 3 – 7 and common elements are labeled with common reference numerals and will not be further described in detail except to the degree necessary to understand the structure and function of the embodiment shown in Figure 8a.

In this embodiment, the reference transmitter is an array which includes a second reference transmitter 802 in addition to the first reference transmitter 308 positioned within the housing 302. Both the first and second reference transmitters 308 and 802, respectively are coupled to the signal processor 322 via the DAC 324. The signal processor 322 causes the first and second reference transmitters to emit a pulse train consisting of a periodic signal with known frequency content reference signal 312, and 812 respectively, represented as waveform 801. The first and second reference signals 312 and 812, respectively have a predetermined frequency content and are transmitted at predetermined intervals. The first reference transmitter 308 transmits the pulse train signal along a first transmission path identified by reference numeral 811 which necessarily traverses the patient's heart. The first transmission path 811 insures that the sensors 310a – 310e selectively sense the first composite signal 506 that includes data representing the first reference signal 312 (pulse train) modulated by any motion (noise) along with

the electrical field of the heart. This signal is shown as waveform 810. As shown herein, the sensors 310a – 310e represent a first group of sensors.

The system includes a noise sensor 804 which is part of a second group of sensors and is positioned on the first side of the patient 307 in substantial alignment with the second reference transmitter 802 of the reference transmitter array. The noise sensor 804 is positioned at a distance sufficient from source of the electrical field representing the signal of interest and any other sensor in the first group of sensors to reduce a level of the first signal of interest sensed by the noise sensor 804. The second reference transmitter 802 emits the pulse train signal which is modulated by motion based noise to yield a second composite signal 806 that includes the pulse train and noise caused by motion as shown in waveform 820. The noise sensor 804 should be positioned on the chest side of a patient at a sufficient distance from the other sensors 310a – 310e to reduce the level of the electrical fields associated with the heart sensed thereby. In one embodiment, the first group of sensors 310a-310e are positioned across the chest of the patient and the noise sensor 804 is positioned at a point on the patient between the diaphragm and the navel of the patient. Thus, the noise sensor 804 selectively senses a second composite signal 806. By positioning the noise sensor away from the other sensors 310a – 310e, a dedicated signal for use in characterizing the motion of the system may be provided to the signal processor 322 for use in adaptively filtering the first composite signal to derive the first signal of interest therefrom. An advantage of this configuration is the improved characterization of the noise of the system to be removed by the signal processor 322 via adaptive filtering techniques. This further advantageously simplifies the ability to determine and derive the second patient parameter data signal corresponding to patient respiration. By providing the second composite signal that includes only the pulse train reference 812 and noise associated with motion, the second composite signal may be filtered by a low pass filter in order to obtain data representing the respiration of the patient 305.

Figure 8B is an exemplary block diagram of the components of the signal processor 322 shown in Figure 8A describing how the first and second signal of interests may be derived from the composite signal 506 sensed by the at least one sensors 310a – 310e. The signal processor 322 includes an adaptive filter 330 that employs at least one type of adaptive filtering technique to filter data input thereto. Exemplary adaptive filtering techniques may be implemented by the

adaptive filter 330 by executing at least one adaptive filtering algorithm including one of (a)_a least mean squares (LMS) adaptive filtering algorithm; (b) a recursive least squares (RLS) adaptive filtering algorithm; (c) a sign-data adaptive filtering algorithm; (d) a sign-error adaptive filtering algorithm; (e) sign-sign adaptive filtering algorithm; and (f) a lattice filter adaptive filtering algorithm. These adaptive filtering algorithms are described for purposes of example only and the adaptive filter 330 may implement any adaptive filtering algorithm. The signal processor 322 also includes a summing circuit 332 coupled to the adaptive filter 330. A first analog to digital converter (ADC) 329 is coupled to an input of the adaptive filter 330 and a second analog to digital converter (ADC) 331 is coupled to an input of the summing circuit 332. The composite signal 506 sensed by the at least one sensor 310a – 310e (Fig. 8A) includes a first signal component *s(k)* comprising the signal of interest and a second signal component *n(k)* comprising the reference signal and noise. The first composite signal 506 is represented by waveform 810. The composite signal 506 is provided to the second ADC 331 for sampling thereof to output a digital composite signal *d(k)*. The digital composite signal *d(k)* is provided to the first input of the summing function 332 for removal of the second signal component *n(k)* therefrom in the manner discussed below.

A second composite signal 806 is sensed by the noise sensor (804 in Fig. 8A) that is positioned at a predetermined distance from the source of the signal of interest as provided above. The second composite signal 806 is a reference noise signal *n'(k)* and includes the reference signal and noise and is represented in Figure 8B as *n'(k)* and shown as the waveform 801. The reference noise signal *n'(k)* is correlated to the second signal component *n(k)*. The reference noise signal *n'(k)* is provided to the first ADC 329 for sampling thereof and is output as a digital reference noise signal *x(k)*. The digital reference noise signal *x(k)* is provided as an input to the adaptive filter 330 which dynamically adjusts filtering coefficients to characterize and remove noise from the digital reference noise signal *x(k)*. A filtered reference noise signal *y(k)* is output by the adaptive filter 330 and provided to a negative input of the summing circuit 332. The summing circuit 332 subtracts *y(k)* from *d(k)* to generate the signal of interest *e(k)* representing the patient parameter. To those skilled in the art of adaptive filter design *e(k)* may typically be thought of as an error or noise. However, in the

present filtering arrangement, *e(k)* actually represents the signal of interest that represents the patient parameter.

Reference noise signal *n'(k)* is similar to the second signal component *n(k)* with the exception that it is derived from sensors positioned at different locations from one another on the patient. Thus, *n'(k)* is correlated to *n(k)*. Therefore, so long as the reference noise signal input to the adaptive filter remains correlated with the second signal component of the composite signal 117, the adaptive filter is able to dynamically modify the filtering coefficients to reduce the value of the difference between the output of the adaptive filter *y(k)* and the output of the second ADC 131 *d(k)* enabling the summing circuit to remove noise on the resulting signal of interest *e(k)* which should be as close to *s(k)* as possible.

Figure 9 are graphical depictions of the various waveforms used by the signal processor 322 shown in Figure 8 when deriving heart signal data and respiration data for a particular patient. The signal processor 322 controls the first and second reference transmitters to transmit a pulse train reference signal through the body from the back of the patient towards the chest of the patient, the pulse train signal being represented by waveform 801. The patient generates noise associated with respiratory motion as shown in the waveform labeled 901. The noise sensor that is in substantial alignment with the second reference transmitter selectively senses the second composite signal shown as waveform 820. Simultaneously, the ECG sensors 310a – 310e senses the first composite signal that includes data representing the pulse train 801, motion-based noise and electrical field data from the heart of the patient. The first composite signal is represented in waveform 810.

In operation, the signal processor 322 automatically causes the second composite signal to be low pass filtered to derive motion data therefrom. The motion data may be provided to the patient monitoring device for use in determining respiration data for the patient. The motion data is also provided as input to a filtering algorithm that advantageously enables the signal processor 322 to extract from the first composite signal, data representing a signal of interest that is selectively used by a patient monitoring device as an input signal to calculate and determine ECG waveform data from the patient. By providing the motion data (e.g. noise), the signal processor 322 may automatically subtract the known pulse train reference signal and the motion signal from the first composite signal to

yield heart signal data that may be used by a patient monitoring device, alone or in combination with other derived heart signal data, to determine an ECG waveform data for the particular patient.

Figures 10A and 10B are illustrative views of an exemplary housing 302 for use with the system according to invention principles. In the embodiments shown in Figures 10A and 10B, the housing 302 is a shirt. Figure 10A depicts the first side 1002 of the shirt being the chest side. Positioned at various locations on the chest side 1002 of the shirt are a plurality of electrodes able to sense an electrical field generated by the patient, for example, the patient's heart. The position of the electrodes may be in any configuration known to determined ECG waveform data for the patient. As shown herein the sensors positioned on the shirt include the RA, LA, LL and V1 – V6 electrodes. Additionally, a noise electrode for sensing a noise signal is also shown positioned on the shirt at a predetermined distance from the RA, LA, LL and V1-V6 electrodes. The noise electrode is positioned at a distance to reduce the level of the signal of interest sensed by sensors RA, LA, LL and V1 – V6 sensed thereon to allow the system to adaptively filter the signal of interest sensed on RA, LA, LL and V1 – V6. However, the housing may be formed so as to accommodate any number of electrodes. As discussed above, and while the sensors are shown as circles on the housing 302, the sensors are actually between the housing and the skin of the patient. This advantageously enables the housing 302 which is made from a conductive material to shield the sensors from any external electrical fields. Thus, the sensors are only able to sense electrical fields within the shielded area thereby improving the likelihood that data sensed by the sensors is one of heart signal data or reference signal data. Furthermore, as discussed above with respect to Figure 2, each respective sensor is retained in a predetermined position by a positioning mechanism such as a pocket on an inner surface of the garment. The material that forms the pocket should only be conductive on a side at which the pocket contacts a surface of the shirt thereby ensuring that the sensor is not shielded from electrical fields generated by the patient. Additionally, the shirt 302 may be formed from an elastomeric material (e.g. spandex) material that is light and breathable (e.g. porous). The shirt being substantially form fitting advantageously minimizes artifacts on the sensor that would be associated with inadvertent movement of the sensor on the chest of the patient thereby changing the distance

between the sensor and the patient's heart. Furthermore, the material should be porous and breathable to allow any heat generated by the sensors to escape to maximize patient comfort.

Figure 10B is the second back side 1004 of the housing 302. The back side of the housing includes the reference transmitter array 308 that is retained between the housing and the skin of the patient thereby maintaining the reference transmitter in a substantially constant position. The reference transmitter array 308 may also include the second reference transmitter (802 in Fig. 8) in a constant position thereby enabling both the first and second reference transmitters to emit reference signals for use in characterizing noise associated with motion in the manner discussed above. In the embodiment where the reference transmitter array 308 includes the first reference transmitter and second reference transmitter, the first reference transmitter is positioned substantially aligned with the sensors RA, LA, LL and V1 – V6 shown in Fig. 10A and the second reference transmitter is substantially aligned with the noise electrode shown in Fig. 10A.

Figures 11A and 11B are illustrative views of another exemplary housing 302 for use with the system according to invention principles. In the embodiments shown in Figures 10A and 10B, the housing 302 is a strap. The properties of the housing as discussed above with respect to Figures 10A and 10B remain constant. The difference is the housing that is substantially smaller and formed from a conductive fabric that wraps around a selection portion of the chest and back of the user. As shown in Figure 11A, the chest strap 1102 includes the RA and LA sensors along with the V1 and V2 chest leads. Figure 11B shows back side view of the patient wherein the strap 1002 includes the reference transmitter 308 positioned thereon. The electrodes and the reference transmitter, although shown as if they were on the surface of the strap 1102 are positioned between the strap 1102 and the skin of the user thereby enabling the conductive fabric to shield the electrodes and reference transmitter therein to minimize external electrical interference.

