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(54) Title: IDENTIFYING SEIZURES USING HEART DATA FROM TWO OR MORE WINDOWS

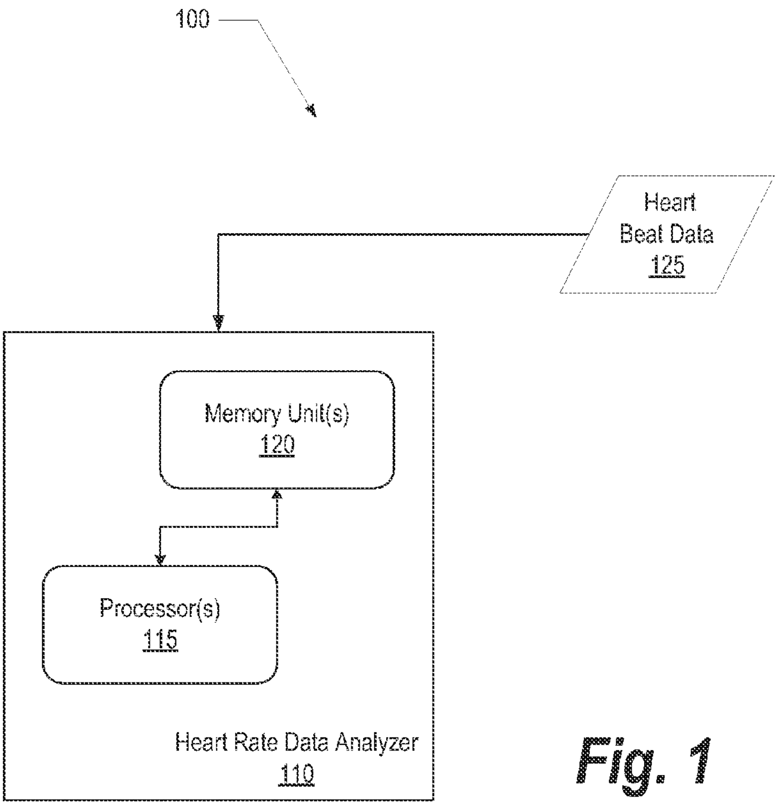

Fig. 1

(57) **Abstract**: Methods and systems for characterizing a seizure event in a patient, including determining a time of beat sequence of the patient's heart, determining a first HR measure for a first window, determining a second HR measure for a second window, wherein at least a portion of the first window occurs after the second window, determining at least one HR parameter based upon said first HR measure and said second HR measure, identifying an onset of the seizure event in response to determining that at least one HR parameter crosses an onset threshold, identifying an end of the seizure event in response to determining that at least one HR parameter crosses an offset threshold.

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Description/Specification

Title:
Identifying Seizures Using Heart Data from Two or More Windows

A. Cross-reference to Related Applications

[¶1] This application relates to the following commonly assigned co-pending application entitled:

[¶2] "Identifying Seizures Using Heart Rate Decrease," Ser. No. 13/093,475 , filed April 25, 2011.

B. Background

1. Technical Field of the Present Disclosure

[¶3] The present disclosure relates generally to the field of seizure identification and more particularly to the field of identifying seizures by monitoring and comparing heart data from two or more windows.

2. Background of the Present Disclosure

[¶4] Seizures generally are characterized by abnormal/excessive neural activity in the brain. Seizures may involve loss of consciousness or awareness, and cause falls, uncontrollable convulsions, etc. Significant injuries may result not only from the neuronal activity in the brain but also from the associated loss of motor function from falls or the inability to perceive and/or respond appropriately to potential danger or harm.

[¶5] It is important to identify seizures as quickly as possible after the onset of the seizure to allow corrective action to be taken immediately, including administering therapy or intervening to prevent injury to the patient. It is also important to be able to identify and record seizures that have occurred to accurately assess the state of the patient's condition and determine whether therapies are effective or should be modified. Seizure detection algorithms have been proposed using a variety of body parameters to detect seizures, including brain waves (e.g., electroencephalogram or EEG signals), heart beats (e.g., electrocardiogram or EKG signals), and movements (e.g., triaxial accelerometer signals). See, e.g., US Patent Serial No. 5,928,272, and US Application Serial No. 12/770,562, both of which are hereby incorporated by reference herein.

[¶6] Detection of seizures using heart data requires that the algorithm distinguish between pathological changes in the detected heart signal (which indicate a seizure) and non-pathological changes that may be similar to pathological changes but involve normal physiological functioning. For example, the heart rate may rise both when a seizure event occurs and when the patient exercises, climbs stairs or performs other physiologically demanding acts.

[¶7] Seizure detection algorithms, in some instances, may need to distinguish between changes in heart rate due to a seizure and those due to exertional or positional/postural changes. As noted, it is important to detect seizures quickly and accurately. However, current algorithms fail to provide rapid and accurate detection. Current algorithms also fail to provide an indication of when the seizure has ended and the danger to the patient is reduced. The present invention addresses limitations associated with existing cardiac-based seizure detection algorithms.

C. Summary

[¶8] In one respect, disclosed is a method for characterizing a seizure event in a patient, the method comprising determining a time of beat sequence of the patient's heart, determining a first HR measure for a first window, determining a second HR measure for a second window, wherein at least a portion of the first window occurs after the second window, determining at least one HR parameter based upon said first HR measure and said second HR measure, identifying the onset of a seizure event in response to determining that at least one HR parameter crosses an onset threshold, and identifying an end of the seizure event in response to determining that at least one HR parameter crosses an offset threshold.

[¶9] In another respect, disclosed is a system for characterizing seizure events, the system comprising one or more processors, one or more memory units coupled to the one or more processors, the system being configured to determine a time of beat sequence of the patient's heart, determine a first HR measure for a first window, determine a second HR measure for a second window, wherein at least a portion of the first window occurs after the second window, determine at least one HR parameter based upon said first HR measure and said second HR measure, identify the onset of a seizure event in response to determining that at least one HR parameter crosses an onset threshold, and identify an end of the seizure event in response to determining that at least one HR parameter crosses is an offset threshold.

[¶10] In yet another respect, disclosed is a computer program product embodied in a computer-operable medium, the computer program product comprising logic instructions, the logic instructions being effective to determine a first HR measure for a first window in a time series of heart beat data for a patient, determine a second HR measure for a second window, wherein at least a portion of the first window occurs after the second window, determining at least one HR parameter based upon said first HR measure and said second HR measure, identify the onset of a seizure event in response to determining that at least one HR parameter crosses an onset threshold, and identify an end of the seizure event in response to determining that at least one HR parameter crosses an offset threshold.

[¶11] In some respects, disclosed is a method for characterizing a seizure event in a patient, the method comprising determining heart rate (HR) versus time, determining a first HR measure for a first window, determining a second HR measure for a second window, wherein at least a portion of the first window occurs after the second window, and wherein the first window and the second window are separated by an intermediate window, determining at least one HR parameter based upon said first HR measure and said second HR measure, and identifying an onset of the seizure event in response to determining that at least one HR parameter crosses an onset threshold.

[¶12] In some respects, disclosed is a system for characterizing a seizure event in a patient, the system comprising one or more processors, one or more memory units coupled to the one or more processors, the system being configured to determine heart rate (HR) versus time, determine a first HR measure for a first window, determine a second HR measure for a second window, wherein at least a portion of the first window occurs after the second window, and wherein the first window and the second window are separated by an intermediate window, determine at least one HR parameter based upon said first HR measure and said second HR measure, and identify an onset of the seizure event in response to determining that at least one HR parameter crosses an onset threshold.

[¶13] In some respects, disclosed is a computer program product embodied in a computer-operable medium, the computer program product comprising logic instructions, the logic instructions being effective to determine heart rate (HR) versus time, determine a first HR measure for a first window, determine a second HR measure for a second window, wherein at least a portion of the first window occurs after the second window, and wherein the first window and the second window are separated by an intermediate window, determine at least one HR parameter based upon said first HR measure and said second HR measure, and identify an onset of the seizure event in response to determining that at least one HR parameter crosses an onset threshold.

[¶14] Numerous additional embodiments are also possible.

[¶15] One particular advantage provided by at least one of the disclosed embodiments is a seizure detection algorithm that identifies both the start (or onset) of a seizure and the end of the seizure. An additional advantage provided by at least one of the disclosed embodiments is an algorithm with improved accuracy in detecting seizures.

D. Brief Description of the Drawings

[¶16] Other objects and advantages of the present disclosure may become apparent upon reading the detailed description and upon reference to the accompanying drawings.

[¶17] Figure 1 is a block diagram illustrating a system for identifying a seizure using heart beat data, in accordance with some embodiments.

[¶18] Figure 2 is a block diagram illustrating an alternative system for identifying a seizure using heart beat data, in accordance with some embodiments.

[¶19] Figure 3 is diagram illustrating an example of a circular buffer that may be used to store a moving window of heart beat data, in accordance with some embodiments.

[¶20] Figure 4 is a diagram illustrating an example of obtaining heart beat data from a subject using electrocardiogram equipment, in accordance with some embodiments.

[¶21] Figure 5 is a graph of heart rate versus time illustrating an example of identifying the onset of a seizure using heart rate measures in two or three windows, in accordance with some embodiments.

[¶22] Figure 6 is a graph of heart rate versus time illustrating an example of identifying the offset of a seizure using heart rate measures in two or three windows, in accordance with some embodiments.

[¶23] Figure 7 is a flow diagram illustrating a method for identifying a seizure onset and an end of the seizure using heart rate data, in accordance with some embodiments.

[¶24] Figure 8 is a flow diagram illustrating a method for identifying a seizure onset and an end of the seizure using heart rate data using an intermediate window, in accordance with some embodiments.

[¶25] Figure 9 is a flow diagram illustrating an alternative method for identifying a seizure onset and an end of the seizure using heart rate data, in accordance with some embodiments.

[¶26] While the present disclosure is subject to various modifications and alternative forms, specific embodiments of the claimed subject matter are shown by way of example in the drawings and the accompanying detailed description. The drawings and detailed description are not intended to limit the present claimed subject matter to the particular embodiments. This disclosure is instead intended to cover all modifications, equivalents, and alternatives falling within the scope of the present claimed subject matter.

E. Detailed Description

[¶27] One or more embodiments of the present claimed subject matter are described below. It should be noted that these and any other embodiments are exemplary and are intended to be illustrative of the claimed subject matter rather than limiting. While the present claimed subject matter is widely applicable to different types of systems, it is impossible to include all of the possible embodiments and contexts of the present claimed subject matter in this disclosure. Upon reading this disclosure, many alternative embodiments of the present claimed subject matter will be apparent to persons of ordinary skill in the art.

