EXHIBIT 1

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

CARDIONET, INC., Plaintiff and Counterdefendant, and BRAEMAR MANUFACTURING, LLC, Plaintiff, v. MEDNET HEALTHCARE TECHNOLOGIES, INC., Defendant and Counterclaimant, and MEDTEL 24, INC., RHYTHMWATCH LLC, AMI CARDIAC MONITORING, INC., HEARTCARE CORPORATION OF AMERICA, UNIVERSAL MEDICAL INC., and UNIVERSAL MEDICAL LABORATORY, INC., Defendants.	Civil Action No. 12-cv-2517 (JS)

THIRD AMENDED COMPLAINT AND JURY DEMAND

Plaintiffs CardioNet, Inc. and Braemar Manufacturing, LLC, (collectively, "Plaintiffs"), for their Complaint against Mednet Healthcare Technologies, Inc., MedTel 24, Inc., RhythmWatch LLC, AMI Cardiac Monitoring, Inc., Heartcare Corporation of America, Universal Medical Inc., and Universal Medical Laboratory, Inc. (collectively, "Defendants"), allege as follows:

THE PARTIES

1. Plaintiff CardioNet, Inc. ("CardioNet") is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 227 Washington Street, #300, Conshohocken, PA 19428. CardioNet is a leading provider of ambulatory outpatient management solutions for monitoring clinical information regarding an individual's health.

2. Plaintiff Braemar Manufacturing, LLC ("Braemar") is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 1285 Corporate Center Drive, Suite 150, Eagan, MN 55121. Braemar develops and manufactures ambulatory cardiac monitors for leading healthcare companies.

3. On information and belief, defendant Mednet Healthcare Technologies, Inc. is a corporation organized under the laws of the State of New Jersey, having a principal place of business at 275 Phillips Blvd, Ewing, NJ 08618.

4. On information and belief, defendant MedTel 24, Inc. ("MedTel 24") is a corporation organized under the laws of the State of Florida, having a principal place of business at Boca Corporate Center, 4800 T-Rex Avenue, Suite 100, Boca Raton, FL 33431.

5. On information and belief, defendant RhythmWatch LLC ("RhythmWatch") is a corporation organized under the laws of the State of Pennsylvania, having a principal place of business at 3113 Babcock Blvd, Suite 3, Pittsburgh, PA 15237.

6. On information and belief, defendant Heartcare Corporation of America ("HCA") is a corporation organized under the laws of the State of New Jersey, having a principal place of business at 275 Phillips Blvd, Ewing, NJ 08618.

7. On information and belief, defendant Universal Medical Inc. ("UMI") is a corporation organized under the laws of the State of New Jersey, having a principal place of business at 275 Phillips Blvd, Ewing, NJ 08618.

8. On information and belief, defendant Universal Medical Laboratory, Inc. ("UML") is a corporation organized under the laws of the State of New Jersey, having a principal place of business at 275 Phillips Blvd, Ewing, NJ 08618.

9. On information and belief, defendant AMI Cardiac Monitoring, Inc. ("AMI") is a corporation organized under the laws of the State of Maryland, having a principal place of business at 17810 Meeting House Road, Suite 210, Sandy Spring, MD 20860.

JURISDICTION AND VENUE

10. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code.

11. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

12. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

FACTS

13. U.S. Patent 7,212,850, entitled "System And Method For Processing And Presenting Arrhythmia Information To Facilitate Heart Arrhythmia Identification And Treatment" ("'850 Patent") was duly and legally issued on May 1, 2007. CardioNet was the original owner by assignment of all right, title, and interest in and to the '850 Patent, including

without limitation the right to sue and recover for past infringements thereof. A copy of the '850 Patent is attached as Exhibit A to this Complaint.

14. U.S. Patent 7,907,996, entitled "System And Method For Processing And Presenting Arrhythmia Information To Facilitate Heart Arrhythmia Identification And Treatment" ("'996 Patent") was duly and legally issued on March 15, 2011. CardioNet was the original owner by assignment of all right, title, and interest in and to the '996 Patent, including without limitation the right to sue and recover for past infringements thereof. A copy of the '996 Patent is attached as Exhibit B to this Complaint.

15. U.S. Patent 6,569,095, entitled "Adaptive Selection Of A Warning Limit In Patient Monitoring" ("'095 Patent") was duly and legally issued on May 27, 2003. CardioNet was the original owner by assignment of all right, title, and interest in and to the '095 Patent, including without limitation the right to sue and recover for past infringements thereof. A copy of the '095 Patent is attached as Exhibit C to this Complaint.

16. U.S. Patent 7,587,237, entitled "Biological Signal Management" ("'237 Patent") was duly and legally issued on September 8, 2009. CardioNet was the original owner by assignment of all right, title, and interest in and to the '237 Patent, including without limitation the right to sue and recover for past infringements thereof. A copy of the '237 Patent is attached as Exhibit J to this Complaint.

17. U.S. Patent 7,941,207, entitled "Cardiac Monitoring" ("'207 Patent") was duly and legally issued on May 10, 2011. CardioNet was the original owner by assignment of all right, title, and interest in and to the '207 Patent, including without limitation the right to sue and recover for past infringements thereof. A copy of the '207 Patent is attached as Exhibit K to this Complaint.

18. On December 31, 2012, CardioNet assigned all right, title, and interest in the '850 patent, '996 patent, '095 patent, '237 patent and '207 patent (collectively, the "patents-in-suit") to Braemar ("Assignment Agreement"). Effective the same day, Braemar granted CardioNet an exclusive license to make, use, offer to sell, sell, import, license and exploit the patents-in-suit ("License Agreement"). True and correct copies of each of the Assignment Agreement and License Agreement are attached hereto as Exhibits L and M respectively. Specifically, the License Agreement grants CardioNet an exclusive license to the patents-in-suit in the fields of "applications and services for the monitoring and monitoring-related services of medical monitoring and diagnostic devices," while "all other rights, title and interest" in the patents-in-suit are retained by Braemar.

19. On information and belief, defendants Mednet Healthcare Technologies, Inc., HCA, UMI, and/or UML (collectively "Mednet") actively solicit and do business throughout this Judicial District, including using, offering for use, selling, and offering for sale the Heartrak External Cardiac Ambulatory Telemetry ("Heartrak ECAT") System, including both the Heartrak ECAT device and monitoring service associated with the device.

20. On information and belief, MedTel 24 actively solicits and does business throughout this Judicial District, including using, offering for use, selling, and offering for sale monitoring services associated with the Heartrak ECAT device.

21. On information and belief, RhythmWatch actively solicits and does business throughout this Judicial District, including using, offering for use, selling, and offering for sale monitoring services associated with the Heartrak ECAT device.

22. On information and belief, AMI actively solicits and does business throughout this Judicial District, including using, offering for use, selling, and offering for sale monitoring services associated with the Heartrak ECAT device.

23. On information and belief, the Heartrak ECAT System includes both the device that records and processes a patient's electrocardiographic signal and the monitoring service for assessing the cardiac data transmitted by the Heartrak ECAT device provided by Defendants. A copy of Mednet's Heartrak ECAT Specification is attached as Exhibit D to this Complaint.

24. On information and belief, the Heartrak ECAT device compares the time intervals between heartbeats as part of the identification of arrhythmia events.

25. On information and belief, the Heartrak ECAT System identifies arrhythmia events, including atrial fibrillation. A copy of a sample Heartrak ECAT System Daily Report is attached as Exhibit G to this Complaint. A copy of a sample Heartrak ECAT System End of Study Report is attached as Exhibit H to this Complaint.

26. On information and belief, the Heartrak ECAT System identifies more than one type of arrhythmia event, including atrial fibrillation and bradycardia.

27. On information and belief, the Heartrak ECAT System evaluates heart rate trends, and provides graphic reports presenting information regarding heart rate data and identified arrhythmia events. A copy of Mednet's Website advertising the Heartrak ECAT System is attached as Exhibit E to this Complaint.

28. On information and belief, the Heartrak ECAT System implements logic to reduce or eliminate the identification of signal noise as arrhythmia events.

29. On information and belief, the Heartrak ECAT device sends heart rate data, including identification of arrhythmias, to a monitoring station where personnel at Mednet,

MedTel 24, RhythmWatch and/or AMI, assess the heart rate data. A copy of AMI's Website advertising the Heartrak ECAT System is attached as Exhibit F to this Complaint.

30. On information and belief, personnel at Mednet, MedTel 24, RhythmWatch and/or AMI, assess atrial fibrillation events in regular time intervals.

31. On information and belief, based on the assessment of an atrial fibrillation event by personnel at Mednet, MedTel 24, RhythmWatch and/or AMI, a graphic representation of heart rate data is presented on the same time scale with the atrial fibrillation activity.

32. On information and belief, the data transmission from the Heartrak ECAT device to the monitoring station is triggered when arrhythmia events are detected.

33. On information and belief, the triggering of data transmission from the Heartrak ECAT device is based on predetermined parameters which can be reprogrammed. A copy of Mednet's Section 510(k) Statement regarding the Heartrak ECAT device is attached as Exhibit I to this Complaint.

INFRINGEMENT OF '850 PATENT

34. Each of the Defendants has infringed and is continuing to infringe the '850 Patent by making, using, selling, and/or offering for sale, in the United States and in this Judicial District, products, software, and/or services that incorporate or make use of one or more of the inventions covered by the '850 Patent, including but not limited to the Heartrak ECAT System, thereby infringing one or more claims of the '850 Patent.

35. Mednet's Heartrak ECAT System satisfies each and every element of one or more claims of the '850 Patent, for example, and without limitation, claim 31 of the '850 Patent.

36. Claim 31 of the '850 Patent recites:

A system for reporting information related to arrhythmia events comprising:

a monitoring system configured to process and report physiological data, including heart rate data, for a living being and configured to identify arrhythmia events from the physiological data;

a monitoring station for receiving the physiological data from the monitoring system;

a processing system configured to receive arrhythmia information from the monitoring system and configured to receive human-assessed arrhythmia information from the monitoring station wherein the human-assessed arrhythmia information derives from at least a portion of the physiological data and wherein the processing system is capable of pictographically presenting, using a common time scale, information regarding the heart rate data during a defined time period and regarding duration of arrhythmia event activity, according to the identified arrhythmia events, during the defined time period such that heart rate trend is presented with arrhythmia event burden.

37. Claim 31 of the ’850 Patent has the preamble: “A system for reporting information related to arrhythmia events comprising.” The Heartrak ECAT System is a system for reporting information related to arrhythmia events. *See* Ex. D: Heartrak ECAT Specification; Ex. E: Mednet Heartrak ECAT Website.

38. Claim 31 of the ’850 Patent has the element: “a monitoring system configured to process and report physiological data, including heart rate data, for a living being and configured to identify arrhythmia events from the physiological data.” The Heartrak ECAT System is a monitoring system configured to process and report at least a patient’s heart rate data, and to identify arrhythmia events from the heart rate data. *See* Ex. D: Heartrak ECAT Specification; Ex. E: Mednet Heartrak ECAT Website.

39. Claim 31 of the ’850 Patent has the element: “a monitoring station for receiving the physiological data from the monitoring system.” The Heartrak ECAT System includes a central monitoring center which receives physiological data from the Heartrak ECAT device. *See* Ex. D: Heartrak ECAT Specification.

40. Claim 31 of the '850 Patent has the element: "a processing system configured to receive arrhythmia information from the monitoring system and configured to receive human-assessed arrhythmia information from the monitoring station wherein the human-assessed arrhythmia information derives from at least a portion of the physiological data and wherein the processing system is capable of pictographically presenting, using a common time scale, information regarding the heart rate data during a defined time period and regarding duration of arrhythmia event activity, according to the identified arrhythmia events, during the defined time period such that heart rate trend is presented with arrhythmia event burden." The Heartrak ECAT System is a processing system configured to receive arrhythmia information from the Heartrak ECAT device and configured to receive arrhythmia information from the Heartrak ECAT System central monitoring station assessed by Mednet, MedTel 24, RhythmWatch, and/or AMI personnel, wherein the human-assessed arrhythmia information derives from at least a portion of the physiological data. The Heartrak ECAT System is capable of pictographically presenting, using a common time scale, information regarding the heart rate data during a defined time period and regarding duration of arrhythmia event activity, according to the identified arrhythmia events, during the defined time period such that heart rate trend is presented with arrhythmia event burden. *See* Ex. D: Heartrak ECAT Specification; Ex. G: Heartrak ECAT Daily Report; Ex. H: Heartrak ECAT End of Study Report.

41. The acts of infringement by each of the Defendants set forth above have caused and will cause Plaintiffs irreparable harm for which it has no adequate remedy at law, and will continue unless enjoined by this Court.

INFRINGEMENT OF ’996 PATENT

42. Each of the Defendants has infringed and is continuing to infringe the ’996 Patent by making, using, selling, and/or offering for sale, in the United States and in this Judicial District, products and/or software that incorporate or make use of one or more of the inventions covered by the ’996 Patent, including but not limited to the Heartrak ECAT System, thereby infringing one or more claims of the ’996 Patent.

43. Mednet’s Heartrak ECAT System satisfies each and every element of one or more claims of the ’996 Patent, for example, and without limitation, claim 1 of the ’996 Patent.

44. Claim 1 of the ’996 Patent recites:

> A machine-implemented method comprising:
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> identifying atrial fibrillation events in physiological data obtained for a living being, wherein identifying atrial fibrillation events comprises examining the physiological data in multiple time intervals, and identifying intervals in which at least one atrial fibrillation event has occurred;
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> obtaining heart rate data for the living being;
>
> receiving a human assessment of a subset of the identified atrial fibrillation events; and
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> based on the human assessment of the subset of the identified atrial fibrillation events, pictographically presenting, using a common time scale, information regarding the heart rate data for the multiple time intervals during a defined time period in alignment with indications of atrial fibrillation activity for the identified intervals, according to the identified atrial fibrillation events, during the defined time period such that heart rate trend is presented with atrial fibrillation burden, wherein pictographically presenting information regarding the heart rate data comprises displaying for each of the multiple time intervals a range of heart rates and a heart rate average.

45. Claim 1 of the ’996 Patent has the preamble: “A machine-implemented method comprising.” The Heartrak ECAT System is a system that performs a machine-implemented method.

46. Claim 1 of the '996 Patent has the element: "identifying atrial fibrillation events in physiological data obtained for a living being, wherein identifying atrial fibrillation events comprises examining the physiological data in multiple time intervals, and identifying intervals in which at least one atrial fibrillation event has occurred." The Heartrak ECAT System identifies atrial fibrillation events in physiological data obtained for a patient by examining the patient's physiological data in multiple time intervals, and identifying intervals in which an atrial fibrillation event has occurred. *See* Ex. D: Heartrak ECAT Specification.

47. Claim 1 of the '996 Patent has the element: "obtaining heart rate data for the living being." The Heartrak ECAT System obtains at least a patient's heart rate data. *See* Ex. D: Heartrak ECAT Specification.

48. Claim 1 of the '996 Patent has the element: "receiving a human assessment of a subset of the identified atrial fibrillation events." The Heartrak ECAT System receives an assessment of a subset of the identified atrial fibrillation events by Mednet, MedTel 24, RhythmWatch, and/or AMI personnel. *See* Ex. D: Heartrak ECAT Specification.

49. Claim 1 of the '996 Patent has the element: "based on the human assessment of the subset of the identified atrial fibrillation events, pictographically presenting, using a common time scale, information regarding the heart rate data for the multiple time intervals during a defined time period in alignment with indications of atrial fibrillation activity for the identified intervals, according to the identified atrial fibrillation events, during the defined time period such that heart rate trend is presented with atrial fibrillation burden, wherein pictographically presenting information regarding the heart rate data comprises displaying for each of the multiple time intervals a range of heart rates and a heart rate average." Based on the assessment of a subset of the identified atrial fibrillation events by Mednet, MedTel 24, RhythmWatch, and/or

AMI personnel, the Heartrak ECAT System pictographically presents, using a common time scale, information regarding the heart rate data for the multiple time intervals during a defined time period in alignment with indications of atrial fibrillation activity for the identified intervals, according to the identified atrial fibrillation events, during the defined time period such that heart rate trend is presented with atrial fibrillation burden, wherein pictographically presenting information regarding the heart rate data comprises displaying for each of the multiple time intervals a range of heart rates and a heart rate average. *See* Ex. D: Heartrak ECAT Specification; Ex. G: Heartrak ECAT Daily Report; Ex. H: Heartrak ECAT End of Study Report.

50. The acts of infringement by each of the Defendants set forth above have caused and will cause Plaintiffs irreparable harm for which it has no adequate remedy at law, and will continue unless enjoined by this Court.

INFRINGEMENT OF ’095 PATENT

51. Each of the Defendants has infringed and is continuing to infringe the ’095 Patent by making, using, selling, and/or offering for sale, in the United States and in this Judicial District, products and/or software that incorporate or make use of one or more of the inventions covered by the ’095 Patent, including but not limited to the Heartrak ECAT System, thereby infringing one or more claims of the ’095 Patent.

52. Mednet’s Heartrak ECAT System satisfies each and every element of one or more claims of the ’095 Patent, for example, and without limitation, claim 1 of the ’095 Patent.

53. Claim 1 of the ’095 Patent recites:

A method of monitoring a patient, comprising the steps:

establishing a current warning limit for a physiological characteristic of the patient;

providing a sensor for the physiological characteristic;

measuring a measured value of the physiological characteristic of the patient using the sensor;

comparing the measured value and the current warning limit, and generating a warning signal responsive to the step of comparing; and

selecting a revised warning limit responsive to at least one of the steps of providing and measuring.

54. Claim 1 of the '095 Patent has the preamble: "A method of monitoring a patient, comprising the steps." The Heartrak ECAT System performs a method of monitoring a patient.

55. Claim 1 of the '095 Patent has the element: "establishing a current warning limit for a physiological characteristic of the patient." The Heartrak ECAT System establishes a current warning limit for a physiological characteristic, such as heart rate, of the patient. *See* Ex. D: Heartrak ECAT Specification; Ex. I: Mednet 510(k).

56. Claim 1 of the '095 Patent has the element: "providing a sensor for the physiological characteristic." The Heartrak ECAT System includes the Heartrak ECAT device with sensors for one or more physiological characteristics, such as heart rate, which is provided to the patient.

57. Claim 1 of the '095 Patent has the element: "measuring a measured value of the physiological characteristic of the patient using the sensor." The Heartrak ECAT System measures a measured value of the physiological characteristic of the patient, such as heart rate, using the sensor on the Heartrak ECAT device. *See* Ex. D: Heartrak ECAT Specification; Ex. I: Mednet 510(k).

58. Claim 1 of the '095 Patent has the element: "comparing the measured value and the current warning limit, and generating a warning signal responsive to the step of comparing." The Heartrak ECAT System compares the measured value and the current warning limit, and

generates a warning signal in response which is sent to the monitoring station. *See* Ex. D: Heartrak ECAT Specification; Ex. I: Mednet 510(k).

59. Claim 1 of the ’095 Patent has the element: “selecting a revised warning limit responsive to at least one of the steps of providing and measuring.” The Heartrak ECAT System selects a revised warning limit in response to the steps of providing a sensor and/or measuring the physiological characteristic, such as heart rate. *See* Ex. D: Heartrak ECAT Specification; Ex. I: Mednet 510(k).

60. The acts of infringement by each of the Defendants set forth above have caused and will cause Plaintiffs irreparable harm for which it has no adequate remedy at law, and will continue unless enjoined by this Court.

INFRINGEMENT OF ’237 PATENT

61. Each of the Defendants has infringed and is continuing to infringe the ’237 Patent by making, using, selling, and/or offering for sale, in the United States and in this Judicial District, products, software, and/or services that incorporate or make use of one or more of the inventions covered by the ’237 Patent, including but not limited to the Heartrak ECAT System, thereby infringing one or more claims of the ’237 Patent.

62. Through discovery in this case, Plaintiffs have learned that Mednet had notice of the ‘237 patent at least as early at October 28, 2009. On October 28, 2009, Michael D. Solop, Mednet’s Director of National Sales, sent an email to Chris Keane, Frank Movizzo, Brian Pike and Stan Biletsky entitled “came across this today” in which he copied a Business Wire article covering CardioNet’s announcement of the issuance of the ‘237 patent. A true and correct copy of this correspondence (MHT-0215780) is attached as Exhibit N.

63. On information and belief, Messrs. Keane, Movizzo, Pike and Biletsky were Mednet's President, CEO, VP of Sales & Marketing and VP of Research & Development, respectively, at the time of email. On further information and belief, each of these gentlemen still currently occupies their same position.

64. Later on October 28, 2009, shortly after receiving the email in Exhibit N, Mr. Pike sent a separate email to Joyce Dean, another Mednet employee, asking her if she had or knew of "an easy way to pull patents?" He then specifically identified the '237 patent as the patent he was interested in. A true and correct copy of this correspondence (MHT-0078609) is attached as Exhibit O.

65. Mednet's Heartrak ECAT System satisfies each and every element of one or more claims of the '237 Patent, for example, and without limitation, claim 1 of the '237 Patent.

66. Claim 1 of the '237 Patent recites:

> A method of monitoring a cardiac biological signal using electrocardiographic monitoring instrumentation, comprising:
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> receiving, at the electrocardiographic monitoring instrumentation, the cardiac biological signal that includes information describing events, wherein events comprise periods in time when an information content of the cardiac biological signal is of increased relevance to a particular purpose and the events are demarcated by periods of time that are not of increased relevance to the particular purpose;
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> at the electrocardiographic monitoring instrumentation, classifying the events into two or more categories based on cardiac conditions indicated by the information describing each event;
>
> at the electrocardiographic monitoring instrumentation, determining a measure of merit of the information describing each event, wherein the measure of merit embodies a severity of the cardiac condition associated with the event and an amount of noise in the information describing the event;
>
> comparing, at the electrocardiographic monitoring instrumentation, the measure of merit of information describing each event with a first merit criterion;

transmitting, for medical purposes, information describing a first proper subset of the events in a first of the categories that have merits meeting the first merit criterion from the electrocardiographic monitoring instrumentation to a remote medical receiver, wherein the remote medical receiver is not located at the same site at the electrocardiographic monitoring instrumentation;

at the electrocardiographic monitoring instrumentation, discarding information describing a second proper subset of the events in the first of the categories that have measures of merit that fail to meet the first merit criterion;

comparing, at the electrocardiographic monitoring instrumentation, the measure of merit of information describing each event with a second merit criterion;

transmitting, for medical purposes, information describing a third proper subset of the events in a second of the categories that have measures of merit meeting the second merit criterion from the electrocardiographic monitoring instrumentation to the remote medical receiver, wherein the second category differs from the first category and the second merit criterion differs from the first merit criterion; and

at the electrocardiographic monitoring instrumentation, discarding information describing a fourth proper subset of the events in the second of the categories that have measures of merit that fail to meet the second merit criterion.

67. Claim 1 of the ’237 Patent has the preamble: “A method of monitoring a cardiac biological signal using electrocardiographic monitoring instrumentation, comprising.” The Heartrak ECAT System performs a method of monitoring a patient’s cardiac signal using electrocardiographic monitoring instrumentation. *See* Ex. D: Heartrak ECAT Specification; Ex. E: Mednet Heartrak ECAT Website.

68. Claim 1 of the ’237 Patent has the element: “receiving, at the electrocardiographic monitoring instrumentation, the cardiac biological signal that includes information describing events, wherein events comprise periods in time when an information content of the cardiac biological signal is of increased relevance to a particular purpose and the events are demarcated by periods of time that are not of increased relevance to the particular purpose.” The Heartrak ECAT device, which is electrocardiographic monitoring instrumentation, receives the patient’s cardiac signal that includes information describing events,

for example atrial fibrillation events. These events comprise periods in time when the information content of the cardiac signal is of increased relevance for, for example, monitoring the cardiac health of the patient, and are demarcated by periods of time that do not have increased relevance. *See* Ex. D: Heartrak ECAT Specification; Ex G: Heartrak ECAT Daily Report.

69. Claim 1 of the ’237 Patent has the element: “at the electrocardiographic monitoring instrumentation, classifying the events into two or more categories based on cardiac conditions indicated by the information describing each event.” The Heartrak ECAT device classifies the events into two or more categories, for example sinus bradycardia and atrial fibrillation. *See* Ex. D: Heartrak ECAT Specification; Ex G: Heartrak ECAT Daily Report; Ex. H: Heartrak ECAT End of Study Report.

70. Claim 1 of the ’237 Patent has the element: “at the electrocardiographic monitoring instrumentation, determining a measure of merit of the information describing each event, wherein the measure of merit embodies a severity of the cardiac condition associated with the event and an amount of noise in the information describing the event.” The Heartrak ECAT device determines a measure of merit of the information describing each event, wherein the measure of merit embodies a severity of the cardiac condition associated with the event and an amount of noise in the information describing the event. *See* Ex. D: Heartrak ECAT Specification; Ex F: AMI Website.

71. Claim 1 of the ’237 Patent has the element: “comparing, at the electrocardiographic monitoring instrumentation, the measure of merit of information describing each event with a first merit criterion.” The Heartrak ECAT device compares the measure of

merit of information describing each event with a first merit criterion. *See* Ex. D: Heartrak ECAT Specification; Ex F: AMI Website.

72. Claim 1 of the '237 Patent has the element: "transmitting, for medical purposes, information describing a first proper subset of the events in a first of the categories that have merits meeting the first merit criterion from the electrocardiographic monitoring instrumentation to a remote medical receiver, wherein the remote medical receiver is not located at the same site at the electrocardiographic monitoring instrumentation." The Heartrak ECAT device transmits to a remote medical receiver, for medical purposes, information describing a proper subset of the events in a first category of events that have met or exceeded the first merit criterion. The remote medical receiver, for example Mednet's monitoring facility, is in a different location than the Heartrak ECAT device. *See* Ex. D: Heartrak ECAT Specification; Ex. E: Mednet Heartrak ECAT Website.

73. Claim 1 of the '237 Patent has the element: "at the electrocardiographic monitoring instrumentation, discarding information describing a second proper subset of the events in the first of the categories that have measures of merit that fail to meet the first merit criterion." The Heartrak ECAT device discards a second subset of the events in the first category of events which failed to meet the first merit criterion. *See* Ex F: AMI Website.

74. Claim 1 of the '237 Patent has the element: "comparing, at the electrocardiographic monitoring instrumentation, the measure of merit of information describing each event with a second merit criterion." The Heartrak ECAT device compares the measure of merit of information describing each event with a second merit criterion. *See* Ex. D: Heartrak ECAT Specification; Ex F: AMI Website.

75. Claim 1 of the ’237 Patent has the element: “transmitting, for medical purposes, information describing a third proper subset of the events in a second of the categories that have measures of merit meeting the second merit criterion from the electrocardiographic monitoring instrumentation to the remote medical receiver, wherein the second category differs from the first category and the second merit criterion differs from the first merit criterion.” The Heartrak ECAT device transmits to a remote medical receiver, for medical purposes, information describing a proper subset of the events in a second category of events that have met or exceeded the second merit criterion. The first and second categories of events differ, as well as the first and second merit criteria. *See* Ex. D: Heartrak ECAT Specification; Ex. E: Mednet Heartrak ECAT Website.

76. Claim 1 of the ’237 Patent has the element: “at the electrocardiographic monitoring instrumentation, discarding information describing a fourth proper subset of the events in the second of the categories that have measures of merit that fail to meet the second merit criterion.” The Heartrak ECAT device discards a fourth subset of the events in the second category of events which failed to meet the second merit criterion. *See* Ex F: AMI Website.

77. Upon information and belief, Mednet’s acts of infringement are willful, intentional and without lawful justification, entitling Plaintiffs to damages and treble damages pursuant to 35 U.S.C. § 284 and reasonable attorney fees and costs incurred in prosecuting this action pursuant to 35 U.S.C. § 285.

78. The acts of infringement by each of the Defendants set forth above have caused and will cause Plaintiffs irreparable harm for which it has no adequate remedy at law, and will continue unless enjoined by this Court.

INFRINGEMENT OF ’207 PATENT

79. Each of the Defendants has infringed and is continuing to infringe the ’207 Patent by making, using, selling, and/or offering for sale, in the United States and in this Judicial District, products, software, and/or services that incorporate or make use of one or more of the inventions covered by the ’207 Patent, including but not limited to the Heartrak ECAT System, thereby infringing one or more claims of the ’207 Patent.

80. Mednet’s Heartrak ECAT System satisfies each and every element of one or more claims of the ’207 Patent, for example, and without limitation, claim 1 of the ’207 Patent.

81. Claim 1 of the ’207 Patent recites:

A device comprising:

a beat detector to identify a beat-to-beat timing of cardiac activity;

a ventricular beat detector to identify ventricular beats in the cardiac activity;

variability determination logic to determine a variability in the beat-to-beat timing of a collection of beats;

relevance determination logic to identify a relevance of the variability in the beat-to-beat timing to at least one of atrial fibrillation and atrial flutter; and

an event generator to generate an event when the variability in the beat-to-beat timing is identified as relevant to the at least one of atrial fibrillation and atrial flutter in light of the variability in the beat-to-beat timing caused by ventricular beats identified by the ventricular beat detector.

82. Claim 1 of the ’207 Patent has the element: “A device comprising: a beat detector to identify a beat-to-beat timing of cardiac activity.” The Heartrak ECAT device receives information from ECG sensors describing a timing of heart beats of an individual includes a beat detector to identify a beat-to-beat timing of cardiac activity. *See* Ex. D: Heartrak ECAT Specification; Ex. E: Mednet Heartrak ECAT Website.

83. Claim 1 of the '207 Patent has the element: "a ventricular beat detector to identify ventricular beats in the cardiac activity." The Heartrak ECAT device includes a ventricular beat detector to identify ventricular beats in the cardiac activity. *See* Ex. I: Mednet 510(k).

84. Claim 1 of the '207 Patent has the element: "variability determination logic to determine a variability in the beat-to-beat timing of a collection of beats." The Heartrak ECAT device includes variability determination logic to determine a variability in the beat-to-beat timing of a collection of beats. *See* Ex. I: Mednet 510(k).

85. Claim 1 of the '207 Patent has the element: "relevance determination logic to identify a relevance of the variability in the beat-to-beat timing to at least one of atrial fibrillation and atrial flutter." The Heartrak ECAT device includes relevance determination logic to identify a relevance of the variability in the beat-to-beat timing to atrial fibrillation. *See* Ex. I: Mednet 510(k).

86. Claim 1 of the '207 Patent has the element: "an event generator to generate an event when the variability in the beat-to-beat timing is identified as relevant to the at least one of atrial fibrillation and atrial flutter in light of the variability in the beat-to-beat timing caused by ventricular beats identified by the ventricular beat detector." The Heartrak ECAT device includes an event generator to generate an event when the variability in the beat-to-beat timing is identifies as relevant to atrial fibrillation in light of the variability in the beat-to-beat timing caused by ventricular beats identified by the ventricular beat detector. *See* Ex. D: Heartrak ECAT Specification; Ex. E: Mednet Heartrak ECAT Website; Ex. I: Mednet 510(k).

87. The acts of infringement by each of the Defendants set forth above have caused and will cause Plaintiffs irreparable harm for which it has no adequate remedy at law, and will continue unless enjoined by this Court.

WHEREFORE, Plaintiffs pray for judgment against Defendants as follows:

A. For a declaration that the ’850 Patent was duly and legally issued, and is valid and enforceable;

B. For a declaration that the ’996 Patent was duly and legally issued, and is valid and enforceable;

C. For a declaration that the ’095 Patent was duly and legally issued, is valid and enforceable;

D. For a declaration that the ’237 Patent was duly and legally issued, is valid and enforceable;

E. For a declaration that the ’207 Patent was duly and legally issued, is valid and enforceable;

F. Each Defendant has infringed the ’850 Patent;

G. Each Defendant has infringed the ’996 Patent;

H. Each Defendant has infringed the ’095 Patent;

I. Each Defendant has infringed the ’237 Patent;

J. Defendant Mednet has willfully infringed the ‘237 Patent;

K. Each Defendant has infringed the ’207 Patent;

L. That Plaintiffs be awarded damages caused by each Defendant's infringement, including all lost profits resulting from each Defendant's acts of infringement, and reasonable royalties, together with pre-judgment and post-judgment interest;

M. That Plaintiffs be awarded treble damages for infringement of the '237 patent as a consequence of Mednet's willful infringement;

N. Enjoining each Defendant, its officers, agents, servants, employees, attorneys, all parent and subsidiary corporations and affiliates, its assigns and successors in interest, and those persons in active concert or participation with each Defendant who receives notice of the injunction, from continuing acts of infringement of the '850, '996, '095, '237 and/or '207 Patents;

O. Adjudging this an exceptional case and awarding to Plaintiffs their reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

P. Awarding to Plaintiffs their costs and disbursements incurred in this action; and

Q. Awarding to Plaintiffs such other and further relief as this Court may deem just and proper.

Respectfully submitted,

DILWORTH PAXSON LLP

Dated: July 2, 2013

By: _____

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EXHIBIT A

US007212850B2

(12) **United States Patent**
Prystowsky et al.