Figure 12 is another exemplary embodiment of a housing for use with the system according to invention principles. In this embodiment, the system is an electroencephalograph system that determines EEG data for a patient. In this embodiment, the housing is a cap 1202 that is formed from a conductive material and which includes a plurality of electrodes positioned thereon. Similarly to the

ECG system, the cap 1202 ensures that the electrodes are maintained between the housing and the skin of the user. Thus, the cap 1202 acts as a shield for the electrodes enabling the electrodes to sense electrical field emitted by the brain. The cap 1202 may be retained in place by a strap 1204 that extends under a chin of the patient. In this embodiment, the reference transmitter 1208 may be positioned on an underside of the chin to ensure that the reference signal travels in the desired direction away from the reference transmitter 1208 and towards the electrodes 1206.

The operation of the system will be described with respect to the flow diagram of Figure 13. In step 1300, a housing is provided that retains a reference transmitter on a first side of a patient and at least one electrode able to sense an electrical field on a second side of a patient opposite the first side. The reference transmitter automatically transmits a reference signal having a predetermined frequency content at predetermined time intervals in a direction through the body of the patient and towards the at least one electrode in step 1302. The at least one electrode senses a composite signal including the reference signal, noise associated with patient motion and an electrical field generated by the patient in step 1304. In one embodiment, the electrical field generated by the patient is generated by the patient's heart. In step 1306, the composite signal is provided to a signal processor to characterize the noise on the composite signal. In step 1308, in response to characterization of noise data, the signal processor subtracts noise data and reference signal data from the composite signal and derives a signal of interest in step 1310. This signal of interest determined in step 1310 represents heart signal data that may be used for determining an ECG waveform for the patient. In step 1312, steps 1304 – 1310 are repeated for each respective electrode in order to derive a plurality of different input signals for use in determining ECG waveform data for the particular patient.

The system and apparatus describe above with respect to Figures 1 – 13 advantageously enables patient parameter data to be sensed using dry electrodes that do not require direct contact with the patient's skin. The system advantageously includes a housing that shields the sensor components from external and common mode noise and improves the ability of the sensors to sense the signal of interest which is derived from an a electrical field generated by a source from within the patient (e.g. heart and/or brain). A reference transmitter is

advantageously provided and transmits the reference signal that is also sensed by the dry electrode sensors and functions as a neutral driver. The reference signal advantageously enables the system to characterize and remove any noise present therein to produce a signal of interest representing a patient parameter (e.g. ECG data or EEG data). The system is able to dynamically filter the signals sensed by the sensors to subtract the unwanted noise component and reference signal therefrom. The system further advantageously enables a second different patient parameter data to be derived by using the noise sensed by the sensor. In this manner, the dry electrode measurement system is able to derive diagnostic quality patient parameter data using sensors that do not require a direct connection to the patient by compensating for noise associated with patient movement and extracting the noise to produce patient parameter data.

Although the invention has been described in terms of exemplary embodiments, it is not limited thereto. Rather, the appended claims should be construed broadly to include other variants and embodiments of the invention which may be made by those skilled in the art without departing from the scope and range of equivalents of the invention. This disclosure is intended to cover any adaptations or variations of the embodiments discussed herein.

CLAIMS

What is claimed is:

1. A system for determining at least one patient parameter using electrophysiological signals from the patient comprising:

a housing;

a reference transmitter array that emits at least one reference signal having predetermined frequency content, the reference transmitter array being retained in a predetermined position by said housing on a first side of the patient's body;

at least one sensor that senses a composite signal including at least one signal generated by the patient's body and a modified reference signal, the modified reference signal being the reference signal received on the second side of the patient's body and including noise, the sensor being retained in a predetermined position by said housing on a second side of the patient's body opposite the first side;

a signal processor electrically coupled to the reference transmitter array and the at least one sensor, wherein the signal processor controls the reference transmitter array to emit the at least one reference signal and receives the composite signal from the at least one sensor and filters the composite signal to remove the at least one reference signal and noise therefrom to produce a first signal of interest for use in determining a first patient parameter.

2. The system as recited in claim 1, wherein

said reference transmitter transmits said reference signal through the patient in a direction towards the at least one sensor.

3. The system as recited in claim 1, wherein

said signal processor automatically identifies the noise signal within the composite signal by comparing the modified reference signal with the reference signal.

4. The system as recited in claim 3, wherein

the noise signal includes is generated by at least one of (a) patient motion and (b) motion of the at least one sensor.

5. The system as recited in claim 1, wherein

the modified reference signal is generated by amplitude modulation of the reference signal due to patient respiration.

6. The system as recited in claim 5, wherein

the signal processor amplitude demodulates the modified reference signal to identify an envelope of the modified reference signal to produce a second signal of interest for use in determining a second different patient parameter.

7. The system as recited in claim 1, wherein

the reference transmitter array transmits a second reference signal, said second reference signal being modulated by noise upon passing though the patient's body.

8. The system as recited in claim 8, wherein

said at least one sensor includes a plurality of sensors able to sense at least one electrical field, wherein a respective one of said plurality of sensors senses the modulated second reference and said signal processor automatically compares the modulated second reference signal with the reference signal to identify and extract a second signal of interest for use in determining a second different patient parameter.

9. The system as recited in claim 8, wherein

said second reference signal is transmitted at a predetermined distance from the at least one reference signal.

10. The system as recited in claim 1, wherein

said housing is formed from a conductive material and shields the at least one sensor and reference transmitter from external noise.

11. The system as recited in claim 1,

wherein the a housing is one of a (a) a strap that is wrapped around at least a portion of the patient; (b) a shirt; and (c) a cap.

12. The system as recited in claim 1, wherein

the at least one sensor includes a plurality of sensors for sensing an electrical field of a patient's heart in order to determine data representing an ECG waveform for the patient.

13. The system as recited in claim 6, wherein

the second patient parameter is data representing patient respiration.

14. A method for determining at least one patient parameter using electrophysiological signals from the patient comprising the activities of:

controlling, by a signal processor, a reference transmitter array to transmit at least one reference signal;

emitting the at least one reference signal having predetermined frequency content by the reference transmitter array, the reference transmitter array being retained in a predetermined position by a housing on a first side of the patient's body;

sensing, by at least one sensor positioned on a second side of the patient's body, a composite signal including at least one signal generated by the patient's body and a modified reference signal, the modified reference signal being the reference signal received on the second side of the patient's body and including noise, the at least one sensor being retained in a predetermined position by the housing on a second side of the patient's body opposite the first side;

receiving the composite signal from the at least one sensor; and

filtering the composite signal to remove the reference signal and noise therefrom to produce a first signal of interest for use in determining a first patient parameter.

15. The method as recited in claim 14, wherein the activity of emitting further comprises

emitting said reference signal through the patient in a direction towards the at least one sensor.

16. The method as recited in claim 14, further comprising the activity of

identifying the noise signal within the composite signal by comparing the modified reference signal with the reference signal.

17. The method as recited in claim 16, wherein

the noise signal includes is generated by at least one of (a) patient motion and (b) motion of the at least one sensor.

18. The method as recited in claim 14, further comprising the activity of

amplitude modulating the reference signal by patient respiration to generate the modified reference signal.

19. The method as recited in claim 18, further comprising the activity of

amplitude demodulating the modified reference signal by the signal processor to identify an envelope of the modified reference signal to produce a second signal of interest for use in determining a second different patient parameter.

20. The method as recited in claim 14, further comprising the activity of

transmitting a second reference signal from the reference transmitter array, the second reference signal being modulated by noise upon passing though the patient's body.

21. The method as recited in claim 20, wherein

sensing the modulated second reference signal by a sensor and

comparing, by the signal processor, the modulated second

reference signal with the reference signal to identify and extract a second signal of interest for use in determining a second different patient parameter.

22. The method as recited in claim 14, further comprising the activity of

shielding the at least one sensor and reference transmitter from external noise using a conductive material positionable on the patient.

23. The method as recited in claim 14, wherein the activity of sensing includes

sensing an electrical field of a patient's heart in order to determine data representing an ECG waveform for the patient.