[¶28] The various illustrative logical blocks, modules, circuits, and algorithm steps described in connection with the embodiments disclosed here may be implemented as electronic/computer hardware, computer software, or combinations of the two. Various illustrative components, blocks, modules, circuits, and steps are described generally in terms of their functionality. Whether such functionality is implemented as hardware or software may depend upon the particular application and imposed design constraints. The described functionality may be implemented in varying ways for each particular application, but such implementation decisions should not be interpreted as causing a departure from the scope of the present claimed subject matter.

[¶29] In general, a seizure may cause an increase in a subject's heart rate (HR) during the onset of the seizure and a corresponding decrease in HR during/after the offset of a seizure. Typically, the HR may be at a resting HR before the seizure, may increase at the beginning of a seizure, rise to a certain peak HR during the seizure, and then decrease back to a resting HR after the seizure has ended. This series of HR changes associated with the seizure may be used in the seizure identification process.

[¶30] Referring to Figure 1, a particular illustrative embodiment of a block diagram illustrating a system for identifying a seizure using heart rate data is shown and generally designated 100. System 100 may include a heart rate data analyzer 110, which is configured to receive and analyze heart beat data 125. Heart beat data 125 may be a series of heart beats at given points in time. The heart beat data may be received in real time or near real time from a subject or the heart beat data may be data that was previously recorded and is being received from a storage device. In some embodiments, heart rate may be computed from the received heart beat data. In alternative embodiments, heart rate data may be received directly instead of or in addition to the heart beat data.

[¶31] In some embodiments, heart rate data analyzer 110 may be configured to analyze the heart beat data 125 and identify seizure events that the subject may have suffered and/or is currently suffering. Heart rate data analyzer 110 may be configured to monitor the heart rate within a certain window. In some embodiments, the window may comprise two or more windows of heart rate data or heart beat data 125. In some embodiments, a seizure onset (or seizure beginning) and a seizure end may be identified by comparing statistical measures of heart rate values in the windows.

[¶32] The functionality of heart rate data analyzer 110 may be implemented using one or more processors such as processor(s) 115 and one or more memory units coupled to the one or more processors such as memory unit(s) 120. The system 100 may be configured to determine heart rate (HR) versus time, to determine a first HR measure for a first window, and to determine a second HR measure for a second window, where at least a portion of the first window occurs after the second window. "HR measure" may refer to an instantaneous HR or may refer to a statistical measure of central tendency (e.g., a median or an average/mean) in a window (e.g., a time window or a number-of-beats window). Parameters such as HRV measures, or differences and/or ratios of short and long windows may be used to provide meaningful indications of changes in the cardiac status of a patient.

[¶33] The system 100 may be further configured to determine at least one HR parameter based upon said first HR measure and said second HR measure, to identify an onset of the seizure event in response to determining that at least one HR parameter crosses an onset threshold, and to identify an end of the seizure event in response to determining that at least one HR parameter crosses an offset threshold.

[¶34] Additionally, the first window and the second window may be separated by an intermediate window. The first window, the intermediate window, and the second window may be windows in either a time domain or a heart beat domain.

[¶35] Additionally, the first HR measure may be a first median HR in the first window, the second HR measure may be a second median HR in the second window, at least one HR parameter may be a ratio of the first median HR to the second median HR, the at least one HR parameter crossing the onset threshold may comprise the HR parameter being greater than the onset threshold. In one embodiment, the onset threshold may be 1.25, and the offset threshold may be a number less than 1.0, for example about 0.9.

[¶36] Additionally, the at least one HR parameter crossing the offset threshold may comprise the HR parameter being less than the offset threshold.

[¶37] Referring to Figure 2, a block diagram is provided showing one example of an embodiment of a system for identifying a seizure using heart beat data.

[¶38] The system, generally designated 200, may include a heart rate data analyzer 210, a heart beat detector 230 operative to provide heart beat data 225 to the heart rate data analyzer 210, a human interface input device 235, and a human interface output device 240.

The heart rate data analyzer 210 may include one or more memory unit(s) 220 and one or more processor(s) 215.

[¶39] In some embodiments, heart rate data analyzer 210 may be configured to receive and analyze heart beat data 225. Heart beat data 225 may be a time series of heart beat values sensed at given points in time. The heart beat data may be being received in real time or near real time from heart beat detection equipment, such as heart beat detector 230, connected to a subject. Heart beat detector 230, in some embodiments may comprise electrocardiogram equipment, which is configured to couple to a subject's body in order to detect the subject's heart beat. In some embodiments, a seizure may be identified by comparing median or average heart rate values in the windows.

[¶40] In some embodiments, heart rate data analyzer 210 may be configured to analyze the heart beat data and identify one or more of an onset (beginning) and an end of a seizure event that the patient may have suffered. The functionality of heart rate data analyzer 210 may be implemented using one or more processors such as processor(s) 215 and one or more memory units coupled to the one or more processors such as memory unit(s) 220.

[¶41] Heart rate data analyzer 110 of Fig. 1 and heart rate data analyzer 210 of Fig. 2 may be configured to monitor the heart rate within a certain window. In some embodiments, the window may comprise two or more windows of heart beat data. In some embodiments, a seizure onset and/or offset may be identified by determining one or more parameters based on the statistical measures of heart rate in the windows, and by comparing those parameters to seizure onset and/or seizure end thresholds, respectively.

[¶42] Heart rate data analyzer 210 may also be coupled to human interface input device 235 and human interface output device 240. Human interface input device 235 may be configured to allow a user of the system to input data into the system and to generally control various options. Accordingly, human interface input device 235 may be at least one of a keyboard, a touch screen, a microphone, a video camera, etc.

[¶43] Human interface output device 240 may be configured to provide information to a user of the system visually, audibly, etc. Accordingly, human interface output device 240 may be at least one of a display, one or more audio speakers, haptic feedback device, etc. In some embodiments, input device 235 and output device 240 may comprise a single physical unit. In some embodiments, heart rate data analyzer 210, input device 235, and output device 240 may comprise a single physical unit.

[¶44] Referring to FIG. 3, a particular embodiment of a circular buffer used to store a moving window of heart beat data is shown and generally designated 310. The circular buffer 310 may be configured to store two or more windows of heart beat data, for which computations may be performed in order to identify the onset and/or offset of an epileptic seizure. Circular buffer 310 may comprise first window 325, intermediate window 320, and second window 315. First window 325 may comprise the newest heart beat data, intermediate window 320 may comprise intermediate heart beat data, and second window 315 may comprise the oldest heart beat data.

[¶45] In some embodiments, circular buffer 310 is configured to store a moving window of heart beat data versus time. Heart beat data in the circular buffer 310 shifts to the left as new heart beat data enters the right side of the circular buffer 310. As the heart rate data shifts to the left, the older data at the left side of the circular buffer 310 is overwritten, and thereby removed, at the left side of the circular buffer 310. Therefore, as newer heart beat data enters the circular buffer 310, the windows "move" to the right in time.

[¶46] In some embodiments, circular buffer 310 may be configured to store two or more windows of heart beat data, for which computations may be performed in order to identify the onset and/or offset of a seizure. In some embodiments, only data from first window 325 and second window 315 may be used in the calculations while data from intermediate window 320 may be discarded as discussed here. Circular buffer 310 may be implemented similarly for either time windows, number-of-beats windows, or embodiments in which some of the windows 325, 320, and 315 are time windows and others are number-of-beats windows.

[¶47] Referring to Figure 4, a particular embodiment of a system for monitoring heart beat data from a subject is shown and generally designated 400. System 400 may include a computer 410, a heart beat sensor 440, and a controller 455.

[¶48] In some embodiments, heart beat and/or heart rate data may be collected by using an external or implanted heart beat sensor and related electronics (such as heart beat sensor 440), and a controller that may be wirelessly coupled to the sensor for detecting seizure events based upon the patient's heart signal, such as controller 455. In one embodiment, sensor 440 may comprise electrodes in an externally worn patch adhesively applied to a skin surface of patient 485. The patch may include electronics for sensing and determining a heart beat signal (e.g., an ECG signal), such as an electrode, an amplifier and associated filters for processing the raw heart beat signal, an A/D converter, a digital signal processor, and in some embodiments, an RF transceiver wirelessly coupled to a separate controller unit, such as controller 455. In some embodiments, the controller unit may be part of the patch electronics.

[¶49] The controller 455 may implement an algorithm for detection of seizure events based on the heart signal. It may comprise electronics and memory for performing computations of, e.g. HR parameters such as median HR values for the first and second windows, determination of ratios and/or differences of the first and second HR measures, and determination of seizure onset and offset times according to the foregoing disclosure. In some embodiments, the controller 455 may include a display and an input/output device. The controller 455 may comprise part of a handheld computer such as a PDA, a cellphone, an iPod® or iPad®, etc.

[¶50] In the example shown, patch 440 may be placed on a body surface suitable for detection of heart signals. Electrical signals from the sensing electrodes may be then fed into patch electronics for filtering, amplification and A/D conversion and other preprocessing, and creation of a time-of-beat sequence (e.g., an R-R interval data stream), which may then be transmitted to controller 455. Patch 440 may be configured to perform various types of processing to the heart rate data, including filtering, determination of R-wave peaks, calculation of R-R intervals, etc. In some embodiments, the patch electronics may include the functions of controller 455, illustrated in Fig. 4 as separate from patch 440.

[¶51] The time-of-beat sequence may be then provided to controller 455 for processing and determination of seizure onset and offset times and related seizure metrics. Controller 455 may be configured to communicate with computer 410. Computer 410 may be located in the same location or computer 410 may be located in a remote location from controller 455. Computer 410 may be configured to further analyze the heart data, store the data, retransmit the data, etc. Computer 410 may comprise a display for displaying information and results to one or more users as well as an input device from which input may be received by the one or more users. In some embodiments, controller 455 may be configured to perform various tasks such as calculating first and second HR measures, HR parameters, comparing HR parameters to appropriate thresholds, and determining of seizure onset and seizure end times, and other seizure metrics.

[¶52] In some respects, disclosed is a computer program product embodied in a computer-operable medium, the computer program product comprising logic instructions, the logic instructions being effective to determine heart rate (HR) versus time, to determine a first HR measure for a first window, to determine a second HR measure for a second window, where at least a portion of the first window occurs after the second window. The logic instructions are further effective to determine at least one HR parameter based upon said first HR measure and said second HR measure, to identify an onset of the seizure event in response to determining that at least one HR parameter crosses an onset threshold, and to identify an end of the seizure event in response to determining that at least one HR parameter crosses an offset threshold.

[¶53] Additionally, in some embodiments the first window and the second window are separated by an intermediate window. The first window, the intermediate window, and the second window may be windows in either a time domain or heart beat domain.