(10) **Patent No.: US 7,212,850 B2**
(45) **Date of Patent: May 1, 2007**

(54) **SYSTEM AND METHOD FOR PROCESSING AND PRESENTING ARRHYTHMIA INFORMATION TO FACILITATE HEART ARRHYTHMIA IDENTIFICATION AND TREATMENT**

(75) Inventors: **Eric N. Prystowsky**, Carmel, IN (US); **Lev Korzinov**, San Diego, CA (US); **Eric Baumann**, San Diego, CA (US); **Scott Denis**, Murrieta, CA (US); **Manuel E. Jaime**, Solana Beach, CA (US); **Justin James**, San Diego, CA (US)

(73) Assignee: **CardioNet, Inc.**, San Diego, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 411 days.

(21) Appl. No.: **10/760,122**

(22) Filed: **Jan. 16, 2004**

(65) **Prior Publication Data**

US 2005/0113706 A1 May 26, 2005

Related U.S. Application Data

(60) Provisional application No. 60/525,386, filed on Nov. 26, 2003.

(51) **Int. Cl.**
A61B 5/044 (2006.01)

(52) **U.S. Cl.** **600/523**; 600/518

(58) **Field of Classification Search** 600/515–523
See application file for complete search history.

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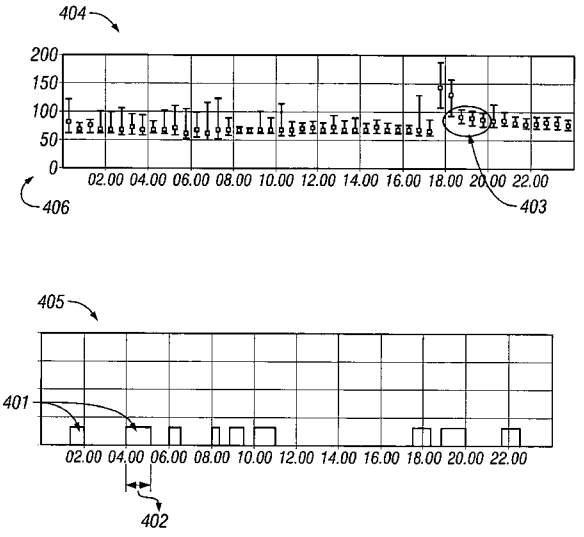
(74) *Attorney, Agent, or Firm*—Fish & Richardson P.C.

(57) **ABSTRACT**

A system and method for presenting information relating to heart data can involve operations including identifying arrhythmia events in physiological data obtained for a living being, receiving human assessments of at least a portion of the arrhythmia events, determining a measure of correlation between the human assessments and the identified events, and selectively presenting information regarding the identified events based on the measure of correlation. The operations can also include identifying atrial fibrillation events in physiological data obtained for a living being, obtaining heart rate data for the living being, and presenting information regarding the heart rate data and duration of the atrial fibrillation events together with a common time scale to pictographically represent heart rate trend with atrial fibrillation burden during a defined time period.

44 Claims, 6 Drawing Sheets



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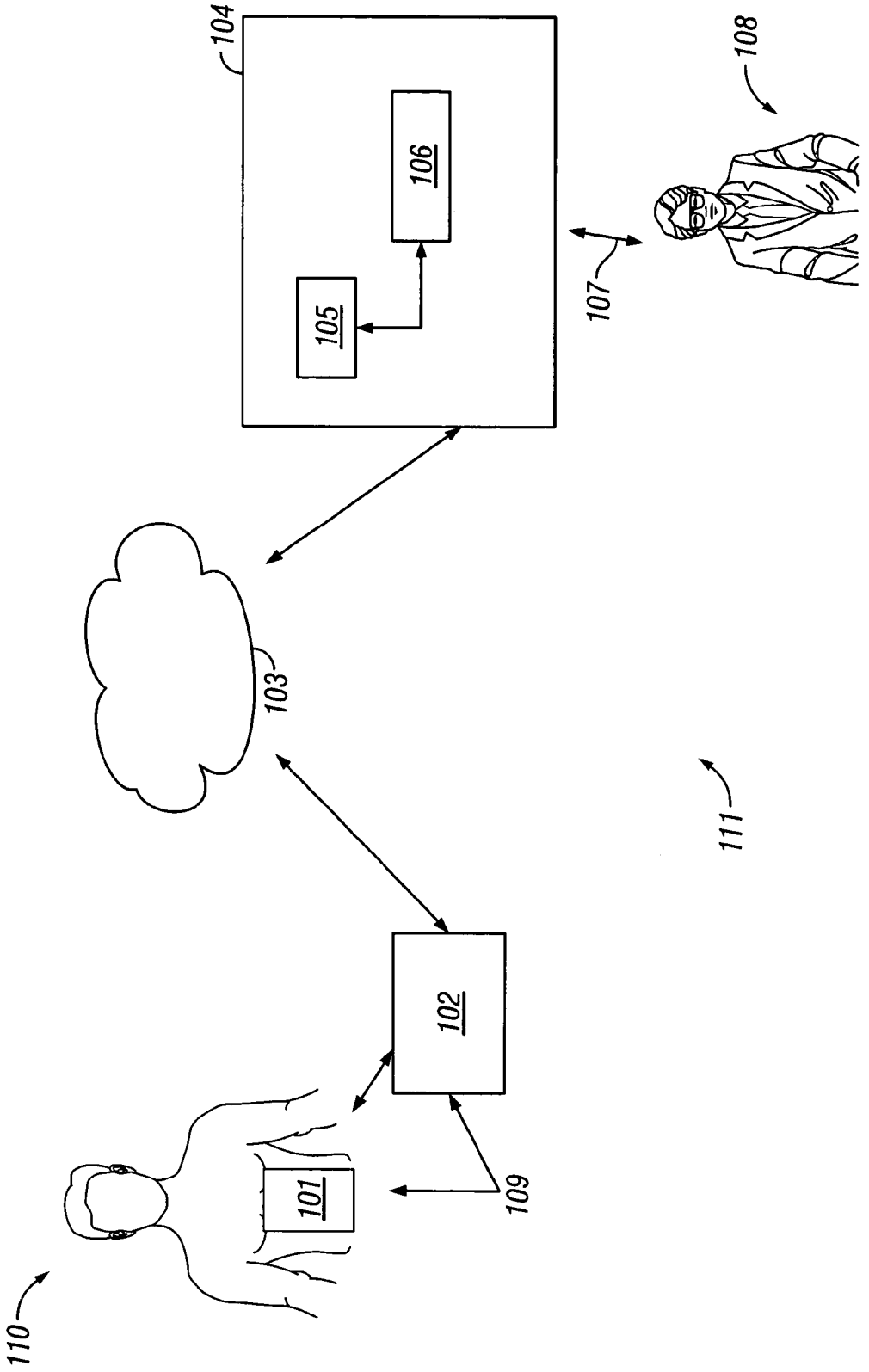

FIG. 1

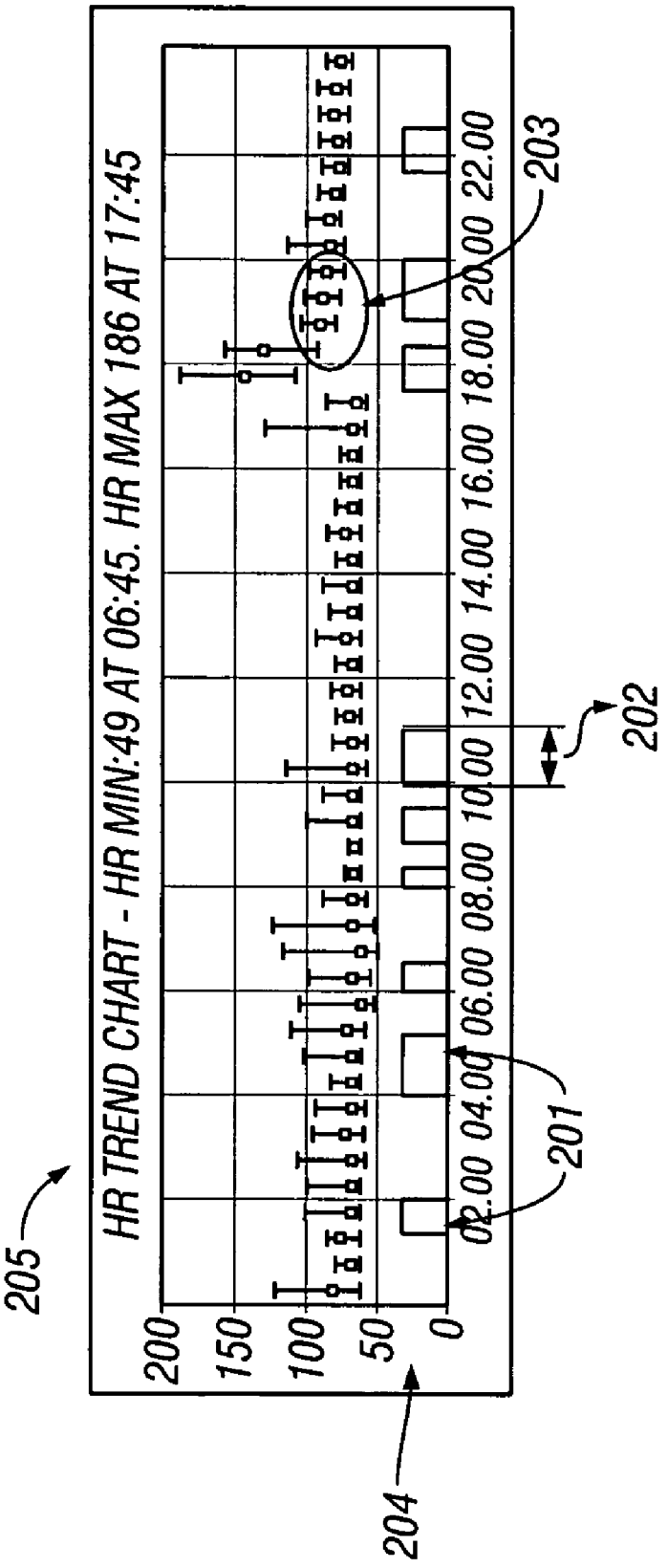
HR TREND CHART - HR MIN:49 AT 06:45. HR MAX 186 AT 17:45
200
150
100
50
0
02.00 04.00 06.00 08.00 10.00 12.00 14.00 16.00 18.00 20.00 22.00
201
202
203
204
205

FIG. 2

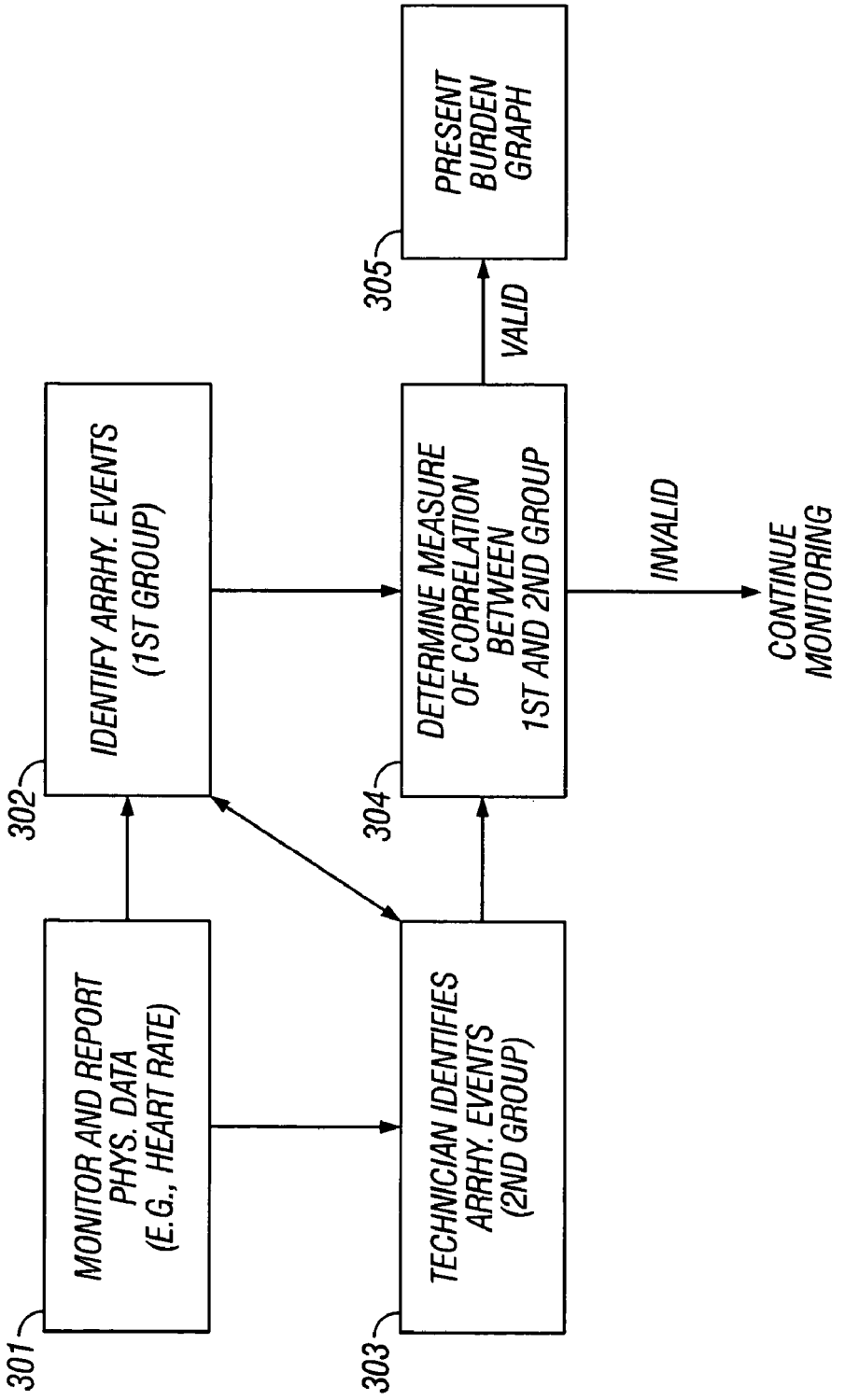
MONITOR AND REPORT PHYS. DATA (E.G., HEART RATE)
301
IDENTIFY ARRHY. EVENTS (1ST GROUP)
302
TECHNICIAN IDENTIFIES ARRHY. EVENTS (2ND GROUP)
303
DETERMINE MEASURE OF CORRELATION BETWEEN 1ST AND 2ND GROUP
304
VALID
PRESENT BURDEN GRAPH
305
INVALID
CONTINUE MONITORING

FIG. 3

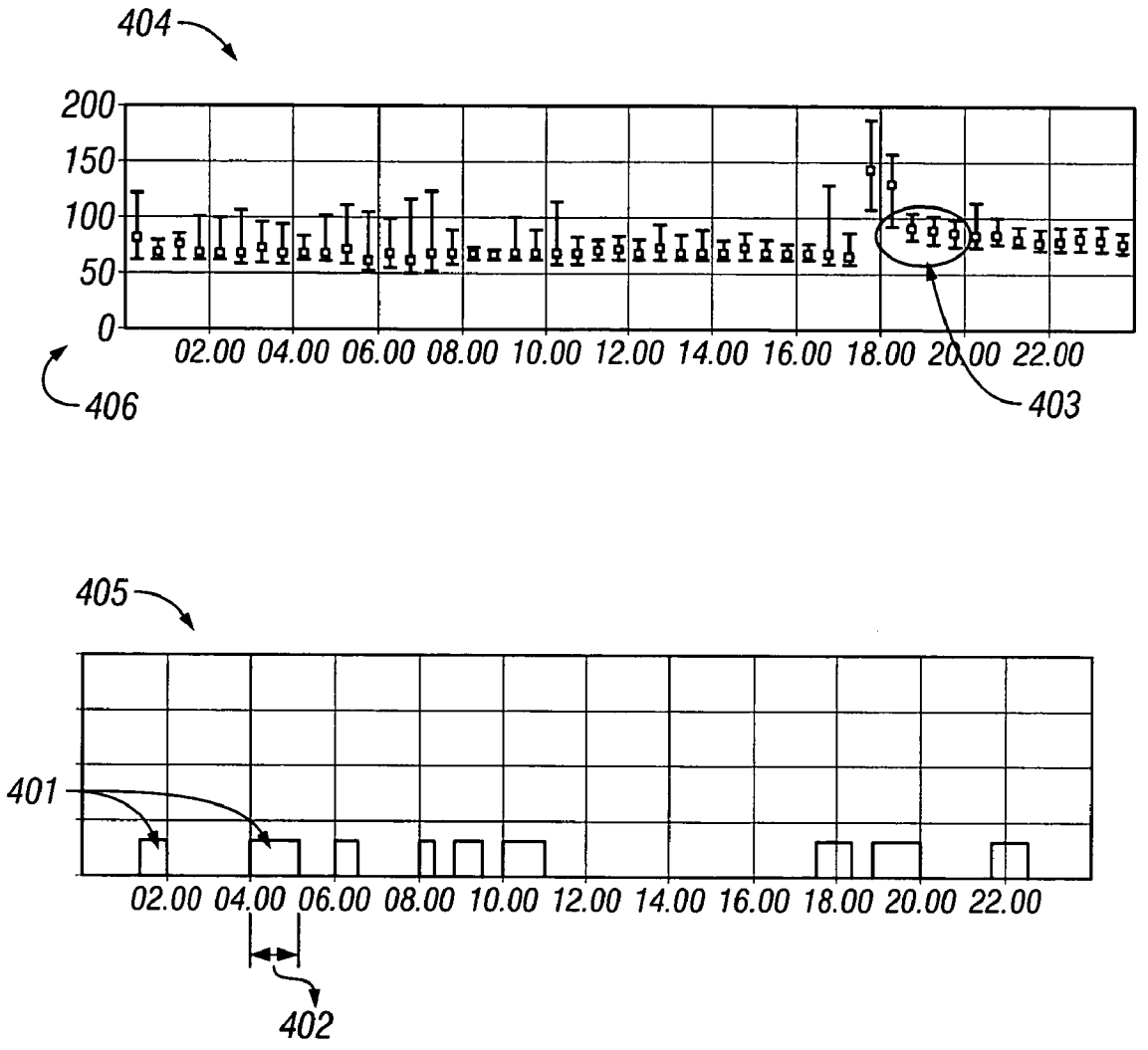
404
200
150
100
50
0
02.00 04.00 06.00 08.00 10.00 12.00 14.00 16.00 18.00 20.00 22.00
406
403
405
401
02.00 04.00 06.00 08.00 10.00 12.00 14.00 16.00 18.00 20.00 22.00
402

FIG. 4

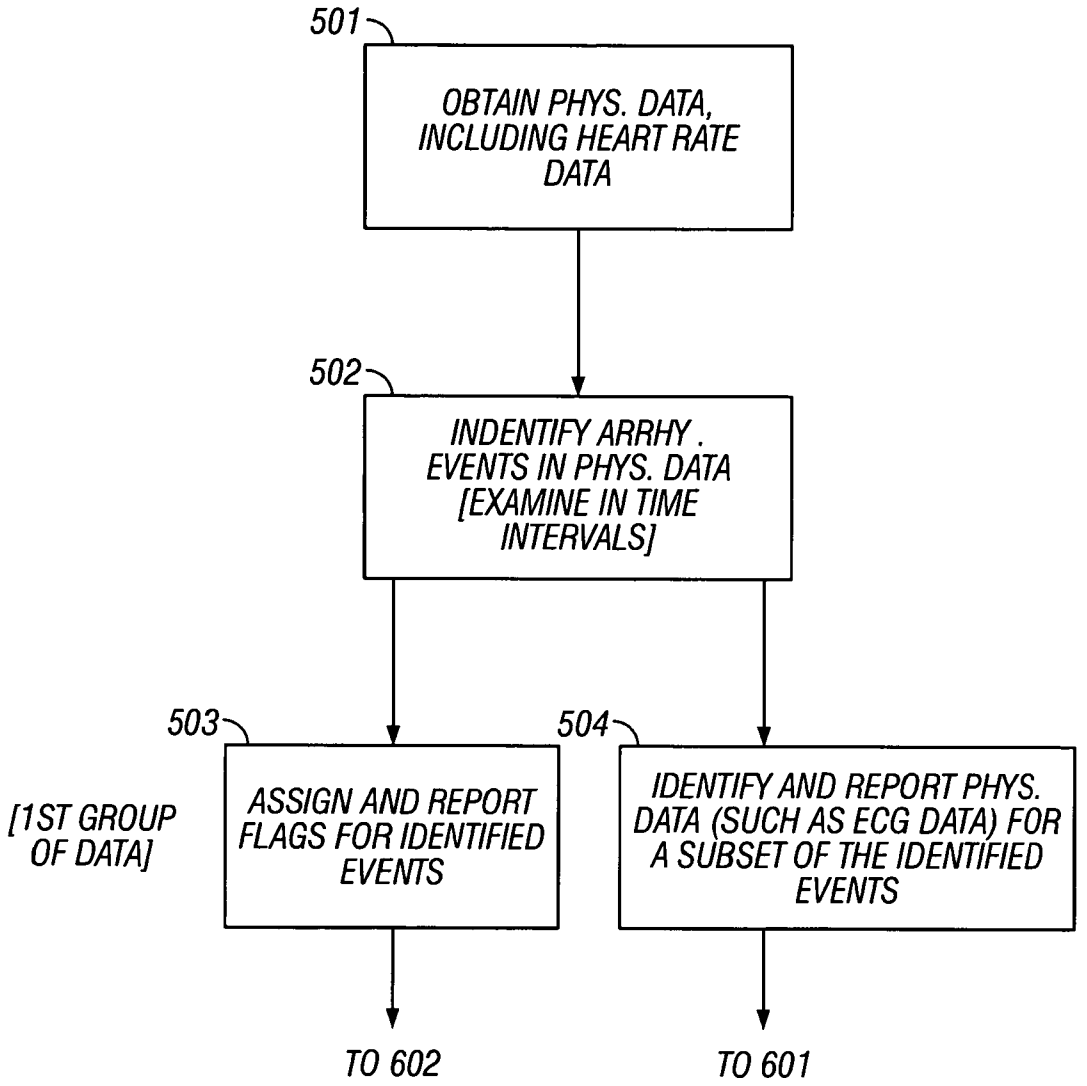
501
OBTAIN PHYS. DATA, INCLUDING HEART RATE DATA
502
INDENTIFY ARRHY . EVENTS IN PHYS. DATA [EXAMINE IN TIME INTERVALS]
503
504
[1ST GROUP OF DATA]
ASSIGN AND REPORT FLAGS FOR IDENTIFIED EVENTS
IDENTIFY AND REPORT PHYS. DATA (SUCH AS ECG DATA) FOR A SUBSET OF THE IDENTIFIED EVENTS
TO 602
TO 601

FIG. 5

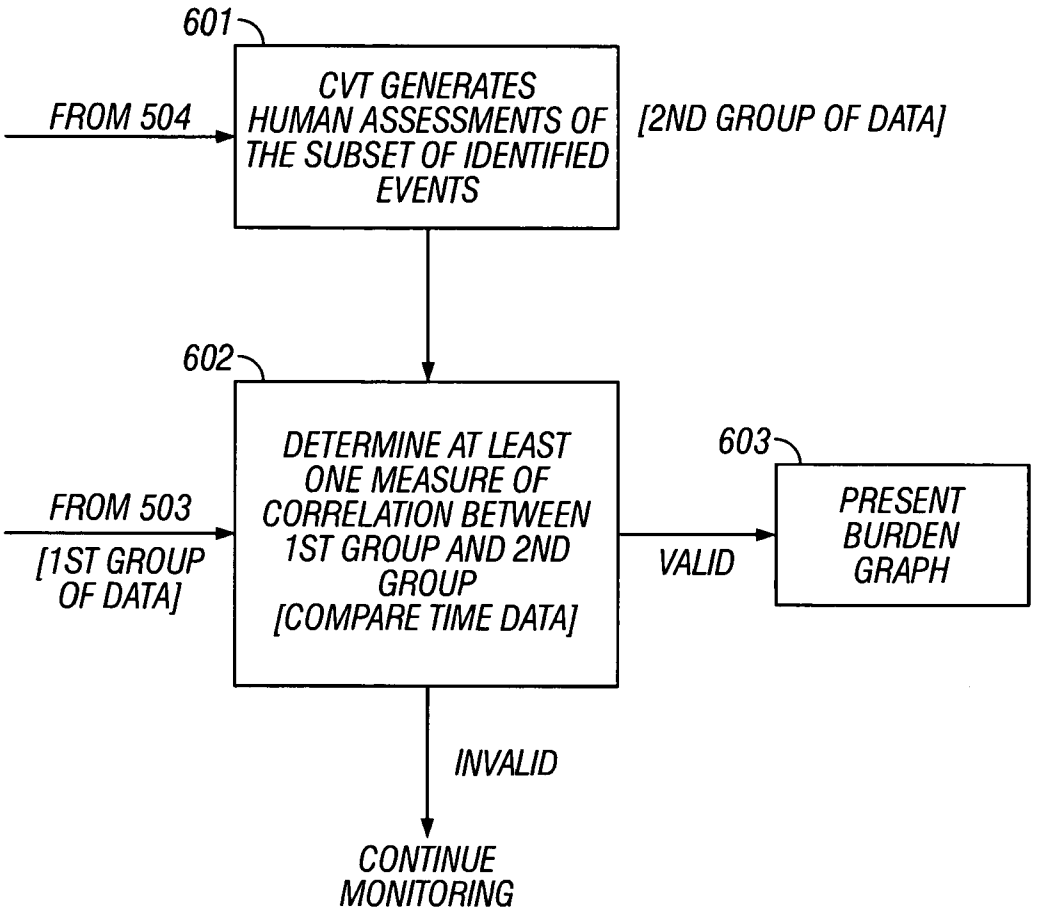
601
CVT GENERATES HUMAN ASSESSMENTS OF THE SUBSET OF IDENTIFIED EVENTS
FROM 504
[2ND GROUP OF DATA]
602
DETERMINE AT LEAST ONE MEASURE OF CORRELATION BETWEEN 1ST GROUP AND 2ND GROUP [COMPARE TIME DATA]
FROM 503
[1ST GROUP OF DATA]
603
PRESENT BURDEN GRAPH
VALID
INVALID
CONTINUE MONITORING

FIG. 6

SYSTEM AND METHOD FOR PROCESSING AND PRESENTING ARRHYTHMIA INFORMATION TO FACILITATE HEART ARRHYTHMIA IDENTIFICATION AND TREATMENT

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of priority from U.S. Provisional Application entitled "Presenting Arrhythmia Information to Facilitate Heart Arrhythmia Identification and Treatment," filed Nov. 26, 2003, Application Ser. No. 60/525,386.

BACKGROUND

The present application describes systems and techniques relating to processing and presenting arrhythmia event information from physiological data, for example, selectively presenting atrial fibrillation events to a medical practitioner.

Over the years, various devices have been used for monitoring hearts in living beings. Additionally, systems have been used to collect and report on heart information obtained from patients.

SUMMARY

In general, in one aspect, a heart monitoring system collects heart data from a monitored individual and stores the data at a monitoring center. Collected data can be processed, and graphical representations of the collected information can be presented to medical practitioners to assist in treating heart arrhythmias, such as atrial fibrillation. A system and method can involve operations including identifying arrhythmia events in physiological data obtained for a living being, receiving human assessments of at least a portion of the arrhythmia events, determining a measure of correlation between the human assessments and the identified events, and selectively presenting information regarding the identified events based on the measure of correlation. The operations also can include identifying atrial fibrillation events in physiological data obtained for a living being, obtaining heart rate data for the living being, and presenting information regarding the heart rate data and duration of the atrial fibrillation events together with a common time scale to pictographically represent heart rate trend with atrial fibrillation burden during a defined time period.

One or more of the following advantages can be realized. The heart monitor can loop every twenty-four hours and can automatically transmit heart data at least every twenty-four hours. The system can automatically generate a daily graphical summary of atrial fibrillation (AF) burden for review by a medical practitioner, which can be presented effectively anywhere using one or more communication networks. The AF burden graph can be used for asymptomatic AF detection, drug therapy (rate, rhythm, anti-coagulants), pre/post ablation monitoring, and CHF (congestive heart failure) decompensation. The system can provide an overall sensitivity of 96%, a positive predictivity of over 99%, and artifact rejection of over 90%. In one implementation, the graph only displays events where AF detection is validated by a technician finding AF in over 50% of the automatically identified events.

The details of one or more embodiments are set forth in the accompanying drawings and the description below.

Other features and advantages will become apparent from the description, the drawings, and the claims.

DRAWING DESCRIPTIONS

FIG. **1** illustrates, according to an exemplary embodiment, a system for reporting information related to arrhythmia events.

FIG. **2** shows, according to one embodiment, a graph presenting an example of atrial fibrillation burden and heart rate trend.

FIG. **3** is a diagram illustrating, according to an exemplary embodiment, a procedure for monitoring, processing, and reporting information related to arrhythmia events.

FIG. **4** shows, according to an exemplary embodiment, one graph presenting an example of atrial fibrillation burden and one graph presenting an example of heart rate trend.

FIGS. **5** and **6** are diagrams illustrating, according to another exemplary embodiment, a procedure for monitoring, processing, and reporting information related to arrhythmia events.

DETAILED DESCRIPTION

FIG. **1** illustrates, according to one embodiment, a system for reporting information related to arrhythmia events, such as atrial fibrillation events. In this embodiment, monitoring system **109** can communicate (via devices **101** and **102**) ECG (electrocardiogram), cardiac event, and other data to monitoring center **104**. The system **109** can include, for example, an implantable medical device (IMD), such as an implantable cardiac defibrillator and an associated transceiver or pacemaker and an associated transceiver, or a monitoring device **101** that a patient **110** wears. Further, monitoring system **109** can include a monitor processing device **102** that can send standard physiological data (received from monitoring device **101**) to monitoring center **104** and that can detect arrhythmia events (such as atrial fibrillation events). In one implementation, the devices **101** and **102** are integrated into a single device. Moreover, the system **109** can be implemented using, for example, the CardioNet Mobile Cardiac Outpatient Telemetry (MCOT) device, which is commercially available and provided by CardioNet, Inc of San Diego, Calif.

Monitor processing device **102** can transmit physiological data (including data related to arrhythmia events) through a communication network **103**, which can be a local area network (LAN), a landline telephone network, a wireless network, a satellite communication network, or other suitable network to facilitate two-way communication with monitoring center **104**. Advantageously, monitoring center **104** can be located in the same location (e.g., in the same room or building) as monitoring system **109** or at some remote location.

The monitoring center **104** can include a monitoring (or display) station **105** and a processing system **106**. In one implementation, a cardiovascular technician (CVT) can use the monitoring station **105** to evaluate physiological data received from monitoring system **109**, identifying and reporting, among other things, arrhythmia events (such as atrial fibrillation events). The CVT reports these assessments of the physiological data to the processing system **106**, which also receives information related to the arrhythmia events identified by monitoring system **109**. As will be explained further below, processing system **106** analyzes this arrhythmia event data (both the human-assessed data from the CVT and the data reported by monitoring system

109) and determines whether to generate a graph (or other similar presentation) related to these events. In certain circumstances, the processing system will send a report related to both arrhythmia and heart rate data to, for example, a physician or other health care provider **108** via transmission path **107**—which may be part of the network **103**.

FIG. **3** illustrates, according to one embodiment, a procedure for monitoring, processing, and reporting arrhythmia event data (such as data associated with atrial fibrillation events). In this embodiment, the monitoring system **109** (illustrated in FIG. **1**) monitors and reports physiological data (including data related to heart rate) at **301**. At **302**, various parts of this physiological data can be analyzed (for example, RR variability and QRS morphology) and arrhythmia events can be identified based on predefined criteria—the information relating to these events (among other possible information) constituting a first group of data. In one implementation, the monitoring system **109** identifies certain of the arrhythmia events that are urgent or representative and reports those events to both a CVT at **303** and to the processing system at **304**. Alternatively, the system could simply report the events identified at **302** to the processing system. Further, at **303**, a CVT, using station **105**, evaluates various parts of the physiological data received from **302** and/or **301** and also identifies arrhythmia events—the information relating to these human-assessed events (among other possible information) constituting a second group of data. Here, if needed, the CVT can request additional data from monitoring system **109**.