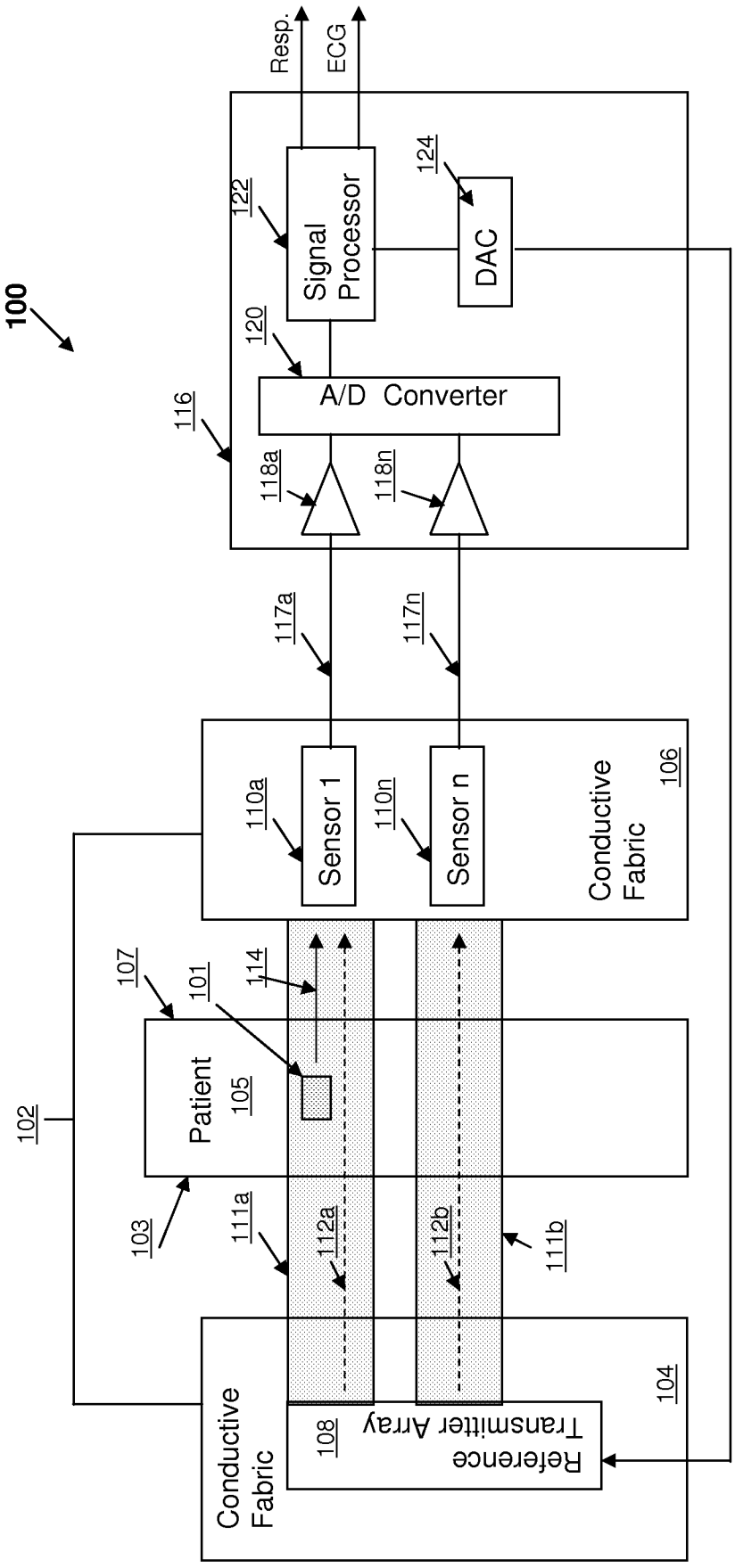

100
Resp.
ECG
122
Signal Processor
124
DAC
120
A/D Converter
116
118a
118n
117a
117n
110a
Sensor 1
110n
Sensor n
Conductive Fabric
106
107
101
114
Patient
105
102
103
111a
112a
112b
111b
Conductive Fabric
104
108
Reference Transmitter Array

Fig 1A

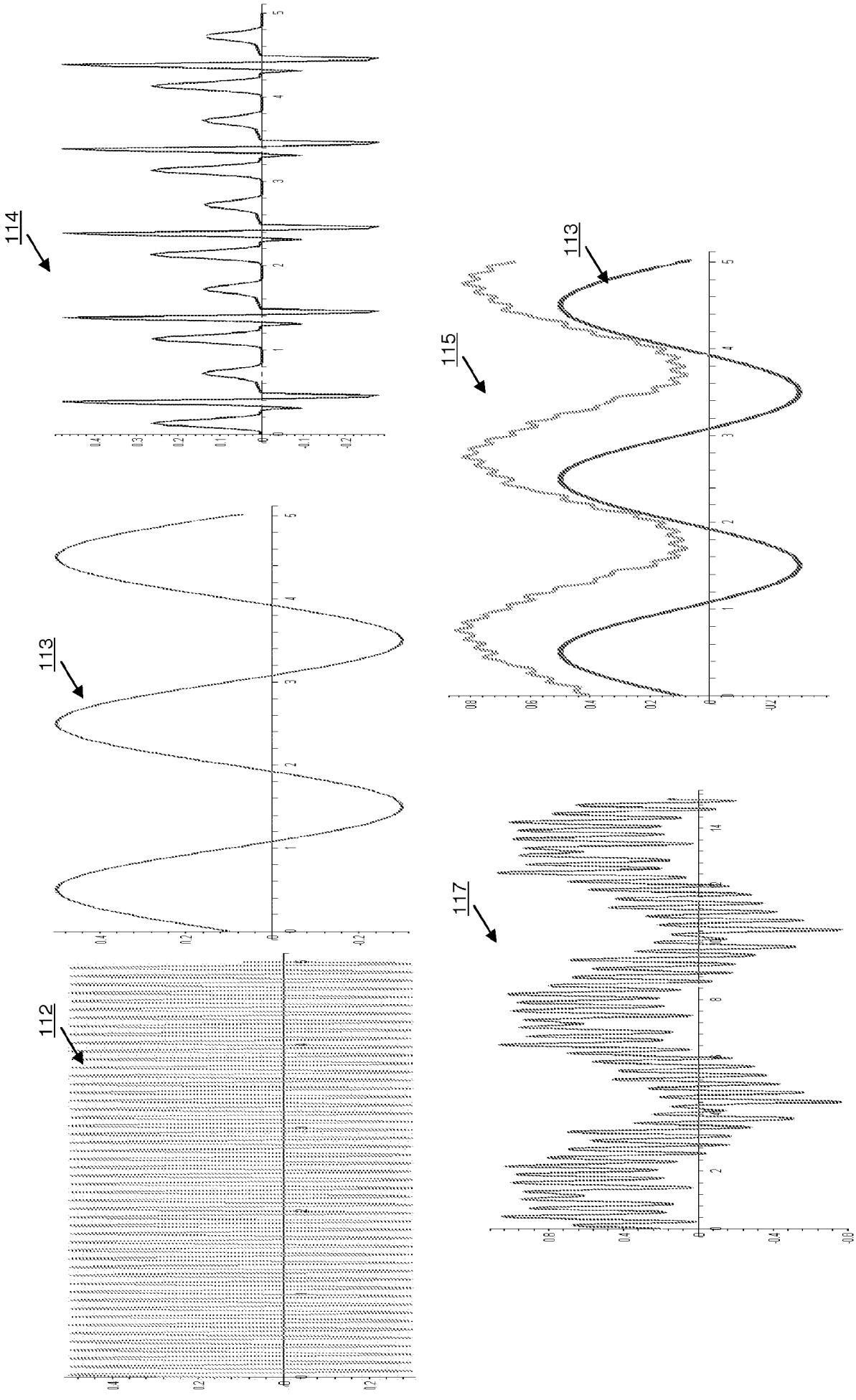


Fig. 1B

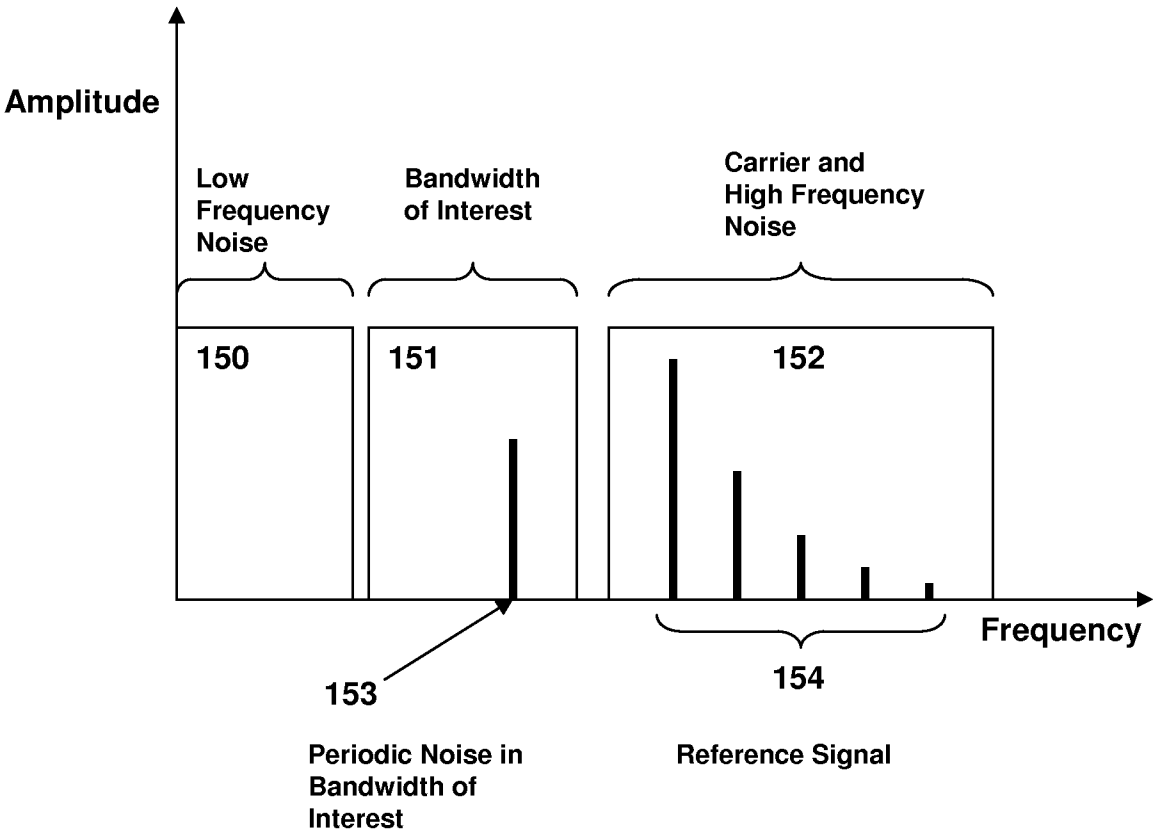

Amplitude
Low Frequency Noise
Bandwidth of Interest
Carrier and High Frequency Noise
150
151
152
Frequency
153
154
Periodic Noise in Bandwidth of Interest
Reference Signal