[¶54] Additionally, the first HR measure may be a statistical measure of central tendency of heart rate in the first window (e.g., a median or average), the second HR measure may be a statistical measure of central tendency of heart rate in the second window, the at least one HR parameter may be a ratio of the first HR measure and the second HR measure, the at least one HR parameter crossing the onset threshold may comprise the HR parameter being greater than the onset threshold. In one embodiment, the onset threshold may be 1.25, and the offset threshold may be 1.1.

[¶55] Additionally, the at least one HR parameter crossing the offset threshold may comprise the HR parameter being less than the offset threshold.

[¶56] Additionally, the first window, the intermediate window, and the second window may be moving windows stored in a circular buffer, such as the circular buffer 310 of Figure 3.

[¶57] In some embodiments, system 400 may be configured to detect a seizure by monitoring heart beat data versus time data for a subject/patient. The subject's time of beat sequence may be obtained in real time or near real time using various methods, including well-known electrocardiogram (ECG) processes. In alternative embodiments, previously stored/recorded HR data may be provided for analysis.

[¶58] It should also be noted that the heart beat data may be also received as a series of heart beats, each with a time stamp. In such embodiments, HR may be computed from the heart beat data. In some embodiments, the HR may be computed by dividing 60 by the time (in seconds) between two consecutive heart beats. In other embodiments, more advanced mathematical methods may be implemented (such as filtering, etc.) to more accurately compute HR data from heart beat data. In some embodiments, calculations may be performed using heart beat data (e.g., R-R intervals) instead of heart rate data. Although many particular embodiments hereinafter are described with calculations based on heart rate and/or heart rate parameters, similar or equivalent calculations may be performed using heart beat data and/or parameters, without determining heart rate.

[¶59] In general, a seizure may cause an increase in a subject's HR during the onset of the seizure and a corresponding decrease in HR during/after the offset of a seizure. Typically, the HR may be at a resting HR before the seizure, may increase at the beginning of a seizure, rise to a certain peak HR during the seizure, and then decrease back to a resting HR after the seizure has ended. This series of HR changes associated with the seizure may be used in the seizure identification process.

[¶60] Referring to FIG. 5, a particular illustrative embodiment of a graph of heart rate versus time illustrating an example of identifying the onset of a seizure using heart rate measures in two or three windows is shown and generally designated 510.

[¶61] Graph 510 shows the rise of a subject's heart rate (HR) from a pre-ictal baseline HR to a peak HR (at point 540) following the onset of a seizure at time S 545. Graph 510 also shows the decrease of a subject's heart rate (HR) from peak HR 540 to a post-ictal baseline HR (at point 550) following the end of a seizure. Examples of moving time windows of HR data are also shown. In this example, the moving windows comprise first window 525, intermediate window 520, and second window 515, determined for a time Td occurring at the end of the first window, at a time when a seizure event is detected. As illustrated, window 525 comprises an immediately preceding time period relative to time Td 547, and may be referred to as a foreground time window. Time window 515, in contrast, occurs in a time period prior to window 525, and may be referred to as a background time window. Time window 520 occurs between windows 525 and 515 and may be termed an intermediate window. As time moves forward from time Td 547, the windows 525, 520, and 515 would also move forward, and HR measures determined for those windows would likewise change as the heart beats falling within the windows change.

[¶62] As illustrated in Figure 5, intermediate window 520 occurs in the early phase of an HR increase, and comprises a period of time later than second window 515, which occurs in a period of time prior to the emergence of an HR increase, while first window 525 occurs in a later phase of an HR increase, and comprises a period of time later than intermediate window 520.

[¶63] In some embodiments, the onset of a seizure may be identified by computing and comparing heart rate measures for first window 525 and second window 515 as discussed here. The data from intermediate window 520, which may contain transient values, may be discarded.

[¶64] Without being limited by theory, it is believed that providing an intermediate window allows the transitional effect of moving from a stable heart rate (second window) to an increasing heart rate (first window) to be isolated and removed. Consequently, the contrast between a relatively stable heart rate (second window) and an increasing heart rate (first window), as measured by a ratio of the windows, is detected more quickly. As shown in Fig. 5 for a point Td 547 at which a seizure is detected, the average or median heart rate for the background (second) window 515 remains low while the average or median heart rate for the foreground (first) window has risen noticeably above the background rate. Because of intermediate window 20, the value of the background (second window) heart rate does not reflect any of the increase in HR that began at point S, associated with a HR increase caused by a seizure. Thus the ratio HR1/HR2 reaches a threshold value sooner.

[¶65] Referring to FIG. 6, a particular embodiment of a graph of heart rate versus time illustrating an example of identifying the end of a seizure using heart beat data in two or three windows is shown and generally designated 610.

[¶66] Graph 610 shows the rise of a subject’s heart rate (HR) from a stable HR (at point S 645) to a peak HR (at point 640) following the onset of a seizure. Graph 610 also shows the decrease of a subject’s heart rate (HR) from a peak HR (at point 640) to a stable HR (at point 650) following the end of a seizure. An example of a moving time window of HR data is shown. In this example, the moving window comprises first window 625, intermediate window 620, and second window 615.

[¶67] In some embodiments, the offset of the seizure may be identified by computing and comparing heart rate measures for first window 625 and second window 615 as discussed here. The data from intermediate window 620, which may contain transient values, may be discarded.

[¶68] Referring to Figures 5-6, a window of HR (or heart beat) values versus time may be processed in order to identify a seizure event. The window may be a moving window in time, and in some embodiments, the window may be a moving window in real time in order to provide real time or near real time detection of seizures. In some embodiments, the moving window may be a number-of-beats window instead of a time window. The window may be implemented using the circular buffer 310 of Figure 3. In some embodiments, newer values may enter the buffer on one side as older values are deleted from the buffer on the other side. In some embodiments, the circular buffer 310 may be implemented using one or more pointers to indicate the memory location of the buffer "sides", such that newer values simply overwrite the older values while the side pointer(s) point to a new location.

[¶69] In some embodiments, the time window may comprise two time/heart beat windows: a first window and a second window, where at least a portion of the first window occurs after the second window. The first window may have a chosen first time/heart beat width, and the second window may have a chosen second time/heart beat width. The first and second widths may be each chosen in such a way as to optimize the identification of seizures. For example, the widths may be chosen by maximizing the accuracy of the identification process using binary statistics.

[¶70] In some embodiments, a first HR measure may be computed for the first window, a second HR measure may be computed for the second window, and at least one HR parameter may be determined based on the first HR measure and the second HR measure. A seizure onset may then be identified in response to determining that at least one HR parameter crosses an onset threshold. Similarly, a seizure offset may be identified in response to determining that at least one HR parameter crosses an offset threshold.

[¶71] In some embodiments, the first HR measure may be a first statistical measure of central tendency of HR in the first window, and the second HR measure may be a second statistical measure of central tendency of HR in the second window. In some embodiments, the first HR measure and the second HR measure may be computed using various averaging methods such the mean, the median, Gaussian-weighted values centered around a point in the window, etc.

[¶72] In some embodiments, at least one of the HR parameters may be a ratio of the first HR measure to the second HR measure. In alternative embodiments, at least one of the HR parameters may be a difference between the first HR measure and the second HR measure. A seizure onset may be then identified in response to determining that the HR parameter is greater than an onset threshold value. Similarly, a seizure offset (the end of the seizure) may be identified in response to determining that the HR parameter is less than an offset threshold value.

[¶73] In some embodiments, at least one of the HR parameters may be a duration of another HR parameter exceeding a threshold value. For example, a seizure onset may be identified only when a ratio of the first HR measure and the second HR measure exceeds a threshold value for at least a defined time period, such as 5, 10, or 15 seconds. Such a duration constraint threshold could be used to avoid a false positive detection when the patient undergoes a brief period of HR elevation such as standing from a sitting or reclined position, or climbing a flight of stairs.

[¶74] In some embodiments, the first HR measure may be a first standard deviation of HR in the first window, and the second HR measure may be a second standard deviation of HR in the second window. In some embodiments, at least one of the HR parameters may be the difference between the first standard deviation HR and the second standard deviation HR. In some embodiments, at least one of the HR parameters may be a ratio of the first standard deviation and the second standard deviation. A seizure onset or offset may be then identified (or in some embodiments, the seizure identification may be confirmed) in response to determining that the HR parameter is greater than an onset or offset threshold value.

[¶75] In some embodiments, a seizure detection (i.e., the detection of a seizure onset) may be additionally confirmed by determining that the end of the seizure occurs within a certain time range from the seizure detection or onset. Accordingly, by restricting the time range within which the offset of a seizure may occur after the onset of the seizure to typical time ranges for a seizure, events with time ranges between detection of seizure onset and detection of seizure end that do not fall within typical or known time ranges of seizures may be rejected as seizures. In some embodiments, the time ranges may be patient-specific, i.e., determined from historical data for the patient's own seizures, while in other embodiments the ranges may be based upon aggregate data for particular patient populations. In alternative embodiments, events falling outside seizure duration ranges may be classified as other (non-seizure) events based on factors such as the magnitude, duration and trajectory of the rise and fall of the patient's heart rate. For example, events with a time range of less than 5 seconds and greater than 10 minutes may be rejected as seizures in some embodiments. In some embodiments, other data (e.g., a triaxial accelerometer) may be used to confirm or reject seizures in conjunction with the foregoing time ranges between seizure onset and seizure end.

[¶76] In some embodiments, an intermediate window may be introduced between the first and second windows. In some embodiments, HR values in the intermediate window may be discarded and not used in either the first or the second window calculations. The intermediate window may be introduced in order to discard transient values that may occur between the first window, in which HR may have already increased, and the second window, where the HR may be substantially at a stable value. By discarding transient values in the intermediate window, the ability to distinguish between a relatively stable HR and an increasing HR based on the first and second HR measures is increased.

[¶77] In embodiments where moving windows are used, as the windows move, new HR measures (and thus HR parameters) may be computed for each set of windows and the seizure (onset and/or offset) identification test may be applied repeatedly.

[¶78] In one exemplary embodiment, a circular buffer of a window of 50 heart beats or samples may be used. The first window may be assigned 9 samples, the intermediate window may be assigned 14 samples, and the second window may be assigned 27 samples, for example. Accordingly, a seizure onset may be identified in response to determining that the first average HR is greater than the second average HR (in embodiments where the HR measures are average HRs for the respective windows) by 25%, or equivalently that the ratio of the first HR measure to the second HR measure exceeds 1.25. Similarly, a seizure offset may be identified in response to determining that the first average HR is smaller than the second average HR (in embodiments where the HR measures are average HRs); i.e., the ratio of the first HR measure and the second HR measure falls below 1 after initially rising above a threshold exceeding 1. In one embodiment, the detection may occur when the first average HR is more than 10% smaller than the second average HR, or equivalently that the ratio of the first HR measure to the second HR measure is less than about 0.9.