At **304**, the processing system **106** analyzes both the first and second group of data, determining a measure of correlation between these groups. This process can involve, for example, determining whether a correlation measure exceeds and/or equals a predetermined correlation parameter or whether a correlation measure is less than and/or equals that parameter. If, based on the correlation analysis, the information related to the arrhythmia events is determined to be valid, then the system generates a report relating to both heart rate trend and the arrhythmia events at **305**, such as the graph shown in FIG. **2** or the graphs shown in FIG. **4**. If, on the other hand, there is insufficient correlation, then the system does not generate a report and monitoring continues.

To illustrate, in one implementation, every ten minutes, the monitoring system **109** transmits a "flag" if it has detected an atrial fibrillation (AF) event in the last ten minutes. In this implementation, the processing system **106** only generates a graph (or graphs) related to heart rate trend and atrial fibrillation burden—such as the graph shown in FIG. **2** or the graphs shown in FIG. **4**—if more than 50% of the ten minute flags (generated at **302**) match events identified by a CVT (at **303**)—a correlation (with respect to the time period at issue) indicating a high positive predictivity for the identification of AF events. If this 50% threshold is not met, then the system does not generate a graph (or graphs) based on the data at issue and simply continues to process data.

The term "atrial fibrillation burden" (or more generally, "arrhythmia event burden") refers generally to the overall amount of time that a patient is in atrial fibrillation (or arrhythmia) over a specified time period, taking into account the number and duration of episodes. Advantageously, employing pictographic presentations, such as those of FIGS. **2** and **4**, a medical practitioner can see whether a patient is more likely to experience an arrhythmia, such as AF, at certain times of the day, and this can affect therapeutic approaches in some cases.

FIG. **2** represents one example of how to pictographically present both heart rate trend and atrial fibrillation burden on a common time scale (to "pictographically present" such data, however, a graph is not required.). The graph **205** contains information relating to, for example, daily AF incidence and time of occurrence **201**, AF duration **202**, and heart rate (**203** and **204**). A scale **204** (in this example) indicates heart rate in average beats-per-minute and the dots and lines shown at **203** (for example) indicate values on that scale, standard deviations associated with these values, and heart rates during AF. Further, graph **205** shows heart rate data at 15 minutes and 45 minutes past the hour. Finally, in this graph, the presence of one or more AF events in a given 10-minute period is graphed as a 10-minute interval.

Like FIG. **2**, FIG. **4** represents an example of how to pictographically present heart rate trend and atrial fibrillation burden on a common time scale. Although FIG. **4**, unlike FIG. **2**, uses two graphs, FIG. **4** presents the same information as FIG. **2**. Specifically, graphs **404** and **405** contain information relating to, for example, daily AF incidence and time of occurrence **401**, AF duration **402**, and heart rate (**403** and **406**). A scale **406** (in this example) indicates heart rate in average beats-per-minute and the dots and lines shown at **403** (for example) indicate values on that scale, standard deviations associated with these values, and heart rates during AF.

FIGS. **5** and **6** are diagrams illustrating another implementation of the invention. Specifically, at **501**, the system **111**, employing monitoring system **109**, obtains physiological data, including heart rate data. In turn, at **502**, the system identifies the presence of arrhythmia events (such as AF events) in this physiological data, examining this data in time intervals. At **503**, the system assigns flags indicating the presence of arrhythmia events and reports those flags—which represent a first group of data—to the processing system. Similarly, at **504**, the system identifies and reports physiological data, such as ECG data, for a subset of the events identified at **502** and reported at **503**. Notably, the system, in this implementation, need not report physiological data for each flag assigned at **503**, but need only report data associated with the most significant events identified at **502**, thereby minimizing the data sent to a CVT.

At **601**, the CVT analyzes this data and reports whether arrhythmia events have occurred, thereby generating a second group of data. The processing system then determines (at **602**), based on comparing time stamps associated with each group of data, at least one measure of correlation between the first group of data and the second group of data. To illustrate, if enough of the human-assessed events reported at **601** match the events reported at **503**, then the system determines that the data is valid, that is, that there is a high positive predictivity for the identification of arrhythmia events. If such a determination is made, the data associated with each flag reported at **503** is pictographically presented in a form such as FIG. **2** or FIG. **4**. Significantly, in this implementation, while this pictographic representation can contain all such data, the CVT need only review a subset of this data. In short, the system achieves increased accuracy in the presentation of information relating to arrhythmia events while minimizing the data that the CVT reviews.

The disclosed system and all of the functional operations described and illustrated in this specification can be implemented in digital electronic circuitry, or in computer hard-

ware, firmware, software, or in combinations of the foregoing. Apparatus can be implemented in a software product (e.g., a computer program product) tangibly embodied in a machine-readable storage device for execution by a programmable processor, and processing operations can be performed by a programmable processor executing a program of instructions to perform functions by operating on input data and generating output. Further, the system can be implemented advantageously in one or more software programs that are executable on a programmable system. This programmable system can include the following: 1) at least one programmable processor coupled to receive data and instructions from, and to transmit data and instructions to, a data storage system; 2) at least one input device; and 3) at least one output device. Moreover, each software program can be implemented in a high-level procedural or object-oriented programming language, or in assembly or machine language if desired; and in any case, the language can be a compiled or an interpreted language.

Also, suitable processors include, by way of example, both general and special purpose microprocessors. Generally, a processor will receive instructions and data from a read-only memory, a random access memory, and/or a machine-readable signal (e.g., a digital signal received through a network connection). Generally, a computer will include one or more mass storage devices for storing data files. Such devices can include magnetic disks, such as internal hard disks and removable disks, magneto-optical disks, and optical disks. Storage devices suitable for tangibly embodying software program instructions and data include all forms of non-volatile memory, including, by way of example, the following: 1) semiconductor memory devices, such as EPROM (electrically programmable read-only memory); EEPROM (electrically erasable programmable read-only memory) and flash memory devices; 2) magnetic disks such as internal hard disks and removable disks; 3) magneto-optical disks; and 4) CD-ROM disks. Any of the foregoing can be supplemented by, or incorporated in, ASICs (application-specific integrated circuits).

To provide for interaction with a user (such as the CVT), the system can be implemented on a computer system having a display device such as a monitor or LCD (liquid crystal display) screen for displaying information to the user and a keyboard and a pointing device such as a mouse or a trackball by which the user can provide input to the computer system. The computer system can be programmed to provide a graphical user interface through which computer programs interact with users.

Finally, while the foregoing system has been described in terms of particular implementations, other embodiments are within the scope of the following claims. For example, the disclosed operations can be performed in a different order and still achieve desirable results. Moreover, the system need not employ 10-minute intervals; many different time intervals are possible (as is no interval at all), including 1 minute, 30 second, and 30-minute intervals. Indeed, because time intervals are not required, the graphs of FIGS. **2** and **4** could be modified to show continuous heart rate trend (accompanied by corresponding AF data) rather than just specific instances of this trend. Further, while FIGS. **2** and **4** show examples of (among other things) pictographically presenting atrial fibrillation burden (one type of arrhythmia event burden), one could present the same or similar information for another type of arrhythmia event. In fact, one could employ both the format and procedures associated with generating FIG. **2** or FIG. **4** (or a similar figure) to pictographically present information related to a number of different types of arrhythmia event burdens.

What is claimed is:

1. A machine-implemented method comprising:

identifying atrial fibrillation events in physiological data obtained for a living being;

obtaining heart rate data for the living being; and

pictographically presenting, using a common time scale, information regarding the heart rate data during a defined time period and regarding duration of atrial fibrillation activity, according to the identified atrial fibrillation events, during the defined time period such that heart rate trend is presented with atrial fibrillation burden;

wherein presenting information comprises selectively presenting the information based on a measure of correlation between the identified atrial fibrillation events and human-assessments of at least a portion of the identified atrial fibrillation events.

2. The method of claim **1**, wherein pictographically presenting information comprises presenting information regarding both incidence and duration of identified atrial fibrillation events during the defined time period.

3. The method of claim **1**, wherein the heart rate data comprise information presented in beats-per-minute.

4. The method of claim **3**, wherein the heart rate data comprise information presented in average beats-per-minute and comprises information regarding standard deviation of heart rate.

5. The method of claim **1**, wherein pictographically presenting information comprises presenting heart rate trend juxtaposed with atrial fibrillation burden.

6. The method of claim **1**, wherein pictographically presenting information comprises presenting heart rate trend and atrial fibrillation burden on the same graph.

7. The method of claim **1**, wherein pictographically presenting information comprises presenting heart rate trend and atrial fibrillation burden on different graphs.

8. The method of claim **1**, wherein identifying atrial fibrillation events comprises examining the physiological data in time intervals, and identifying the intervals in which at least one atrial fibrillation event has occurred, and wherein presenting information comprises displaying the identified intervals in alignment with the information regarding the heart rate data on the common time scale.

9. The method of claim **1**, further comprising receiving input specifying the defined time period.

10. A machine-implemented method comprising;

identifying arrhythmia events in physiological data obtained for a living being, the identified arrhythmia events representing a first group of data;

receiving a second group of data that includes human assessments of at least a portion of the arrhythmia events;

determining at least one measure of correlation between the first group of data and the second group of data; and

if the measure of correlation matches or exceeds at least one predetermined value, selectively presenting, based on this measure of correlation, information regarding at least a portion of the arrhythmia events.

11. The method of claim **10**, wherein identifying arrhythmia events comprises identifying atrial fibrillation events, and selectively presenting information comprises presenting information regarding the atrial fibrillation events and heart rate data for the living being, during a defined time period, together with a common time scale if the measure of

correlation indicates a high positive predictivity for the identification of atrial fibrillation events during the defined time period.

12. The method of claim **11**, wherein receiving human assessments comprises receiving human assessments of a subset of the atrial fibrillation events, and identifying atrial fibrillation events comprises:

examining the physiological data in time intervals,

identifying the intervals in which at least one atrial fibrillation event has occurred, and

reporting the identified intervals.

13. The method of claim **12**, wherein presenting the information comprises displaying the identified intervals in alignment with the information regarding the heart rate data on the common time scale.

14. The method of claim **12**, further comprising identifying a subset of the atrial fibrillation events that are urgent or representative, the identified subset being the human assessed subset.

15. The method of claim **12**, wherein determining a measure of correlation between the human assessments and the identified events comprises:

assessing, based on comparing at least time data, a number of the identified intervals that encompass at least a portion of human-assessed arrhythmia events.

16. The method of claim **12**, wherein presenting the information regarding the heart rate data comprises displaying a heart rate trend graph including maximum heart rates in time intervals.

17. The method of claim **16**, wherein each of the heart rate intervals is thirty minutes, and each of the atrial fibrillation intervals is ten minutes.

18. The method of claim **11**, wherein presenting the information comprises displaying the information in two graphs using the common time scale.

19. The method of claim **11**, wherein presenting the information comprises displaying the information in a single graph using the common time scale.

20. An article comprising a machine-readable medium embodying information indicative of instructions that when performed by one or more machines result in operations comprising:

identifying atrial fibrillation events in physiological data obtained for a living being;

obtaining heart rate data for the living being; and

pictographically presenting, using a common time scale, information regarding the heart rate data during a defined time period and regarding duration of atrial fibrillation activity, according to the identified atrial fibrillation events, during the defined time period such that heart rate trend is presented with atrial fibrillation burden;

wherein presenting information comprises selectively presenting the information based on a measure of correlation between the identified atrial fibrillation events and human-assessments of at least a portion of the identified atrial fibrillation events.

21. The article of claim **20**, wherein identifying atrial fibrillation events comprises examining the physiological data in time intervals, and identifying the intervals in which at least one atrial fibrillation event has occurred, and wherein presenting information comprises displaying the identified intervals in alignment with the information regarding the heart rate data on the common time scale.

22. An article comprising a machine-readable medium embodying information indicative of instructions that when one formed by one or more machines result in operations comprising:

identifying arrhythmia events in physiological data obtained for a living being, the identified arrhythmia events representing a first group of data;

receiving a second group of data that includes human assessments of at least a portion of the arrhythmia events;

determining at least one measure of correlation between the first group of data and the second group of data; and

if the measure of correlation matches or exceeds at least one predetermined value, selectively presenting, based on this measure of correlation, information regarding at least a portion of the arrhythmia events.

23. The article of claim **22**, wherein identifying arrhythmia events comprises identifying atrial fibrillation events, and selectively presenting information comprises presenting information regarding the atrial fibrillation events and heart rate data for the living being, during a defined time period, together with a common time scale if the measure of correlation indicates a high positive predictivity for the identification of atrial fibrillation events during the defined time period.

24. The article of claim **23**, wherein receiving human assessments comprises receiving human assessments of a subset of the atrial fibrillation events, and identifying atrial fibrillation events comprises:

examining the physiological data in time intervals,

identifying the intervals in which at least one atrial fibrillation event has occurred, and

reporting the identified intervals.

25. A machine-implemented method comprising:

identifying arrhythmia events in physiological data obtained for a living being, the identified arrhythmia events representing a first group of data;

receiving a second group of data that includes human assessments of at least a portion of the arrhythmia events:

determining at least one measure of correlation between the first group of data and the second group of data; and

if the measure of correlation matches or is less than at least one predetermined value, selectively presenting, based on this measure of correlation, information regarding at least a portion of the arrhythmia events.

26. The method of claim **25**, wherein identifying arrhythmia events comprises identifying atrial fibrillation events and selectively presenting information comprises presenting information regarding the atrial fibrillation events and heart rate data for the living being, during a defined time period, together with a common time scale if the measure of correlation indicates a high positive predictivity for the identification of atrial fibrillation events during the defined time period.

27. An article comprising a machine-readable medium embodying information indicative of instructions that when performed by one or more machines result in operations comprising:

identifying arrhythmia events in physiological data obtained for a living being, the identified arrhythmia events representing a first group of data;

receiving a second group of data that includes human assessments of at least a portion of the arrhythmia events;

determining at least one measure of correlation between the first group of data and the second group of data;

if the measure of correlation matches or is less than at least one predetermined value, selectively presenting, based on this measure of correlation, information regarding at least a portion of the arrhythmia events.

28. The article of claim **27**, wherein identifying arrhythmia events comprises identifying atrial fibrillation events and selectively presenting information comprises presenting information regarding the atrial fibrillation events and heart rate data for the living being, during a defined time period, together with a common time scale if the measure of correlation indicates a high positive predictivity for the identification of atrial fibrillation events during the defined time period.

29. A system for reporting information related to arrhythmia events comprising:

a monitoring system configured to process and report physiological data for a living being and configured to identify arrhythmia events from the physiological data;

a monitoring station for receiving the physiological data from the monitoring system;

a processing system configured to receive arrhythmia information from the monitoring system and configured to receive human-assessed arrhythmia information from the monitoring station wherein the human-assessed arrhythmia information derives from at least a portion of the physiological data and wherein the processing system reports information regarding arrhythmia events if a correlation measure relating to a correlation between the arrhythmia information from the monitoring system and the human-assessed arrhythmia information matches or exceeds a predetermined value.

30. The system of claim **29**, wherein the processing system is capable of presenting information regarding atrial fibrillation events and heart rate data for the living being, during a defined time period, together with a common time scale if the correlation measure indicates a high positive predictivity for the identification of atrial fibrillation events during the defined time period.

31. A system for reporting information related to arrhythmia events comprising:

a monitoring system configured to process and report physiological data, including heart rate data, for a living being and configured to identify arrhythmia events from the physiological data;

a monitoring station for receiving the physiological data from the monitoring system;

a processing system configured to receive arrhythmia information from the monitoring system and configured to receive human-assessed arrhythmia information from the monitoring station wherein the human-assessed arrhythmia information derives from at least a portion of the physiological data and wherein the processing system is capable of pictographically presenting, using a common time scale, information regarding the heart rate data during a defined time period and regarding duration of arrhythmia event activity, according to the identified arrhythmia events, during the defined time period such that heart rate trend is presented with arrhythmia event burden.

32. The system of claim **31** wherein the monitoring system is capable of examining the physiological data in time intervals and identifying the intervals in which at least one atrial fibrillation event has occurred and wherein the processing system is capable of displaying the identified intervals in alignment with the information regarding the heart rate data on the common time scale.

33. A system for reporting information related to arrhythmia events comprising:

monitoring means for processing and reporting physiological data, including heart, rate data, for a living being and for identifying arrhythmia events from the physiological data;

display means for receiving the physiological data from the monitoring means and for displaying the physiological data to a human user;

processing means for receiving arrhythmia information from the monitoring system and for receiving human-assessed arrhythmia information from the display means wherein the human-assessed arrhythmia information derives from at least a portion of the physiological data and wherein the processing means is capable of pictographically presenting, using a common time scale, information regarding the heart rate data during a defined time period and regarding duration of arrhythmia event activity, according to the identified arrhythmia events, during the defined time period such that heart rate trend is presented with arrhythmia event burden.

34. The system of claim **33** wherein the monitoring means is capable of examining the physiological data in time intervals and identifying the intervals in which at least one atrial fibrillation event has occurred and wherein the processing means is capable of displaying the identified intervals in alignment with the information regarding the heart rate data on the common time scale.

35. A machine implemented method comprising:

obtaining heart rate data for a living being;

identifying atrial fibrillation events in physiological data obtained for the living being, the identified atrial fibrillation events representing a first group of data, and wherein identifying atrial fibrillation events includes examining the physiological data in time intervals and identifying the intervals in which at least one atrial fibrillation event has occurred;

receiving a second group of data that includes human assessments of at least a portion of the atrial fibrillation events;

determining at least one measure of correlation between the first group of date and the second group of data, wherein determining at least one measure of correlation includes assessing, based on comparing at least time data, a number of the identified intervals that encompass at least a portion of the human-assessed atrial fibrillation events;

if the measure of correlation matches or exceeds at least one predetermined value, pictographically presenting, using a common time scale, information regarding the heart rate data during a defined time period and regarding duration of atrial fibrillation activity, according to the identified atrial fibrillation events, during the defined time period such that heart rate trend is juxtaposed with atrial fibrillation burden and wherein pictographically presenting includes displaying the identified intervals in alignment with the information regarding the heart rate data on the common time scale.

36. The method of claim **35**, wherein pictographically presenting comprises presenting information regarding the atrial fibrillation events and heart rate data for the living being, during a defined time period, together with a common time scale if the measure of correlation indicates a high positive predictivity for the identification of atrial fibrillation events during the defined time period.

37. An apparatus comprising:
means for identifying atrial fibrillation events in physiological data obtained for a living being;
means for obtaining heart rate data for the living being; and
means for pictographically presenting, using a common time scale, information regarding the heart rate data during a defined time period and regarding duration of atrial fibrillation activity, according to the identified atrial fibrillation events, during the defined time period such that heart rate trend is presented with atrial fibrillation burden;
wherein the means for pictographically presenting information comprises means for selectively presenting the information based on a measure of correlation between the identified atrial fibrillation events and human-assessments of at least a portion of the identified atrial fibrillation events.

38. The apparatus of claim 37, wherein the means for pictographically presenting is capable of presenting information regarding the atrial fibrillation events and heart rate data for the living being, during a defined time period, together with a common time scale if the measure of correlation indicates a high positive predictivity for the identification of atrial fibrillation events during the defined time period.

39. An apparatus comprising:
means for identifying arrhythmia events in physiological data obtained for a living being, the identified arrhythmia events representing a first group of data;
means for receiving a second group of data that includes human assessments of at least a portion of the arrhythmia events;
means for determining at least one measure of correlation between the first group of data and the second group of data;
means for selectively presenting, based on this measure of correlation, information regarding at least a portion of the arrhythmia events if the measure of correlation matches or exceeds at least one predetermined value.

40. The apparatus of claim 39, wherein the arrhythmia events comprise atrial fibrillation events and wherein the means for selectively presenting is capable of presenting information regarding the atrial fibrillation events and heart rate data for the living being, during a defined time period, together with a common time scale if the measure of correlation indicates a high positive predictivity for the identification of atrial fibrillation events during the defined time period.

41. A machine implemented method comprising:
obtaining heart, rate data for a living being;
identifying arrhythmia events in physiological data obtained for the living being, the identified arrhythmia events representing a first group of data, and wherein identifying arrhythmia events includes examining the physiological data in time intervals and identifying the intervals in which at least one arrhythmia events event has occurred;
receiving a second group of data that includes human assessments of at least a portion of the arrhythmia events;
determining at least one measure of correlation between the first group of data and the second group of data, wherein determining at least one measure of correlation includes assessing, based on comparing at least time data, a number of the identified intervals that encompass at least a portion of the human-assessed arrhythmia events;
if the measure of correlation matches or exceeds at least one predetermined value, pictographically presenting, using a common time scale, information regarding the heart rate data during a defined time period and regarding duration of arrhythmia events activity, according to the identified arrhythmia events, during the defined time period such that heart rate trend is juxtaposed with arrhythmia event burden and wherein pictographically presenting includes displaying the identified intervals in alignment with the information regarding the heart rate data on the common time scale.

42. The method of claim 41, wherein pictographically presenting comprises presenting information regarding the arrhythmia events and heart rate data for the living being, during a defined time period, together with a common time scale if the measure of correlation indicates a high positive predictivity for the identification of arrhythmia events during the defined time period.

43. A machine-implemented method comprising:
identifying arrhythmia events in physiological data obtained for a living being, the identified arrhythmia events representing a first group of data;
receiving a second group of data that includes human assessments of at least a portion of the arrhythmia events;
determining at least one measure of correlation between the first group of data and the second group of data; and
if the measure of correlation matches or exceeds at least one predetermined value, selectively presenting, based on this measure of correlation, information regarding at least a portion of the identified arrhythmia events and wherein selectively presenting information comprises presenting information regarding the identified arrhythmia events and heart rate data for the living being, during a defined time period, together with a common time scale if the measure of correlation indicates a high positive predictivity for the identification of arrhythmia events during the defined time period.

44. The method of claim 43, wherein receiving human assessments comprises receiving human assessments of a subset of the identified arrhythmia events, and identifying arrhythmia events comprises:
examining the physiological data in time intervals,
identifying the intervals in which at least one identified arrhythmia event has occurred, and
reporting the identified intervals.

* * * * *

EXHIBIT B

US007907996B2

(12) **United States Patent**
Prystowsky et al.

(10) **Patent No.: US 7,907,996 B2**
(45) **Date of Patent: *Mar. 15, 2011**

(54) **SYSTEM AND METHOD FOR PROCESSING AND PRESENTING ARRHYTHMIA INFORMATION TO FACILITATE HEART ARRHYTHMIA IDENTIFICATION AND TREATMENT**

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(73) Assignee: **CardioNet, Inc.**, Conshohocken, PA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 767 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **11/739,037**

(22) Filed: **Apr. 23, 2007**

(65) **Prior Publication Data**

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Related U.S. Application Data

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(60) Provisional application No. 60/525,386, filed on Nov. 26, 2003.

(51) **Int. Cl.**
A61B 5/0402 (2006.01)

(52) **U.S. Cl.** **600/523**; 600/518

(58) **Field of Classification Search** 600/508–523
See application file for complete search history.

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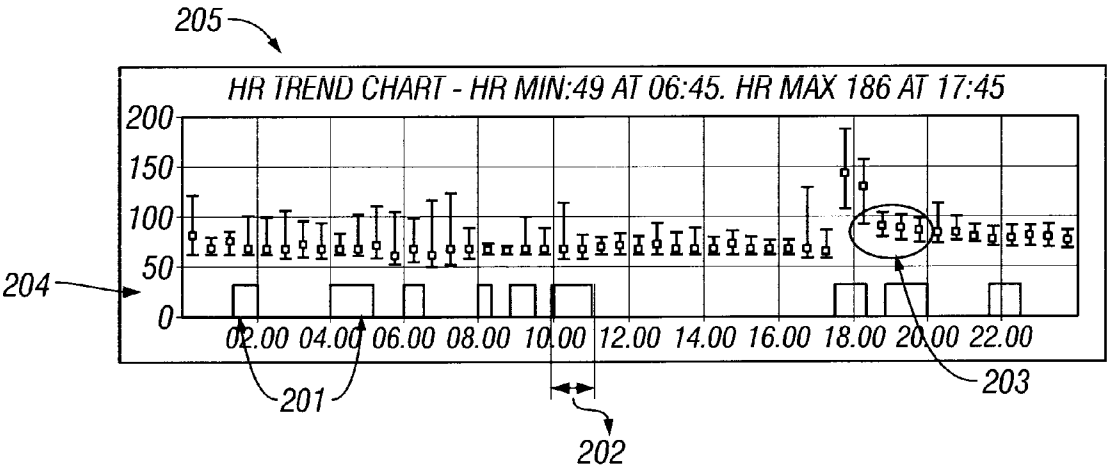
(74) *Attorney, Agent, or Firm* — Fish & Richardson P.C.

(57) **ABSTRACT**

A system and method for presenting information relating to heart data can involve operations including identifying arrhythmia events in physiological data obtained for a living being, receiving human assessments of at least a portion of the arrhythmia events, determining a measure of correlation between the human assessments and the identified events, and selectively presenting information regarding the identified events based on the measure of correlation. The operations can also include identifying atrial fibrillation events in physiological data obtained for a living being, obtaining heart rate data for the living being, and presenting information regarding the heart rate data and duration of the atrial fibrillation events together with a common time scale to pictographically represent heart rate trend with atrial fibrillation burden during a defined time period.

28 Claims, 6 Drawing Sheets



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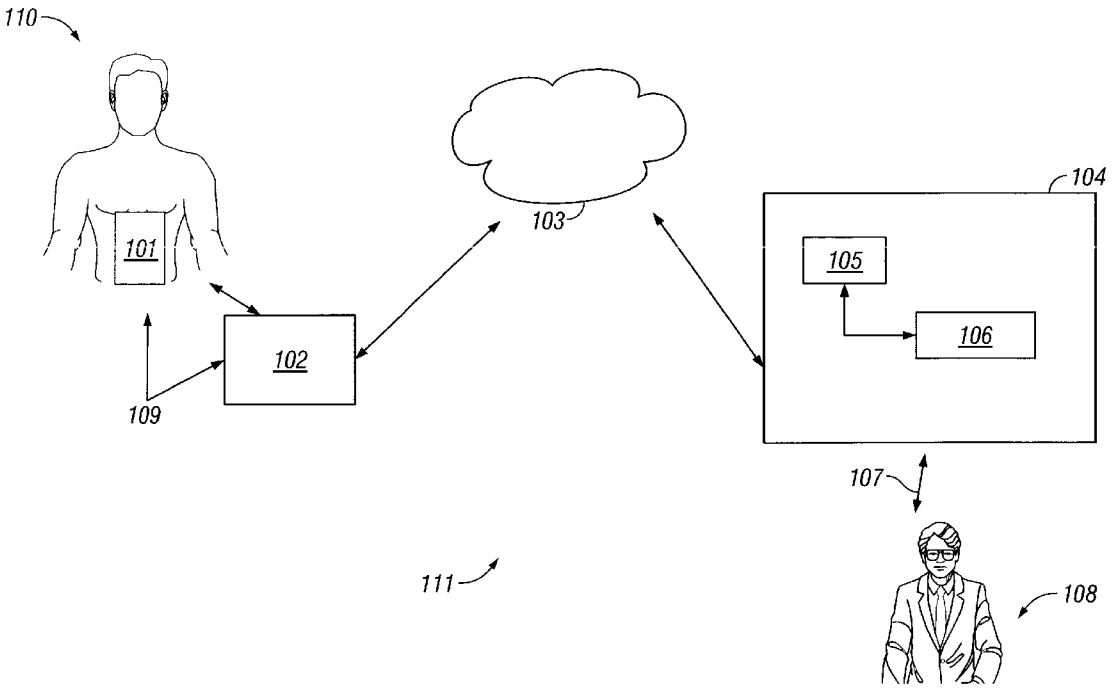
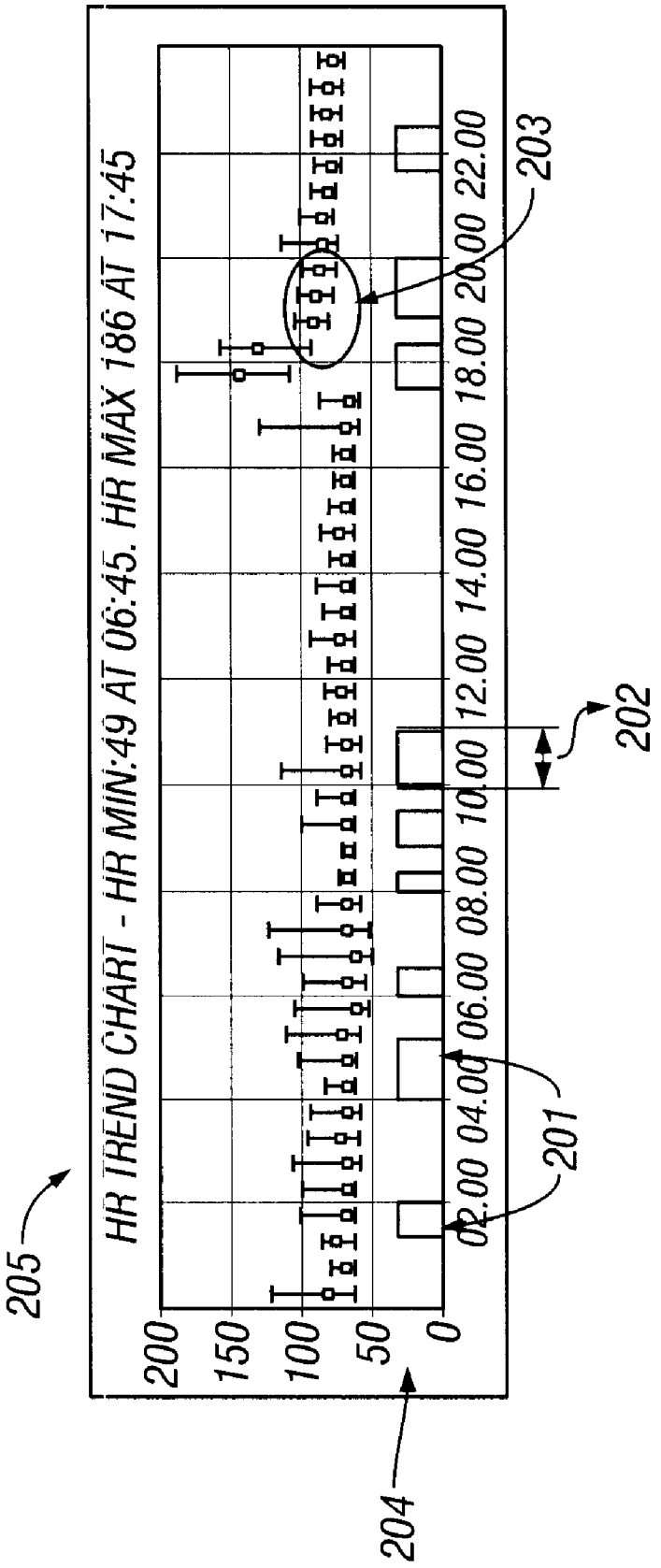


FIG. 1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150
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201
202
203
204
205