Fig. 1C

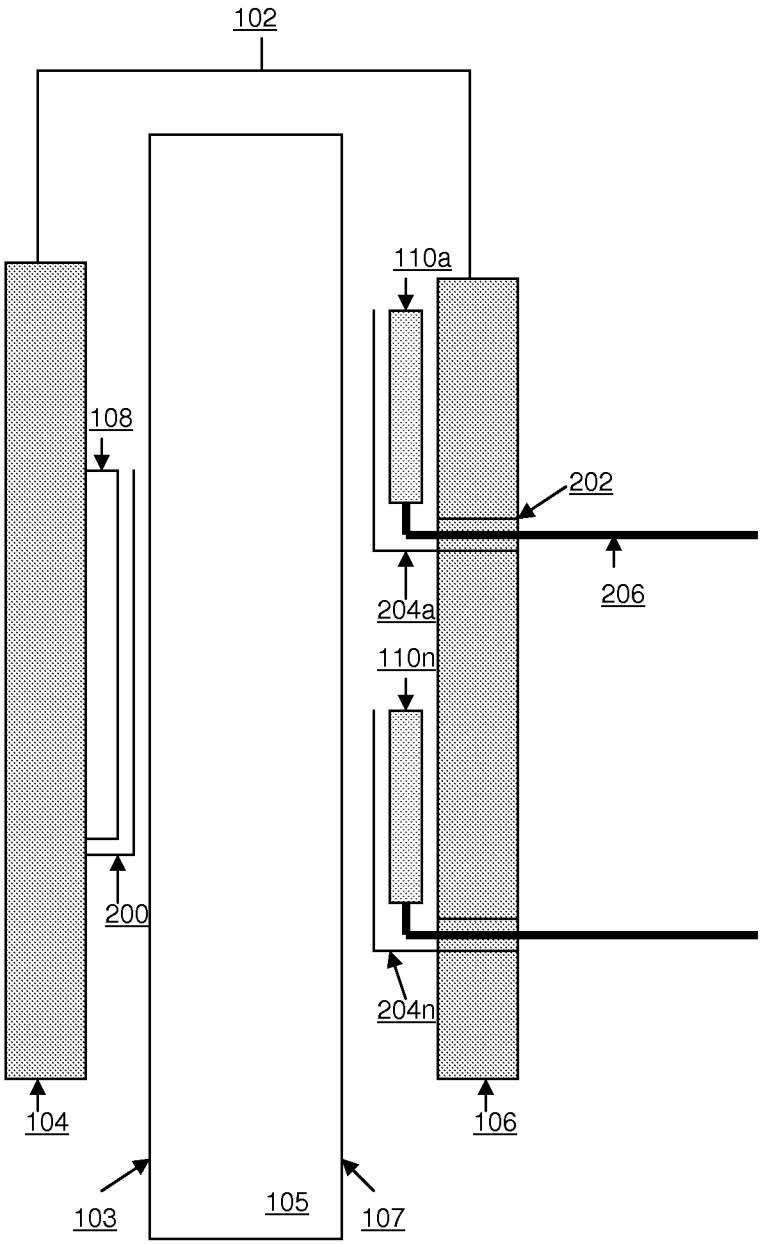


Fig. 2

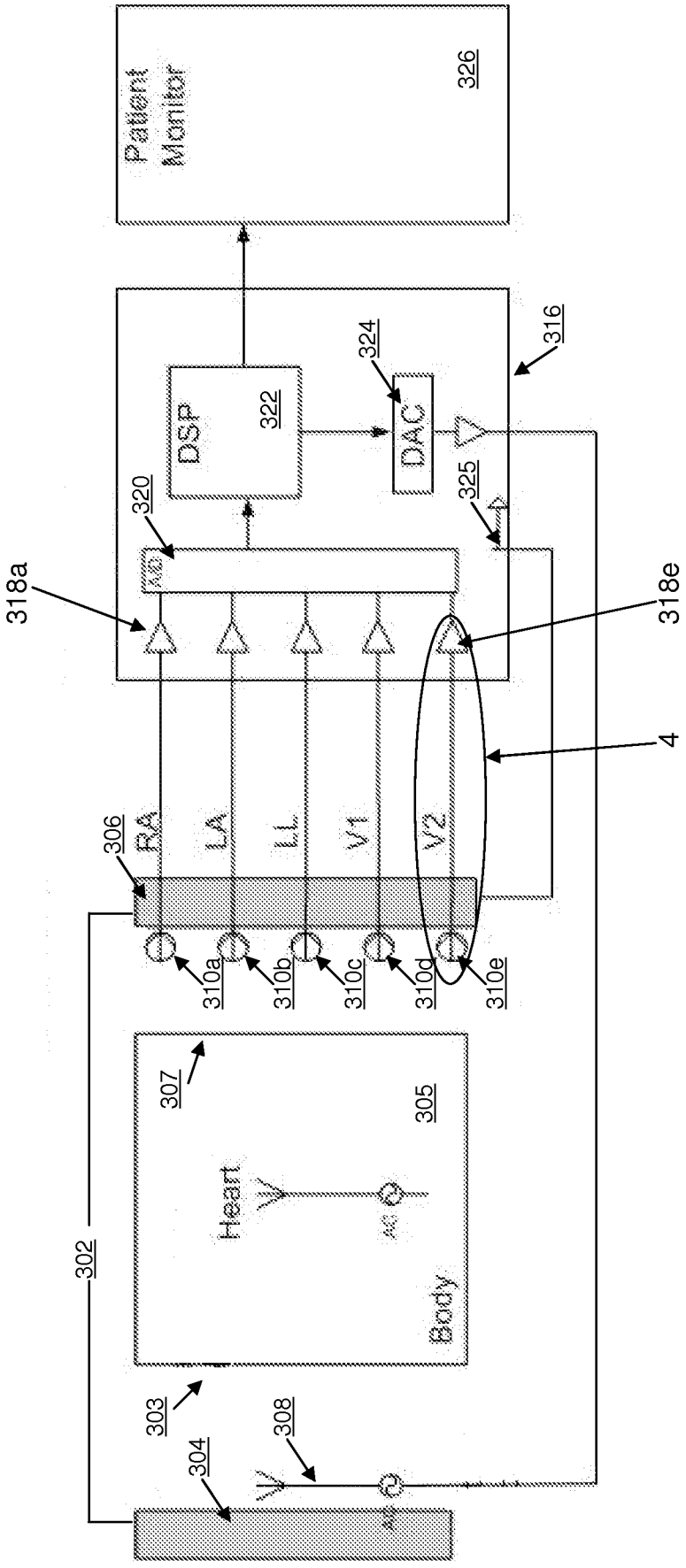

Patient Monitor
326
316
DSP
322
324
DAC
325
320
318a
318e
4
306
RA
LA
LL
V1
V2
310a
310b
310c
310d
310e
307
305
Heart
Body
302
303
304
308

Fig. 3

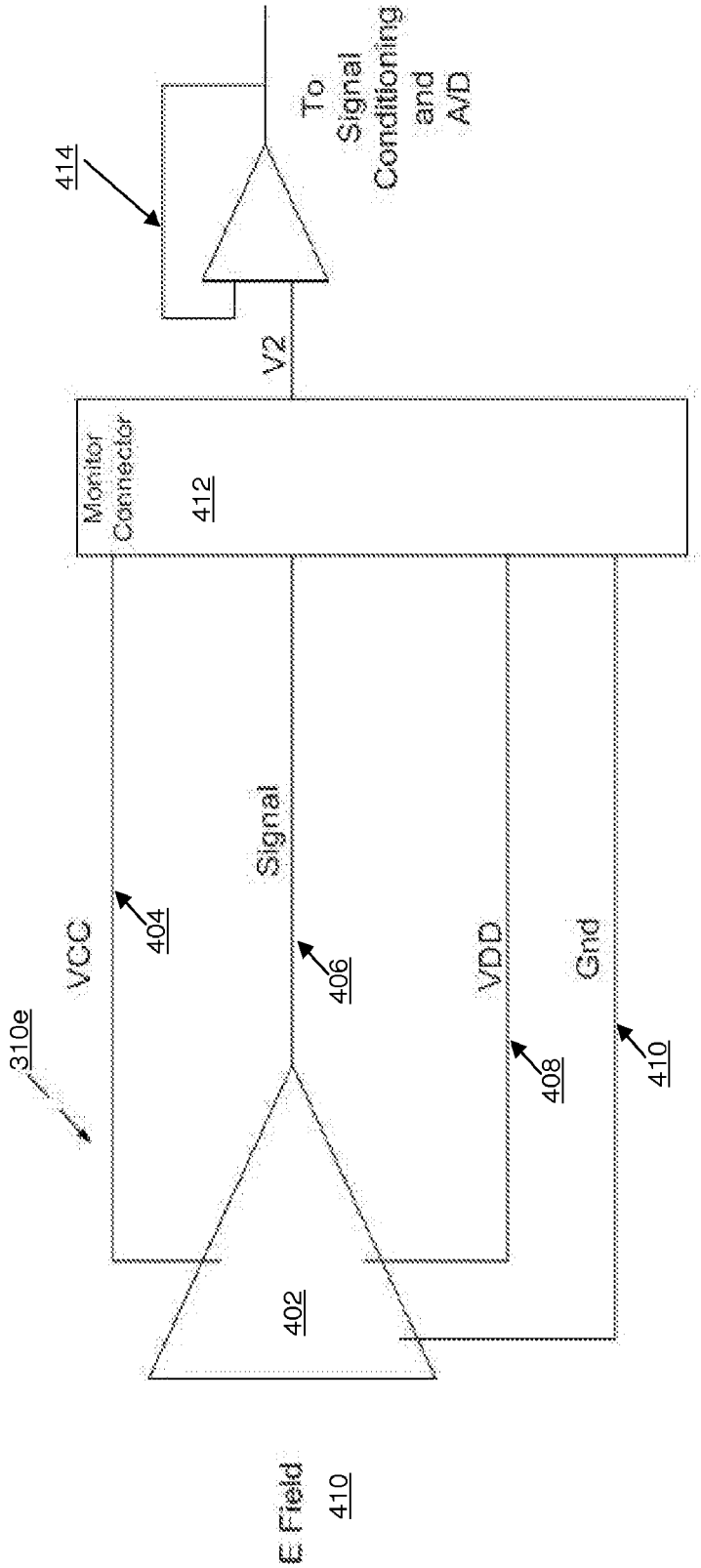

To Signal Conditioning and A/D
414
V2
Monitor Connector
412
Signal
VCC
404
406
VDD
Gnd
310e
408
410
402
E Field
410