[¶79] In another embodiment, a moving time window may be used such that the beats within a short-term window (for example 10 seconds) may be used to determine a median HR based on all of the beats within that window. Since the window is a time window, the number of beats used in determining the median HR may vary. An intermediate time window may also be proposed in which beats occurring in that window are ignored. This window would typically be a relatively short time window, such as 5-10 seconds, although shorter or longer intermediate windows are permissible. Lastly, a longer time window, for example the 300 seconds prior to the intermediate window, may define a second window for determination of a background HR based upon a statistical measure of central tendency of the beats within that window. As with the first window, the number of beats would not be fixed.

[¶80] It should also be noted that, in some embodiments, the invention may be implemented using a time-of-beat sequence for a patient's heart. In such embodiments, a sequence of times is provided at which a characteristic cardiac value (such as R waves) are detected by a sensing element. It will be appreciated that HR is determined from successive R waves by determining the R-R interval (RRI) through the formula HR = 60/RRI. Heart rate may be measured on an instantaneous basis using only the two immediately preceding R waves, although such calculations are frequently characterized by significant variations relating to the natural heart rate variability (HRV) associated with the respiratory and other systems. For this reason, median or moving average HR values may be used over longer time frames, such as 5 seconds, 10 seconds or 30 seconds, to "smooth" the HR and provide a more meaningful indication of patient status.

[¶81] Referring to FIG. 7, a particular embodiment of a flow diagram illustrating a method for identifying a seizure onset and a seizure end using heart rate data is shown and generally designated 700.

[¶82] In some embodiments, the method illustrated in this figure may be performed by one or more of the systems illustrated in Figures 1-3.

[¶83] At block 710 of method 700, heart beat data versus time is determined. In some embodiments, the data may be provided in real time or near real time or the data may be previously stored data that may be retrieved from storage.

[¶84] At block 715, a first HR measure for a first window is determined, and at block 720, a second HR measure for a second window is determined, where at least a portion of the first window occurs after the second window.

[¶85] At block 725, at least one HR parameter based upon said first HR measure and said second HR measure is determined. In one nonlimiting example, one of the HR parameters may be a ratio of the first and second HR measures. In another nonlimiting example, the difference between the first HR measure and the second HR measure may also be used as a HR parameter

[¶86] At block 730, an onset of the seizure event may be identified in response to determining that at least one HR parameter crosses an onset threshold. At block 735, an end of the seizure event may be identified in response to determining that at least one HR parameter crosses an offset threshold. In one nonlimiting example, a seizure onset may be identified when the ratio of the first and second HR measures exceeds 1.25, and the seizure end may be identified when the ratio falls below a threshold of about 1.0 (about 0.9, for example). In another example, an end of a seizure may be detected when the first HR value reaches a peak value and begins to decline, or declines by more than a threshold percentage or a threshold bpm magnitude. Other HR parameters may be used to determine seizure onset and end. For example, duration constraints may also be required, such that the seizure onset and offset may not be declared unless the onset or offset threshold is exceeded for 5 consecutive seconds. For example, the end of a seizure may be declared when the ratio of the first and second threshold falls below 1.0 and remains below 1.0 for 10 consecutive seconds, or alternatively that the first HR value declines for 10 consecutive seconds.

[¶87] Additionally, the method 700 may further comprise an intermediate window separating the first window and the second window. The first window, the intermediate window, and the second window may be windows in either a time domain or heart beat domain. Additionally, the first window, the intermediate window, and the second window may be moving windows stored in a circular buffer.

[¶88] Additionally, the first HR measure may be a statistical measure of central tendency of heart rate in the first window (e.g., a median or average), the second HR measure may be a statistical measure of central tendency of heart rate in the second window, at least one HR parameter may be a ratio of the first HR measure and the second HR measure, identifying an onset of the seizure event may comprise the HR parameter being greater than the onset threshold, and identifying the end of the seizure event may comprise the HR parameter being less than the offset threshold.

[¶89] Referring to FIG. 8, a particular illustrative embodiment of a flow diagram illustrating a method for identifying a seizure using heart rate data is shown and generally designated 800. In some embodiments, the method illustrated in this figure may be performed by one or more of the systems illustrated in Figures 1-3.

[¶90] At block 810 of method 800, heart beat data versus time is determined. In some embodiments, the data may be provided in real time or near real time or the data may be previously stored data that may be retrieved from storage.

[¶91] At block 815, a first HR measure for a first window is determined, and at block 820, a second HR measure for a second window is determined, where at least a portion of the first window occurs after the second window, and where the first window and the second window are separated by an intermediate window such that at least a portion of the intermediate window occurs after the second window and before the first window.

[¶92] At block 825, at least one HR parameter is determined based upon said first HR measure and said second HR measure.

[¶93] At block 830, an onset of the seizure event is identified in response to determining that at least one HR parameter crosses an onset threshold.

[¶94] Additionally, the method 800 may further comprise identifying an end of the seizure event in response to determining that at least one HR parameter crosses an offset threshold.

[¶95] Referring to FIG. 9, a particular illustrative embodiment of a flow diagram illustrating a method for identifying a seizure using heart rate data is shown and generally designated 900.

[¶96] In some embodiments, the method illustrated in this figure may be performed by one or more of the systems illustrated in FIGS. 1-3.

[¶97] At block 910, heart beat from a subject is detected. In some embodiments, an electrocardiogram may be used to detect an R-wave sequence and determine a time-of-beat sequence of a heart beat of the patient.

[¶98] At block 915, a statistical measure of central tendency of heart rate in a first window is determined using the detected time-of-beat sequence. The statistical measure may be determined for R-R intervals rather than heart rate; the R-waves in the R-wave sequence need not be mathematically transformed into heart rate using the formula HR = 60/(R-R interval). Other heart rate measures for the first window. For example standard deviation of heart rate, may also be determined.

[¶99] At block 920, a statistical measure of central tendency of heart rate in a second window is determined from the time-of-beat sequence, where the first window and the second window are separated by an intermediate window such that at least a portion of the intermediate window occurs after the second window and before the first window. Other heart rate measures for the second window, for example standard deviation of heart rate, may also be determined.

[¶100] At block 930, one or more heart rate parameters may be determined for the first and second windows from the heart rate measures determined in steps 915 and 920. The heart rate parameters may include, for example, a ratio of the statistical measures of central tendency of heart rate in the first and second windows; a difference between the statistical measure of central tendency of heart rate in the first and second windows; a difference between the first standard deviation of heart rate in the first window and the second window; and a ratio of the standard deviations of heart rate in the first and second windows.

[¶101] At decision 935, a determination is made as to whether at least one of one or more seizure detection criteria is met. In one embodiment, the detection criteria may include one or more of: 1) whether the ratio of the statistical measure of central tendency of heart rate for the first window to the statistical measure of central tendency of heart rate for the second window is greater than an onset threshold ratio (e.g., 1.25); and 2) whether the difference between the statistical measure of central tendency of heart rate for the first window minus the statistical measure of central tendency of heart rate for the second window exceeds a first difference threshold. In some embodiments, the detection criteria may also include one or more of: whether the first standard deviation is less than the second standard deviation; and whether the ratio of the first standard deviation to the second standard deviation is less than a threshold (e.g., 0.9). If the detection criteria of decision 935 is/are false, decision 935 branches to the "no" branch and processing continues at block 910, where new data is processed.

[¶102] On the other hand, if the condition(s) of decision 935 is/are true, decision 935 branches to the "yes" branch where, at block 940, the time at which the decision criteria became true (e.g., a timestamp) is indicated as a seizure onset time. In some embodiments, a detection (i.e., seizure onset) flag is set. In some embodiments, setting the detection flag indicates that a seizure onset has been detected, a fact that will be used later during the processing.

[¶103] At decision 945, a determination is made as to whether at least one of one or more seizure end decision criteria is met. In one embodiment, the seizure end criteria may include one or more of: 1) whether the ratio of the statistical measure of central tendency of heart rate in the first window to the statistical measure of central tendency in the second window is below an offset threshold (e.g. 0.9); 2) whether an absolute value of a difference between the statistical measure of central tendency of heart rate in the first window and the statistical measure of central tendency of heart rate in the second window is above an offset difference threshold (e.g., 10 bpm); and 3) whether the detection flag is set. If the condition(s) of decision 945 is false, decision 945 branches to the "no" branch and processing continues at block 910, where new data is processed.

[¶104] On the other hand, if the condition(s) of decision 945 is true, decision 945 branches to the "yes" branch where, at block 950, the time at which the offset criteria became true is indicated as a seizure end time, and in embodiments the detection (i.e., seizure onset) flag is reset and/or cleared, or a seizure end flag may be set. Appropriate determination and logging of statistical and other measures of the seizure event (e.g., onset and offset time, duration, magnitude of HR increase/decrease, etc.) may also be determined.

[¶105] Processing subsequently returns to block 910, where new data is processed.

[¶106] In some respects, disclosed is a method for characterizing a seizure event in a patient, the method comprising determining heart rate (HR) versus time, determining a first HR measure for a first window, determining a second HR measure for a second window, wherein the first window occurs after the second window, and wherein the first window and the second window are separated by an intermediate window, determining at least one HR parameter based upon said first HR measure and said second HR measure, identifying an onset of the seizure event in response to determining that at least one HR parameter crosses an onset threshold and crosses a seizure end threshold after crossing the onset threshold.

[¶107] In some respects, disclosed is a system for characterizing a seizure event in a patient, the system comprising one or more processors, one or more memory units coupled to the one or more processors, the system being configured to determine a time of beat sequence of the patient's heart, determine a first HR measure for a first window, determine a second HR measure for a second window, wherein at least a portion of the first window occurs after the second window, determine at least one HR parameter based upon the first HR measure and the second HR measure, identify a seizure event in response to determining 1) that at least a first HR parameter crosses an onset threshold,, and 2) that at least a second HR parameter crosses a seizure end threshold after the first HR parameter crosses the onset threshold.

[¶108] Additionally, the first window and the second window may be separated by an intermediate window. The first window, the intermediate window, and the second window may be windows in either a time domain or a heart beat domain.

[¶109] Additionally, the first HR measure may be a first median HR in the first window, the second HR measure may be a second median HR in the second window, a first and second HR parameter may be a ratio of the first median HR to the second median HR, the at least a first HR parameter crossing the onset threshold may comprise the ratio of the first median HR to the second median HR being greater than the onset threshold, and the at least a second HR parameter crossing the seizure end threshold may comprise the ratio of the first median HR to the second median HR being less than the offset threshold. In one embodiment, the onset threshold may be 1.25, and the offset threshold may be 1.0.

[¶110] In some respects, disclosed is a system for characterizing a seizure event in a patient, the system comprising one or more processors, one or more memory units coupled to the one or more processors, the system being configured to determine a time of beat sequence of the patient's heart, determine a first HR measure for a first window, determine a second HR measure for a second window, wherein the first window occurs after the second window, and wherein the first window and the second window are separated by an intermediate window, determine at least one HR parameter based upon the first HR measure and the second HR measure, identify a seizure event in response to determining that at least one HR parameter crosses an onset threshold.