FIG. 2

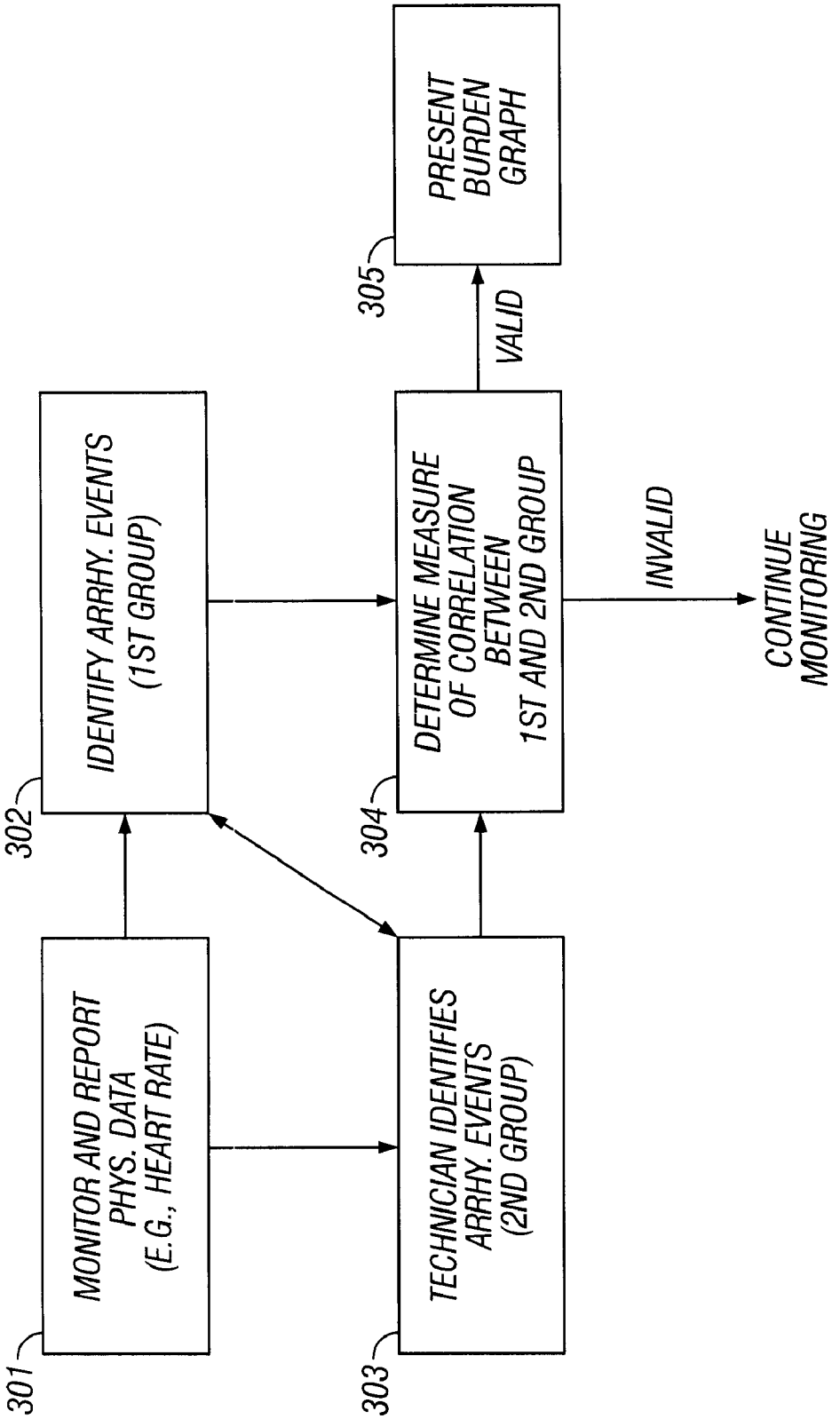
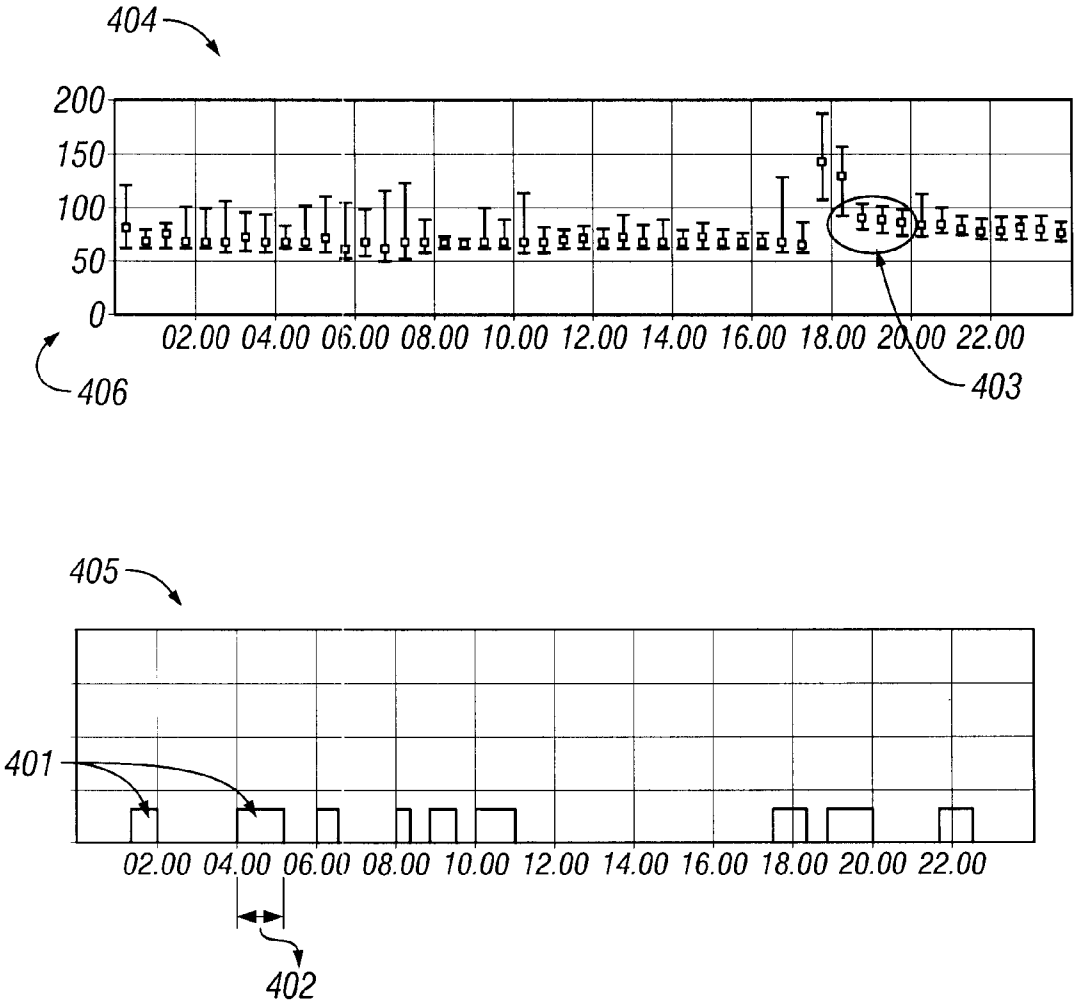

MONITOR AND REPORT PHYS. DATA (E.G., HEART RATE)
301
IDENTIFY ARRHY. EVENTS (1ST GROUP)
302
TECHNICIAN IDENTIFIES ARRHY. EVENTS (2ND GROUP)
303
DETERMINE MEASURE OF CORRELATION BETWEEN 1ST AND 2ND GROUP
304
PRESENT BURDEN GRAPH
305
VALID
INVALID
CONTINUE MONITORING

FIG. 3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100
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02.00 04.00 06.00 08.00 10.00 12.00 14.00 16.00 18.00 20.00 22.00
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402

FIG. 4

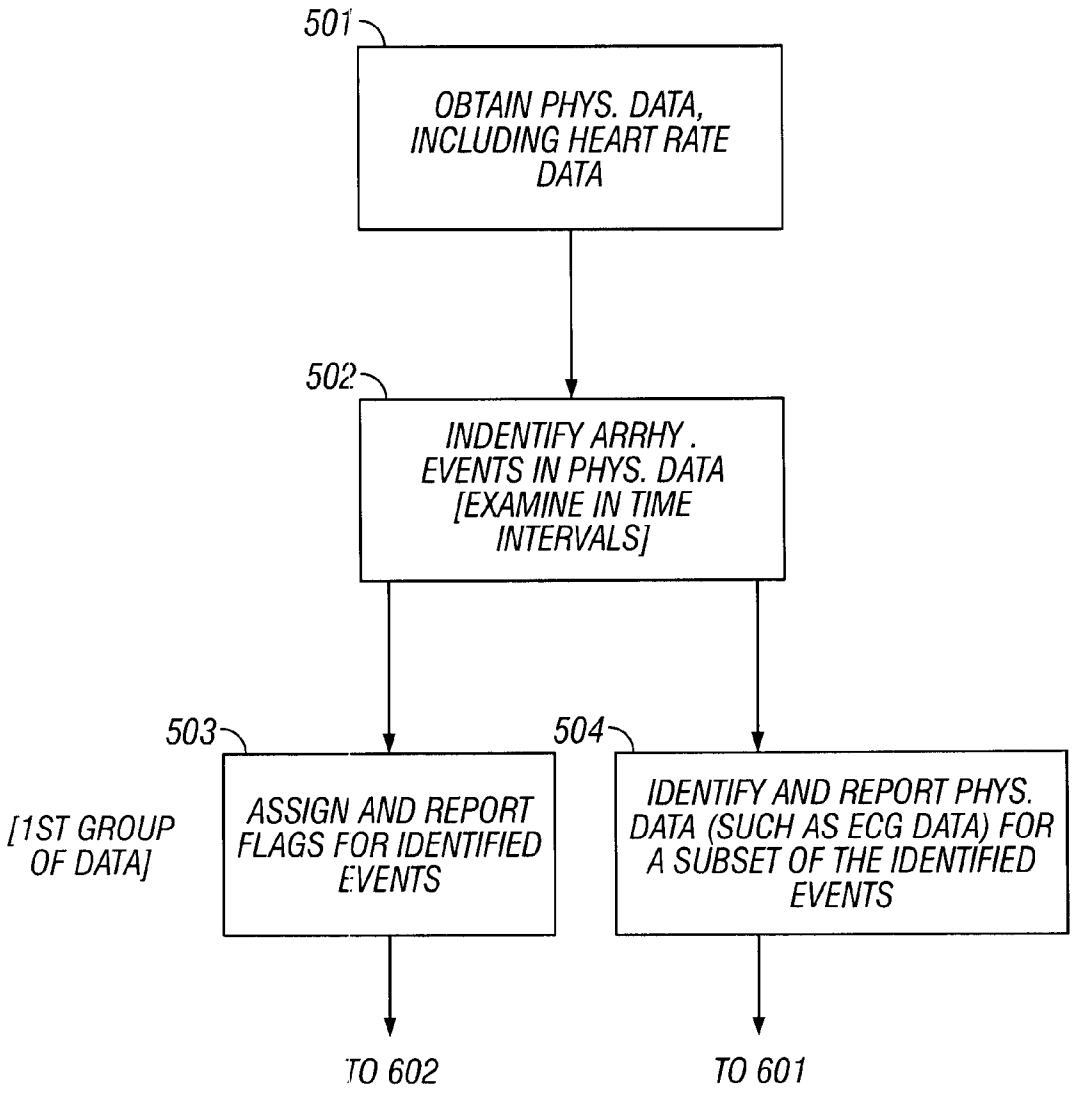
501
OBTAIN PHYS. DATA, INCLUDING HEART RATE DATA
502
INDENTIFY ARRHY . EVENTS IN PHYS. DATA [EXAMINE IN TIME INTERVALS]
503
504
[1ST GROUP OF DATA]
ASSIGN AND REPORT FLAGS FOR IDENTIFIED EVENTS
IDENTIFY AND REPORT PHYS. DATA (SUCH AS ECG DATA) FOR A SUBSET OF THE IDENTIFIED EVENTS
TO 602
TO 601

FIG. 5

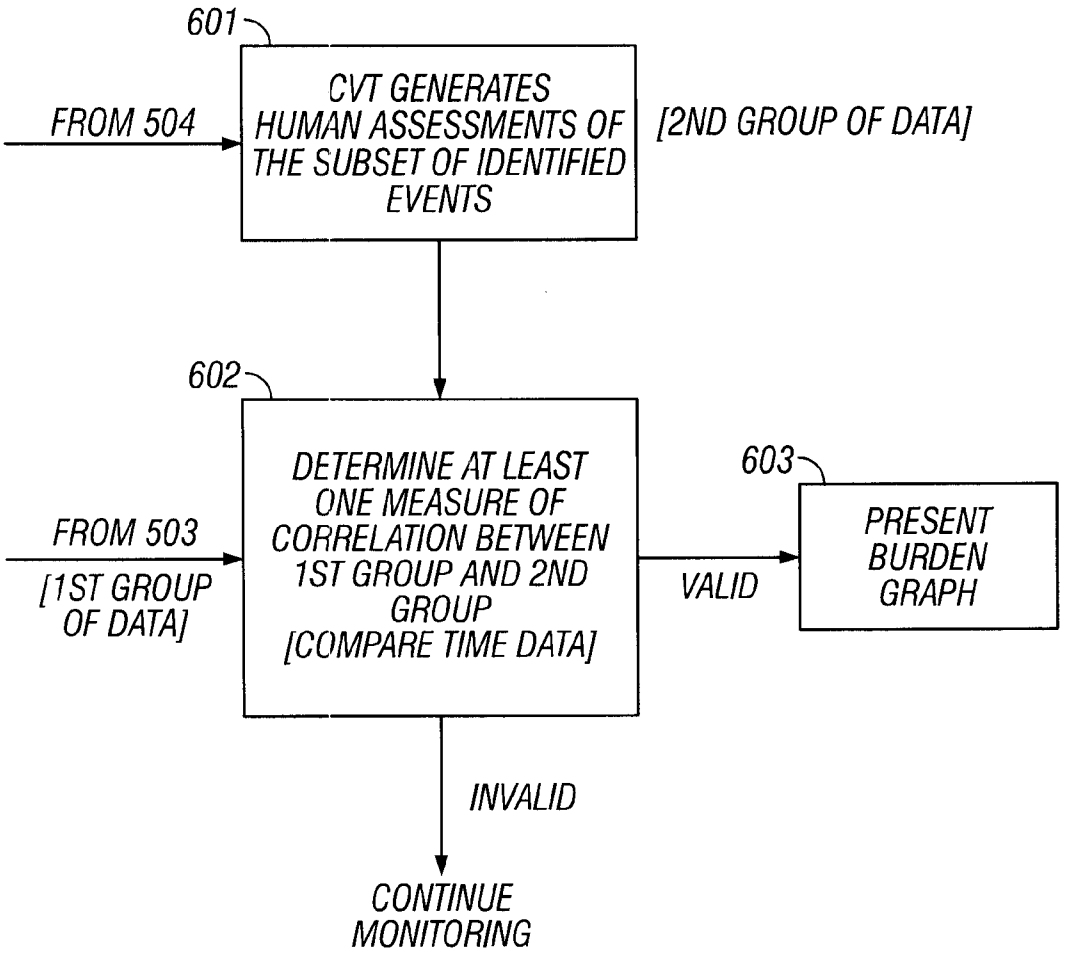
601
CVT GENERATES HUMAN ASSESSMENTS OF THE SUBSET OF IDENTIFIED EVENTS
FROM 504
[2ND GROUP OF DATA]
602
DETERMINE AT LEAST ONE MEASURE OF CORRELATION BETWEEN 1ST GROUP AND 2ND GROUP [COMPARE TIME DATA]
603
PRESENT BURDEN GRAPH
FROM 503
[1ST GROUP OF DATA]
VALID
INVALID
CONTINUE MONITORING

FIG. 6

SYSTEM AND METHOD FOR PROCESSING AND PRESENTING ARRHYTHMIA INFORMATION TO FACILITATE HEART ARRHYTHMIA IDENTIFICATION AND TREATMENT

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation application of and claims the benefit of priority from the U.S. Application entitled "System And Method For Processing And Presenting Arrhythmia Information To Facilitate Heart Arrhythmia Identification And Treatment," filed Jan. 16, 2004, application Ser. No. 10/760,122, and claims priority from U.S. Provisional Application entitled "Presenting Arrhythmia Information to Facilitate Heart Arrhythmia Identification and Treatment," filed Nov. 26, 2003, Application Ser. No. 60/525,386.

BACKGROUND

The present application describes systems and techniques relating to processing and presenting arrhythmia event information from physiological data, for example, selectively presenting atrial fibrillation events to a medical practitioner.

Over the years, various devices have been used for monitoring hearts in living beings. Additionally, systems have been used to collect and report on heart information obtained from patients.

SUMMARY

In general, in one aspect, a heart monitoring system collects heart data from a monitored individual and stores the data at a monitoring center. Collected data can be processed, and graphical representations of the collected information can be presented to medical practitioners to assist in treating heart arrhythmias, such as atrial fibrillation. A system and method can involve operations including identifying arrhythmia events in physiological data obtained for a living being, receiving human assessments of at least a portion of the arrhythmia events, determining a measure of correlation between the human assessments and the identified events, and selectively presenting information regarding the identified events based on the measure of correlation. The operations also can include identifying atrial fibrillation events in physiological data obtained for a living being, obtaining heart rate data for the living being, and presenting information regarding the heart rate data and duration of the atrial fibrillation events together with a common time scale to pictographically represent heart rate trend with atrial fibrillation burden during a defined time period.

One or more of the following advantages can be realized. The heart monitor can loop every twenty-four hours and can automatically transmit heart data at least every twenty-four hours. The system can automatically generate a daily graphical summary of atrial fibrillation (AF) burden for review by a medical practitioner, which can be presented effectively anywhere using one or more communication networks. The AF burden graph can be used for asymptomatic AF detection, drug therapy (rate, rhythm, anti-coagulants), pre/post ablation monitoring, and CHF (congestive heart failure) decompensation. The system can provide an overall sensitivity of 96%, a positive predictivity of over 99%, and artifact rejection of over 90%. In one implementation, the graph only displays events where AF detection is validated by a technician finding AF in over 50% of the automatically identified events.

The details of one or more embodiments are set forth in the accompanying drawings and the description below. Other features and advantages will become apparent from the description, the drawings, and the claims.

DRAWING DESCRIPTIONS

FIG. **1** illustrates, according to an exemplary embodiment, a system for reporting information related to arrhythmia events.

FIG. **2** shows, according to one embodiment, a graph presenting an example of atrial fibrillation burden and heart rate trend.

FIG. **3** is a diagram illustrating, according to an exemplary embodiment, a procedure for monitoring, processing, and reporting information related to arrhythmia events.

FIG. **4** shows, according to an exemplary embodiment, one graph presenting an example of atrial fibrillation burden and one graph presenting an example of heart rate trend.

FIGS. **5** and **6** are diagrams illustrating, according to another exemplary embodiment, a procedure for monitoring, processing, and reporting information related to arrhythmia events.

DETAILED DESCRIPTION

FIG. **1** illustrates, according to one embodiment, a system for reporting information related to arrhythmia events, such as atrial fibrillation events. In this embodiment, monitoring system **109** can communicate (via devices **101** and **102**) ECG (electrocardiogram), cardiac event, and other data to monitoring center **104**. The system **109** can include, for example, an implantable medical device (IMD), such as an implantable cardiac defibrillator and an associated transceiver or pacemaker and an associated transceiver, or a monitoring device **101** that a patient **110** wears. Further, monitoring system **109** can include a monitor processing device **102** that can send standard physiological data (received from monitoring device **101**) to monitoring center **104** and that can detect arrhythmia events (such as atrial fibrillation events). In one implementation, the devices **101** and **102** are integrated into a single device. Moreover, the system **109** can be implemented using, for example, the CardioNet Mobile Cardiac Outpatient Telemetry (MCOT) device, which is commercially available and provided by CardioNet, Inc of San Diego, Calif.

Monitor processing device **102** can transmit physiological data (including data related to arrhythmia events) through a communication network **103**, which can be a local area network (LAN), a landline telephone network, a wireless network, a satellite communication network, or other suitable network to facilitate two-way communication with monitoring center **104**. Advantageously, monitoring center **104** can be located in the same location (e.g., in the same room or building) as monitoring system **109** or at some remote location.

The monitoring center **104** can include a monitoring (or display) station **105** and a processing system **106**. In one implementation, a cardiovascular technician (CVT) can use the monitoring station **105** to evaluate physiological data received from monitoring system **109**, identifying and reporting, among other things, arrhythmia events (such as atrial fibrillation events). The CVT reports these assessments of the physiological data to the processing system **106**, which also receives information related to the arrhythmia events identified by monitoring system **109**. As will be explained further

below, processing system **106** analyzes this arrhythmia event data (both the human-assessed data from the CVT and the data reported by monitoring system **109**) and determines whether to generate a graph (or other similar presentation) related to these events. In certain circumstances, the processing system will send a report related to both arrhythmia and heart rate data to, for example, a physician or other health care provider **108** via transmission path **107**—which may be part of the network **103**.

FIG. **3** illustrates, according to one embodiment, a procedure for monitoring, processing, and reporting arrhythmia event data (such as data associated with atrial fibrillation events). In this embodiment, the monitoring system **109** (illustrated in FIG. **1**) monitors and reports physiological data (including data related to heart rate) at **301**. At **302**, various parts of this physiological data can be analyzed (for example, RR variability and QRS morphology) and arrhythmia events can be identified based on predefined criteria—the information relating to these events (among other possible information) constituting a first group of data. In one implementation, the monitoring system **109** identifies certain of the arrhythmia events that are urgent or representative and reports those events to both a CVT at **303** and to the processing system at **304**. Alternatively, the system could simply report the events identified at **302** to the processing system. Further, at **303**, a CVT, using station **105**, evaluates various parts of the physiological data received from **302** and/or **301** and also identifies arrhythmia events—the information relating to these human-assessed events (among other possible information) constituting a second group of data. Here, if needed, the CVT can request additional data from monitoring system **109**.

At **304**, the processing system **106** analyzes both the first and second group of data, determining a measure of correlation between these groups. This process can involve, for example, determining whether a correlation measure exceeds and/or equals a predetermined correlation parameter or whether a correlation measure is less than and/or equals that parameter. If, based on the correlation analysis, the information related to the arrhythmia events is determined to be valid, then the system generates a report relating to both heart rate trend and the arrhythmia events at **305**, such as the graph shown in FIG. **2** or the graphs shown in FIG. **4**. If, on the other hand, there is insufficient correlation, then the system does not generate a report and monitoring continues.

To illustrate, in one implementation, every ten minutes, the monitoring system **109** transmits a "flag" if it has detected an atrial fibrillation (AF) event in the last ten minutes. In this implementation, the processing system **106** only generates a graph (or graphs) related to heart rate trend and atrial fibrillation burden—such as the graph shown in FIG. **2** or the graphs shown in FIG. **4**—if more than 50% of the ten minute flags (generated at **302**) match events identified by a CVT (at **303**)—a correlation (with respect to the time period at issue) indicating a high positive predictivity for the identification of AF events. If this 50% threshold is not met, then the system does not generate a graph (or graphs) based on the data at issue and simply continues to process data.

The term "atrial fibrillation burden" (or more generally, "arrhythmia event burden") refers generally to the overall amount of time that a patient is in atrial fibrillation (or arrhythmia) over a specified time period, taking into account the number and duration of episodes. Advantageously, employing pictographic presentations, such as those of FIGS. **2** and **4**, a medical practitioner can see whether a patient is more likely to experience an arrhythmia, such as AF, at certain times of the day, and this can affect therapeutic approaches in some cases.

FIG. **2** represents one example of how to pictographically present both heart rate trend and atrial fibrillation burden on a common time scale (to "pictographically present" such data, however, a graph is not required.). The graph **205** contains information relating to, for example, daily AF incidence and time of occurrence **201**, AF duration **202**, and heart rate (**203** and **204**). A scale **204** (in this example) indicates heart rate in average beats-per-minute and the dots and lines shown at **203** (for example) indicate values on that scale, standard deviations associated with these values, and heart rates during AF. Further, graph **205** shows heart rate data at **15** minutes and 45 minutes past the hour. Finally, in this graph, the presence of one or more AF events in a given 10-minute period is graphed as a 10-minute interval.

Like FIG. **2**, FIG. **4** represents an example of how to pictographically present heart rate trend and atrial fibrillation burden on a common time scale. Although FIG. **4**, unlike FIG. **2**, uses two graphs, FIG. **4** presents the same information as FIG. **2**. Specifically, graphs **404** and **405** contain information relating to, for example, daily AF incidence and time of occurrence **401**, AF duration **402**, and heart rate (**403** and **406**). A scale **406** (in this example) indicates heart rate in average beats-per-minute and the dots and lines shown at **403** (for example) indicate values on that scale, standard deviations associated with these values, and heart rates during AF.

FIGS. **5** and **6** are diagrams illustrating another implementation of the invention. Specifically, at **501**, the system **111**, employing monitoring system **109**, obtains physiological data, including heart rate data. In turn, at **502**, the system identifies the presence of arrhythmia events (such as AF events) in this physiological data, examining this data in time intervals. At **503**, the system assigns flags indicating the presence of arrhythmia events and reports those flags—which represent a first group of data—to the processing system. Similarly, at **504**, the system identifies and reports physiological data, such as ECG data, for a subset of the events identified at **502** and reported at **503**. Notably, the system, in this implementation, need not report physiological data for each flag assigned at **503**, but need only report data associated with the most significant events identified at **502**, thereby minimizing the data sent to a CVT.

At **601**, the CVT analyzes this data and reports whether arrhythmia events have occurred, thereby generating a second group of data. The processing system then determines (at **602**), based on comparing time stamps associated with each group of data, at least one measure of correlation between the first group of data and the second group of data. To illustrate, if enough of the human-assessed events reported at **601** match the events reported at **503**, then the system determines that the data is valid, that is, that there is a high positive predictivity for the identification of arrhythmia events. If such a determination is made, the data associated with each flag reported at **503** is pictographically presented in a form such as FIG. **2** or FIG. **4**. Significantly, in this implementation, while this pictographic representation can contain all such data, the CVT need only review a subset of this data. In short, the system achieves increased accuracy in the presentation of information relating to arrhythmia events while minimizing the data that the CVT reviews.

The disclosed system and all of the functional operations described and illustrated in this specification can be implemented in digital electronic circuitry, or in computer hardware, firmware, software, or in combinations of the forgoing. Apparatus can be implemented in a software product (e.g., a computer program product) tangibly embodied in a machine-readable storage device for execution by a programmable processor, and processing operations can be performed by a

programmable processor executing a program of instructions to perform functions by operating on input data and generating output. Further, the system can be implemented advantageously in one or more software programs that are executable on a programmable system. This programmable system can include the following: 1) at least one programmable processor coupled to receive data and instructions from, and to transmit data and instructions to, a data storage system; 2) at least one input device; and 3) at least one output device. Moreover, each software program can be implemented in a high-level procedural or object-oriented programming language, or in assembly or machine language if desired; and in any case, the language can be a compiled or an interpreted language.

Also, suitable processors include, by way of example, both general and special purpose microprocessors. Generally, a processor will receive instructions and data from a read-only memory, a random access memory, and/or a machine-readable signal (e.g., a digital signal received through a network connection). Generally, a computer will include one or more mass storage devices for storing data files. Such devices can include magnetic disks, such as internal hard disks and removable disks, magneto-optical disks, and optical disks. Storage devices suitable for tangibly embodying software program instructions and data include all forms of non-volatile memory, including, by way of example, the following: 1) semiconductor memory devices, such as EPROM (electrically programmable read-only memory); EEPROM (electrically erasable programmable read-only memory) and flash memory devices; 2) magnetic disks such as internal hard disks and removable disks; 3) magneto-optical disks; and 4) CD-ROM disks. Any of the foregoing can be supplemented by, or incorporated in, ASICs (application-specific integrated circuits).

To provide for interaction with a user (such as the CVT), the system can be implemented on a computer system having a display device such as a monitor or LCD (liquid crystal display) screen for displaying information to the user and a keyboard and a pointing device such as a mouse or a trackball by which the user can provide input to the computer system. The computer system can be programmed to provide a graphical user interface through which computer programs interact with users.

Finally, while the foregoing system has been described in terms of particular implementations, other embodiments are within the scope of the following claims. For example, the disclosed operations can be performed in a different order and still achieve desirable results. Moreover, the system need not employ 10-minute intervals; many different time intervals are possible (as is, no interval at all), including 1 minute, 30 second, and 30-minute intervals. Indeed, because time intervals are not required, the graphs of FIGS. **2** and **4** could be modified to show continuous heart rate trend (accompanied by corresponding AF data) rather than just specific instances of this trend. Further, while FIGS. **2** and **4** show examples of (among other things) pictographically presenting atrial fibrillation burden (one type of arrhythmia event burden), one could present the same or similar information for another type of arrhythmia event. In fact, one could employ both the format and procedures associated with generating FIG. **2** or FIG. **4** (or a similar figure) to pictographically present information related to a number of different types of arrhythmia event burdens.

What is claimed is:

1. A machine-implemented method comprising:

identifying atrial fibrillation events in physiological data obtained for a living being, wherein identifying atrial fibrillation events comprises examining the physiological data in multiple time intervals, and identifying intervals in which at least one atrial fibrillation event has occurred;

obtaining heart rate data for the living being;

receiving a human assessment of a subset of the identified atrial fibrillation events; and

based on the human assessment of the subset of the identified atrial fibrillation events, pictographically presenting, using a common time scale, information regarding the heart rate data for the multiple time intervals during a defined time period in alignment with indications of atrial fibrillation activity for the identified intervals, according to the identified atrial fibrillation events, during the defined time period such that heart rate trend is presented with atrial fibrillation burden, wherein pictographically presenting information regarding the heart rate data comprises displaying for each of the multiple time intervals a range of heart rates and a heart rate average.

2. The method of claim **1**,

further comprising determining that the identified atrial fibrillation events are valid when a threshold percentage of the identified atrial fibrillation events match events identified by the human assessment; and

wherein pictographically presenting based on the human assessment comprises pictographically presenting based on the determining.

3. The method of claim **2**, wherein pictographically presenting the indications of atrial fibrillation activity comprises presenting information regarding duration of the identified atrial fibrillation events during the defined time period.

4. The method of claim **2**, wherein the heart rate data comprise information presented in beats-per-minute.

5. The method of claim **4**, wherein the range of heart rates comprises standard deviation of heart rate.

6. The method of claim **2**, wherein pictographically presenting information comprises presenting the heart rate trend juxtaposed with the atrial fibrillation burden.

7. The method of claim **2**, wherein pictographically presenting information comprises presenting heart rate trend and atrial fibrillation burden on the same graph.

8. The method of claim **2**, wherein pictographically presenting information comprises presenting heart rate trend and atrial fibrillation burden on different graphs.

9. The method of claim **2**, further comprising receiving input specifying the defined time period.

10. The method of claim **2**, further comprising displaying an indication of a time interval of the multiple time intervals having a minimum heart rate for the multiple time intervals.

11. The method of claim **2**, further comprising displaying an indication of a time interval of the multiple time intervals having a maximum heart rate for the multiple time intervals.

12. An article comprising a machine-readable medium embodying information indicative of instructions that when performed by one or more machines result in operations comprising:

identifying atrial fibrillation events in physiological data obtained for a living being, wherein identifying atrial fibrillation events comprises examining the physiological data in multiple time intervals, and identifying intervals in which at least one atrial fibrillation event has occurred;

obtaining heart rate data for the living being;

receiving a human assessment of a subset of the identified atrial fibrillation events; and

based on the human assessment of the subset of the identified atrial fibrillation events, pictographically present-

ing, using a common time scale, information regarding the heart rate data for the multiple time intervals during a defined time period in alignment with indications of atrial fibrillation activity for the identified intervals, according to the identified atrial fibrillation events, during the defined time period such that heart rate trend is presented with atrial fibrillation burden, wherein pictographically presenting information regarding the heart rate data comprises displaying for each of the multiple time intervals a range of heart rates and a heart rate average.

13. The article of claim **12**,

determining that the identified atrial fibrillation events are valid when a threshold percentage of the identified events match events identified by the human assessment; and

wherein pictographically presenting based on the human assessment comprises pictographically presenting based on the determining.

14. The article of claim **13**, wherein pictographically presenting the indications of atrial fibrillation activity comprises presenting information regarding duration of the identified atrial fibrillation events during the defined time period.

15. The article of claim **13**, wherein pictographically presenting information comprises presenting the heart rate trend juxtaposed with the atrial fibrillation burden.

16. The article of claim **13**, wherein the operations further comprise receiving input specifying the defined time period.

17. The article of claim **13**, wherein the operations further comprise displaying an indication of a time interval of the multiple time intervals having a maximum heart rate for the multiple time intervals.

18. An apparatus comprising:

means for identifying atrial fibrillation events in physiological data obtained for a living being based on examination of the physiological data in multiple time intervals to identify intervals in which at least one atrial fibrillation event has occurred;

means for obtaining heart rate data for the living being;

means for receiving a human assessment of a subset of the identified atrial fibrillation events; and

means for pictographically presenting, based on the human assessment of the subset of the identified atrial fibrillation events, information regarding the heart rate data for the multiple time intervals during a defined time period in alignment with indications of atrial fibrillation activity for the identified intervals, according to the identified atrial fibrillation events, during the defined time period such that heart rate trend is presented with atrial fibrillation burden, and a range of heart rates and a heart rate average are displayed for each of the multiple time intervals.

19. The apparatus of claim **18**, further comprising means for determining that the identified atrial fibrillation events are valid when a threshold percentage of the identified events match events identified by the human assessment; and

wherein the means for pictographically presenting is coupled to operate based on output of the means for determining.

20. The apparatus of claim **19**, wherein the indications of atrial fibrillation activity comprise information regarding duration of the identified atrial fibrillation events during the defined time period.