Fig. 4

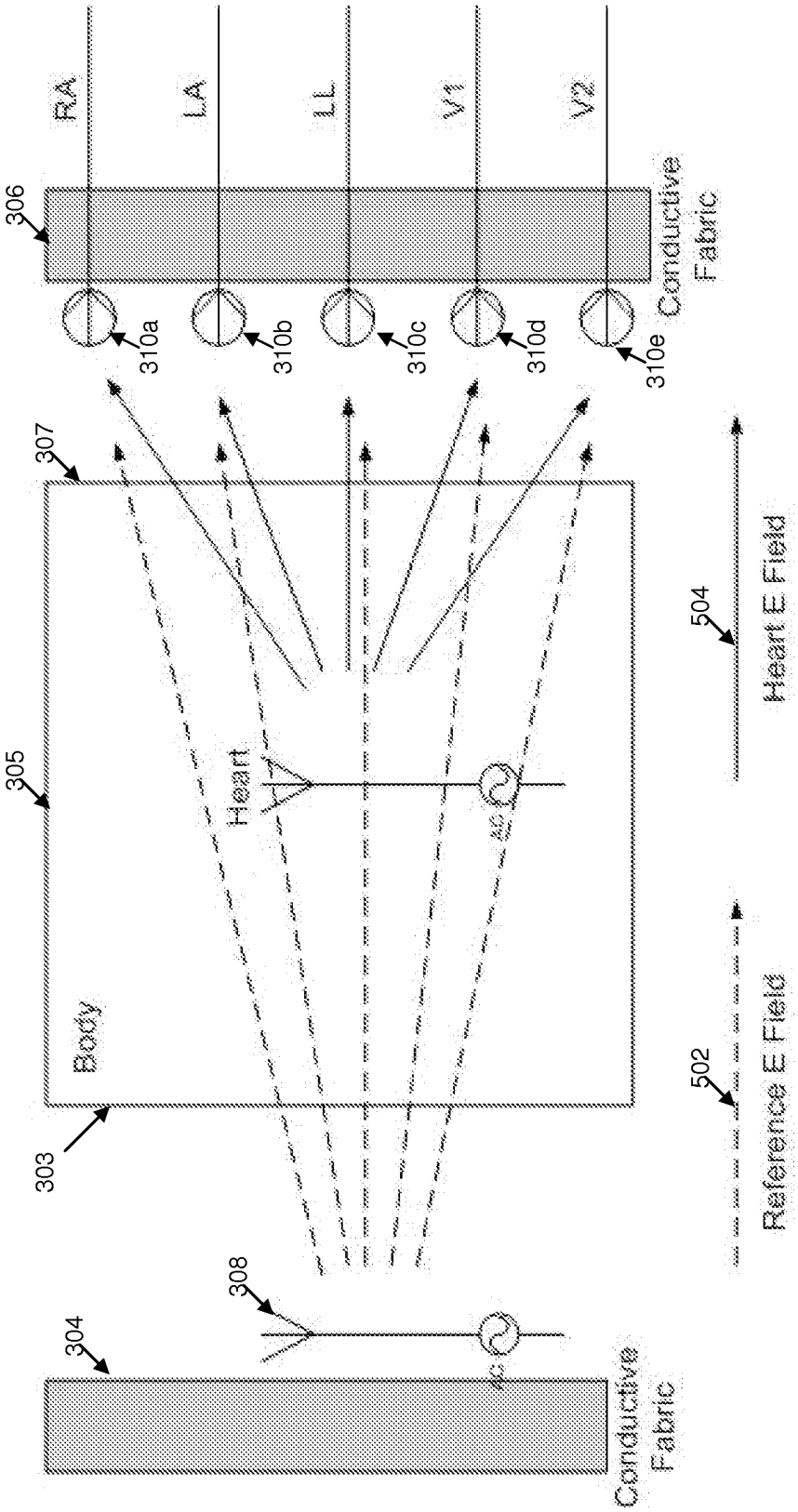

RA
LA
LL
V1
V2
306
Conductive Fabric
310a
310b
310c
310d
310e
307
305
Body
Heart
303
308
304
Conductive Fabric
504
Heart E Field
502
Reference E Field

Fig. 5

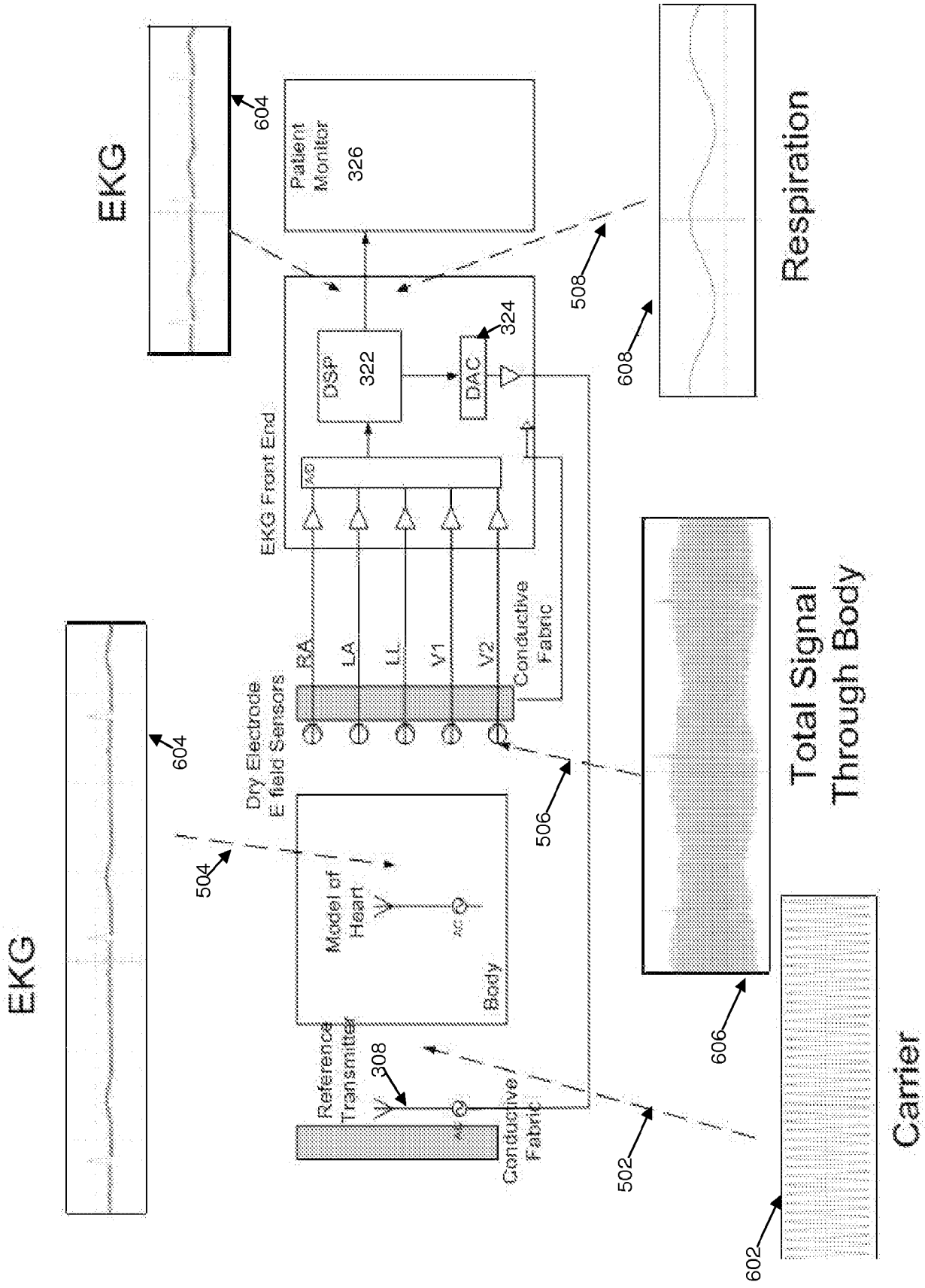

EKG
604
Patient Monitor
326
Respiration
508
608
DSP
322
DAC
324
EKG Front End
A/D
RA
LA
LL
V1
V2
Conductive Fabric
Dry Electrode E field Sensors
504
506
Model of Heart
Body
Reference Transmitter
308
Conductive Fabric
Total Signal Through Body
606
502
Carrier
602
EKG
604

Fig. 6

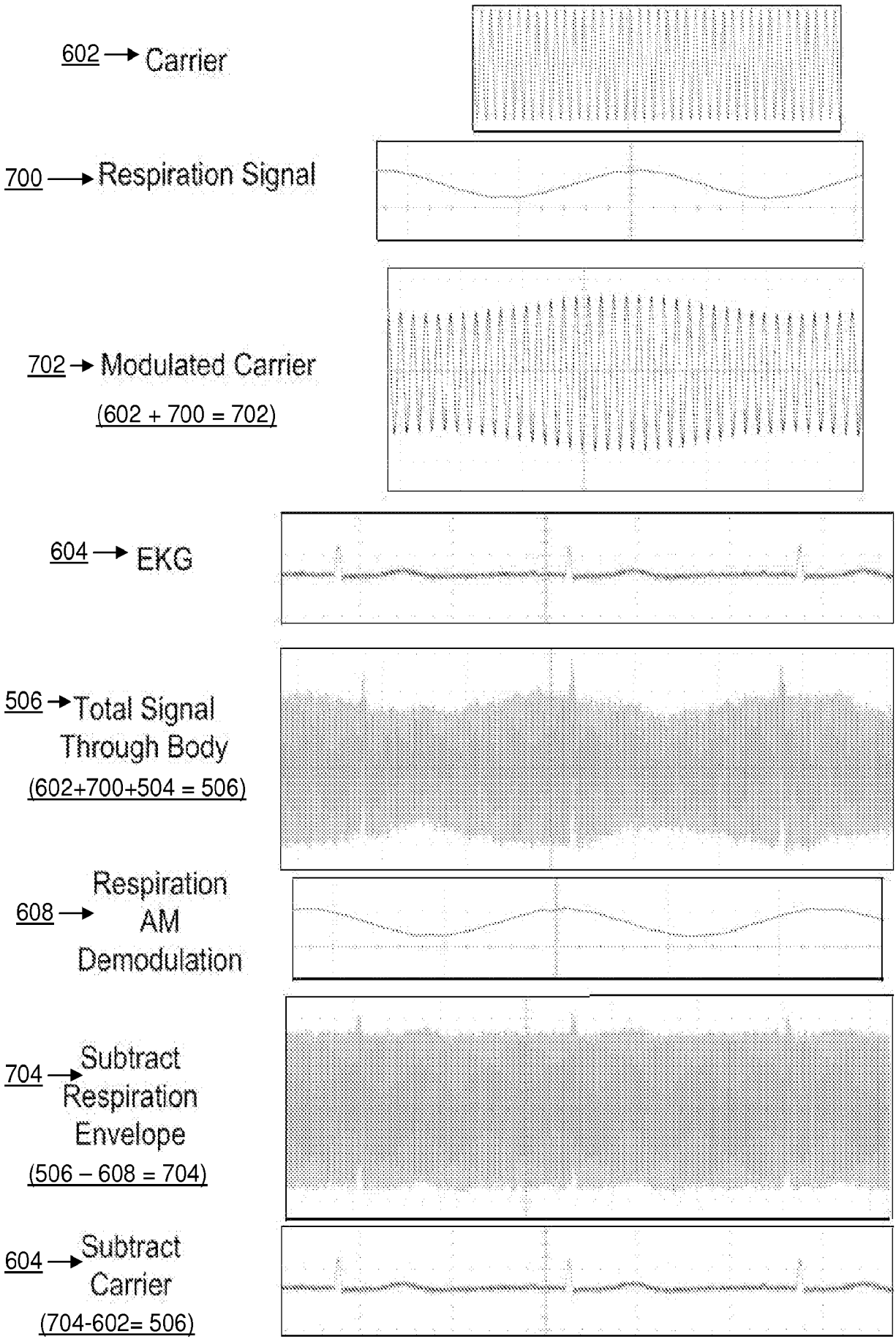

602 → Carrier
700 → Respiration Signal
702 → Modulated Carrier
(602 + 700 = 702)
604 → EKG
506 → Total Signal Through Body
(602+700+504 = 506)
608 → Respiration AM Demodulation
704 → Subtract Respiration Envelope
(506 – 608 = 704)
604 → Subtract Carrier
(704-602= 506)