[¶111] Additionally, the system may be further configured to identify an end of the seizure event in response to determining that at least one HR parameter crosses a seizure end threshold.

[¶112] In some respects, disclosed is a computer program product embodied in a computer-operable medium, the computer program product comprising logic instructions, the logic instructions being effective to determine a time of beat sequence of the patient's heart, determine a first HR measure for a first window, determine a second HR measure for a second window, wherein at least a portion of the first window occurs after the second window, determine at least one HR parameter based upon the first HR measure and the second HR measure, and identify a seizure event in response to determining 1) that at least a first HR parameter crosses an onset threshold, and 2) that at least a second HR parameter crosses an end of seizure threshold after the first HR parameter crosses the onset threshold.

[¶113] Additionally, in some embodiments the first window and the second window are separated by an intermediate window. The first window, the intermediate window, and the second window may be time windows or number-of-beat windows.

[¶114] In some respects, disclosed is a computer program product embodied in a computer-operable medium, the computer program product comprising logic instructions, the logic instructions being effective to determine a time of beat sequence of the patient's heart, determine a first HR measure for a first window, determine a second HR measure for a second window, wherein the first window occurs after the second window, and wherein the first window and the second window are separated by an intermediate window, determine at least one HR parameter based upon the first HR measure and the second HR measure, and identify a seizure event in response to determining that at least one HR parameter crosses an onset threshold.

[¶115] Additionally, the instructions may be further effective to identify an end of the seizure event in response to determining that at least one HR parameter crosses a seizure end threshold.

[¶116] In many embodiments previously discussed, identification of seizures is disclosed in terms of "heart rate measures" or "heart rate parameters." In some embodiments, calculations may be performed using heart beat data (e.g., R-R intervals) instead of heart rate data. Calculations performed for seizure detection may be made using either heart rate data or heart beat data. Thus, in embodiments involving calculations of "heart rate" measures and/or parameters, similar or equivalent calculations may be performed using heart beat data, without determining heart rate. "HR measure" may refer to an instantaneous HR or may refer to a statistical measure of central tendency (e.g., a median or an average/mean) in a window (e.g., a time window or a number-of-beats window).

[¶117] "HR measure" may refer to an instantaneous HR or may refer to a statistical measure of central tendency (e.g., a median or an average/mean) in a window (e.g., a time window or a number-of-beats window). Parameters such as differences and/or ratios of short and long windows may be used to provide meaningful indications of changes in the cardiac status of a patient. Additional parameters, such as duration constraints, may also be imposed to minimize false positive and/or negative seizure detections. Duration constraints may require, for example, that threshold crossings be maintained for a defined duration or longer, or must occur for a defined duration or less.

[¶118] The previous description of the disclosed embodiments is provided to enable persons skilled in the art to make or use the present claimed subject matter. Various modifications to these embodiments will be readily apparent to those skilled in the art, and the claimed subject matter is not intended to be limited to the embodiments shown herein but is to be accorded the widest scope consistent with the principles and novel features disclosed herein.

[¶119] The benefits and advantages that may be provided by the present claimed subject matter have been described above with regard to specific embodiments. These benefits and advantages, and any elements or limitations that may cause them to occur or to become more pronounced are not to be construed as critical, required, or essential features of any or all of the claims. As used here, the terms “comprises,” “comprising,” or any other variations thereof, are intended to be interpreted as non-exclusively including the elements or limitations which follow those terms. Accordingly, a system, method, or other embodiment that comprises a set of elements is not limited to only those elements and may include other elements not expressly listed or inherent to the claimed embodiment.

[¶120] While the present claimed subject matter has been described with reference to particular embodiments, it should be understood that the embodiments are illustrative and that the scope of the claimed subject matter is not limited to these embodiments. Many variations, modifications, additions and improvements to the embodiments described above are possible. It is contemplated that these variations, modifications, additions and improvements fall within the scope of the present disclosure as detailed within the following claims.

Claims

What is claimed is:

1. A method for characterizing a seizure event in a patient, the method comprising:

   determining a time of beat sequence of the patient's heart;

   determining a first HR measure for a first window;

   determining a second HR measure for a second window, wherein at least a portion of the first window occurs after the second window;

   determining at least one HR parameter based upon said first HR measure and said second HR measure;

   identifying an onset of the seizure event in response to determining that at least one HR parameter crosses an onset threshold; and

   identifying an end of the seizure event in response to determining that at least one HR parameter crosses a seizure end threshold.

2. The method of claim 1, further comprising an intermediate window, where at least a portion of the intermediate window occurs after the second window and before the first window.

3. The method of claim 2, where the first window, the intermediate window, and the second window are one of time windows and number-of-beats windows.

4. The method of claim 1,

   where the first HR measure is a statistical measure of central tendency of HR in the first window;

   where the second HR measure is a statistical measure of central tendency of HR in the second window;

where at least one HR parameter is a ratio of the first HR measure to the second HR measure;

where the at least one HR parameter crossing the onset threshold comprises the HR parameter being greater than the onset threshold.

5. The method of claim 4, where the at least one HR parameter crossing the seizure end threshold comprises the HR parameter being less than the seizure end threshold.

6. The method of claim 5, where the statistical measure of central tendency of HR in the first window is a median HR in a foreground time window, and the statistical measure of central tendency of HR in the second window is a median HR in a background window prior to the first window.

7. A system for identifying seizures, the system comprising:

one or more processors;

one or more memory units coupled to the one or more processors;

the system being configured to:

determine a time of beat sequence of the patient's heart;

determine a first HR measure for a first window;

determine a second HR measure for a second window, wherein at least a portion of the first window occurs after the second window;

determine at least one HR parameter based upon said first HR measure and said second HR measure;

identify an onset of the seizure event in response to determining that at least one HR parameter crosses an onset threshold;

identify an end of the seizure event in response to determining that at least one HR parameter crosses a seizure end threshold.

8. The system of claim 7, further comprising an intermediate window, where at least a portion of the intermediate window occurs after the second window and before the first window.

9. The system of claim 8, where the first window, the intermediate window, and the second window are one of time windows and number-of-beats windows.

10. The system of claim 7,

where the first HR measure is a statistical measure of central tendency of HR in the first window;

where the second HR measure is a statistical measure of central tendency of HR in the second window;

where at least one HR parameter is a ratio of the first HR measure to the second HR measure;

where the at least one HR parameter crossing the onset threshold comprises the HR parameter being greater than the onset threshold.

11. The system of claim 7, where the at least one HR parameter crossing the seizure end threshold comprises the HR parameter being less than the seizure end threshold.

12. The system of claim 11, where the statistical measure of central tendency of HR in the first window is a median HR in a foreground time window, and the statistical measure of central tendency of HR in the second window is a median HR in a background window prior to the first window.

13. A computer program product embodied in a computer-operable medium, the computer program product comprising logic instructions, the logic instructions being effective to:

determine a first HR measure for a first window in a time series of heart beat data for a patient;

determine a second HR measure for a second window, wherein at least a portion of the first window occurs after the second window;

determine at least one HR parameter based upon said first HR measure and said second HR measure;

identify an onset of the seizure event in response to determining that at least one HR parameter crosses an onset threshold;

identify an end of the seizure event in response to determining that at least one HR parameter crosses a seizure end threshold.

14. The product of claim 13, further comprising an intermediate window, where at least a portion of the intermediate window occurs after the second window and before the first window.

15. The product of claim 14, where the first window, the intermediate window, and the second window are one of time windows and number-of-beat windows.

16. The product of claim 13,

where the first HR measure is a statistical measure of central tendency of HR in the first window;

where the second HR measure is a statistical measure of central tendency of HR in the second window;

where at least one HR parameter is a ratio of the first HR measure to the second HR measure;

where the at least one HR parameter crossing the onset threshold comprises the HR parameter being greater than the onset threshold.

17. The product of claim 16, where the at least one HR parameter crossing the seizure end threshold comprises the HR parameter being less than the seizure end threshold.

18. The product of claim 17, where statistical measure of central tendency of HR in the first window is a median HR in a foreground time window, and the statistical measure of central tendency of HR in the second window is a median HR in a background window prior to the first window.