21. The apparatus of claim **19**, wherein the means for pictographically presenting comprises means for presenting the heart rate trend juxtaposed with the atrial fibrillation burden.

22. The apparatus of claim **19**, further comprising means for receiving input specifying the defined time period.

23. A system for reporting information related to arrhythmia events comprising:

a monitoring system configured to process and report physiological data, including heart rate data, for a living being, configured to identify atrial fibrillation events from the physiological data, and configured to examine the physiological data in multiple time intervals to identify intervals in which at least one atrial fibrillation event has occurred;

a monitoring station for receiving the physiological data from the monitoring system; and

a processing system configured to:

receive a human assessment of a subset of the identified atrial fibrillation events, and

pictographically present based on the human assessment of the subset of the identified atrial fibrillation events, information regarding the heart rate data for the multiple time intervals during a defined time period in alignment with indications of atrial fibrillation activity for the identified intervals, according to the identified atrial fibrillation events, during the defined time period such that heart rate trend is presented with atrial fibrillation burden, and a range of heart rates and a heart rate average are displayed for each of the multiple time intervals.

24. The system of claim **23**, wherein the processing system is configured to determine that the identified atrial fibrillation events are valid when a threshold percentage of the identified events match events identified by the human assessment, and configured to present the information regarding the heart rate data based on said determination.

25. The system of claim **24**, wherein the processing system is configured to display an indication of a time interval of the multiple time intervals having a maximum heart rate for the multiple time intervals.

26. The system of claim **24**, wherein the indications of atrial fibrillation activity comprise duration of the identified atrial fibrillation events during the defined time period.

27. The system of claim **24**, wherein the processing system is configured to present the heart rate trend juxtaposed with the atrial fibrillation burden.

28. The system of claim **24**, wherein the processing system is configured to receive input specifying the defined time period.

* * * * *

EXHIBIT C

US006569095B2

(12) **United States Patent**
Eggers

(10) **Patent No.: US 6,569,095 B2**
(45) **Date of Patent: May 27, 2003**

(54) **ADAPTIVE SELECTION OF A WARNING LIMIT IN PATIENT MONITORING**

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(73) Assignee: **CardioNet, Inc.**, San Diego, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

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(51) **Int. Cl.**[7] **A61B 5/07**
(52) **U.S. Cl.** **600/300**; 128/903
(58) **Field of Search** 600/300, 301, 600/481, 529, 508, 545; 128/903, 904

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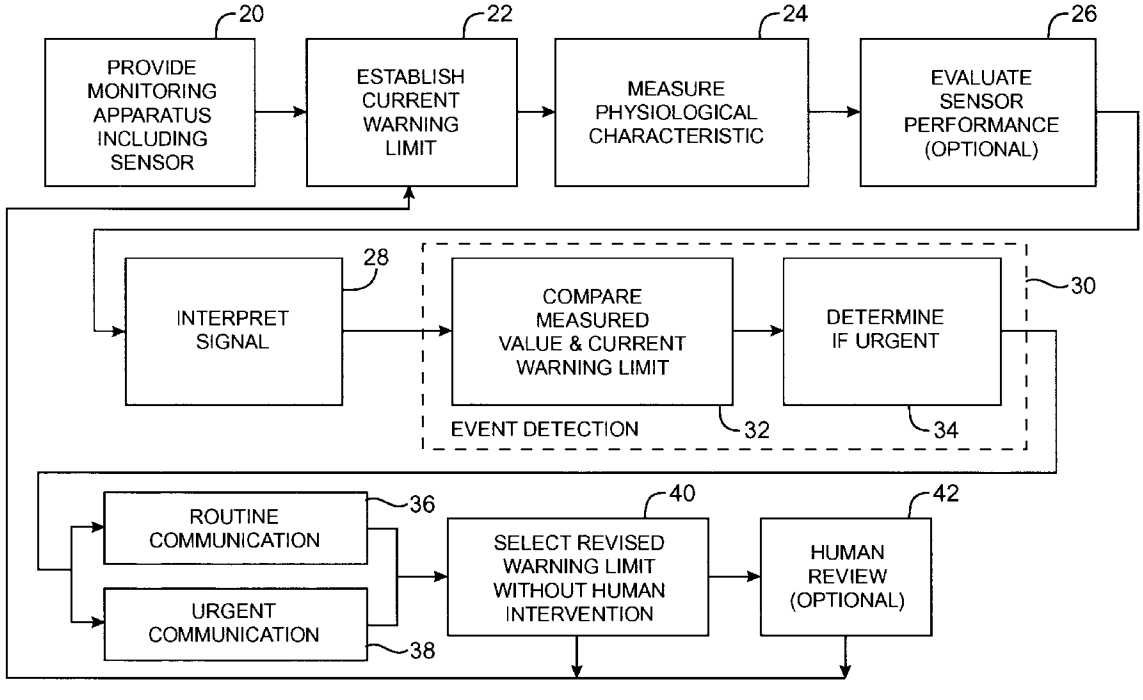
(57) **ABSTRACT**

A patient is monitored by establishing a current warning limit for a physiological characteristic of the patient, providing a sensor for the physiological characteristic, and measuring a measured value of the physiological characteristic of the patient using the sensor. A revised warning limit is selected responsive to at least one of the steps of providing and measuring. The revised warning limit is then typically substituted for the current warning limit. The current warning limit serves to trigger some action in the event that the measured value of the physiological characteristic is not within an acceptable range defined by the current warning limit.

18 Claims, 2 Drawing Sheets



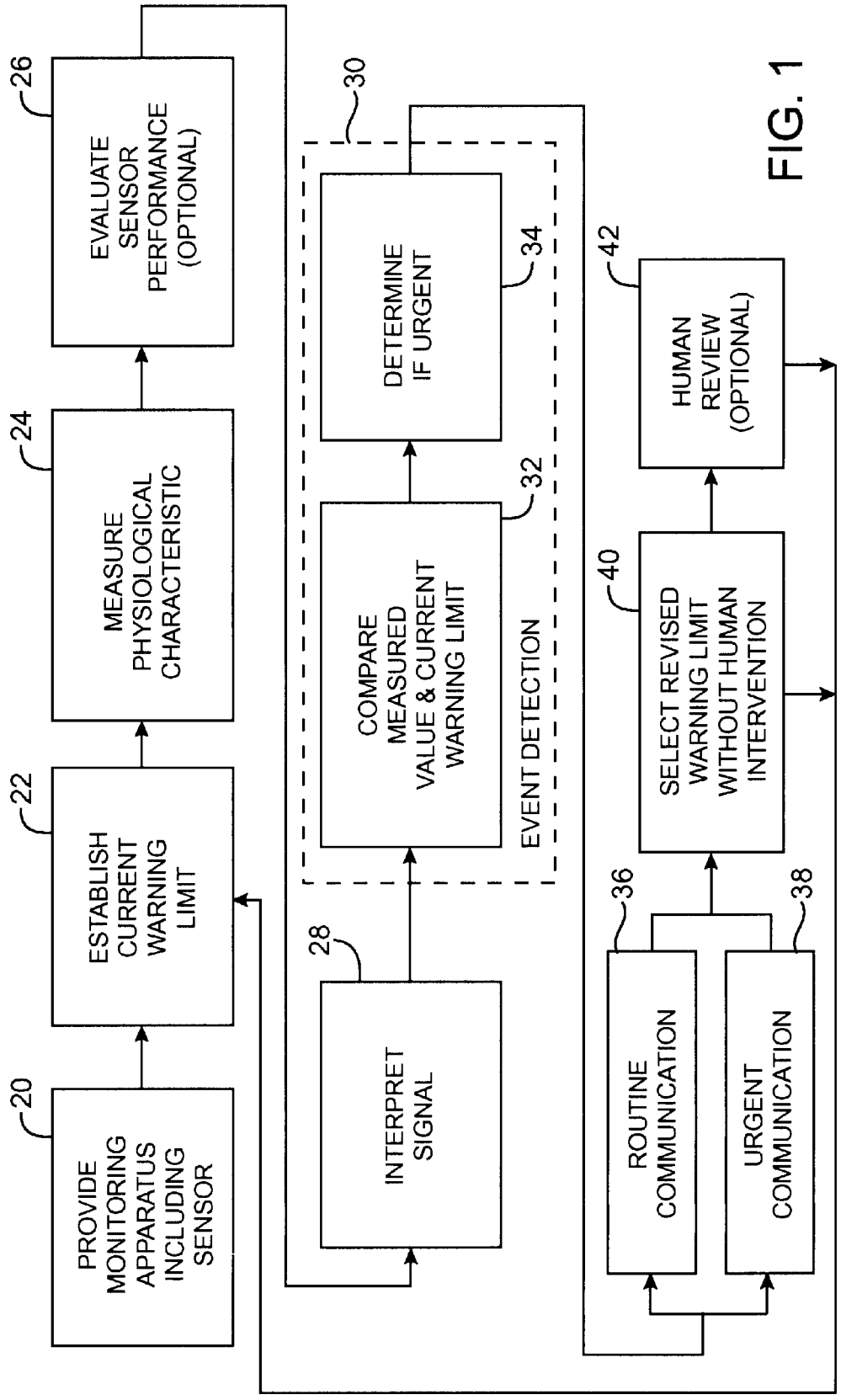

20
PROVIDE MONITORING APPARATUS INCLUDING SENSOR
22
ESTABLISH CURRENT WARNING LIMIT
24
MEASURE PHYSIOLOGICAL CHARACTERISTIC
26
EVALUATE SENSOR PERFORMANCE (OPTIONAL)
28
INTERPRET SIGNAL
30
EVENT DETECTION
32
COMPARE MEASURED VALUE & CURRENT WARNING LIMIT
34
DETERMINE IF URGENT
36
ROUTINE COMMUNICATION
38
URGENT COMMUNICATION
40
SELECT REVISED WARNING LIMIT WITHOUT HUMAN INTERVENTION
42
HUMAN REVIEW (OPTIONAL)

FIG. 1

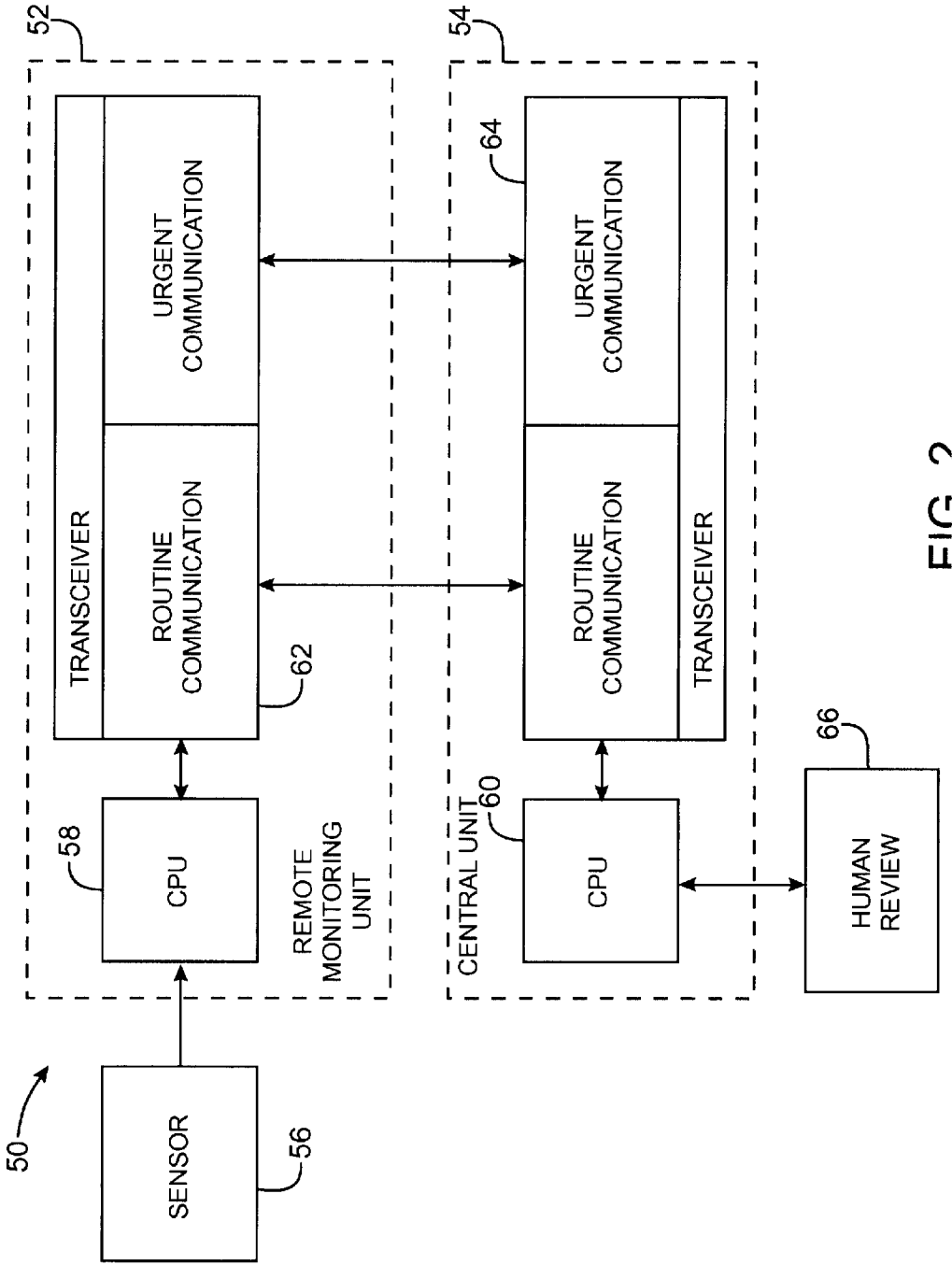

52
54
TRANSCEIVER
URGENT COMMUNICATION
ROUTINE COMMUNICATION
62
64
URGENT COMMUNICATION
ROUTINE COMMUNICATION
TRANSCEIVER
66
58
CPU
REMOTE MONITORING UNIT
CENTRAL UNIT
60
CPU
HUMAN REVIEW
50
SENSOR
56

FIG. 2

ADAPTIVE SELECTION OF A WARNING LIMIT IN PATIENT MONITORING

This invention relates to the monitoring of a physiological characteristic of a patient, and, more particularly, to establishing a warning limit that may be used to indicate a variation of the physiological characteristic that necessitates immediate attention.

BACKGROUND OF THE INVENTION

Advances in sensor technology, electronics, and communications have made it possible for physiological characteristics of patients to be monitored even when the patients are ambulatory and not in continuous, direct contact with a hospital monitoring system. For example, U.S. Pat. No. 5,959,529 describes a monitoring system in which the patient carries a remote monitoring unit with associated physiological sensors. The remote monitoring unit conducts a continuous monitoring of one or more physiological characteristics of the patient according to the medical problem of the patient, such as the heartbeat and its waveform.

Under prescribed conditions, the remote monitoring unit contacts a central unit to communicate information on the condition of the patient. The communication may be accomplished in some cases on a routine reporting basis (e.g., a regular once-a-day report at night on a land telephone line while the patient sleeps) and in other cases on an urgent basis that signifies an event wherein the patient may need immediate attention (e.g., over a cellular telephone link as the patient experiences discomfort or an attack). The remote monitoring unit contains logic, which may be generally be described as a warning limit, that is used to determine whether the communication is to be made on an urgent basis. The warning limit is usually based both on the nature of an evaluation criterion for specific events and also on a quantitative threshold for the selected criterion.

In the studies leading to the present invention, the inventor has observed that the application of these fundamental principles of warning limits is straightforward conceptually but complex in practice. Although many physiological characteristics may be described in a textbook manner, large variations from the textbook description are encountered in everyday situations. For example, variations in sensor performance, individual human characteristics and responses, personal experiences, and the like make it difficult to establish warning limits that are universally applicable, or even applicable for the same patient under all conditions.

The warning limits are normally selected in a conservative manner when viewed from the standpoint of patient safety. That is, it is preferable to make urgent communications more often than necessary, rather than to fail to make an urgent communication when it is necessary. On the other hand, too many urgent communications are wasteful in terms of power consumption of the remote monitoring unit (establishing and maintaining a cell phone connection consumes a relatively large amount of power and thus reduces available battery life), telephone connection time expense, and resource use at the central unit.

For these reasons, it is important to establish realistic warning limits characteristic of situations that are truly urgent. There are not currently available any approaches which meet this requirement, and consequently a need exists for establishing warning limits for use in such situations. The present invention fulfills this need, and further provides related advantages.

SUMMARY OF THE INVENTION

The present approach provides a technique for monitoring a patient in which one or more warning limits are recursively reevaluated as necessary. Proposed changes to the warning limits are made without human intervention, but in some cases the proposed changes may be reviewed by a human being to be certain that they are realistic. The present approach is fully compatible with adjustments to warning limits made by medical personnel. The present approach allows a patient monitoring system to be continuously refined and customized for the individual patient and the individual monitoring system through an adaptive learning process.

In accordance with the invention, a method of monitoring a patient comprises the steps of establishing a current warning limit for a physiological characteristic of the patient. A sensor is provided for the physiological characteristic. such as the heartbeat, for example, and a measured value of the physiological characteristic of the patient is measured using the sensor. The measured value and the current warning limit are compared, and a warning signal may be generated responsive to the step of comparing in the event that the measured value is outside the value defined by the current warning limit. The method includes selecting a revised warning limit responsive to at least one of the steps of providing and measuring, preferably without human intervention (i.e., automatically). However, a human being may review the revised warning limit. That is, the automated system may propose the revision, subject to revision by the human being.

The step of selecting a revised warning limit may be made responsive to any of a wide variety of circumstances. For example, the operating characteristics of the sensor may be determined, and the selecting of the revised warning limit may be made responsive to the determination of the operating characteristics of the sensor. The selecting of a revised warning limit may instead be responsive to the step of measuring, as where the step of measuring is performed as a function of time, and wherein the step of selecting is responsive to time variations in the measured value or is responsive to a value of time. The selecting of the revised warning limit may be additionally responsive to a second physiological characteristic or to a patient history.

In one embodiment, the present invention is practiced using a monitoring apparatus including a remote monitoring unit associated with the patient, a central unit, and a communications device which selectively establishes a communications link between the remote monitoring unit and the central unit responsive to a warning signal. This apparatus provides a real-time urgent communications capability. It may also be practiced in other operable situations, such as monitors whose data are periodically transmitted, non-ambulatory situations, and the like.

The present invention allows the patient to be monitored and acceptable limits for the physiological conditions of the patient to be defined increasingly precisely over time. With continued experience as the monitoring apparatus adapts to the individual patient, the incidence of unnecessary urgent communications is expected to decrease. The result is that the efficiency of resource utilization is expected to increase over time. Additionally, the monitoring apparatus discovers which warning limits are most meaningful for the individual patient, so that the precision of the generation of warnings is increased.

Other features and advantages of the present invention will be apparent from the following more detailed descrip-

tion of the preferred embodiment, taken in conjunction with the accompanying drawings, which illustrate, by way of example, the principles of the invention. The scope of the invention is not, however, limited to this preferred embodiment.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a block flow diagram of a method for practicing the present approach; and

FIG. **2** is a simplified schematic block diagram of a preferred apparatus with which the present invention may be used.

DETAILED DESCRIPTION OF THE INVENTION

FIG. **1** depicts an approach for practicing the present invention. A monitoring apparatus is provided, numeral **20**. The monitoring apparatus may be of any operable form, and one preferred form of the monitoring apparatus **50** is illustrated in FIG. **2**. The monitoring apparatus **50** is shown in a simplified form illustrating only those portions that are required to discuss the present invention. The monitoring apparatus **50** is generally like that disclosed in U.S. Pat. No. 5,959,529, whose disclosure is incorporated by reference, but modified as discussed herein.

The monitoring apparatus **50** includes a remote monitoring unit (RMU) **52** carried by an ambulatory patient, and a central unit (CU) **54**. The central unit **54** is typically a file server or a network. Other remote monitoring units, that are not "portable" but may be at a fixed location in a patient's home or hospital facility, may be used as well. A sensor **56** measures a physiological characteristic of a patient, and is typically in contact with the patient. ("Patient" is used in a broad sense, and refers to a person being monitored.) There may be one sensor or more than one sensor **56**, depending upon the parameters of the patient that are of interest. Examples of operable sensors **56** include a heart monitor sensor, a blood pressure monitor sensor, a temperature monitor sensor, a respiration sensor, a brain wave sensor, a blood chemistry sensor, a blood glucose sensor, a blood oxygen saturation sensor, a patient position sensor, and a patient activity sensor. Sensors of various types are known in the art, and details of their construction and operation does not form a part of the present invention.

In either event, the sensor **56** is in communication with a central processing unit (CPU) **58** of the remote monitoring unit **52**, with intermediate signal conditioning equipment as necessary (not shown here). The central processing unit **58** performs analyses of the signals of the sensor **56**, as will be discussed subsequently. Similarly, the central unit **54** includes a central processing unit (CPU) **60** to perform calculations and analyses, as will be discussed subsequently. (As noted, the central unit **54** and its CPU **60** may be of any operable type, such as a dedicated system, a network, or a file server.) The remote monitoring unit **52** and the central unit **54** may be placed in two-way communication with each other through a transceiver **62** located in the remote monitoring unit **52** and a communicating transceiver **64** located in the central unit **54**. The transceivers **62**, **64** may include any operable type of communications devices. For example, they may include a modem to establish communications over a conventional land-line telephone for routine communications. They may also include a cellular telephone transceiver to establish communications on an urgent basis. The transceivers **62**, **64** may also be equipped for two-way voice communication between the patient and a person at the central unit **54**. The present invention is concerned in part with establishing the criteria for determining when a communication should be routine or urgent, by adaptively selecting the warning limits that signal a need for an urgent communication. The central unit **54** is provided with an interface to allow human review **66** of recommended actions of the central processing unit **60**, as by the patient's physician.

Returning to the discussion of FIG. **1**, a current warning limit is established, numeral **22**. The current warning limit relates to the type of physiological condition being monitored by the sensor **56**. In the case of a heart sensor that measures a voltage as a function of time, for example, the warning limit may relate to any of a wide variety of types of information that may be determined from the heart sensor output to the central processing unit **58**. Examples of warning limits may include, for example, the frequency of heartbeats, the shape of a particular part of the heartbeat waveform, the amplitude of a particular part of the heartbeat signal, or any other feature of the signal. There may also be quantitative values placed on some of these types of warning limits, such as a maximum or minimum number of heartbeats per minute, a maximum or minimum amplitude, a maximum number of features of a particular shape or type per minute (or hour), etc. The current warning limit is normally established in step **22** as input values from the experience of the medical caregiver responsible for the patient.

The physiological characteristics of the patient are measured using the sensor **56**, numeral **24**, and provided to the central processing unit **58**. In the case of a heartbeat sensor, for example, the data output is a series of data pairs of sensor voltage output as a function of time (provided by a clock in the central processing unit **58**).

The central processing unit **58** preliminary evaluates the sensor signals. It optionally evaluates the sensor performance, numeral **26**. For example, it is known that the performance of some sensors degrades over time. That is, if a single feature such as the same heartbeat is measured by two sensors that are otherwise identical but wherein one has been used for five days and the other is new, the output voltages of the two sensors typically vary. If a warning limit is based on this voltage output, then different performance will be obtained for the used sensor and the new sensor. The change of performance of the sensor may be tracked by any operable approach, such as calibration signals or historical information. The sensor evaluation of step **26** keeps track of these changes over time.

The sensor signal is interpreted, numeral **28**. The interpretation step **28** extracts the type of information of interest from the sensor signal. For example, if the information of interest is the frequency of heartbeats, a counting procedure is used. If the information of interest is a shape of the voltage-time output, then curve-shape analysis procedures are used. The methodology of such interpretation techniques is known in the art.

Using this information, event detection is performed, numeral **30**. Event detection preferably includes comparing the measured value of a feature from the interpretation step **28** with the current warning limit for that feature as provided in step **22**. For example, it may be significant if the heartbeat rate exceeds 100 per minute, or if more than a selected number of heartbeat shapes occurs per minute or per hour. Comparisons of other measured physiological characteristics, such as respiration rate, blood pressure, and the like may be made as well.

The comparisons with the current warning limits are used to determine whether an event is occurring that requires urgent communication between the remote monitoring unit **52** and the central unit **54**, numeral **34**. The determination may be based on a single variable or multiple variables. For example, if the heartbeat exceeds a heartbeat warning limit value and the blood oxygen saturation level also exceeds a blood oxygen warning limit value, then an urgent communication may be called for. Based on this determination, the data is stored for a later routine communication, numeral **36**, or the transceivers **62**, **64** are activated for an urgent transmission to the central unit **54**, numeral **38**.

The current warning limit determines whether the remote monitoring unit **52** will establish a telephonic or other communication link with the central unit **54** on an urgent, immediate basis. In that event, the central unit **54** will be called upon to provide assistance to the patient, either directly or by contacting an emergency service provider, or it may determine that in fact no emergency exists. It is important that an urgent communication be established when an emergency truly exists. It is also desirable that instances of establishing communications where no emergency exists be minimized in order to conserve battery power of the remote monitoring unit, to minimize unnecessary cellular telephone time charges, and to minimize the use of medical personnel who may be called upon unnecessarily to review situations that are not truly emergencies.

To improve the efficiency of the system, revised warning limits are selected, preferably but not necessarily without human intervention (i.e., "automatically"), numeral **40**. This selection may be performed by the remote monitoring unit **52** in some cases and by the central unit **54** via the communication link in other cases. Some revisions to the warning limits are mechanical in nature and almost certainly do not require any human review. For example, if the sensitivity of the sensor changes over time so that a voltage output threshold warning limit that formerly was 9.60 millivolts is to be altered to 9.55 millivolts in order to keep the system sensitive to a constant level of signal amplitude, the change in the warning limit may typically be made by the remote monitoring unit **52**. On the other hand, a change that is more closely associated with a medical condition is more likely to require a medical review. Thus, if a heartbeat frequency warning limit of 100 beats per minute is to be changed to 120 beats per minute based on extended experience in order to obtain a better indicator of when urgent communication is required, it is preferred that the central processing unit **60** of the central unit **54** make a recommendation based upon data analysis and without human intervention, and then a human being in the form of the patient's doctor or a medical technician approve the change under the human review **66**. Typically, such changes based upon a medical evaluation occur relatively infrequently and may be made responsive to a routine communication rather than an urgent communication.

A wide variety of grounds for a selection of a revised warning limit are possible, but they generally fall into several classes.

One ground is related to instrumentation, with an example being the change in sensor sensitivity discussed above.

Another ground is a change in a warning limit based on a single-valued measured physiological characteristic. For example, a warning limit of 100 beats per minute may be a significant predictor of distress and an emergency for a first patient, but a second patient may naturally have a higher heart rate slightly above this warning limit so that a warning limit of 100 beats per minute produces many unnecessary urgent communications. Experience gained over time with the second patient will establish a more realistic warning limit for the second patient.

Another ground is a correlation between two or more measured physiological characteristics. For example, a heartbeat rate in excess of 100 beats per minute may signify distress if the patient is at rest and the respiration rate is less than 15 breaths per minute. A heartbeat in excess of 100 beats per minute may be quite normal if the patient is exercising and the respiration rate is equal to or greater than 15 breaths per minute. On the other hand, in the latter case a heartbeat in excess of 130 beats per minute even with a respiration rate faster than 15 breaths per minute may signal an emergency. The heartbeat warning limit may thus be selected responsive to the respiration rate.

Another ground is a correlation of a measured physiological characteristic with a nonphysiological parameter. For example, a heartbeat of 100 beats per minute may be quite normal for 16 hours per day, but during sleep periods from 11 pm to 7 am such an increase in the sleeping heartbeat rate to 100 beats per minute may signify an emergency. The warning limit may therefore correlate to absolute time according to daytime/nighttime activity, or it may correlate to a Circadian rhythm of the patient. In another example, if the remote monitoring unit is equipped with an accelerometer, a heartbeat rate in excess of 100 beats per minute coupled with a high temporary accelerometer reading may indicate that the patient has fallen and is injured but unable to otherwise communicate.

Another ground is a complete change in the information required from the interpretation step **28**. It may initially be believed that a good objective correlator of distress in a patient is a heartbeat rate. Over time, however, it is found that the occurrence of more than three premature ventricular contractions (PVCs) per hour is a more dependable predictor of distress in the patient and an emergency situation. The interpretation step **28** is therefore shifted from a heartbeat count to a waveshape analysis.

The present invention is not intended to identify each specific type of revision that may be made in the warning limits. In fact, there are as many possibilities for types of revisions as there are patients to be monitored. The point of the present invention is to provide a technique and a methodology to allow an adaptive updating of the decision making of the monitoring apparatus as to whether an urgent communication is required instead of a routine communication.

Although a particular embodiment of the invention has been described in detail for purposes of illustration, various modifications and enhancements may be made without departing from the spirit and scope of the invention. Accordingly, the invention is not to be limited except as by the appended claims.

What is claimed is:

1. A method of monitoring a patient, comprising the steps

establishing a current warning limit for a physiological characteristic of the patient;

providing a sensor for the physiological characteristic;

measuring a measured value of the physiological characteristic of the patient using the sensor;

comparing the measured value and the current warning limit, and generating a warning signal responsive to the step of comparing; and

selecting a revised warning limit responsive to at least one of the steps of providing and measuring.

2. The method of claim 1, including an additional step, after the step of selecting, of

a human being reviewing the revised warning limit.

3. The method of claim 1, wherein the step of providing includes the steps of

obtaining the sensor, and

determining the operating characteristics of the sensor, and wherein the step of selecting is responsive to the step of determining the operating characteristics of the sensor.

4. The method of claim 1, wherein the step of selecting is responsive to the step of measuring.

5. The method of claim 1, wherein the step of measuring is performed as a function of time, and wherein the step of selecting is responsive to a value of time.

6. The method of claim 1, wherein the step of selecting is additionally responsive to a second physiological characteristic.

7. The method of claim 1, wherein the step of selecting is additionally responsive to a patient history.

8. The method of claim 1, including an additional step of providing a monitoring apparatus including

a remote monitoring unit associated with the patient,

a central unit, and

a communications device which selectively establishes a communications link between the remote monitoring unit and the central unit responsive to a warning signal, and wherein the step of selecting is performed at least in part by the central unit.

9. The method of claim 1, wherein the physiological characteristic is a characteristic of the heart.

10. The method of claim 1, wherein the step of selecting is performed without human intervention.

11. A method of monitoring a patient, comprising the steps of providing a monitoring apparatus including

a remote monitoring unit associated with the patient,

a central unit, and

a communications device which selectively establishes a communications link between the remote monitoring unit and the central unit responsive to a warning signal;

establishing a current warning limit for a physiological characteristic of the patient;

providing a sensor for the physiological characteristic as a part of the remote monitoring unit;

measuring a measured value of the physiological characteristic of the patient using the sensor;

comparing the measured value and the current warning limit;

generating a warning signal responsive to the step of comparing;

selecting a revised warning limit responsive to at least one of the steps of providing a sensor, comparing, and measuring, and substituting the revised warning limit for the current warning limit, the step of selecting being performed at least in part by the central unit; and

repeating the steps of providing a sensor, measuring, and comparing.

12. The method of claim 11, including an additional step, after the step of selecting, of

a human being reviewing the revised warning limit.

13. The method of claim 11, wherein the step of providing includes the steps of

obtaining the sensor, and

determining the operating characteristics of the sensor, and wherein the step of selecting is responsive to the step of determining the operating characteristics of the sensor.

14. The method of claim 11, wherein the step of selecting is responsive to the step of measuring.

15. The method of claim 11, including an additional step, after the steps of providing and measuring, of

comparing the measured value and the current warning limit, and

generating a warning signal responsive to the step of comparing.

16. The method of claim 11, wherein the step of selecting is performed without human intervention.

17. A method of monitoring a patient, comprising the steps of establishing a current warning limit for a physiological characteristic of the patient;

providing a sensor for the physiological characteristic;

evaluating the characteristics of the sensor as a function of time;

measuring a measured value of the physiological characteristic of the patient as a function of time using the sensor;

comparing the measured value and the current warning limit generating a warning signal responsive to the step of comparing; and

selecting a revised value of the warning limit responsive to at least one of the steps of providing and measuring.