Fig. 7

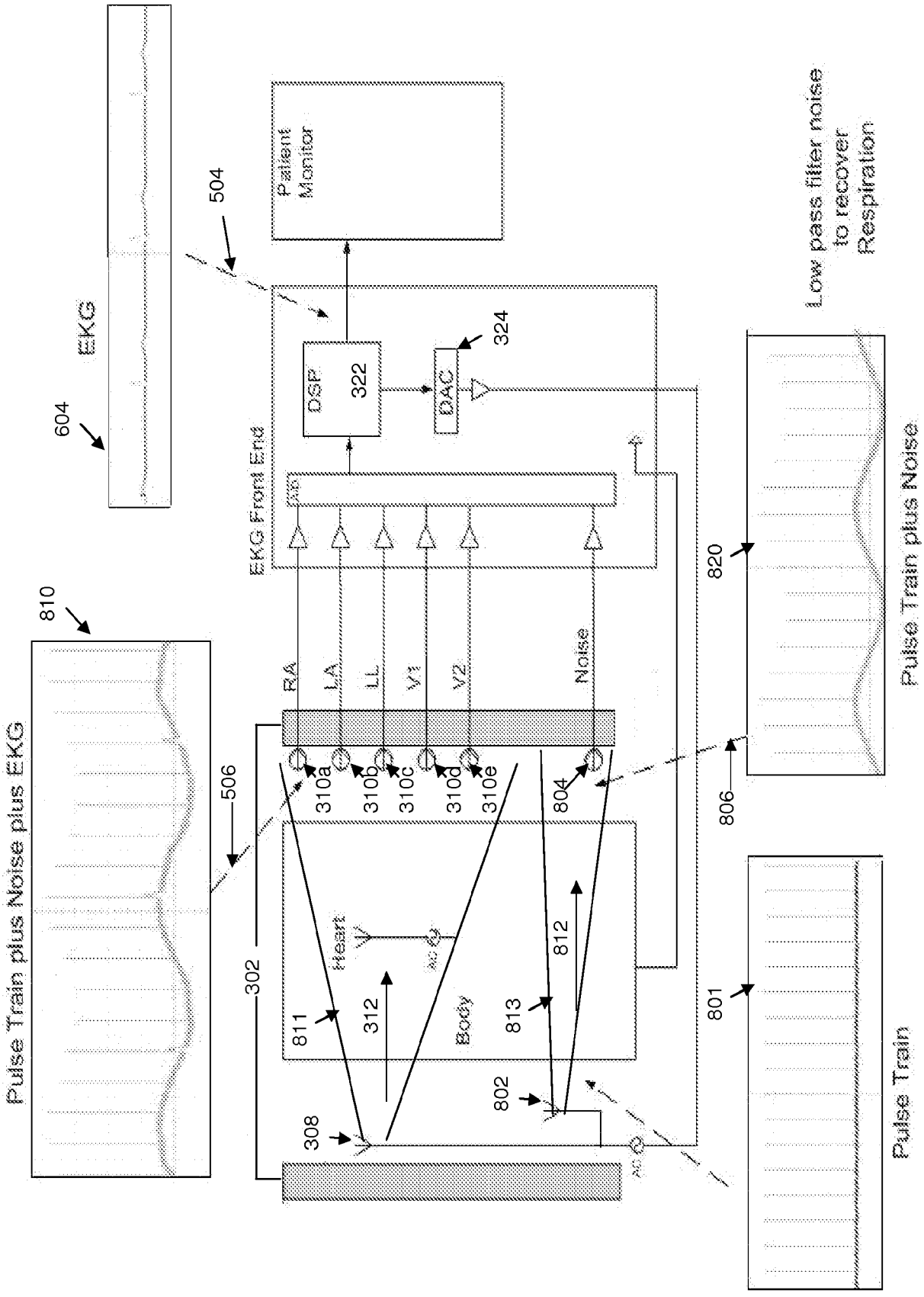

Pulse Train plus Noise plus EKG
810
506
302
EKG
604
504
Patient Monitor
EKG Front End
DSP
322
DAC
324
RA
LA
LL
V1
V2
Noise
310a
310b
310c
310d
310e
804
820
Low pass filter noise to recover Respiration
Pulse Train plus Noise
806
801
Pulse Train
Heart
Body
811
312
813
812
802
308

Fig. 8A

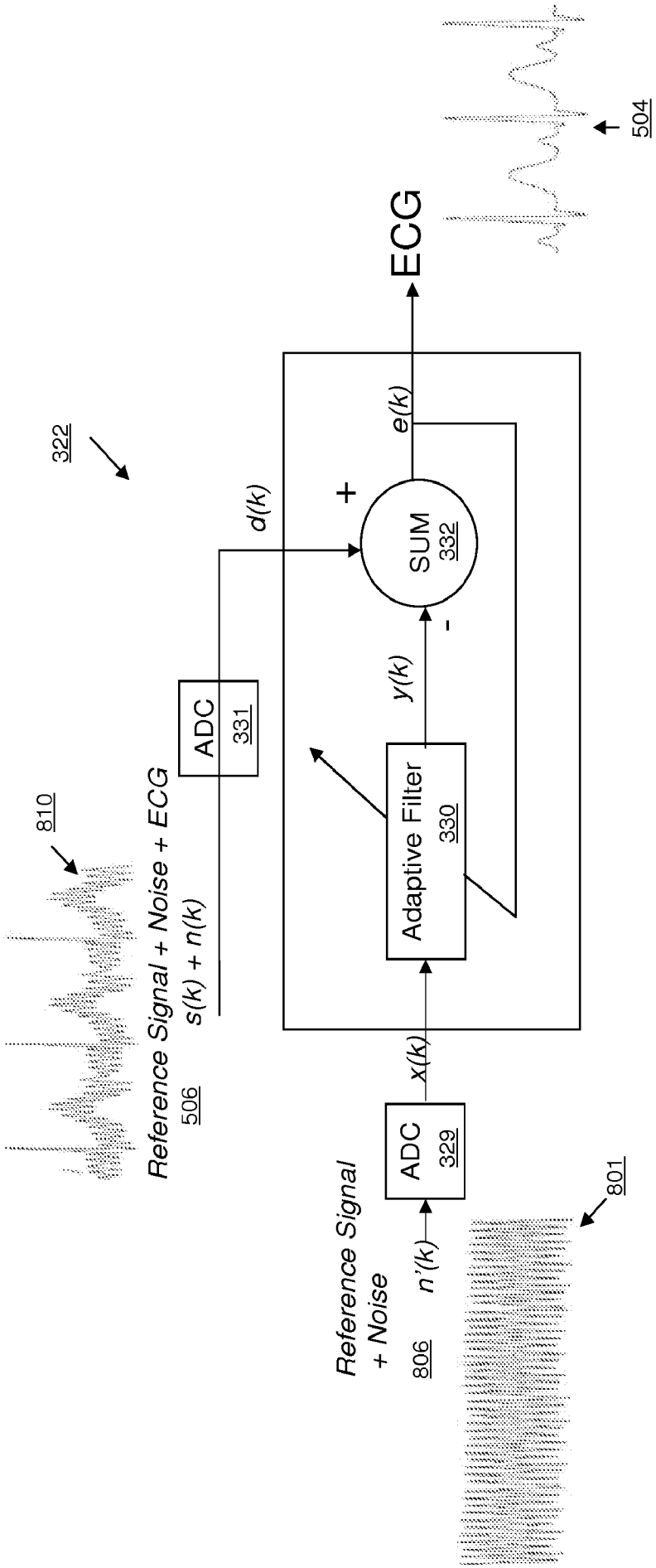
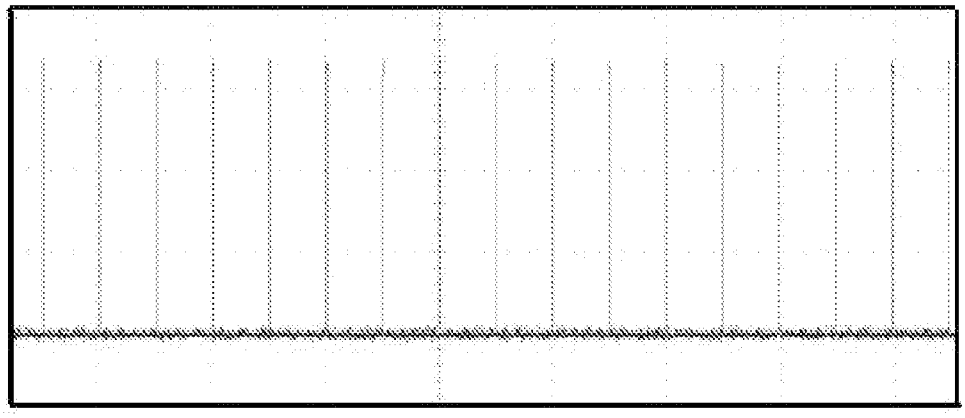
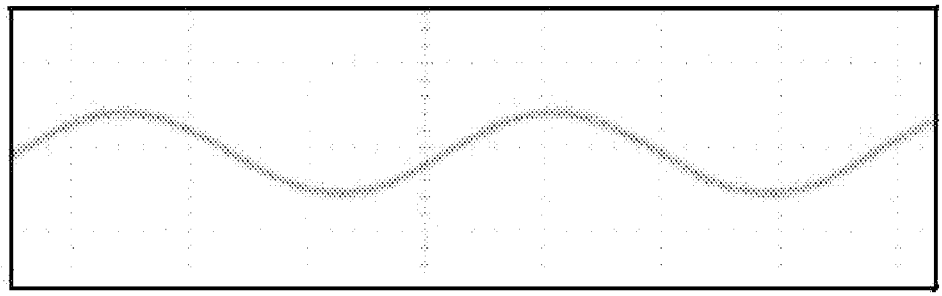

322
ECG
504
e(k)
d(k)
+
SUM
332
-
y(k)
Adaptive Filter
330
ADC
331
Reference Signal + Noise + ECG
506
s(k) + n(k)
810
x(k)
ADC
329
Reference Signal
+ Noise
806
n'(k)
801