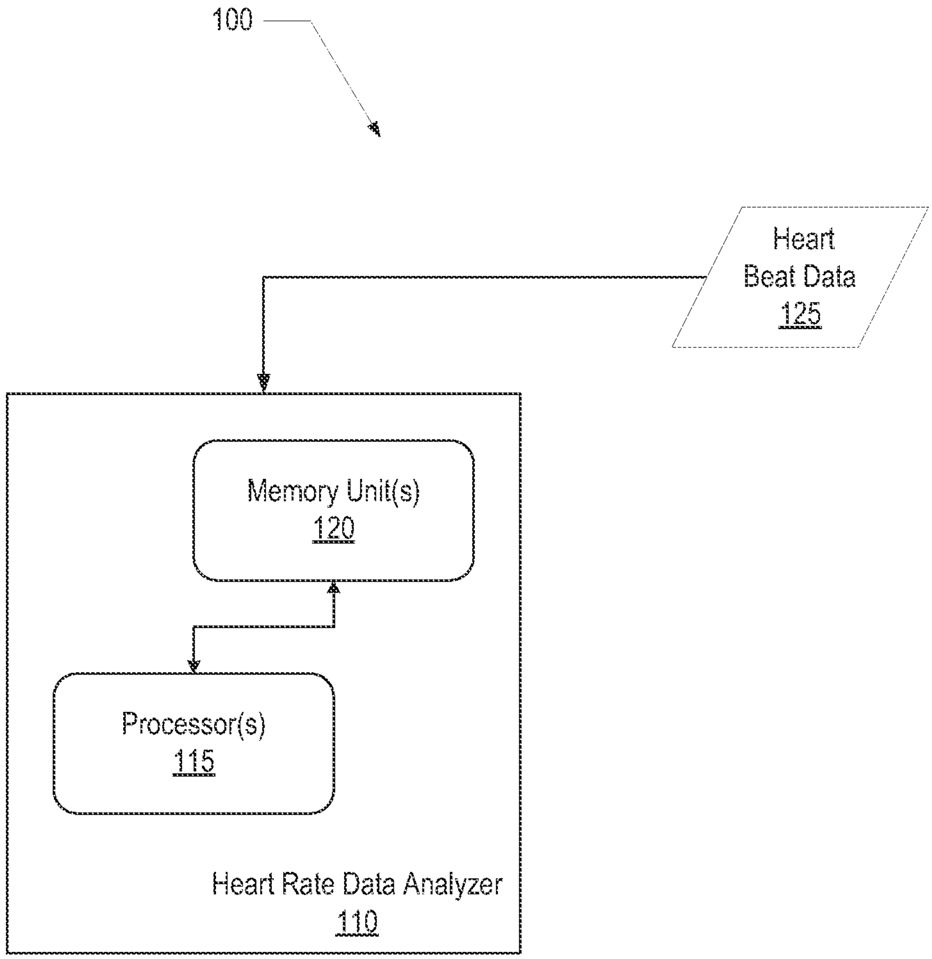

100
Heart
Beat Data
125
Memory Unit(s)
120
Processor(s)
115
Heart Rate Data Analyzer
110

Fig. 1

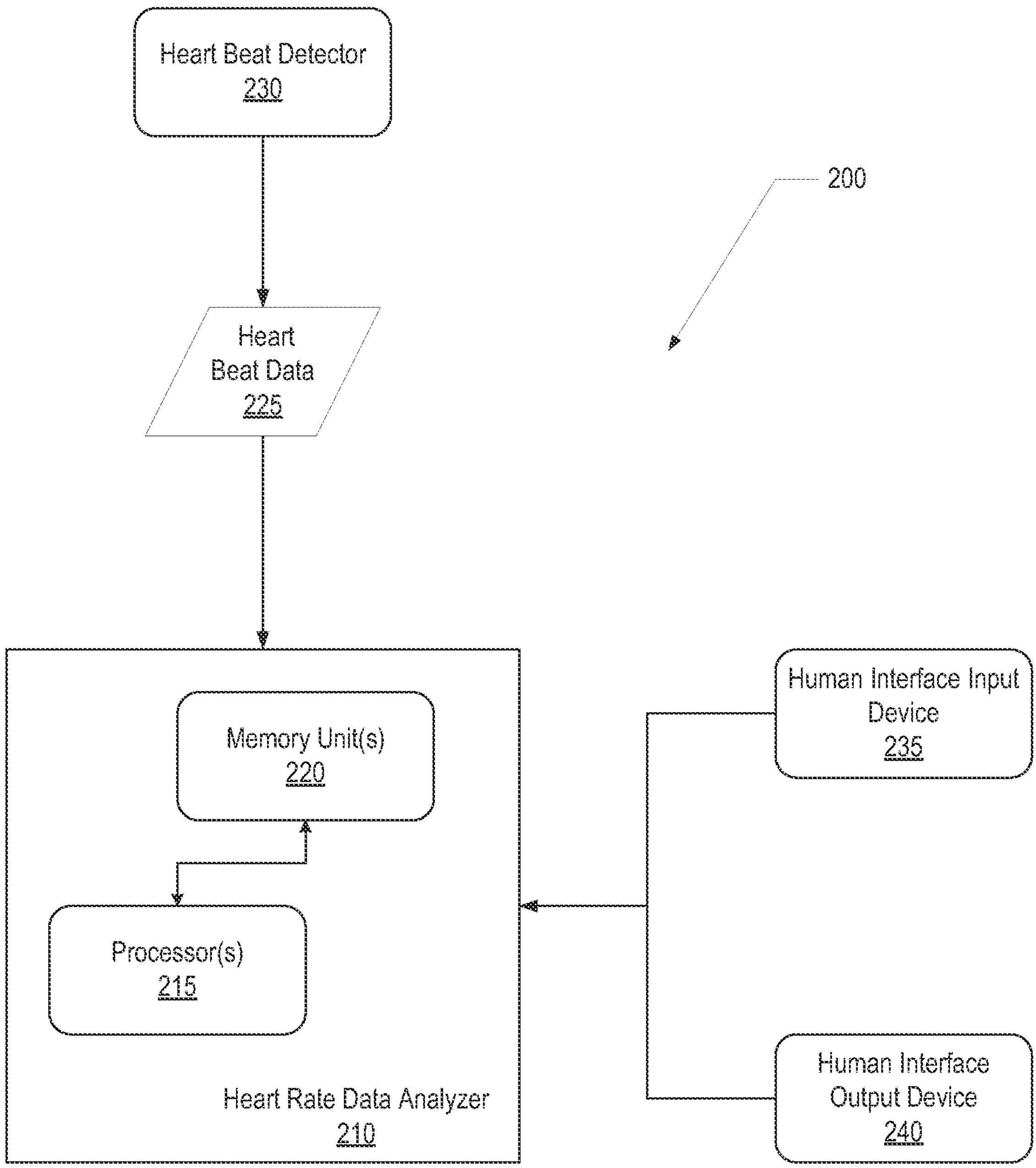
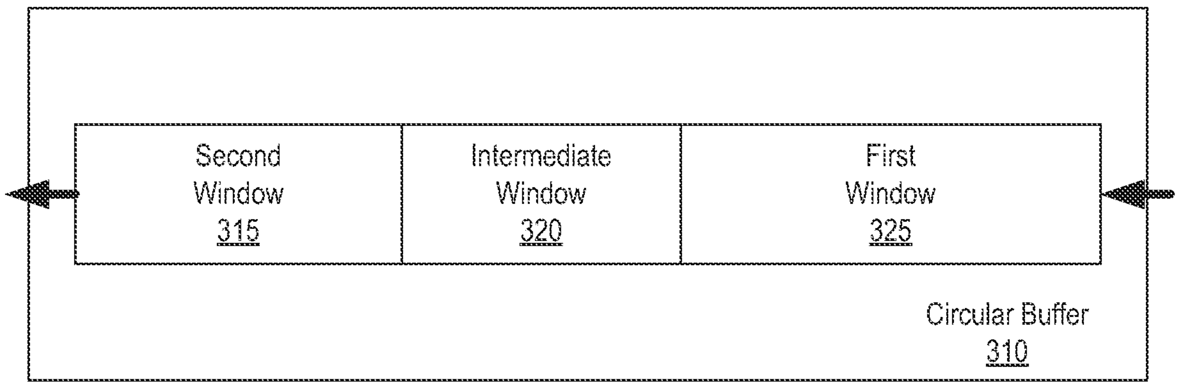

Heart Beat Detector
230
200
Heart
Beat Data
225
Memory Unit(s)
220
Processor(s)
215
Heart Rate Data Analyzer
210
Human Interface Input
Device
235
Human Interface
Output Device
240

Fig. 2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Window
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Intermediate
Window
320
First
Window
325
Circular Buffer
310