18. The method of claim 17, wherein the step of selecting is performed without human intervention.

* * * * *

EXHIBIT D

Heartrak ECAT™

External Cardiac Ambulatory Telemetry

THE NEXT GENERATION IN ARRHYTHMIA DETECTION AND ANALYSIS

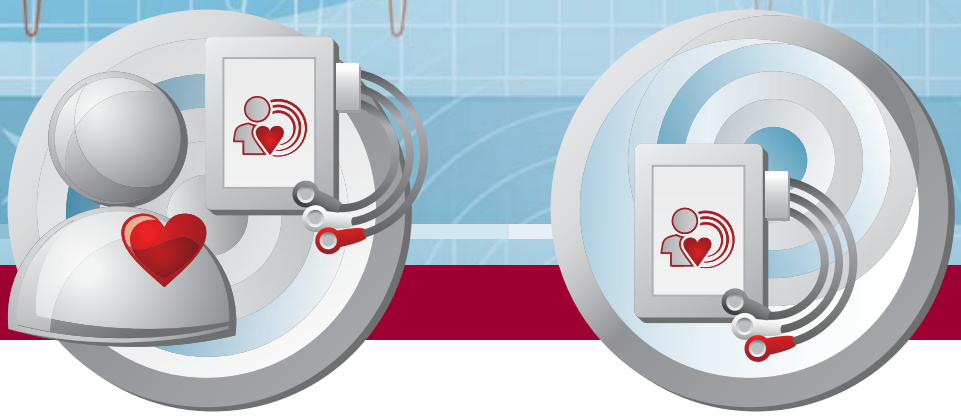
universal medical INCORPORATED
A MEDNET COMPANY

External Cardiac Ambulatory Telemetry

SMALL AND COMFORTABLE MONITOR

- Real-time ECG analysis performed on-board Monitor increases likelihood of documenting breakthrough auto-triggered events.
- Patient-activated, auto-triggered, and trended ECG recordings actively sent wirelessly to Monitoring Center.
- Records and stores every heart beat for up to 30-days of continuous monitoring; areas of interest retrievable on-demand and can be presented in full-disclosure for professional analysis.
- LED status indicators for Monitoring, Battery, and Communication help patients use the monitor.
- Recessed "RECORD" button prevents patient from accidentally recording.

Heartrak ECAT Monitor
(actual size)



Continuous real-time ECG data analysis as patients go about their daily activities

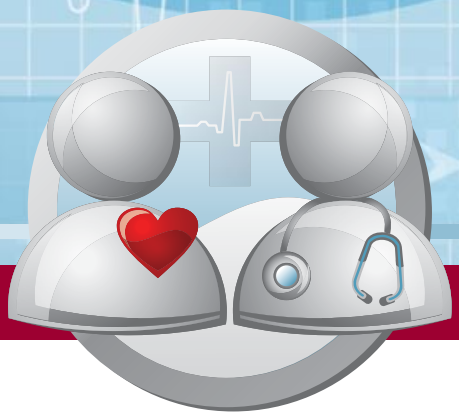
Physician requested data actively sent wirelessly

Communicator

VOICE AND DATA COMMUNICATOR

- Small, lightweight voice and data Communicator actively sends ECG data across AT&T's expansive 3G and EDGE wireless network.
- Voice services enable prompt, 2-way voice communication between patient and Monitoring Center.
- User-friendly screen displays messages to patients to ensure successful monitoring.

ECG data triaged by highly-trained, cardiac technicians



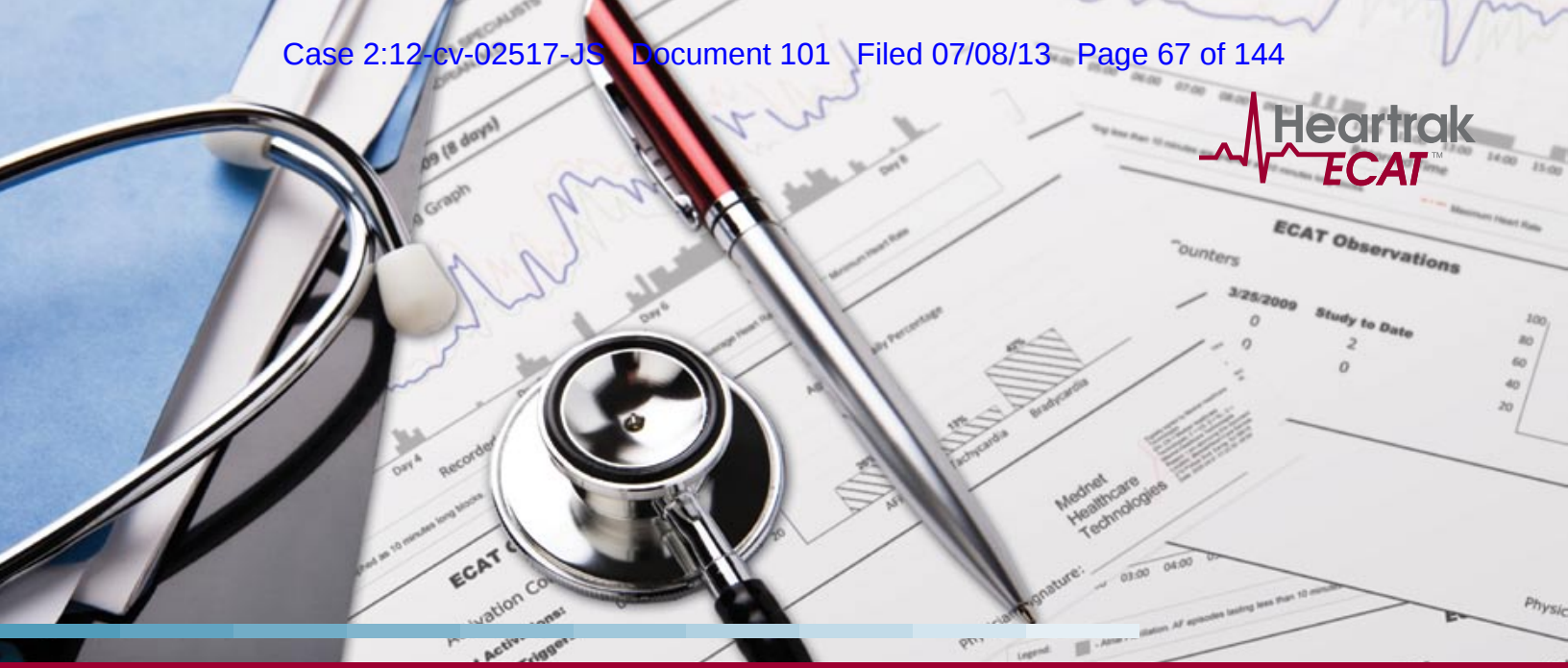
Timely reports for optimized patient treatment

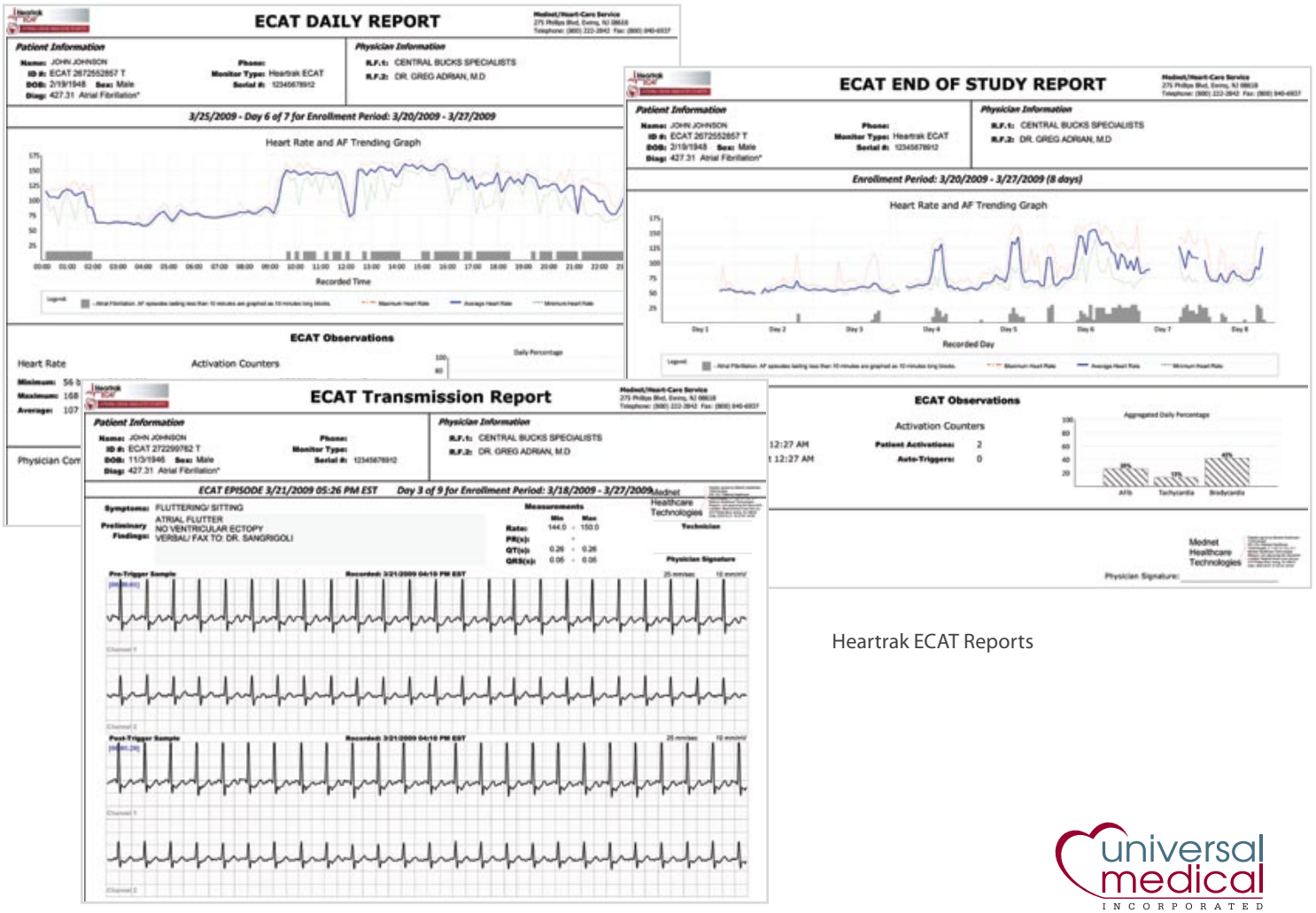
CENTRAL MONITORING CENTER PROVIDES 24/7/365 DATA REVIEW

- Highly skilled cardiac technicians triage all ECG recordings and promptly prepare reports so that patient treatment decisions can be made without delay.
- Urgent or emergent events are confirmed by the Monitoring Center and Transmission Reports are immediately sent to the physician for review based on mutually agreed notification criteria.
- ECAT daily and study overview reports provide rapid review of monitoring results, graphing heart rate and cardiac rhythm data and trends.
- Doctors, clinicians and patients can access support at anytime for ECAT monitoring studies.

universal medical
INCORPORATED
A MEDNET COMPANY

OGY IN EXTENDED DAILY CARDIAC MONITORING





Heartrak ECAT Reports

universal medical INCORPORATED
A MEDNET COMPANY

The Heartrak ECAT™ offers physicians the latest technology in extended daily cardiac monitoring.

Heartrak ECAT™

External Cardiac Ambulatory Telemetry

ECAT MONITOR SPECIFICATIONS

PHYSICAL	
Dimensions	2.9 height x 2.1 width x .7 thickness (in) 7.4 height x 5.3 width x 1.8 thickness (cm)
Weight (with battery)	90 gm (3.17 oz)
WIRELESS TRANSMISSION	
Transmit mode	Bluetooth 2.0 SPP profile
Carrier RF range (open space)	10 m (32.8 ft)
ELECTRICAL	
Bandwidth	0.05 to 30 Hz
Sampling rate	205 Hz
ADC resolution	8 Bits
Input impedance (with supplied leads)	@5 Hz = 2 MOhms minimum
Leads	3,2 channels
MEMORY	
Total recording time	30 days continuous
Memory hold time	10 years minimum
BATTERY	
Type	1.5 V "AA" alkaline (1)
Life	5 days
Warranty	1 year

For more information, contact your Heartrak ECAT Sales Representative:

universal medical
INCORPORATED
A MEDNET COMPANY

EXHIBIT E

MOBILE CARDIAC TELEMETRY

Heartrak ECAT (External Cardiac Ambulatory Telemetry) offers physicians and patients the latest remote monitoring technique in arrhythmia detection and analysis.

Because Heartrak ECAT is convenient for patients to use, patients are more likely to comply with monitoring requirements. Patients are connected by electrodes and discreet lead-wires to a small, pager-sized monitor that is typically worn on the patient's waistline. Patients can go about their normal day-to-day activities without being concerned about finding a landline telephone and calling the monitoring center to transmit or upload their ECG recordings.

The monitor contains proprietary algorithms that continuously analyze each heartbeat for rhythms that may be of clinical concern. Either when the algorithm detects a heartbeat rhythm of concern or when a patient experiences a symptom and presses the record button, Heartrak ECAT will immediately send ECG data to the monitoring center via cellular telephony network. Because Heartrak ECAT records every heart beat for up to 30 days of monitoring, any recording time of clinical interest or significance can be "fetched" remotely and presented to a clinician for further analysis.

Key Advantages:

- Prescribed for up to 30 days of continuous monitoring to detect illusive arrhythmia or quantify arrhythmia burden;
- ECG recordings actively sent (via Cellular) without requiring patient involvement;
- Multi-channel, digital ECG signal (compared to acoustic analog telephone event recorder/signal transmitter);
- Summary Reports with sample ECG recordings that validate existence and quantify persistence of rhythm abnormalities;
- Active voice service on Cell Communicator provides for prompt, 2-way voice communication between patient and Mednet, when necessary.

EXHIBIT F

Patient Instructions - Heartrak ECAT

Heartrak ECAT (External Cardiac Ambulatory Telemetry)

Heartrak ECAT services includes the Heartrak ECAT device which continuously records a patient's ECG rhythm from external electrodes. Segments of the ECG data are automatically (without patient intervention) transmitted to a remote surveillance center via cellular signal. There is a Mobile Cardiac Telemetry device algorithm that determines the segments of the rhythm that are triggered automatically and selected for transmission; this includes a rapid or slow heart rate, or may be triggered by the patient when various symptoms are experienced.

The surveillance center is attended 24/7/365 and technicians can respond to the rhythm or device alert transmissions from the patient as they are generated and transmitted to the surveillance location.

The technology provides for continuous, real-time data analysis by preprogrammed algorithms in the device, as well as attended surveillance of the transmitted rhythm segments. The surveillance center technician will evaluate any arrhythmias, review the data, and may notify the physician on the prescribed notification criteria.

ECAT Package Contents

- Heartrak ECAT Monitor w/ Holster/Clip
- Patient Lead Set
- Communicator w/ Holster/Clip
- Communicator Charger
- AA Batteries (1 per every 5 days enrolled)
- Electrodes (3 per every 1 day enrolled)
- Patient Handbook
- Pre-paid FED-EX return envelope

ECAT Monitor highlights

- 90 grams w/ (1) AA Battery
- 5 day battery life on (1) AA Duracell®
- Real-time ECG analysis on Monitor (not communicator like competitors)
- Capable of recording every heartbeat for 30 days, areas of interest are available at the request of the physician during the service period and for 7 days following the end of service
- 3-leads, 2-Channel
- Event types =>**Patient**, **Trigger**, **Trends** (all with remotely customizable timings)

ECAT Communicator highlights

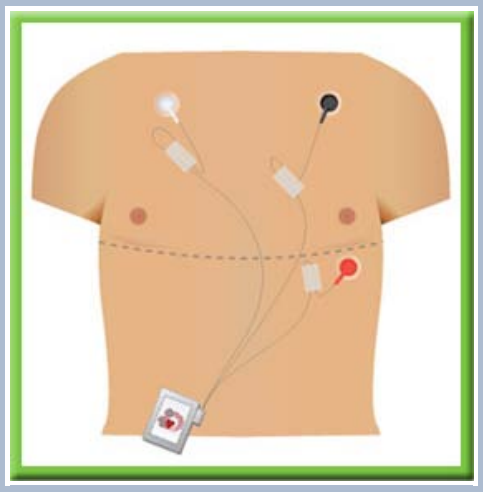
- Maintains 'Active' Communication between ECAT and Monitoring Center up to 30 feet
- Leverages AT&T's expansive 3G and EDGE wireless data footprint
- Active voice services enable prompt, 2-way voice communication between patient and Monitoring Center to correlate symptoms/activities with patient-activated recordings
- User-friendly screen indicates ECAT Communicator Bluetooth® status as well as End of Service Message
- Recommend to charge each night while patient is sleeping within 30 feet of patient to maintain Active monitoring

Central Monitoring Center provides 24/7/365 data review

- Highly skilled cardiac technicians triage all ECG recordings and promptly prepare reports so that patient treatment decisions can be made without delay.
- Urgent or emergent events are confirmed by the Monitoring Center and Transmission Reports are immediately sent to the physician for review based on mutually agreed notification criteria.
- ECAT daily and study overview reports provide rapid review of monitoring results, graphing heart rate and cardiac rhythm data and trends.
- Doctors, clinicians and patients can access support at anytime for ECAT monitoring studies.

ECAT Triggers & Data

ECAT can record up to 30 days of continuous ECG memory, every heart beat, no data compression at 200 samples/second.



To speak with a clinician about scheduling a meeting or demo of services, call us toll-free at: 800-785-4354

AMI Cardiac Monitoring
17810 Meeting House Road Suite 210
Sandy Spring, Maryland 20860

EXHIBIT G

ECAT DAILY REPORT

Mednet ECAT Demo
275 Phillips Blvd, Ewing, NJ 08618
Telephone: (800) 222-2842 Fax: (800) 840-6937

Patient Information

Name: **CONNIE CALDWELLE**
ID #: ECAT 3606216456 T
DOB: 10/28/1947 Sex: Female
Diag: 427.32 Atrial Flutter

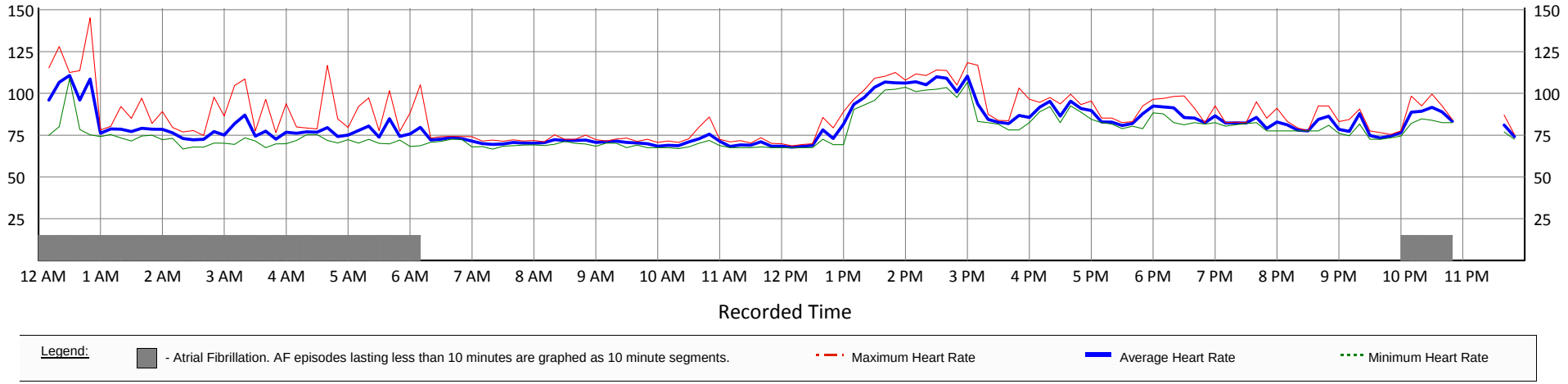
Phone: (360) 621-6478
Monitor Type: Heartrak ECAT
Serial #: 990729

Physician Information

R.F.1: CARDIOLOGY CONSULTANTS OF OH
R.F.2: DR. Doctor ECAT
R.F.3:

2/27/2010 - Day 23 of 30 for Enrollment Period: 2/5/2010 - 3/6/2010

Heart Rate and AF Trending Graph



ECAT Observations

Monitoring Duration: 23 hours 34 minutes

Heart Rate

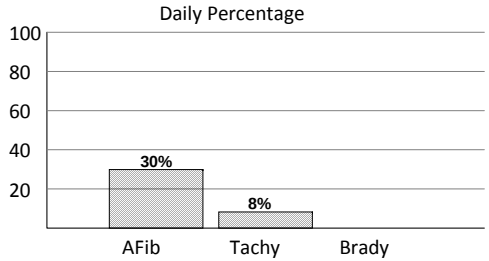
Min: 68 bpm at 10:05 AM
Max: 111 bpm at 12:35 AM
Average: 80 bpm

Activation Counters

	2/27/2010	Study to Date
Patient:	0	5
Auto-Triggers:	0	1

AF Statistics

Total Time in AF: 7 hours 3 minutes
Max HR in AF: 111 bpm at 12:35 AM
Longest AF Episode: 6 hours 10 minutes at 12:00 AM

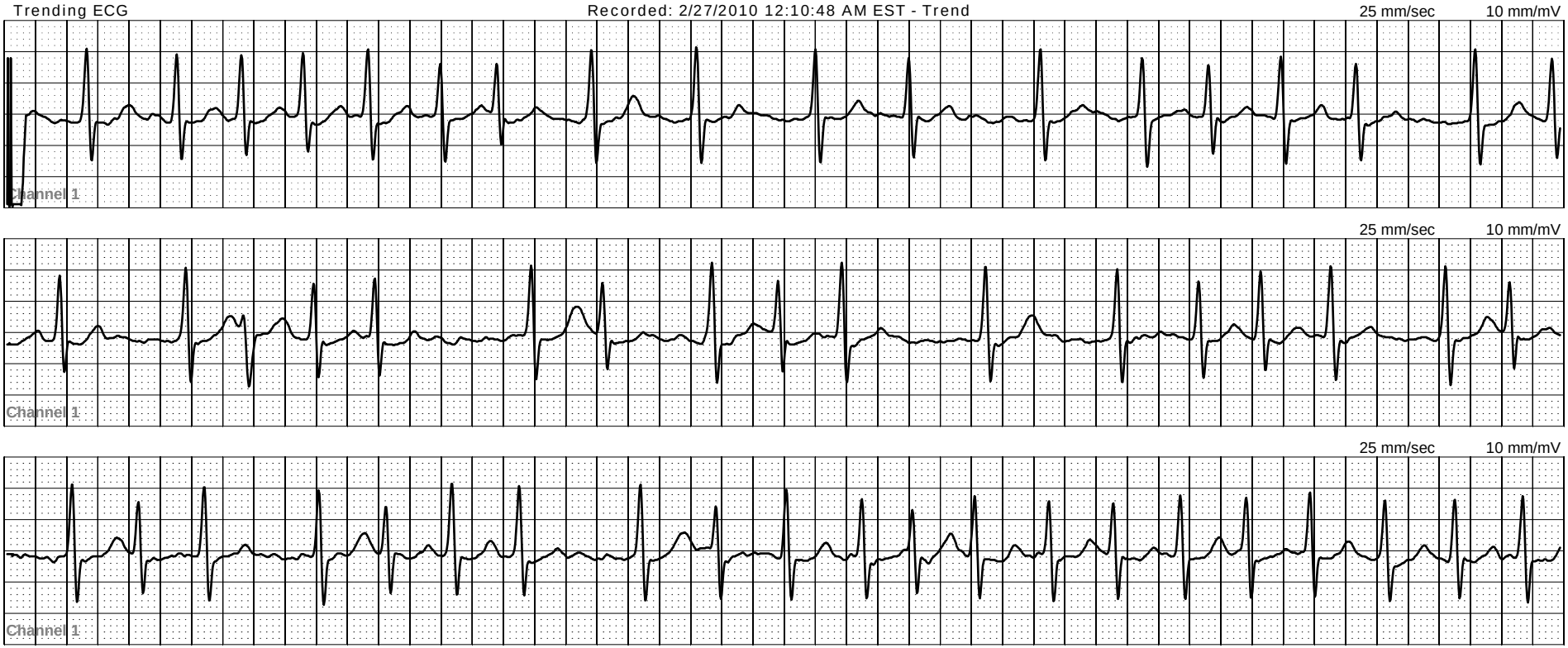


* ECAT Observations are based on average heart rate measurements. All times are reported in Eastern Standard Time.

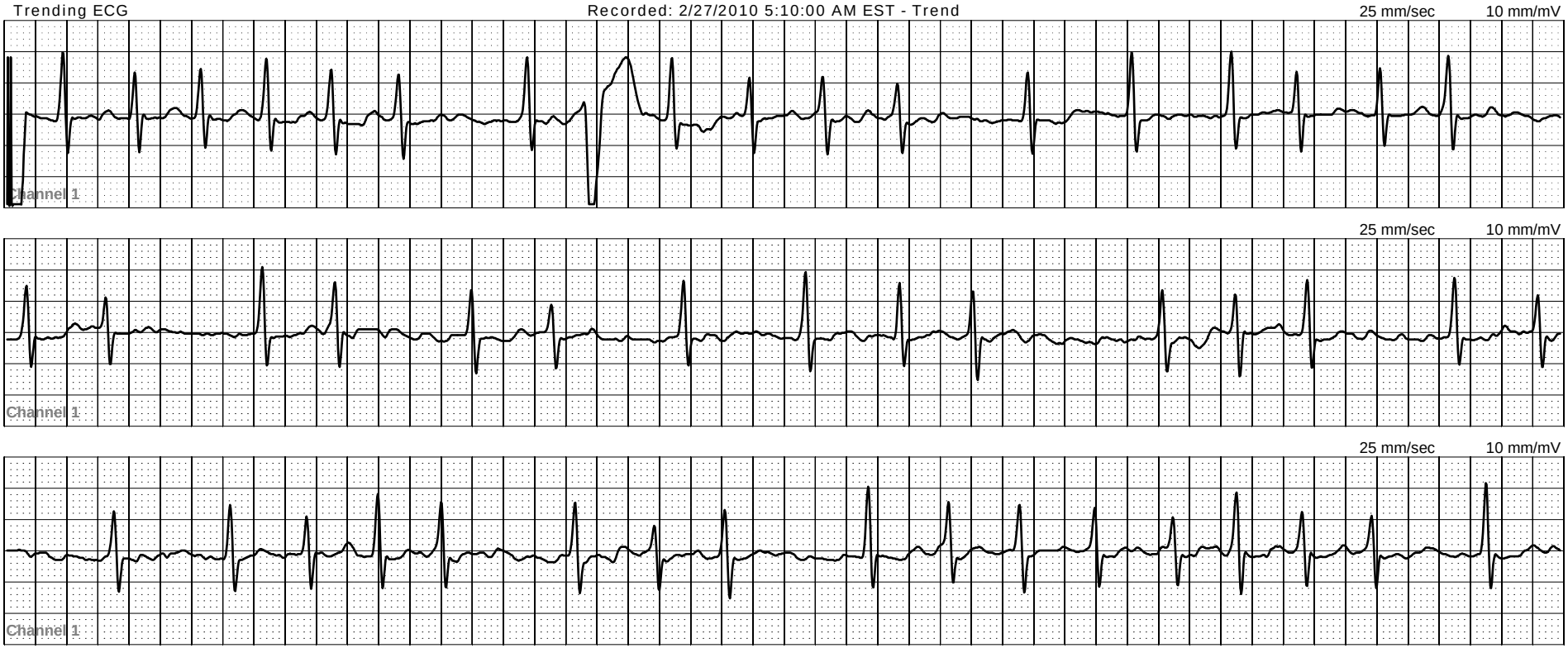
Comments:

Prepared by: _____ Physician Signature: _____

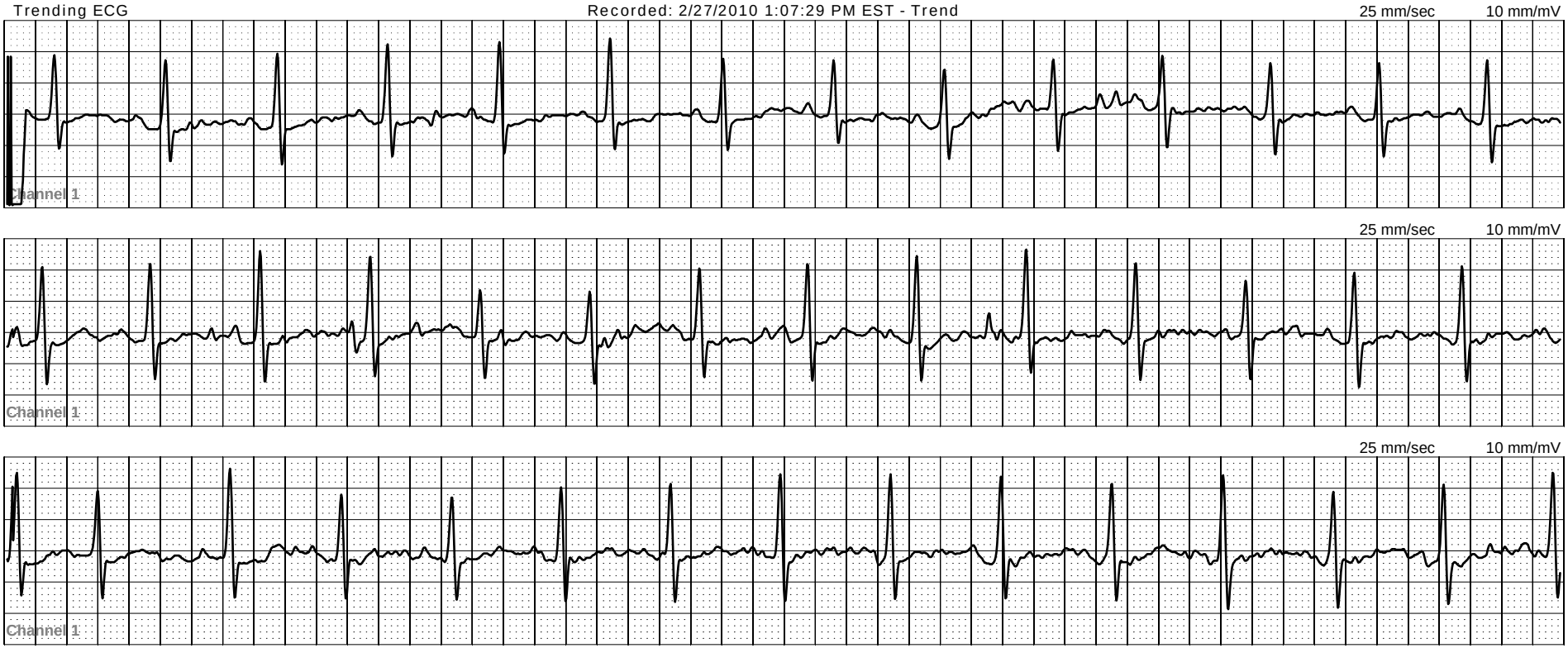
Recorded Date	Trigger Type	Transmission Date	Findings
2/27/2010 12:10:48 AM	TREND	2/27/2010 12:57:11 PM	A-FIB/A-FLUTTER



Recorded Date	Trigger Type	Transmission Date	Findings
2/27/2010 5:10:00 AM	TREND	2/27/2010 1:00:50 PM	A-FIB/A-FLUTTER/ PVC



Recorded Date	Trigger Type	Transmission Date	Findings
2/27/2010 1:07:29 PM	TREND	2/27/2010 1:49:24 PM	SINUS RHYTHM/ PAC



Recorded Date	Trigger Type	Transmission Date	Findings
2/27/2010 1:37:29 PM	TREND	2/27/2010 1:49:42 PM	SINUS TACHYCARDIA