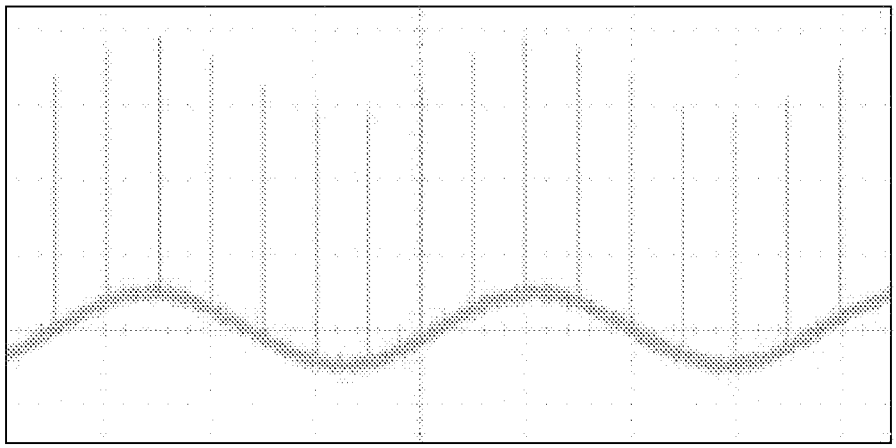
Fig. 8B



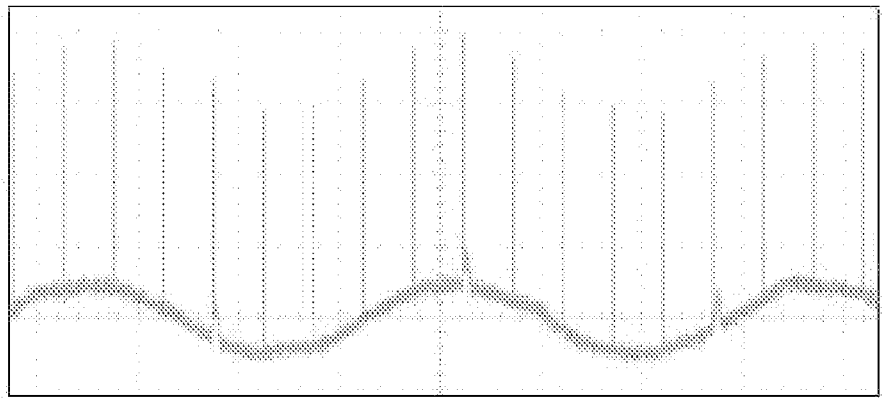
Pulse Train
801



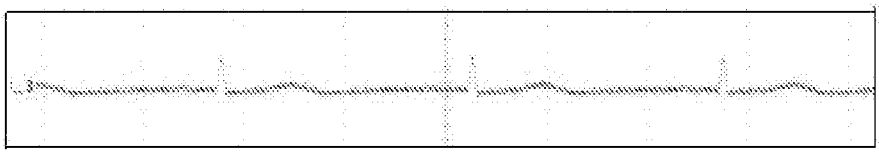
Noise
901



Pulse Train plus Noise
820
(801+901 = 820)



Pulse Train plus Noise plus EKG
810
(820+504 = 810)



EKG
504
(820-810=504)