Fig. 3

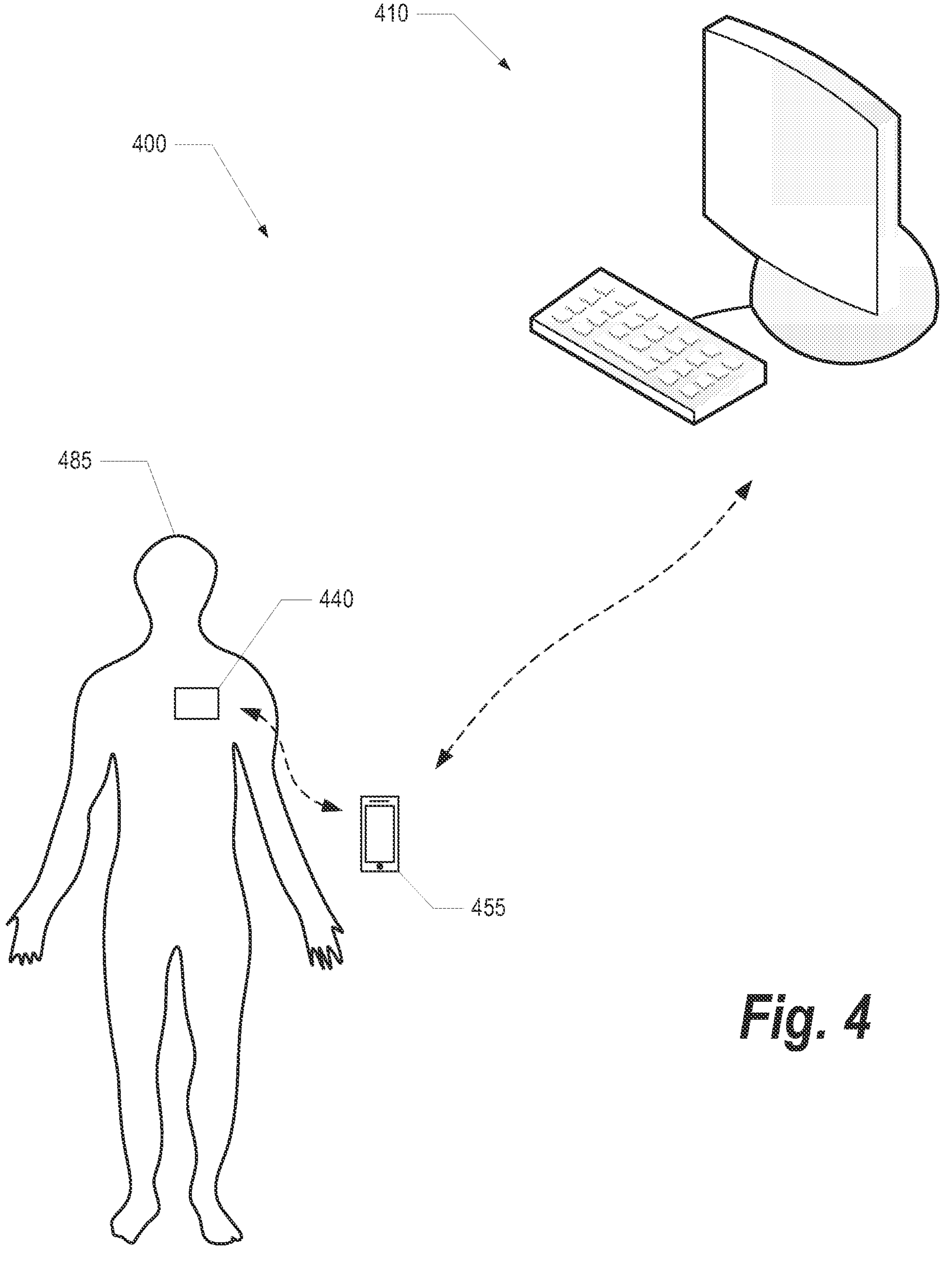

Fig. 4

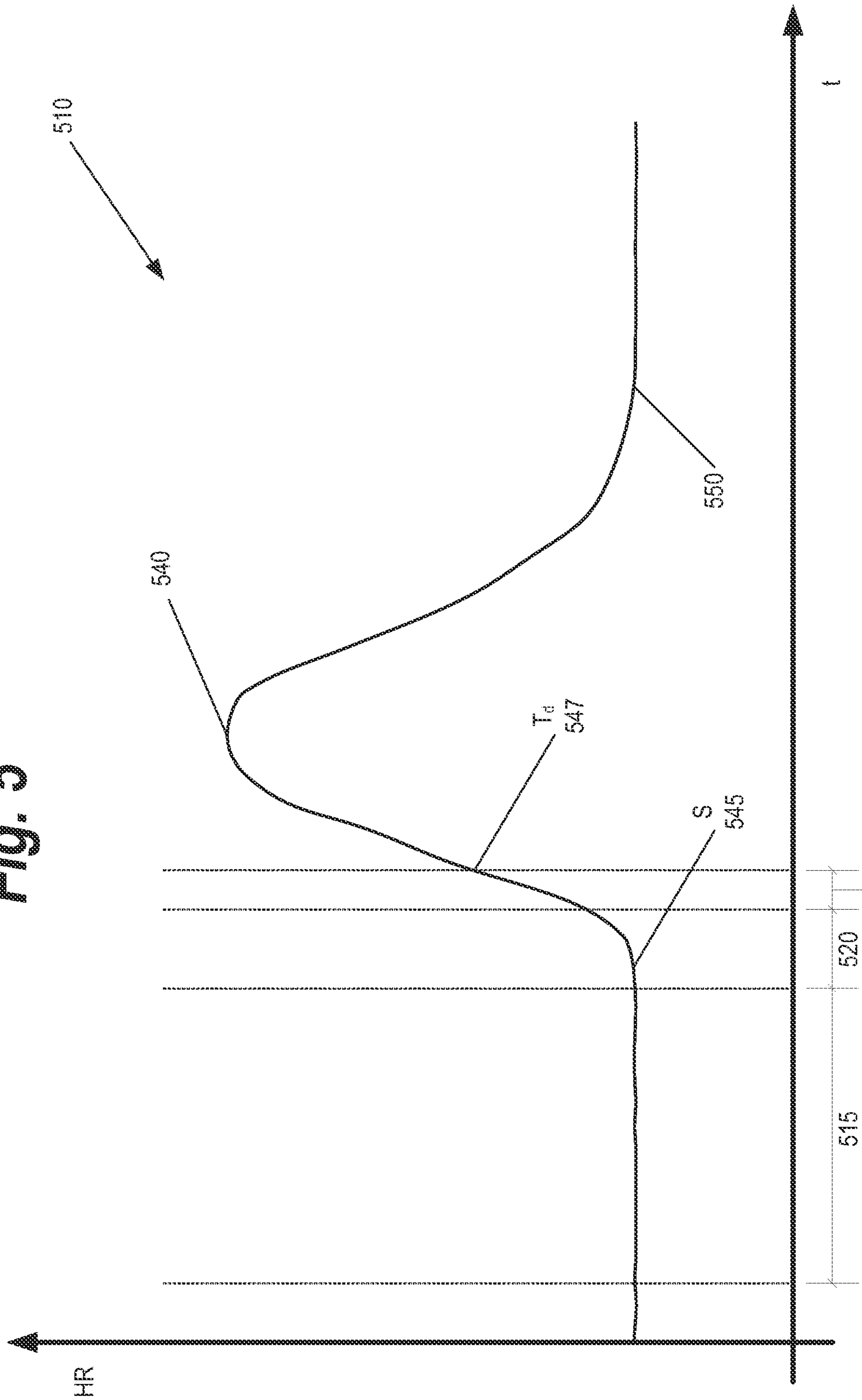

Fig. 5

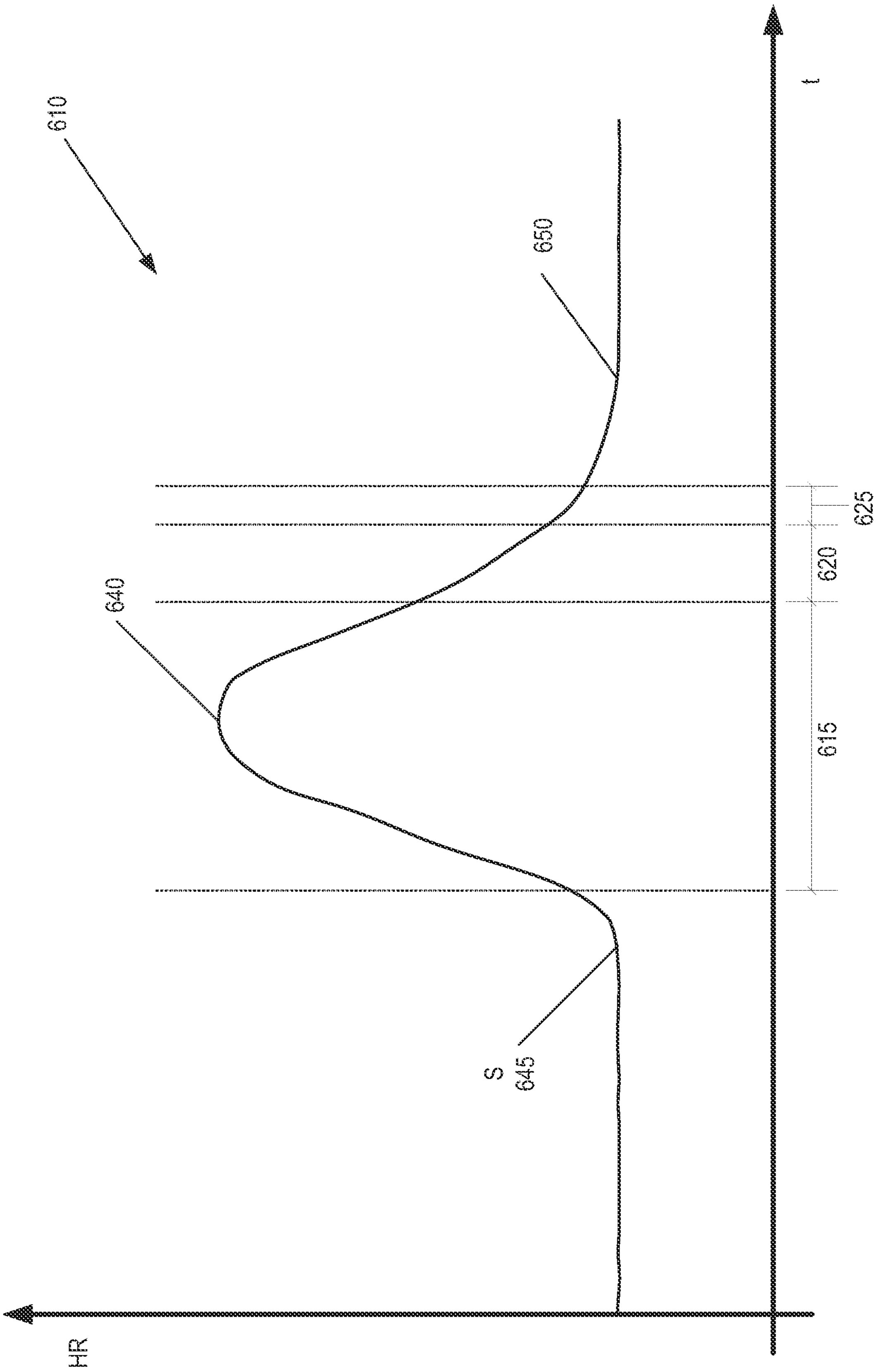

Fig. 6

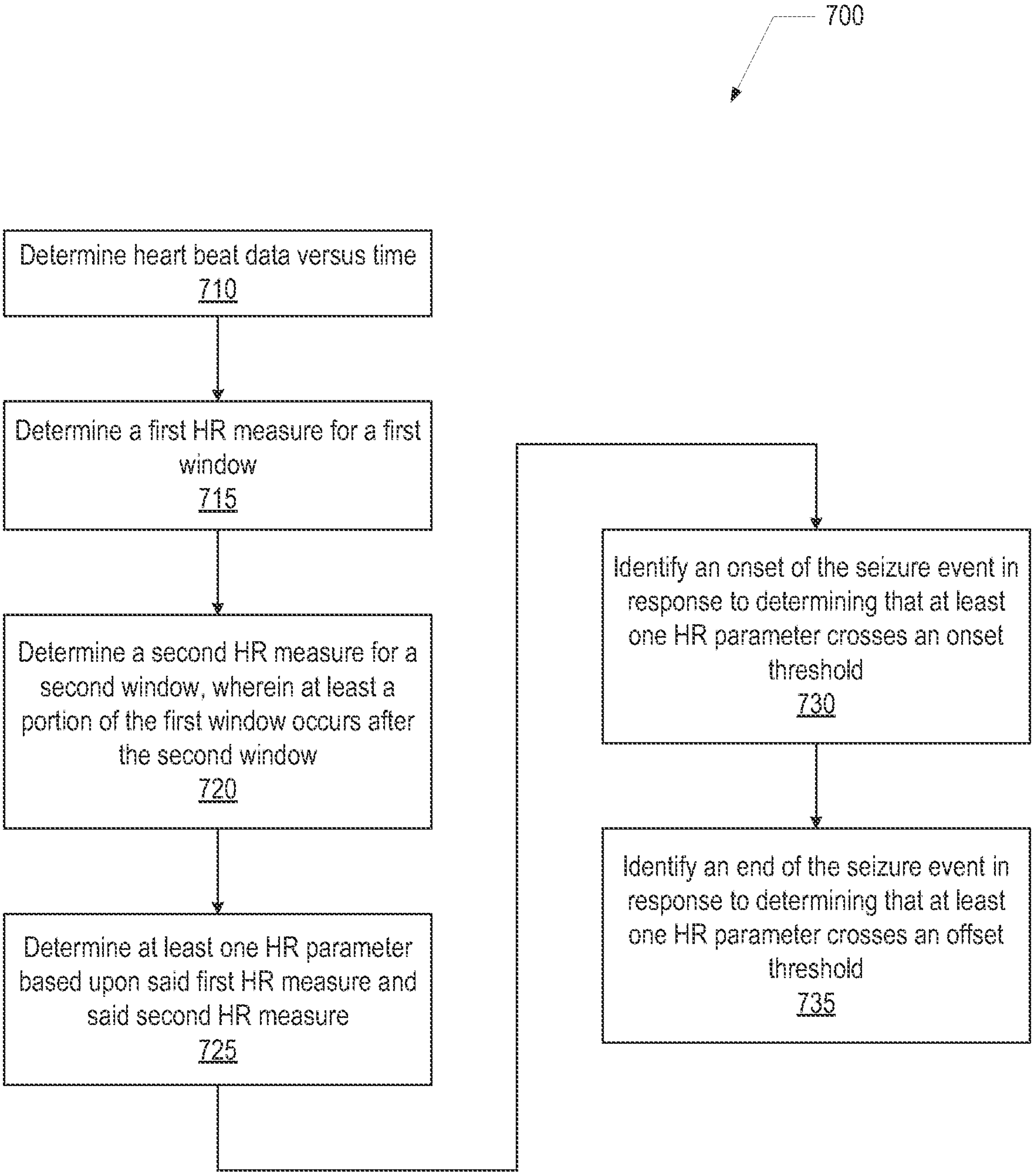
700
Determine heart beat data versus time
710
Determine a first HR measure for a first window
715
Determine a second HR measure for a second window, wherein at least a portion of the first window occurs after the second window
720
Determine at least one HR parameter based upon said first HR measure and said second HR measure
725
Identify an onset of the seizure event in response to determining that at least one HR parameter crosses an onset threshold
730
Identify an end of the seizure event in response to determining that at least one HR parameter crosses an offset threshold
735