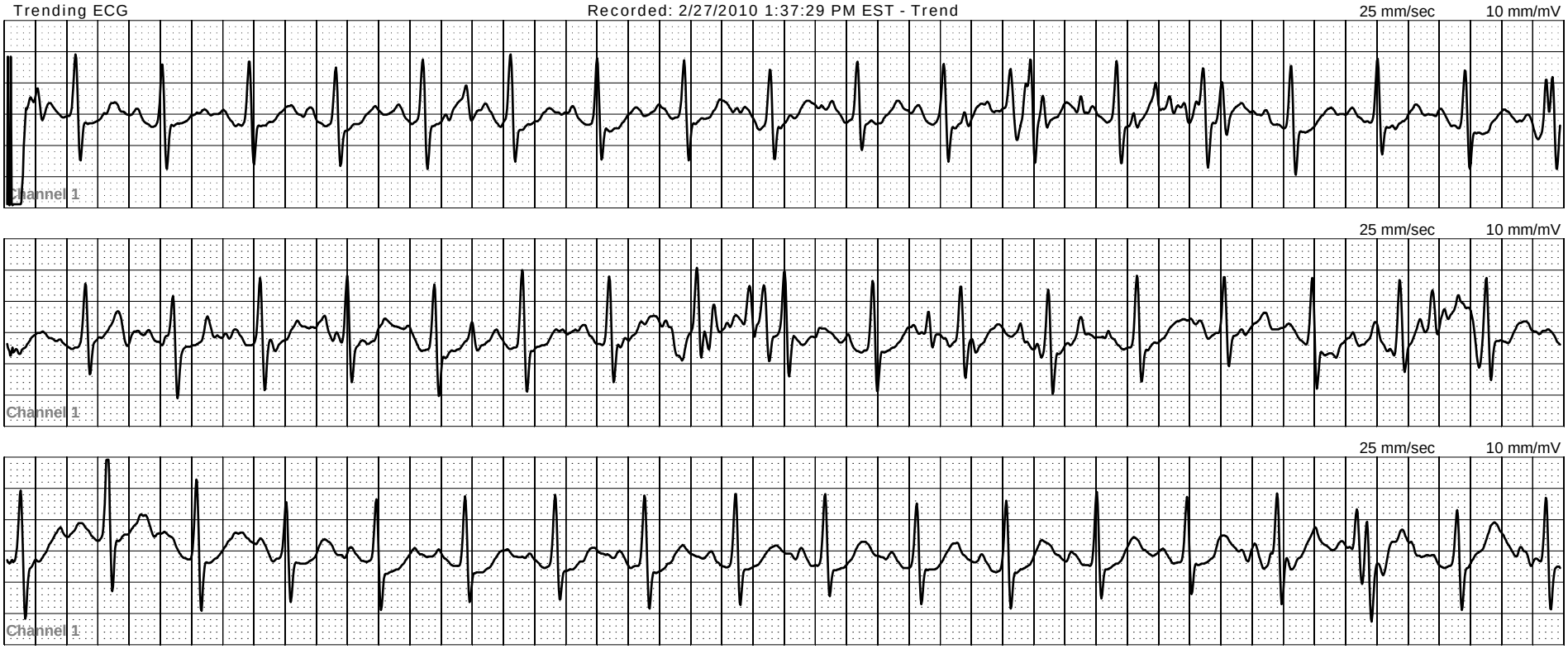


EXHIBIT H

ECAT END OF STUDY REPORT

ECAT Demo
dms-service llc
Telephone: (866 374-0105

Patient Information

Name: _____
ID #: ECAT 3606216456 T
DOB: 10/28/1947 Sex: Female
Diag: 427.32 Atrial Flutter

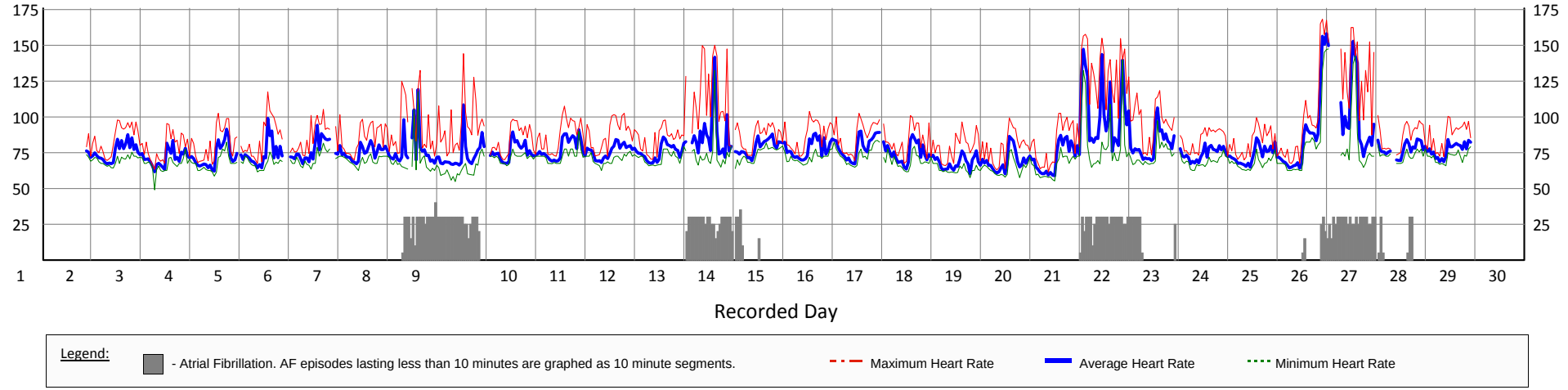
Phone:
Monitor Type: Heartrak ECAT
Serial #: 99072

Physician Information

R.F.1: CARDIOLOGY CONSULTANTS
R.F.2: DR. Doctor ECAT
R.F.3:

Enrollment Period: 2/5/2010 - 3/6/2010 (30 days)

Heart Rate and AF Trending Graph



ECAT Observations

Monitoring Duration: 655 hours 30 minutes

Heart Rate

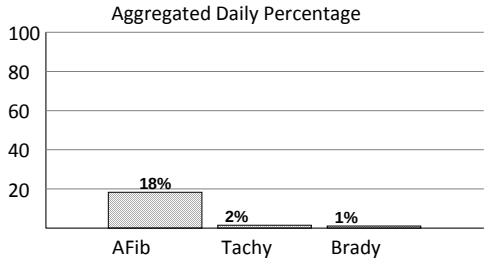
Min: 59 bpm on Day 21 - 02/25/2010
Max: 158 bpm on Day 27 - 03/03/2010
Average: 75 bpm

Activation Counters

Patient: 7
Auto-Triggers: 1

AF Statistics

Total Time in AF: 120 hours 4 minutes
Max HR in AF: 158 bpm on Day 27 at 12:30 AM
Longest AF Episode: 14 hours 0 minutes on Day 8 at 11:38 PM



* ECAT Observations are based on average heart rate measurements. All times are reported in Eastern Standard Time.

Comments:

patient had AF with high-v rate of 160

Prepared by: _____ Physician Signature: _____

Day #	Recorded Date	Trigger Type	Symptoms	Findings	Rate (bpm)
1	02/05/2010 11:23 PM	Patient	RHYTHM STRIP / DX: A FIB	SINUS RHYTHM	73.5 - 77.1
1	02/05/2010 11:54 PM	Trend		SINUS RHYTHM	
2	02/06/2010 11:28 AM	Trend		SINUS RHYTHM	
2	02/06/2010 6:28 PM	Trend		SINUS RHYTHM	
3	02/07/2010 11:54 PM	Trend		SINUS RHYTHM	
4	02/08/2010 12:39 PM	Trend		SINUS RHYTHM AND SINUS BRADYCARDIA	
4	02/08/2010 6:21 PM	Trend		SINUS RHYTHM AND SINUS TACHYCARDIA	
5	02/09/2010 9:58 AM	Trend		SINUS BRADYCARDIA	
5	02/09/2010 2:40 PM	Trend		SINUS TACHYCARDIA	
5	02/09/2010 11:29 PM	Trend		SINUS RHYTHM/PAC'S	
6	02/10/2010 7:17 PM	Trend		SINUS RHYTHM/PACS	
7	02/11/2010 1:15 AM	Trend		SINUS RHYTHM/PACS	
7	02/11/2010 9:18 AM	Trend		SINUS RHYTHM	
8	02/12/2010 3:55 AM	Trend		SINUS RHYTHM/PAC'S	
8	02/12/2010 12:38 PM	Trend		A-FIB/A-FLUTTER	
8	02/12/2010 1:57 PM	Auto	AUTO-TRIGGER	A-FIB	110 - 140
9	02/13/2010 1:35 AM	Trend		A-FIB/A-FLUTTER	
9	02/13/2010 4:46 AM	Trend			
9	02/13/2010 2:21 PM	Patient	ATTEMPTED TO CALL PATIENT FOR SYMPTOMS - NO REPLY	ATRIAL FIBRILLATION	70 - 110
9	02/13/2010 8:34 PM	Trend		A-FIB/ PVCS	
9	02/13/2010 8:44 PM	Trend		SINUS RHYTHM	
10	02/14/2010 12:29 AM	Trend		SINUS RHYTHM	
10	02/14/2010 4:11 AM	Trend		SINUS RHYTHM / PACs	
11	02/15/2010 9:40 AM	Trend		SINUS RHYTHM, PVC	
11	02/15/2010 3:53 PM	Trend		SINUS RHYTHM	
11	02/15/2010 6:14 PM	Trend		SINUS RHYTHM, PACS	
12	02/16/2010 3:42 AM	Trend		SINUS RHYTHM	

Day #	Recorded Date	Trigger Type	Symptoms	Findings	Rate (bpm)
13	02/17/2010 7:24 AM	Trend		SINUS RHYTHM	
13	02/17/2010 10:30 PM	Trend		SINUS RHYTHM	
14	02/18/2010 12:20 AM	Trend		SINUS RHYTHM	
14	02/18/2010 1:22 AM	Patient	PT ACTIVATION - NO SYMPTOMS GIVEN	A-FIB	90 - 100
14	02/18/2010 2:58 AM	Patient	PT ACTIVATION - NO SYMPTOMS GIVEN	A-FIB/PVC	90 - 110
14	02/18/2010 3:40 AM	Trend		A-FIB, PVC	
15	02/19/2010 1:17 AM	Patient	PT ACTIVATION - NO SYMPTOMS GIVEN	A-FIB/A-FLUTTER	80 - 100
15	02/19/2010 3:50 AM	Trend		A-FIB	
15	02/19/2010 9:32 AM	Trend		SINUS RHYTHM/ PVC	
16	02/20/2010 11:38 AM	Trend		SINUS RHYTHM	
16	02/20/2010 8:41 PM	Trend		SINUS RHYTHM	
17	02/21/2010 7:17 PM	Trend		SINUS RHYTHM/PAC	
18	02/22/2010 5:48 AM	Trend		SINUS RHYTHM	
18	02/22/2010 1:01 PM	Trend		SINUS RHYTHM AND SINUS BRADYCARDIA	
19	02/23/2010 4:58 AM	Trend		SINUS RHYTHM	
19	02/23/2010 6:09 AM	Trend		SINUS BRADYCARDIA	
19	02/23/2010 7:44 PM	Trend		SINUS BRADYCARDIA	
20	02/24/2010 5:28 AM	Trend		SINUS RHYTHM AND SINUS BRADYCARDIA	
20	02/24/2010 5:12 PM	Trend		SINUS RHYTHM	
21	02/25/2010 6:24 AM	Trend		SINUS BRADYCARDIA	
22	02/26/2010 12:13 AM	Trend		SINUS RHYTHM	
22	02/26/2010 2:09 AM	Trend		A-FIB/PVC	
23	02/27/2010 12:10 AM	Trend		A-FIB/A-FLUTTER	
23	02/27/2010 5:10 AM	Trend		A-FIB/A-FLUTTER/ PVC	
23	02/27/2010 1:07 PM	Trend		SINUS RHYTHM/ PAC	
23	02/27/2010 1:37 PM	Trend		SINUS TACHYCARDIA	
24	02/28/2010 8:34 AM	Trend		SINUS RHYTHM AND SINUS BRADYCARDIA	
24	02/28/2010 8:37 PM	Trend		SINUS RHYTHM	

Day #	Recorded Date	Trigger Type	Symptoms	Findings	Rate (bpm)
25	03/01/2010 12:29 AM	Trend		SINUS RHYTHM	
25	03/01/2010 1:28 PM	Trend		SINUS RHYTHM / PVC	
26	03/02/2010 9:00 PM	Trend		SINUS RHYTHM	
26	03/02/2010 9:10 PM	Trend		A-FIB/A-FLUTTER	
27	03/03/2010 2:22 AM	Patient	PT ACTIVATION - NO SYMPTOMS GIVEN	A-FIB	120 - 150
27	03/03/2010 1:23 PM	Trend		ATRIAL FIBRILLATION	
27	03/03/2010 3:39 PM	Patient	FLUTTERING	A-FIB	90 - 110
27	03/03/2010 10:27 PM	Trend		ATRIAL FIBRILLATION/ATRIAL FLUTTER	
28	03/04/2010 1:50 AM	Trend		A-FIB	
28	03/04/2010 4:00 AM	Trend		SINUS RHYTHM	
29	03/05/2010 12:03 AM	Trend		SINUS RHYTHM	
29	03/05/2010 8:07 AM	Trend		SINUS RHYTHM	

EXHIBIT I

K083535

5. 510(k) Summary or 510(k) Statement

DEC 15 2008

Date: October 30, 2008

Submitter/Owner: Universal Medical, Inc.

Official Contact Person Authorized by the Submitter:

Mark Job, Third-Party Reviewer
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, MN 55313
Telephone: 763 682 4139
FAX: 763 682 4420
Email: mark@markjob.com

Device Type: cardiac event recorder; electrocardiograph transmitter

Device Class: II

Regulation Number 870.2920

Review Panel: Cardiovascular

Basis for the Submission: new design incorporating wireless technology.

Page 1 of 9

Predicate Devices

Predicate devices for which Universal Medical, Inc. is claiming equivalence:

510(k) Number	Trade or Model Name	Manufacturer	Classification Name	Product Code
K071130	Heartrak Smart AF	Universal Medical, Inc.	transmitters and receivers, electrocardiograph, telephone 870.2920	DXH
K060911	Cg-6108 Arrhythmia ECG Event Recorder	Card Guard Scientific Survival, Ltd.	transmitters and receivers, electrocardiograph, telephone 870.2920	DXH

Device Description

Heartrak Smart ECAT is a cardiac event recorder that is used to continuously scan and capture ECG signals. Patients can use Heartrak Smart ECAT to capture ECG data both before and after they experience a cardiac symptom. Heartrak Smart ECAT can capture and automatically record asymptomatic, infrequent, or illusive arrhythmia events such as Bradycardia, Tachycardia, and Atrial Fibrillation.

Heartrak Smart ECAT can store up to 30 days of ECG data in its memory. The physician can use a compatible wireless device to set event recording times and autotriggering parameters and then upload them to a patient's monitor.

Using wireless technology, Heartrak Smart ECAT, when placed within range (less than 10 meters) of an RF compatible receiver, uploads recorded ECG waveform and ECG parameter data to the receiver. When data upload is complete, data can be reviewed and analyzed at a physician's office, clinic, or monitoring center.

The physician is to instruct the patient on the proper use and care of the Heartrak Smart ECAT monitor. Patients should be told to contact their physician if they have any further questions.

Intended Use

Heartrak ECAT is a hand-held, portable, externally applied, cardiac event recorder; electrocardiograph transmitter.

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Indications for Use

Heartrak Smart ECAT is a wireless ambulatory, multi-channel, continuous ECG event recorder with embedded arrhythmia detection algorithms. Heartrak Smart ECAT registers symptomatic and asymptomatic cardiac events triggered by a patient manually or auto-triggered by embedded arrhythmia detection algorithms. Using wireless technology, Heartrak Smart ECAT, when placed within range of an RF compatible receiver, uploads recorded ECG waveform and ECG parameter data to the receiver. When data upload is complete, data can be reviewed and analyzed at a physician's office, clinic, or monitoring center.

Heartrak Smart ECAT does not deliver any energy, administer any drugs, make any diagnosis, or control a patient's life. Heartrak Smart ECAT is for prescription use only.

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x

Technological Characteristics (Substantial Equivalency Table)

The table below shows that the technological characteristics of Heartrak Smart ECAT are substantially equivalent to the predicate devices:
Heartrak Smart AF (K071130) manufactured by Universal Medical, Inc. in functionality
CG-6108 Arrhythmia ECG Event Recorder (K060911) manufactured by Card Guard Scientific Survival, Ltd. in wireless communication

Table 1 Substantial Equivalency Table

	Heartrak Smart ECAT	CG-6108 Arrhythmia ECG Event Recorder (K060911)	Heartrak Smart AF (K071130)
	Universal Medical, Inc.	Card Guard Scientific Survival, Ltd.	Universal Medical, Inc.
Intended use	Heartrak Smart ECAT is a hand-held, portable, externally applied, cardiac event recorder; electrocardiograph transmitter.	Intended for use by patients who experience transient symptoms that may suggest cardiac arrhythmia.	Heartrak Smart AF is a hand-held, portable, externally applied, cardiac event recorder that is intended for transtelephonic use.
Indications for use	Heartrak Smart ECAT is a wireless ambulatory, multi-channel, continuous ECG event recorder with embedded arrhythmia detection algorithms. Heartrak Smart ECAT registers symptomatic and asymptomatic cardiac events triggered by a patient manually or auto-triggered by embedded arrhythmia detection algorithms. Using	The CG-6108 system is an Arrhythmia ECG Event Recorder designed for self-testing by patients at home and for analysis by medical professionals at a remote monitoring center. It comprises a chest-worn ECG sensor and a handheld device with a proprietary application, configured to process and transmit the ECG recordings.	Heartrak Smart AF is a hand-held, portable, externally applied, cardiac event recorder that is intended for transtelephonic use. Patient calls a receiving center at the hospital or physicians office from the patient's home to play back the recording. Heartrak Smart AF converts electrocardiogram (ECG) signals into audio tones which

	Heartrak Smart ECAT Universal Medical, Inc.	CG-6108 Arrhythmia ECG Event Recorder (K060911) Card Guard Scientific Survival, Ltd.	Heartrak Smart AF (K071130) Universal Medical, Inc.
	wireless technology, Heartrak Smart ECAT, when placed within range of a compatible RF receiver, uploads recorded ECG waveform and ECG parameter data to the receiver. When data upload is complete, data can be reviewed and analyzed at a physician's office, clinic, or monitoring center. Heartrak Smart ECAT does not deliver any energy, administer any drugs, make any diagnosis, or control a patient's life. Heartrak Smart ECAT is for prescription use only.	The chest-worn unit includes 3 electrodes on a harness and it houses a battery, an ASIC and a Bluetooth transceiver for the acquisition, recording, and transmission of the ECG signal. The ECG signals are transmitted via Bluetooth to the handheld device. When an event is detected, it is wirelessly transmitted to the CG Monitoring Center for professional analysis. The handheld device is equipped with shared memory used to record the signal received from the sensor and to allow pre- and post-processing options through the use of this memory in a dual memory loop configuration, both running in parallel. One loop is auto-triggered, with programmable thresholds, which starts recording based on specific rhythms and arrhythmias detected or manually activated by the patient. The second, and longer, recording loop is controlled remotely to provide the physician with more information, when requested by	are transmitted over the telephone lines. Heartrak Smart AF does not deliver any energy, administer any drugs, or control a patient's life. Heartrak Smart AF is not a diagnostic tool and performs no diagnostic functions.

	Heartrak Smart ECAT	CG-6108 Arrhythmia ECG Event Recorder (K060911)	Heartrak Smart AF (K071130)
	Universal Medical, Inc.	Card Guard Scientific Survival, Ltd.	Universal Medical, Inc.
		the CG Monitoring Center. The handheld device automatically transmits the recorded ECG, via cellular link, to the Monitoring Center. When cellular service is unavailable the patient can transmit via landline telephone.	
Monitor Features			
Patient Cable	3-lead patient cable	3-lead patient cable	2-lead patient cable
Lead off Detection	Yes	Unknown	No
Channel Recording	3	3	1
Monitoring Mode	Continuous	Continuous	Loop
Data Transmission	Radio Frequency (RF)	Radio Frequency (RF)	Transtelephonic FM
Recording Button	Yes	Yes	Yes
Playback Button	No (When User puts monitor within range of a compatible RF receiver, the monitor automatically uploads recorded ECG data to the receiver.)	No (When User puts monitor within range of a compatible RF receiver, the monitor automatically uploads recorded ECG data to the receiver.)	Yes
Reset Button	No	No	Yes
Unintentional Erase Data Protection	Yes	Unknown	Yes

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	Heartrak Smart ECAT	CG-6108 Arrhythmia ECG Event Recorder (K060911)	Heartrak Smart AF (K071130)
	Universal Medical, Inc.	Card Guard Scientific Survival, Ltd.	Universal Medical, Inc.
Power Loss Data Protection	Yes	Unknown	Yes
Available Programming/Configuration Options			
Programmable pre/post recording times	Multiple	Yes	Multiple (Total memory 10 minutes)
Number of events	Multiple	Multiple	Multiple
Patient Manual Activation	Yes	Yes	Yes
Silent Recording	Yes	Unknown	Yes
Auto-Triggering	Yes	Yes	Yes
Bradycardia	Yes (configuration option to set range for rate)	Yes (configuration option to set range for rate)	Yes (configuration option to set range for rate)
Tachycardia	Yes (configuration option to set range for rate)	Yes (configuration option to set range for rate)	Yes (configuration option to set range for rate)
Atrial Fibrillation	Yes	Yes	Yes
Auto-Trigger On/OFF capability	Yes	Unknown	Yes
Monitor Physical Characteristics			
Dimensions	7.4 cm length x 5.3 cm wide x 1.8 cm thick Weight with batteries 90 gm	75 x 58 x 23 mm (max.) Net weight 54 gm	7.4 cm length x 5.3 cm wide x 1.8 cm thick Weight with batteries 90 gm

	Heartrak Smart ECAT	CG-6108 Arrhythmia ECG Event Recorder (K060911)	Heartrak Smart AF (K071130)
	Universal Medical, Inc.	Card Guard Scientific Survival, Ltd.	Universal Medical, Inc.
Monitor Technical Characteristics			
Transmission Mode (Bluetooth 2.0 SPP Profile)	Yes	Yes	N/A
RF transmission range	10 meters open space	10 meters open space	N/A
Bandwidth	0.05 – 30 Hz	60 Hz	0.05 – 30 Hz
Recording Period	3 channel, 30 days	1-lead, up to 24 hours	9 minutes
Monitor Electrical Characteristics			
Input Impedance	With supplied leads @ 5Hz 2 MOhm	20 MOhm	With supplied leads @ 5Hz 2 MOhm
Differential Input @ AC 15 Hz	± 3 mV	+5 mVp-p	± 3 mV
Differential Input Range	DC ± 250 mV	DC ± 165 mV	DC ± 250 mV
Common Mode Ratio (CMR)	60 dB	60 dB	60 dB
Common Mode Ratio Range (CMRR) AC + DC	± 0.5V	Unknown	± 0.5V
Monitor Battery			
Battery type	Internal Li-Ion rechargeable battery 3.6V	3.6V AA	AA 1.5V
Battery life	3 days	10 days	14 days (1 event recorded and transmitted each day
Monitor Environmental Characteristics			
Operating temperature	+10 to +40 degrees C	+10 to +40 degrees C	+10 to +40 degrees C

	Heartrak Smart ECAT	CG-6108 Arrhythmia ECG Event Recorder (K060911)	Heartrak Smart AF (K071130)
	Universal Medical, Inc.	Card Guard Scientific Survival, Ltd.	Universal Medical, Inc.
Transport and storage temperature	-20 to 65 degrees C	-20 to 65 degrees C	-20 to 65 degrees C
Relative humidity	10% to 90%	30% to 85%	10% to 90%

Page 9 of 9

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 15 2008

Universal Medical, Inc.
c/o Mr. Mark Job
Regulatory Technology Services, LLC
1394 25th Street NW
Buffalo, Minnesota 55313

Re: K083535
Trade/Device Name: Heartrak Smart ECAT
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter and Receiver
Regulatory Class: Class II
Product Code: DXH
Dated: November 26, 2008
Received: November 28, 2008

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Bachman

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number (if known): K083535

Device Name: Heartrak Smart ECAT

Indications for Use

Heartrak Smart ECAT is a wireless ambulatory, multi-channel, continuous ECG event recorder with embedded arrhythmia detection algorithms. Heartrak Smart ECAT registers symptomatic and asymptomatic cardiac events triggered by a patient manually or auto-triggered by embedded arrhythmia detection algorithms. Using wireless technology, Heartrak Smart ECAT, when placed within range of a compatible RF receiver, uploads recorded ECG waveform and ECG parameter data to the receiver. When data upload is complete, data can be reviewed and analyzed at a physician's office, clinic, or monitoring center.

Heartrak Smart ECAT does not deliver any energy, administer any drugs, make any diagnosis, or control a patient's life. Heartrak Smart ECAT is for prescription use only.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

Donna R. Vachuska
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K083535

EXHIBIT J

US007587237B2

(12) **United States Patent**
Korzinov et al.

(10) **Patent No.: US 7,587,237 B2**
(45) **Date of Patent: Sep. 8, 2009**

(54) **BIOLOGICAL SIGNAL MANAGEMENT**

(75) Inventors: **Lev Korzinov**, San Diego, CA (US); **Eric Baumann**, San Diego, CA (US)

(73) Assignee: **CardioNet, Inc.**, San Diego, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 393 days.

(21) Appl. No.: **10/770,702**

(22) Filed: **Feb. 2, 2004**

(65) **Prior Publication Data**

US 2005/0171448 A1 Aug. 4, 2005

(51) **Int. Cl.**
A61B 5/04 (2006.01)

(52) **U.S. Cl.** **600/509**

(58) **Field of Classification Search** 607/18; 600/509

See application file for complete search history.

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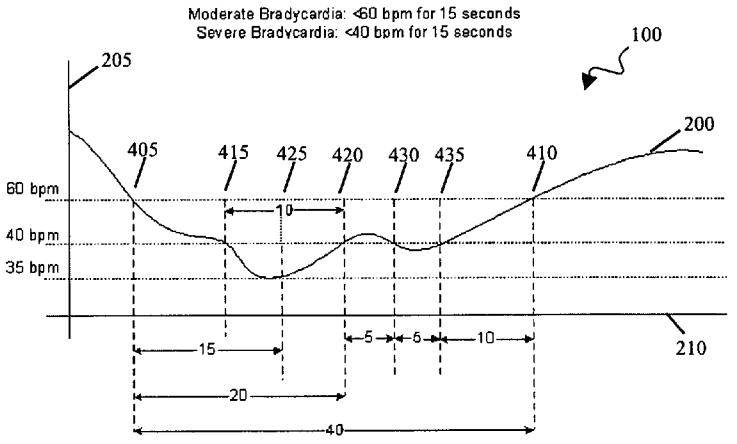
Primary Examiner—Mark W Bockelman
Assistant Examiner—Eric D Bertram
(74) *Attorney, Agent, or Firm*—Fish & Richardson P.C.

(57) **ABSTRACT**

Systems and techniques for managing biological signals. In one implementation, a method includes receiving a cardiac biological signal that includes information describing events, determining a merit of each event based on one or more of a severity of a cardiac condition associated with the event and a quality of the event, and handling a subset of the events that meet a merit criterion. The subset can be handled for medical purposes.

39 Claims, 7 Drawing Sheets



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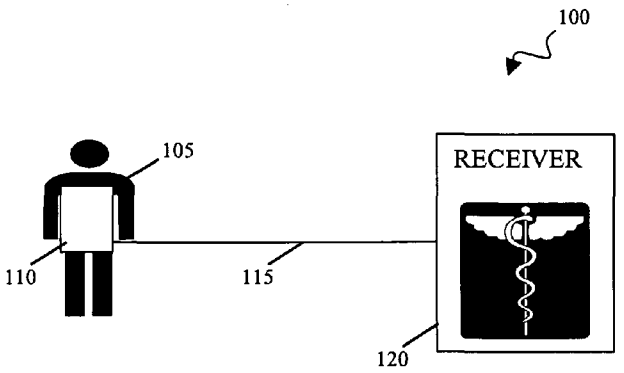


FIG. 1

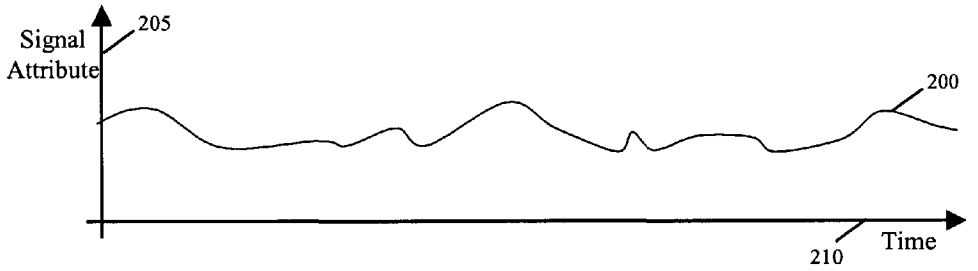


FIG. 2

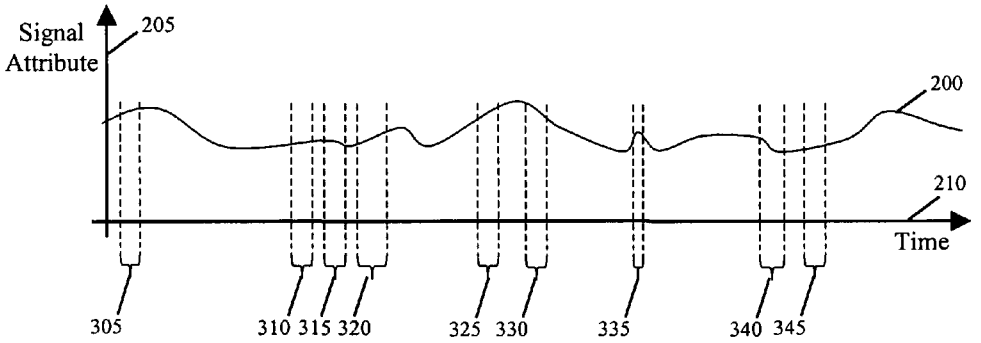


FIG. 3

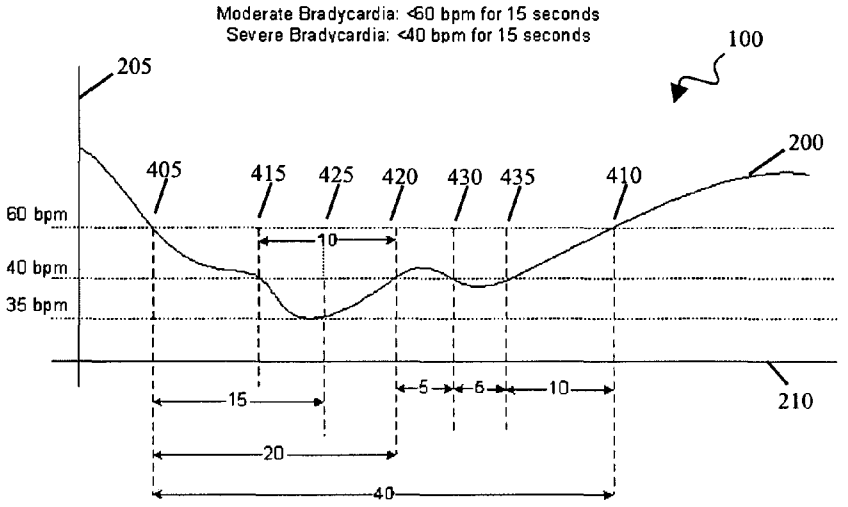

Moderate Bradycardia: <60 bpm for 15 seconds
Severe Bradycardia: <40 bpm for 15 seconds
100
205
200
405
415
425
420
430
435
410
60 bpm
40 bpm
35 bpm
10
15
5
6
10
20
40
210

FIG. 4

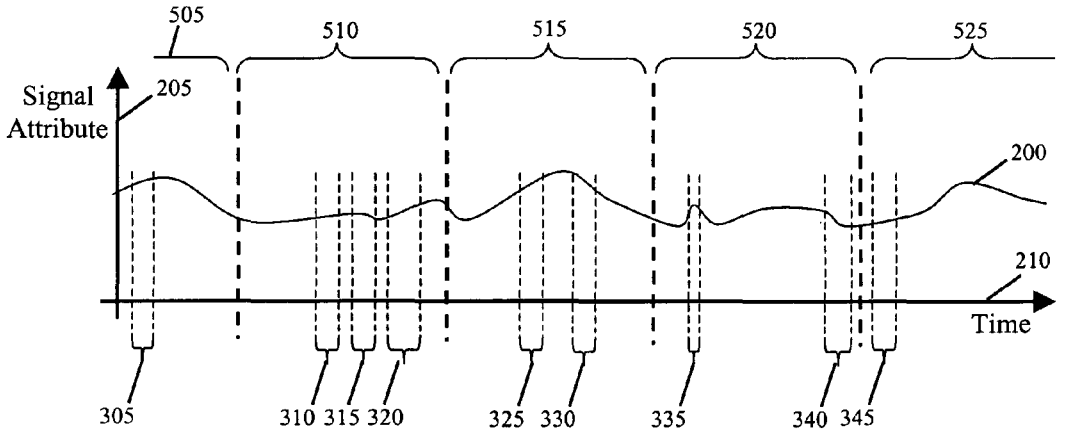

505
510
515
520
525
Signal Attribute
205
200
210
Time
305
310 315 320
325 330
335
340 345