Fig. 9

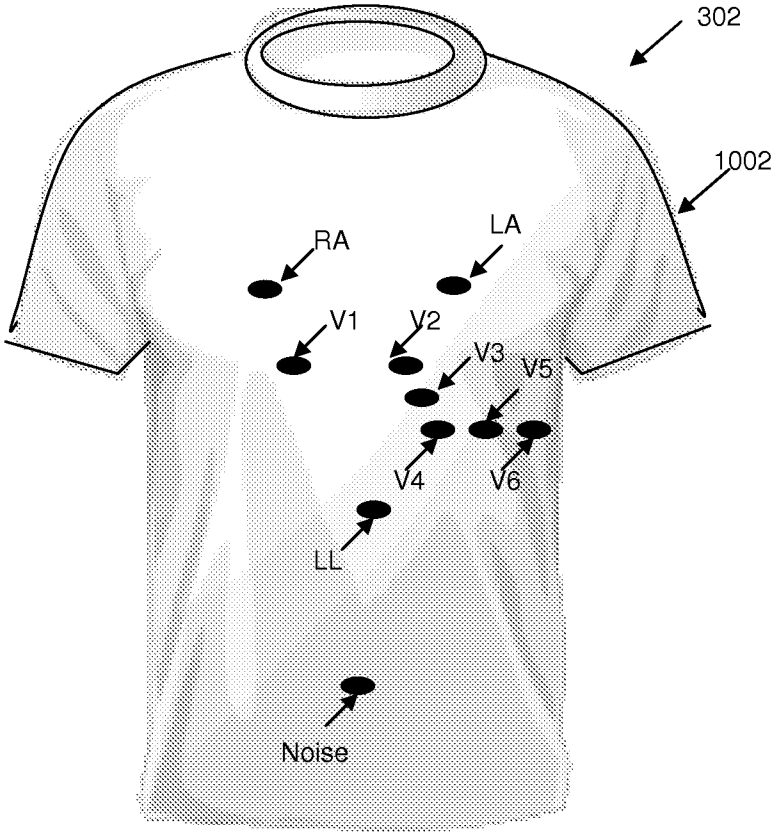


Fig. 10A

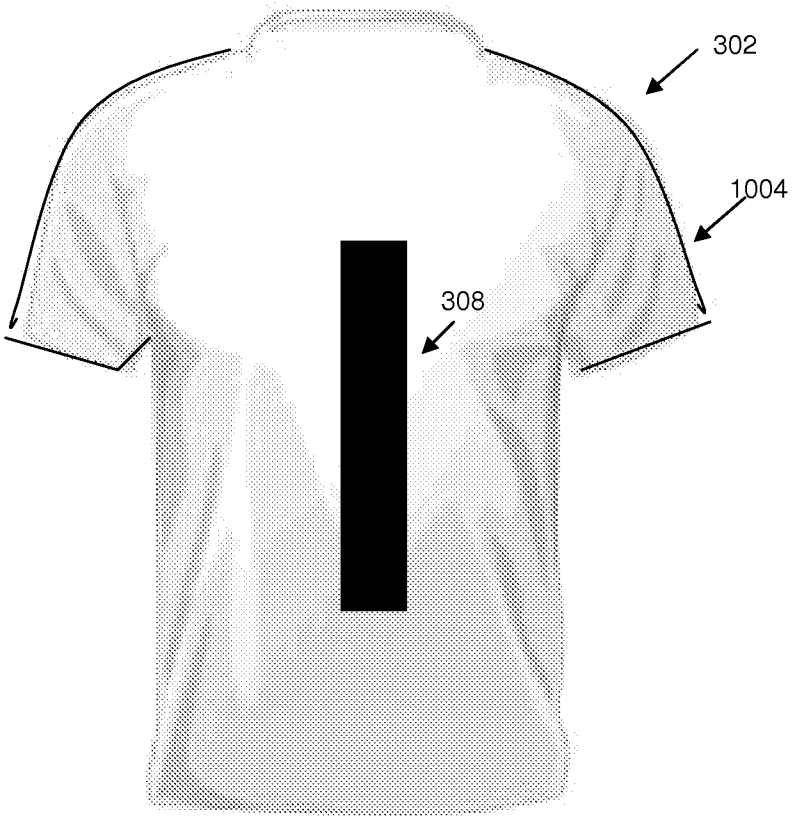


Fig. 10B

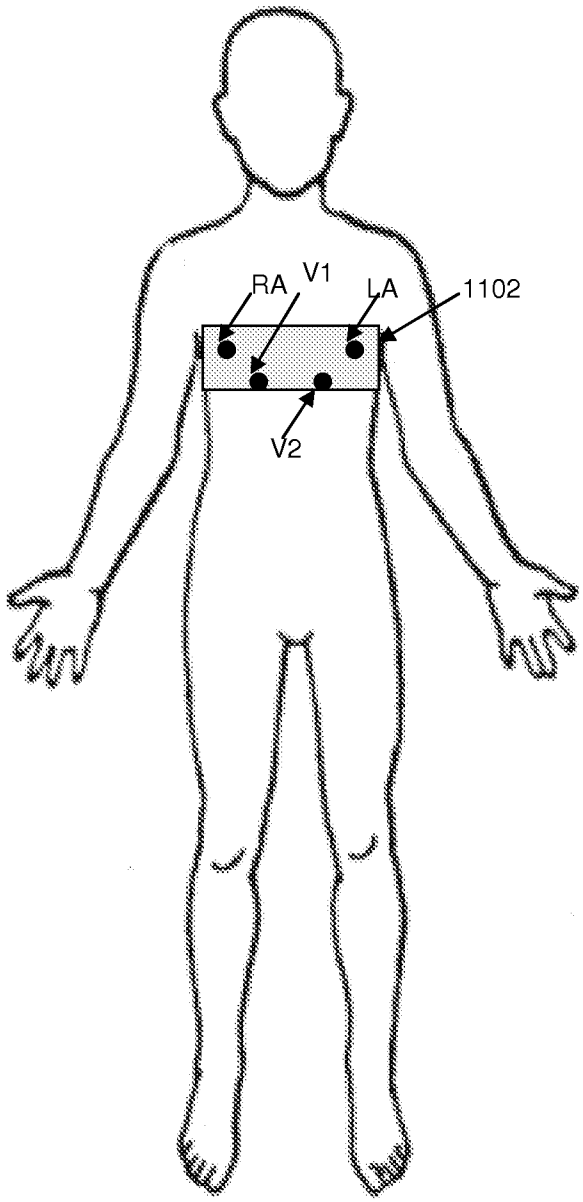


Fig. 11A

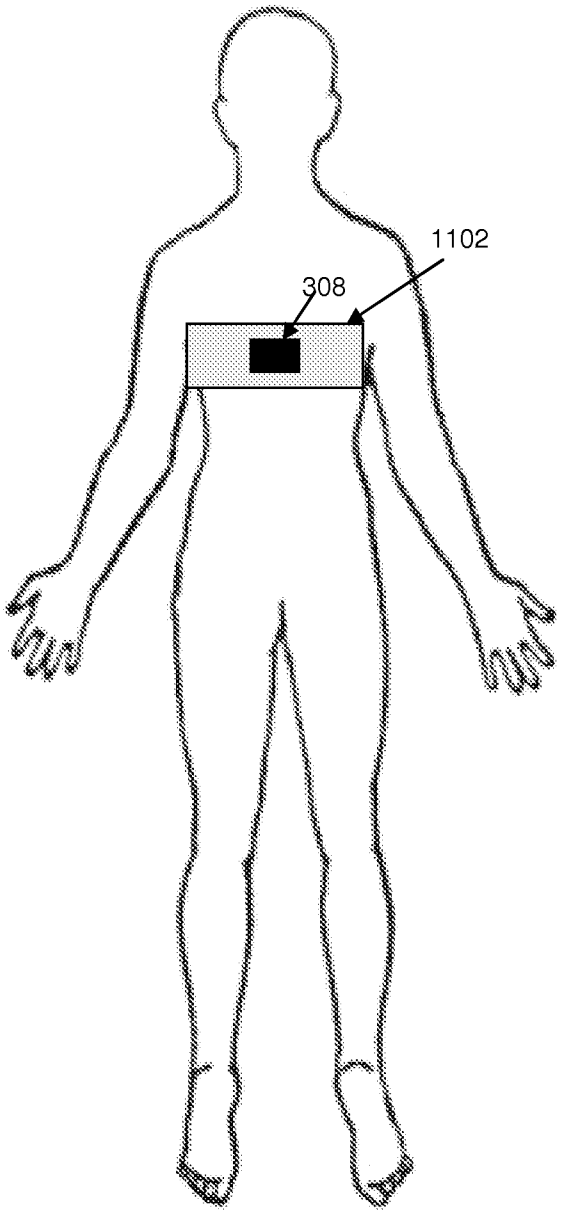


Fig. 11B

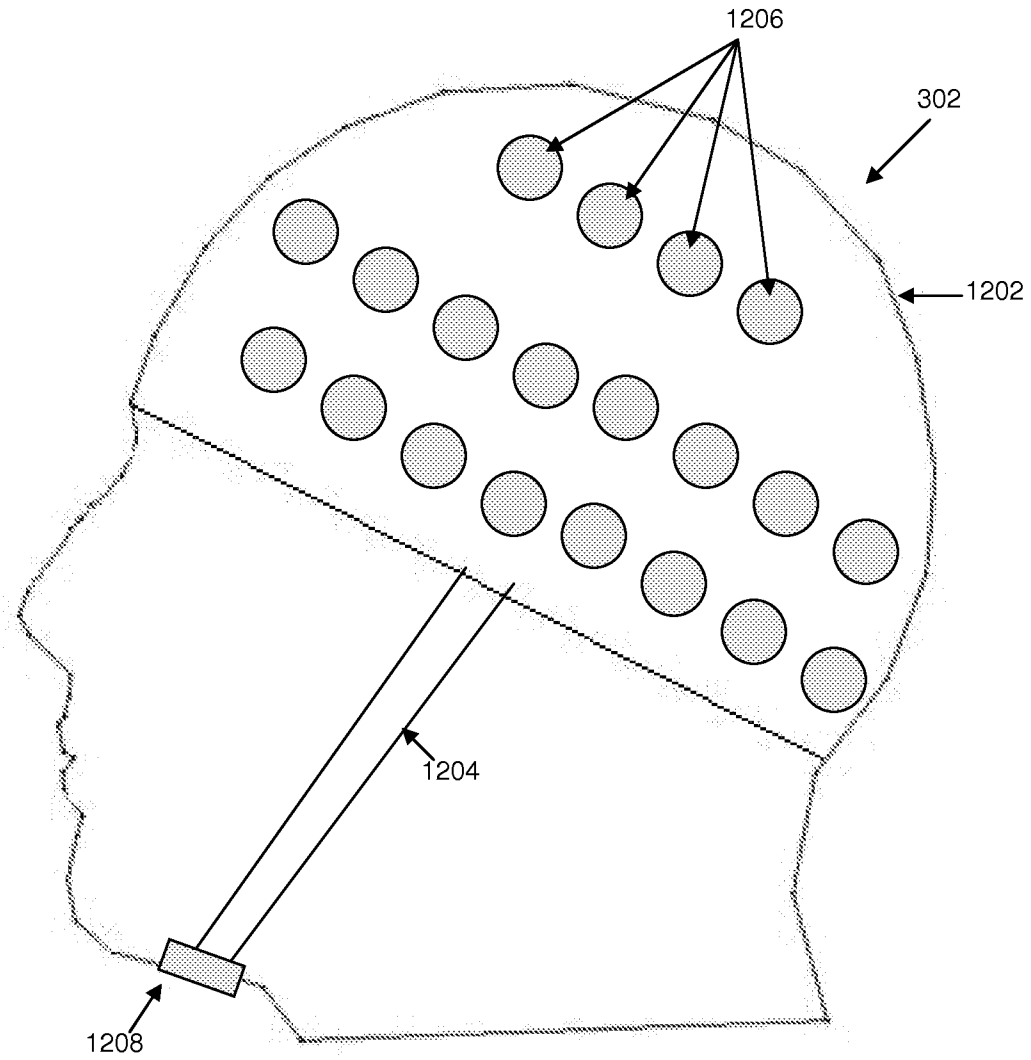


Fig. 12

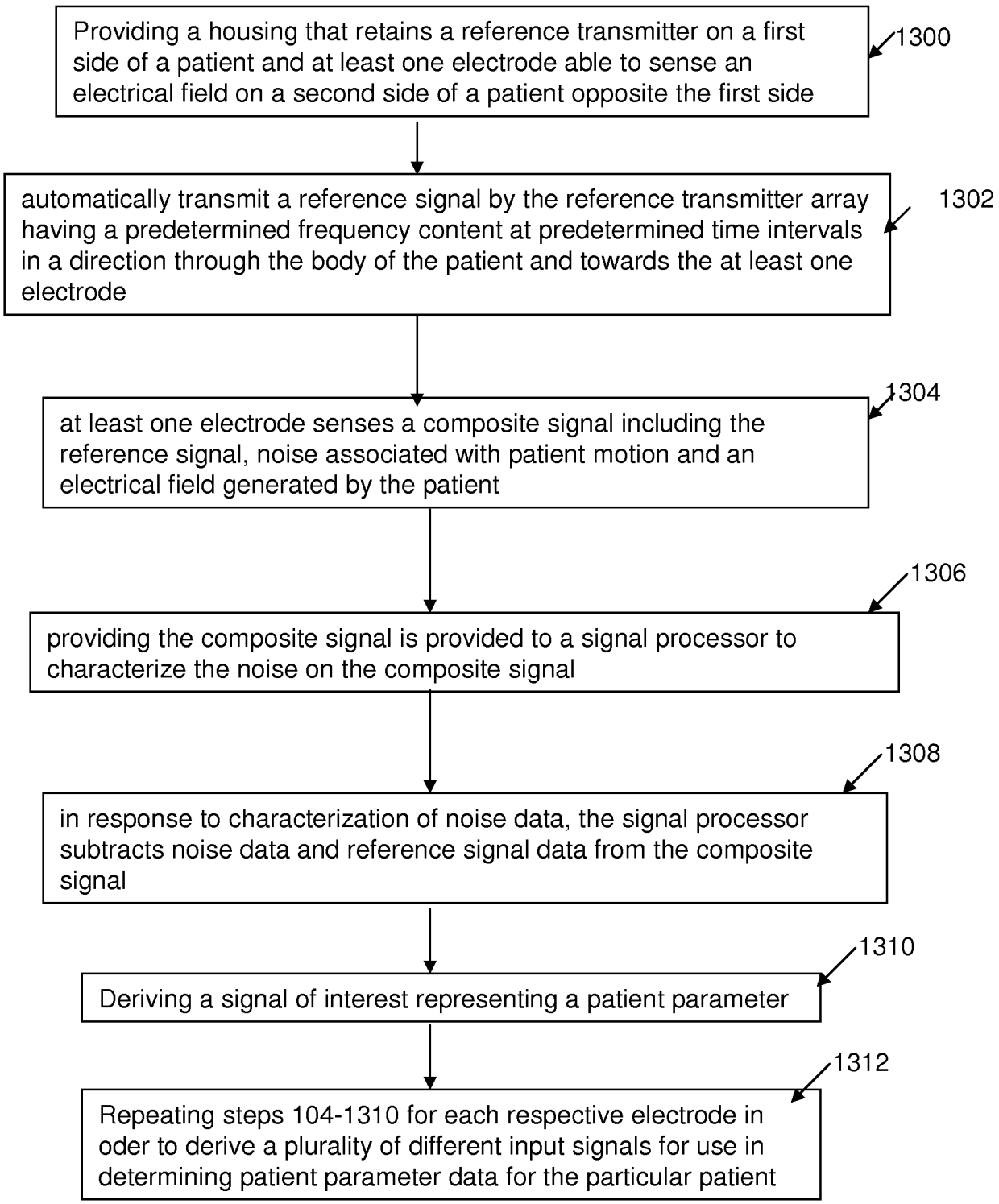

Providing a housing that retains a reference transmitter on a first side of a patient and at least one electrode able to sense an electrical field on a second side of a patient opposite the first side
1300
automatically transmit a reference signal by the reference transmitter array having a predetermined frequency content at predetermined time intervals in a direction through the body of the patient and towards the at least one electrode
1302
at least one electrode senses a composite signal including the reference signal, noise associated with patient motion and an electrical field generated by the patient
1304
providing the composite signal is provided to a signal processor to characterize the noise on the composite signal
1306
in response to characterization of noise data, the signal processor subtracts noise data and reference signal data from the composite signal
1308
Deriving a signal of interest representing a patient parameter
1310
Repeating steps 104-1310 for each respective electrode in oder to derive a plurality of different input signals for use in determining patient parameter data for the particular patient
1312

Fig. 13

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2012/049166

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/0402 A61B5/113
ADD. A61B5/0408

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2011/237904 A1 (KIM JONG-PAL [KR]) 29 September 2011 (2011-09-29) paragraphs [0038] - [0115]; figures 1-3a	1-9, 12-21,23
A	US 2010/007413 A1 (HERLEIKSON EARL C [US] HERLERKSON EARL C [US]) 14 January 2010 (2010-01-14) paragraphs [0018] - [0031]; figure 1	1-9, 12-21,23
A	US 7 502 643 B2 (FARRINGDON JONATHAN [US] ET AL) 10 March 2009 (2009-03-10) the whole document	1-9, 12-21,23

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
4 April 2013	18/07/2013

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Schindler, Martin

1

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2012/049166

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-9, 12-21, 23

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-9, 12-21, 23

   How to filter a signal noise from an digital ECG signal (special technical feature: Signal processor configured to identify noise)

   ---

2. claims: 10, 11, 22

   How to mechanically shield and attach sensors to a patient body (special technical feature: Conductive housing on a strap, shirt or cap)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2012/049166

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2011237904 A1	29-09-2011	KR 20110108186 A	05-10-2011
		US 2011237904 A1	29-09-2011
US 2010007413 A1	14-01-2010	CN 101534708 A	16-09-2009
		EP 2086403 A2	12-08-2009
		JP 2010508935 A	25-03-2010
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		US 2010007413 A1	14-01-2010
		WO 2008056309 A2	15-05-2008
US 7502643 B2	10-03-2009	BR PI0414345 A	07-11-2006
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		IL 174267 A	30-12-2010
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		US 2008161707 A1	03-07-2008
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		US 2008183082 A1	31-07-2008
		US 2008183090 A1	31-07-2008
		US 2010286532 A1	11-11-2010
		WO 2005027720 A2	31-03-2005