Fig. 7

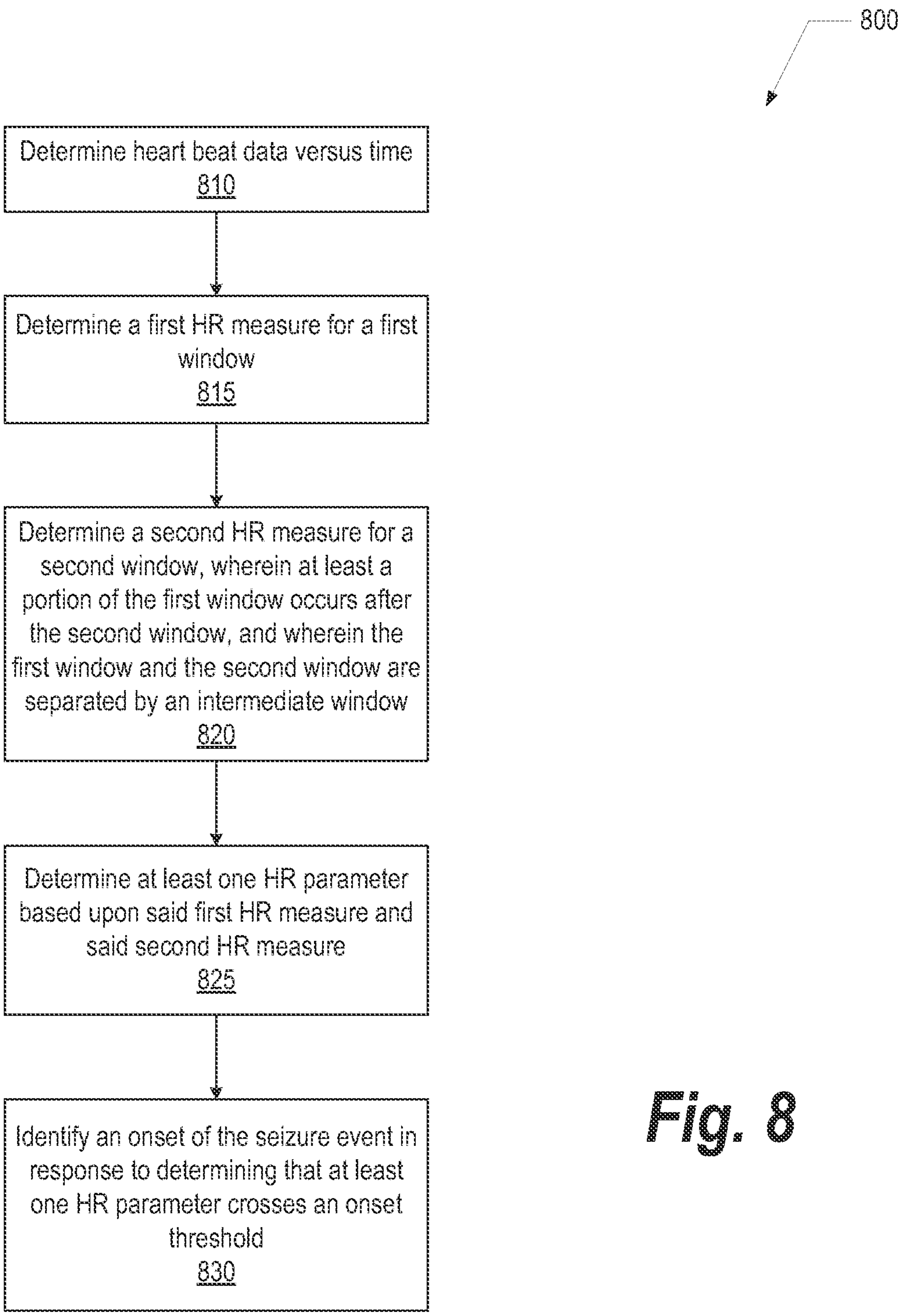
800
Determine heart beat data versus time
810
Determine a first HR measure for a first window
815
Determine a second HR measure for a second window, wherein at least a portion of the first window occurs after the second window, and wherein the first window and the second window are separated by an intermediate window
820
Determine at least one HR parameter based upon said first HR measure and said second HR measure
825
Identify an onset of the seizure event in response to determining that at least one HR parameter crosses an onset threshold
830

Fig. 8

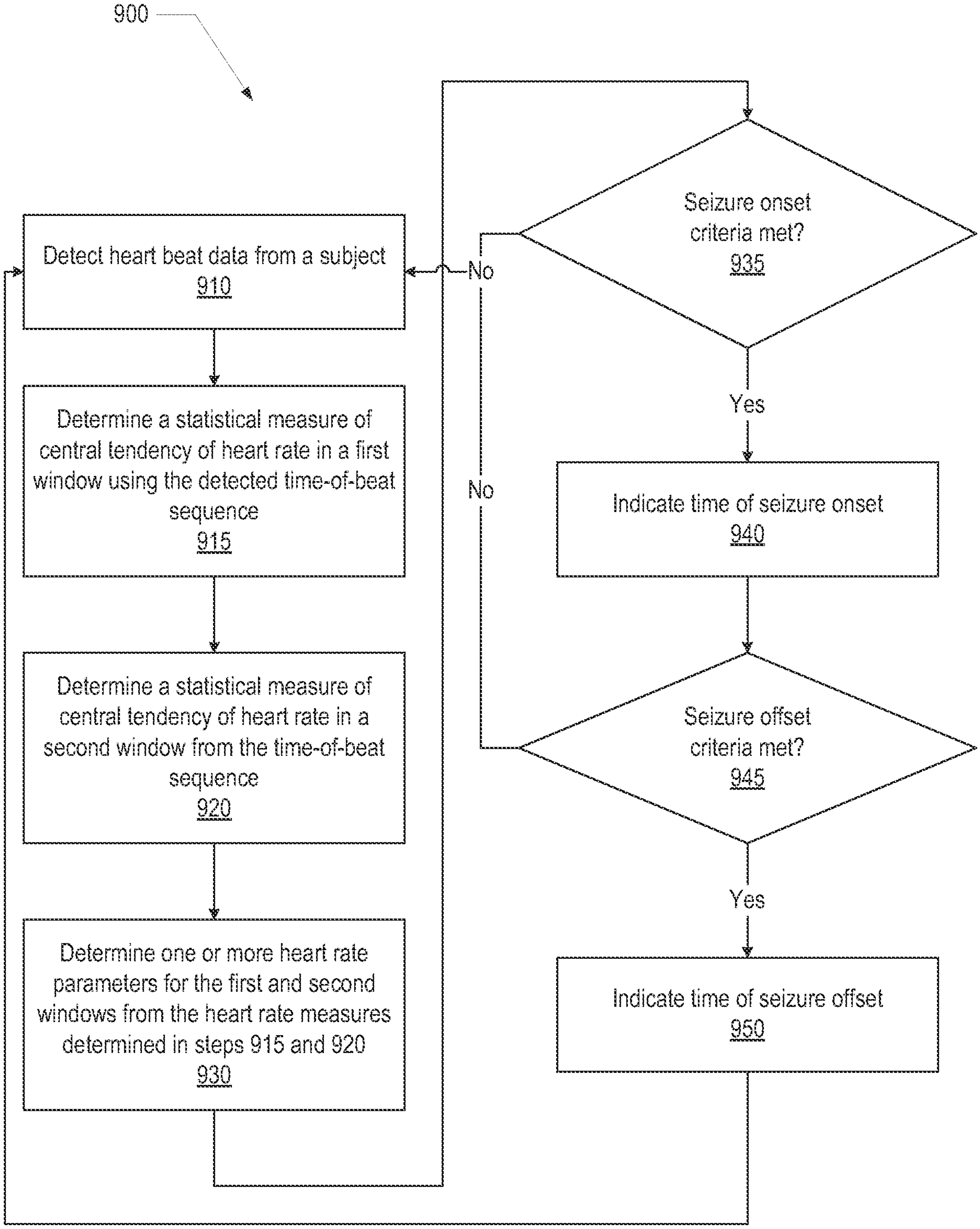
900
Detect heart beat data from a subject
910
Determine a statistical measure of central tendency of heart rate in a first window using the detected time-of-beat sequence
915
Determine a statistical measure of central tendency of heart rate in a second window from the time-of-beat sequence
920
Determine one or more heart rate parameters for the first and second windows from the heart rate measures determined in steps 915 and 920
930
Seizure onset criteria met?
935
No
Yes
Indicate time of seizure onset
940
No
Seizure offset criteria met?
945
Yes
Indicate time of seizure offset
950

Fig. 9

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2012/020329

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/024 A61B5/0245
ADD.

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, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2010/274303 A1 (CYBERONICS INC [US]; BUKHMAN VLADISLAV [US]) 28 October 2010 (2010-10-28) paragraphs [0009] - [0014], [0042] - [0044], [0049] - [0050], [0061] - [0062], [0067] - [0071], [0078], [0085] - [0099], [0106], [0110], [0113]; claims; figures paragraphs [0115] - [0116] -----	7-18
A	EP 2 258 444 A1 (CYBERONICS INC [US]) 8 December 2010 (2010-12-08) paragraphs [0012], [0014] - [0019], [0023], [0027] - [0033], [0035]; claims; figures -----	7-18
	-/--	

[X] Further documents are listed in the continuation of Box C.

[X] 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
9 May 2012	18/05/2012

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	Mundakapadam, S

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

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2012/020329

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2007/143234 A2 (MEDTRONIC INC [US]; CARLSON DAVID L [US]; PANKEN ERIC J [US]; GIFTAKIS) 13 December 2007 (2007-12-13) paragraphs [0039] - [0076]; claims; figures -----	7-18
A	US 2007/238939 A1 (GIFTAKIS JONATHON E [US] ET AL) 11 October 2007 (2007-10-11) paragraphs [0002], [0010], [0092], [0099], [0100]; claims; figures -----	7-18

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2012/020329

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. [X] Claims Nos.: 1-6
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Diagnostic method practised on the human or animal body

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:

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.:

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.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2012/020329

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2010274303 A1	28-10-2010	US 2010274303 A1	28-10-2010
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