FIG. 5

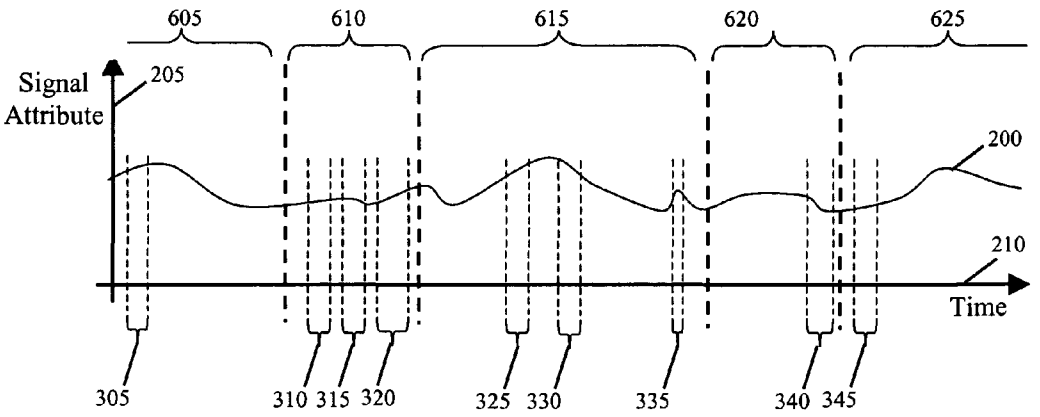


FIG. 6

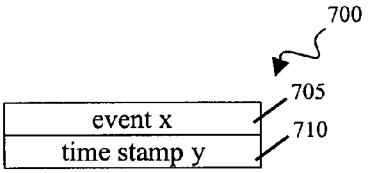


FIG. 7

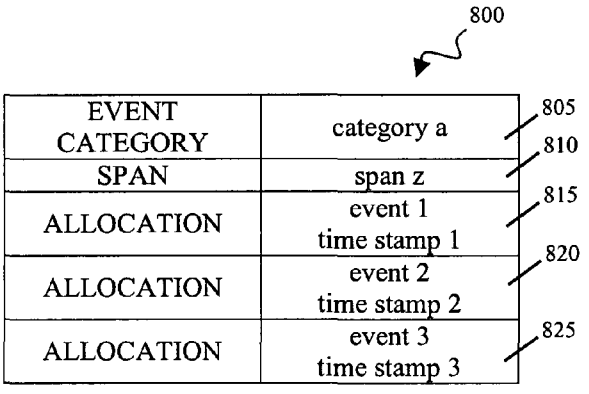


FIG. 8

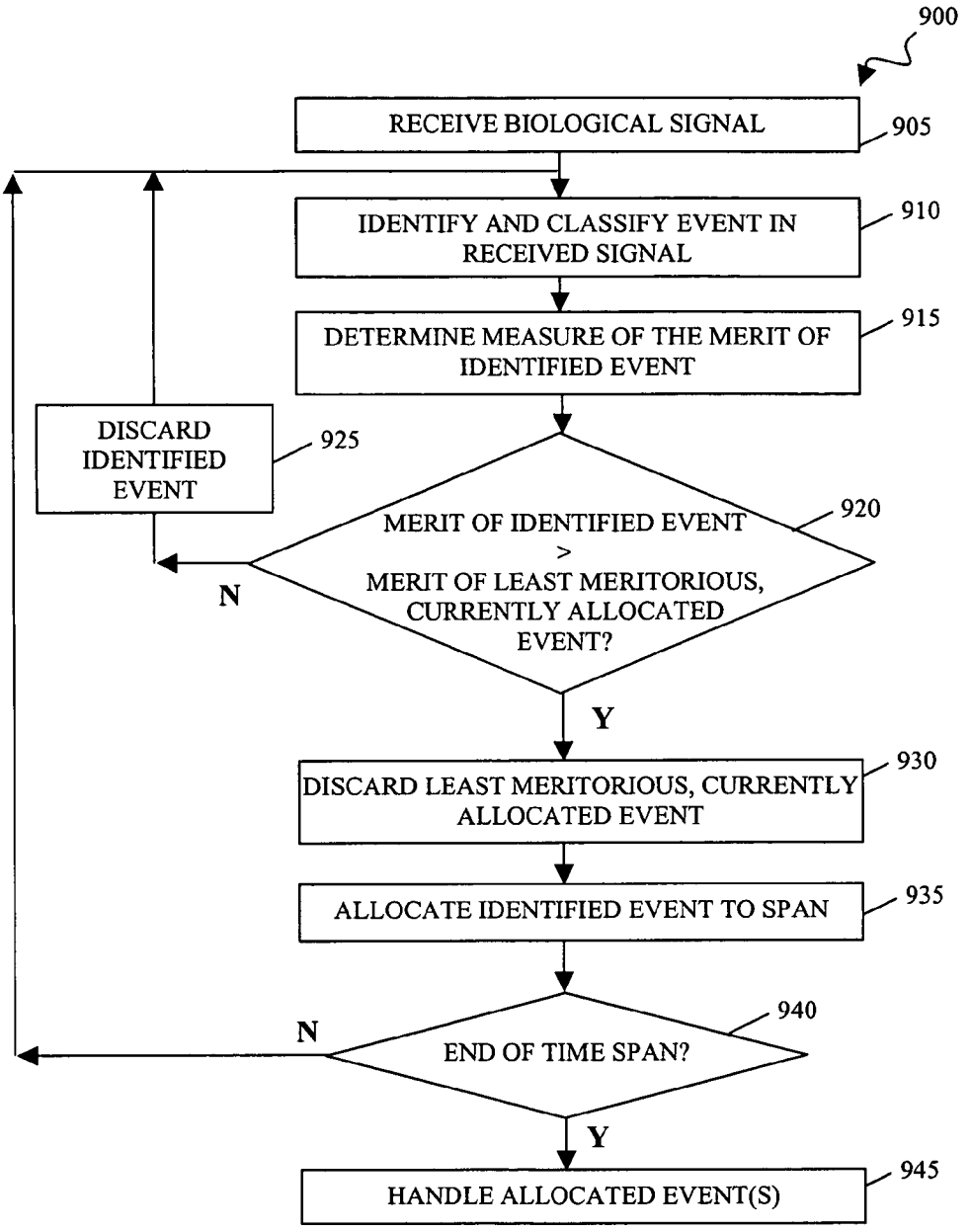

900
RECEIVE BIOLOGICAL SIGNAL
905
IDENTIFY AND CLASSIFY EVENT IN RECEIVED SIGNAL
910
DETERMINE MEASURE OF THE MERIT OF IDENTIFIED EVENT
915
DISCARD IDENTIFIED EVENT
925
MERIT OF IDENTIFIED EVENT > MERIT OF LEAST MERITORIOUS, CURRENTLY ALLOCATED EVENT?
920
N
Y
DISCARD LEAST MERITORIOUS, CURRENTLY ALLOCATED EVENT
930
ALLOCATE IDENTIFIED EVENT TO SPAN
935
END OF TIME SPAN?
940
N
Y
HANDLE ALLOCATED EVENT(S)
945

FIG. 9

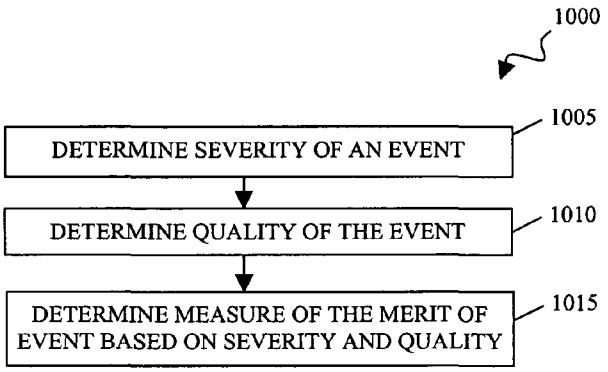

1000
1005
DETERMINE SEVERITY OF AN EVENT
1010
DETERMINE QUALITY OF THE EVENT
1015
DETERMINE MEASURE OF THE MERIT OF EVENT BASED ON SEVERITY AND QUALITY

FIG. 10

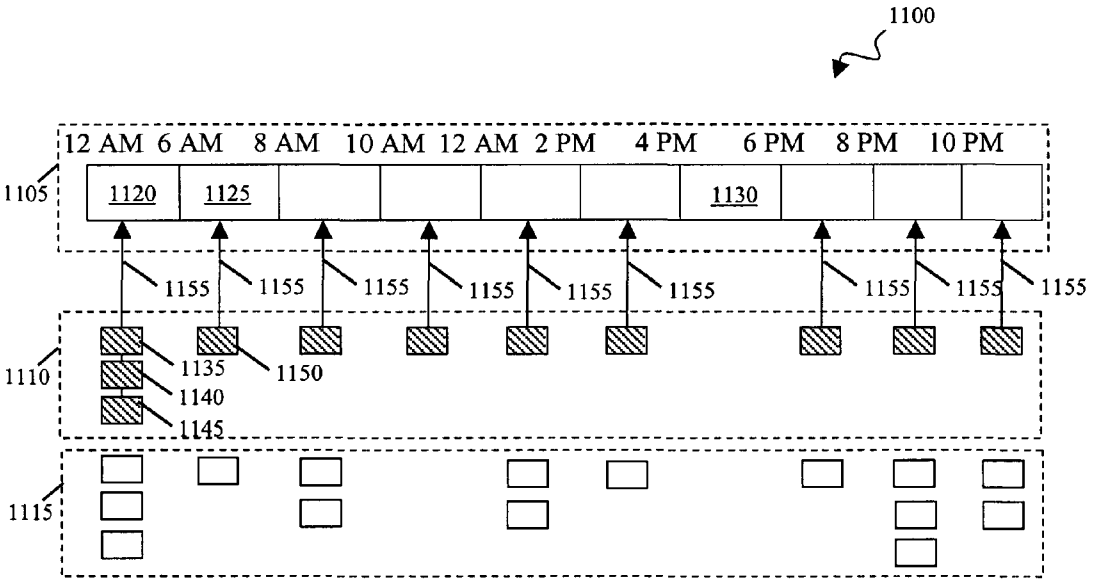

1100
12 AM 6 AM 8 AM 10 AM 12 AM 2 PM 4 PM 6 PM 8 PM 10 PM
1105
1120
1125
1130
1155
1110
1135
1140
1145
1150
1115

FIG. 11

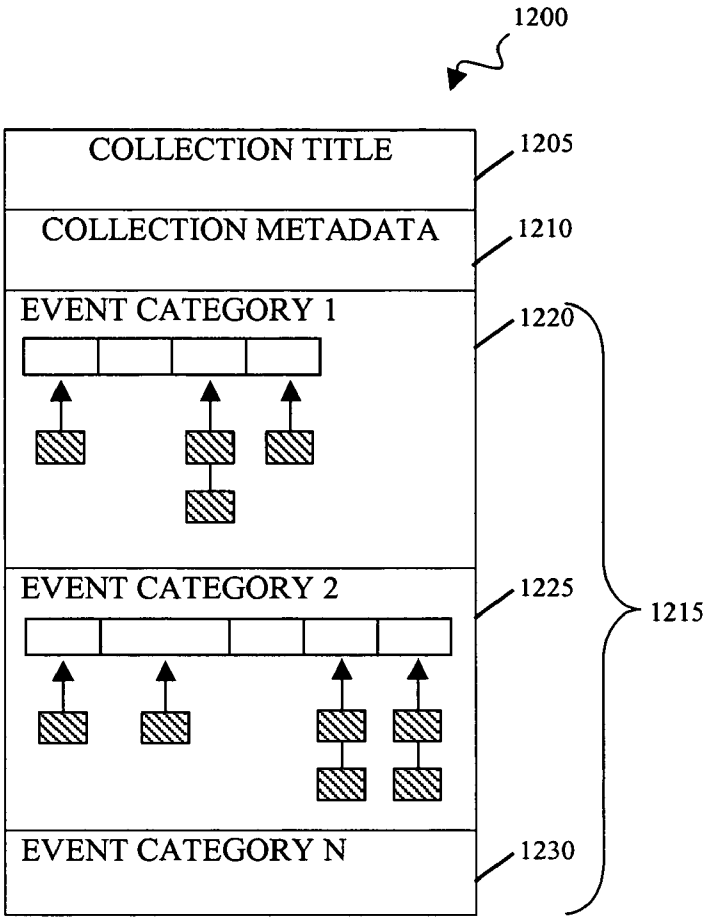

1200
COLLECTION TITLE
1205
COLLECTION METADATA
1210
EVENT CATEGORY 1
1220
EVENT CATEGORY 2
1225
1215
EVENT CATEGORY N
1230

FIG. 12

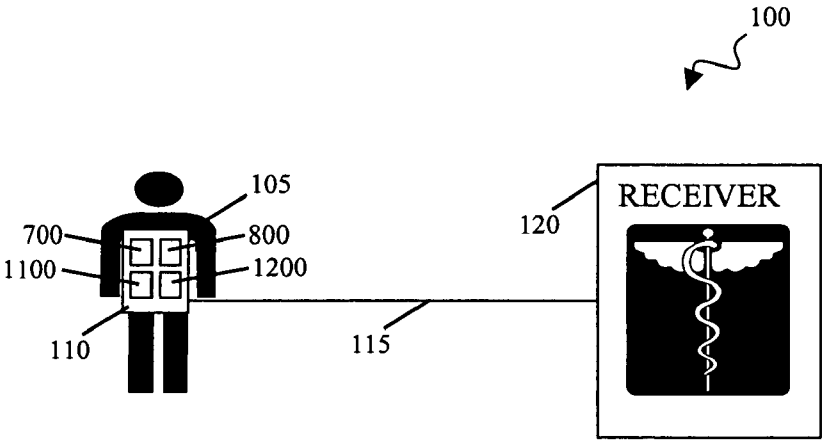

100
105
700
800
1100
1200
110
115
120
RECEIVER

FIG. 13

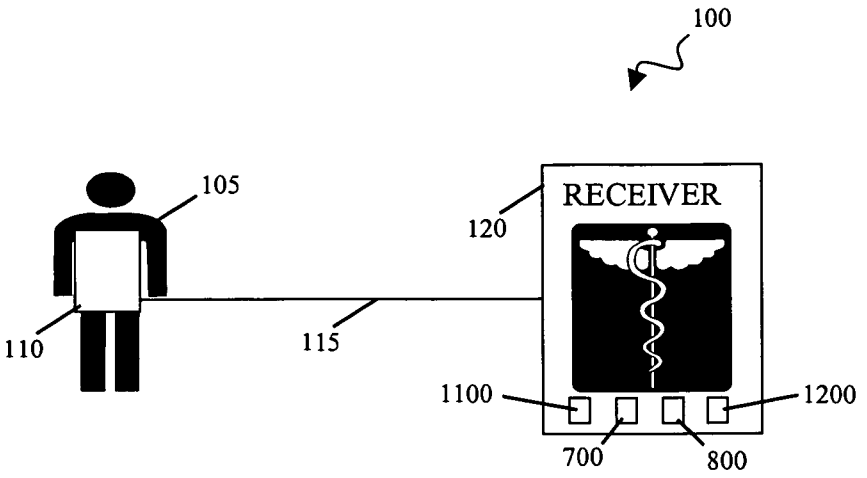

100
105
RECEIVER
120
110
115
1100
1200
700
800

FIG. 14

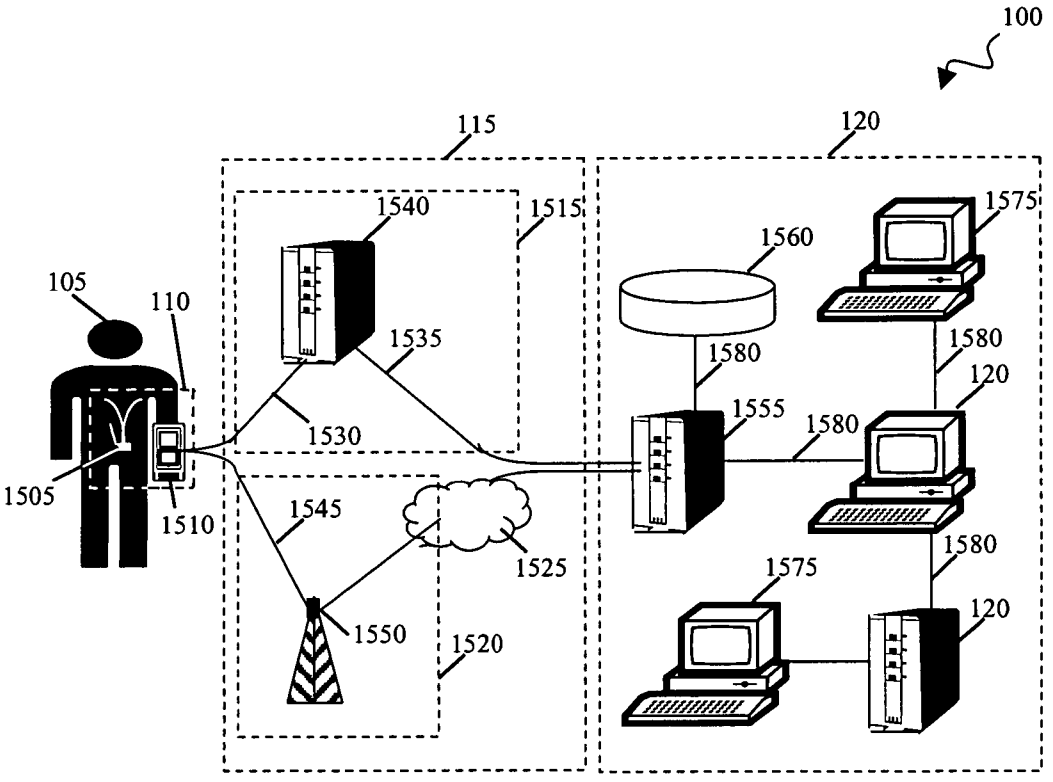

100
115
120
1540
1515
1575
1560
105
110
1535
1580
1580
120
1555
1530
1580
1505
1545
1510
1525
1580
1575
1550
1520
120

FIG. 15

BIOLOGICAL SIGNAL MANAGEMENT

BACKGROUND

This disclosure relates to the management of biological signals.

Biological signals are electrical or optical streams that include information describing or otherwise relating to the state of a biological system. In the medical context, biological signals generally include information relating to the physiological state of an organism. Such information can be used to diagnose and treat disease states of the organism and can be gathered using any of a number of different techniques. Examples of such techniques include electrical potential measurements (e.g., electrocardiography (ECG's), electromyography, and electroencephalography), blood and other body fluid analyte measurements (e.g., pulse oximetry, blood glucose concentration, blood pH and other ion concentrations), and mechanical measurements (e.g., blood pressure measurements, heart sound transduction, height and weight measurements).

SUMMARY

The biological signal management systems and techniques described here may include various combinations of the following features.

In one aspect, a method includes receiving a cardiac biological signal that includes an event relevant to a medical purpose, determining a merit of the event for the medical purpose, associating the event with a time span in which the event occurred if the event's merit is among a certain number of the most meritorious events that occurred in the time span, and handling the association of the time span and the event.

The merit of the event can be determined by determining the severity and the quality of the event. The quality of the event can be determined by determining the noise in the event. An event can be received after the event has been separated from another portion of the cardiac biological signal. The event can also be identified within the received cardiac biological signal. The event can be one or more of an asystole event, a tachycardia event, a bradycardia event, and an atrial fibrillation/flutter event based on identifying characteristics of these events. The event can be identified based on a frequency of heart beats.

A category of the event can be determined. The event can be associated with the time span when the event merit places the event within the certain number of the most meritorious events of the category. The number of the most meritorious events can be predetermined. The association can be handled by generating a data structure having a time stamp associated with the event or by transmitting the association to a remote receiver. The event can have a greater relevance to a medical diagnostic purpose than an average relevance of the biological signal.

In another aspect, a method includes receiving a cardiac biological signal that includes information describing events, determining a merit of each event based on one or more of a severity of a cardiac condition associated with the event and a quality of the event, and handling a subset of the events that meet a merit criterion.

The subset can be handled for medical purposes. The merit criterion can be based on merits of other events. The merit of each event can be determined based on both the severity and the quality of the event. The subset can be the events that have merits among a certain number of the most meritorious and the subset can be the events that occur within a certain time span. For example, the time span can be predetermined. The subset of events can be transmitted to a remote medical receiver.

In another aspect, a method includes receiving a biological signal, identifying an event in the biological signal, determining a merit of the event for the certain purpose, comparing the merit of the event with a second merit of a second event to identify a more meritorious event, creating an episode describing the more meritorious event, associating the episode with a time span in which the events occurred, and transmitting the association of the episode and the time span to a remote receiver. The event can have a greater relevance for a certain purpose than an average relevance of the biological signal.

The episode can be associated with the time span by creating a data structure including the episode and a time stamp indicating when the event occurred. The episode can be created by redacting the more meritorious event. A category of the event can also be determined. The merit of the event can be compared with the second merit of the second event of the same category. The association of the episode and the time span can be associated with a collection of associations of episodes and time spans. The resulting collection of associations of episodes and time spans can be transmitted to the remote receiver.

These biological signal management systems and techniques may provide one or more of the following advantages. For example, the management of biological signals can facilitate a coherent approach to organization and presentation of the information contained in the biological signals. Such management must address various objectives that often oppose one another. For example, the volume of data often should be reduced to minimize data handling costs. At the same, relevant information should not be lost. These objectives are of importance in the medical context, where data review may be carried out by a physician or other trained personnel and hence may prove costly. On the other hand, discarding medically relevant information may hinder or even prevent appropriate diagnosis and/or treatment.

The described biological management systems and techniques can address these and other objectives by increasing the average relevance of data that is handled. Such reductions in data clutter can be used to quickly provide physicians with relevant information, decreasing the cost of data review and increasing the likelihood that diagnosis and/or treatment is appropriately delivered.

Another set of opposing objectives relates to the timing of data handling. In many data handling systems, continuous handling of data is simply too costly. On the other hand, batch handling that only occurs occasionally may result in improper delays. These objectives are also of importance in the medical context, where continuous data handling may be unnecessary or too costly, but delayed handling may endanger patients.

The described biological management systems and techniques can address these and other objectives by selecting the timing of data handling to accommodate both the realities of data handling and the need to ensure patient safety. For example, the timing of handling can be selected to ensure timeliness in any prophylactic or diagnostic efforts without requiring continuous processes.

The details of one or more implementations are set forth in the accompanying drawings and the description below. Other

features, objects, and advantages will be apparent from the description and drawings, and from the claims.

DESCRIPTION OF DRAWINGS

FIG. **1** shows a system in which a biological signal is monitored for medical purposes.

FIG. **2** shows an example biological signal.

FIG. **3** shows a series of events in the biological signal of FIG. **2**.

FIG. **4** illustrates how certain characteristics can be used to identify events.

FIGS. **5** and **6** show the biological signal of FIG. **2** divided into a collection of time spans.

FIGS. **7** and **8** show data structures that associate one or more events with a time span.

FIG. **9** shows a process in which events are associated with a time span.

FIG. **10** shows a process for determining a measure of the merit for an event.

FIG. **11** shows a data structure that can result from handling of events associated with time spans.

FIG. **12** shows a data assembly that can result from handling of events associated with time spans.

FIGS. **13** and **14** illustrate the handling of events associated with time spans by transmission to a receiver.

FIG. **15** shows a system in which events associated with time spans are handled by transmission to a receiver.

Like reference symbols in the various drawings indicate like elements.

DETAILED DESCRIPTION

FIG. **1** shows a system **100** in which a biological signal derived from an individual is monitored for medical purposes. System **100** includes an individual **105**, instrumentation **110**, a signal path **115**, and a receiver **120**. Individual **105** can be a patient or a healthy individual for whom monitoring of one or more biological signals is deemed to be appropriate. Instrumentation **110** can include one or more sensing, calibration, signal processing, control, data storage, and transmission elements suitable for generating and processing the biological signal, as well as relaying all or a portion of the biological signal over path **115**. Path **115** can be any suitable medium for data transmission, including wired and wireless media suitable for carrying optical and/or electrical signals. The receiver **120** can include a receiver element for receiving the transmitted signal, as well as various data processing and storage elements for extracting and storing the information carried by the transmission regarding the state of individual **105**. The receiver **120** can be a medical system in that receiver **120** presents information to medical personnel or to a medical expert system for analysis. The receiver **120** either can reside remotely from instrumentation **110** in that receiver **120** is not located at the same site (e.g., at the same hospital, nursing home, or other medical care facility) as instrumentation **110** or the receiver **120** can reside within the same general area or vicinity as instrumentation **110** (e.g., within the same room, building, or health care facility).

FIG. **2** shows an example of a biological signal **200**. The biological signal **200** is a time variant signal in that an attribute **205** of biological signal **200** changes with time **210**. Attribute **205** of biological signal **200** may continuously change with time and may never reach a steady state value as activity level, metabolic rate, or other factors vary over the course of days, weeks, or even longer periods of time.

Although attribute **205** of biological signal **200** may change continuously, all of the changes may not have the same relevance to a particular purpose for which the biological signal **200** is monitored. FIG. **3** shows the biological signal **200** having a series of events **305**, **310**, **315**, **320**, **325**, **330**, **335**, **340**, **345** identified. Events **305**, **310**, **315**, **320**, **325**, **330**, **335**, **340**, **345** generally are periods in time **210** when the information content of biological signal **200** is deemed to be of increased relevance to a particular purpose for which biological signal **200** is monitored. Events **305**, **310**, **315**, **320**, **325**, **330**, **335**, **340**, **345** need not be of equal or predetermined duration. For example, event **335** is shorter than event **320** and the duration of these and other events can depend on the nature of the increased relevance to the particular purpose for which biological signal **200** is monitored.

The increased relevance of events **305**, **310**, **315**, **320**, **325**, **330**, **335**, **340**, **345** can be determined using a number of approaches. For example, events **305**, **310**, **315**, **320**, **325**, **330**, **335**, **340**, **345** can represent responses to known or controlled stresses on an organism.

Events **305**, **310**, **315**, **320**, **325**, **330**, **335**, **340**, **345** also can be identified based on characteristics of biological signal **200** and classified into categories based on the identifying characteristics. Tables 1 and 2 lists example categories of cardiac events and characteristics that can be used to identify the events. The characteristics identified in Tables 1 and 2 can be used to identify events during cardiac monitoring using electrocardiography.

FIG. **4** illustrates an example of how the characteristics identified in Table 1 can be used to identify cardiac events. In this example, the attribute **205** of biological signal **200** that changes with time **210** (shown in seconds) is heart rate (shown in beats per minute (bpm)). In the illustrated example, the predetermined heart rate for identifying Moderate Bradycardia is 60 bpm and the predetermined duration is 40 seconds. The predetermined heart rate for identifying Severe Bradycardia is 40 bpm and the predetermined duration is 15 seconds.

In FIG. **4**, heart rate attribute 205 drops below 60 bpm at time **405**, where it remains until

TABLE 1

Event Category	Identifying Characteristic(s)	Duration
VFIB	Ventricular fibrillation	NA
Long Pause/ Asystole	No QRS detected for a predetermined duration.	e.g., 3 to 6 seconds
VTACH	Four or more V-beats in row and heart rate more than a predetermined value (e.g., 100 to 200 bpm). Not associated with a VFIB event	4 V-beats
Patient initiated event	Patient indicates event is occurring	Patient selected

TABLE 1-continued

Event Category	Identifying Characteristic(s)	Duration
Severe Tachycardia	Heart rate over a predetermined time (e.g., 10 to 120 seconds) is greater than a predetermined value (e.g., 161 to 220 bpm) Not associated with a VTACH or a VFIB event	e.g., 10 to 120 seconds
Severe Bradycardia	Heart rate over a predetermined time (e.g., 10 to 120 seconds) is less than a predetermined value (e.g., 30 to 39 bpm) Not associated with an asystole or pause event	e.g., 10 to 120 seconds
Atrial Fibrillation/ Flutter with High HR	Heart rate greater than or equal to a predetermined value (e.g., 100 to 220 bpm) Associated with an Atrial Fibrillation/Flutter onset event	e.g., 10 to 120 seconds
Pause	No QRS complex for a predetermined duration (e.g., 2 seconds to duration of Long Pause/Asystole event)	e.g., 2 seconds to duration of Long Pause/ Asystole event
Atrial Fibrillation/ Flutter onset	Irregular rhythm Not associated with a VTACH and VFIB event	e.g., 30 QRS complexes
Moderate Bradycardia	Heart rate for a predetermined duration (e.g., 10 to 120 seconds) is less than a predetermined value and greater than predetermined value in a severe bradycardia event (e.g., severe bradycardia value to 60 bpm) Not associated with an asystole, a pause, or a severe bradycardia event	e.g., 10 to 120 seconds
Moderate Tachycardia	Heart rate for a predetermined duration (e.g., 10 to 120 seconds) is greater than a predetermined value and less than predetermined value in a severe tachycardia event (e.g., 100 bpm to the severe tachycardia value) Not associated with a VTACH, a VFIB, or a severe tachycardia event	e.g., 10 to 120 seconds

time **410**, 40 seconds later. The period between time **405** and time **410** can be identified as a Moderate Bradycardia event. In contrast, at time **415**, heart rate attribute **205** drops below 40 bpm where it remains until time **420**, ten seconds later. Heart rate attribute **205** also reaches a minimum of 35 bpm at a time **425**. Despite reaching this minimum, the duration of the period between time **415** and time **420** (i.e., 10 seconds) is too short to be identified as a Severe Bradycardia event. At time **430**, heart rate attribute **205** again drops below 40 bpm, where it remains until time **435**, five seconds later. The duration of the period between time **430** and time **435** is too short to be identified as a Severe Bradycardia event.

FIGS. **5** and **6** show that time **215** can be divided into a collection of time spans **505**, **510**, **515**, **520**, **525**, **605**, **610**, **615**, **620**, **625**. Spans **505**, **510**, **515**, **520**, **525**, **605**, **610**, **615**,

TABLE 2

EVENT CATEGORY	IDENTIFYING CHARACTERISTICS	EXAMPLE IDENTIFYING THRESHOLD
TACHYCARDIA 1 - Severe Tachycardia 2 - Moderate Tachycardia	Sustained heart rate (e.g., heart rate for 10 to 120 seconds) exceeds a heart rate threshold	1 - Sustained heart rate exceeds a High Heart Rate (HHR) threshold of 190 bpm 2 - Sustained heart rate exceeds a Low Heart Rate (LHR) threshold of 140 bpm
ATRIAL FIBRILLATION 1 - Atrial Fibrillation/ Flutter with High HR 2 - Atrial Fibrillation	Loss of synchrony between the atria and the ventricles (shown, e.g., by variability in beat-to-beat period)	1 - Heart rate exceeds a Atrial Fibrillation High Heart Rate (AFHHR) threshold of 130 bpm 2 - No heart rate threshold
PAUSE 1 - Asystole 2 - Pause	No QRS detected for a specified threshold duration	1 - No QRS for a high threshold of 4 seconds 2 - No QRS for a low threshold of 2 seconds
BRADYCARDIA 1 - Severe Bradycardia 2 - Moderate Bradycardia	Sustained heart rate (e.g., heart rate for 10 to 120 seconds) is below a specified threshold	1 - Sustained heart rate is below a Low Heart Rate (LHR) threshold of 35 bpm 2 - Sustained heart rate is below a High Heart Rate (HHR) threshold of 40 bpm

620, 625 can have equal durations (such as spans 505, 510, 515, 520, 525) or spans can be of variable durations (such as spans 605, 610, 615, 620, 625). In general, the duration of spans 505, 510, 515, 520, 525, 605, 610, 615, 620, 625 is proportional to the duration of the events sought to be identified. The duration of spans 505, 510, 515, 520, 525, 605, 610, 615, 620, 625 can be selected based on consideration of two or more factors, such as the number of events likely to occur in each span and the need to handle events for a particular purpose for which biological signal 200 is monitored. In particular, if spans 505, 510, 515, 520, 525, 605, 610, 615, 620, 625 are too short, then spans 505, 510, 515, 520, 525, 605, 610, 615, 620, 625 may lack an event. On the other hand, if spans 505, 510, 515, 520, 525, 605, 610, 615, 620, 625 are too long, then the delay in handling events may be too large. Such a delay may be particularly harmful in the medical context, where an excessive delay may hinder prophylactic or diagnostic efforts. In the context of cardiac monitoring, a span duration of between one half and four hours, such as between one and three hours or approximately two hours, is effective to address such considerations.

The duration of spans 505, 510, 515, 520, 525, 605, 610, 615, 620, 625 can also accommodate physiological rhythms of a biological system. For example, in cardiac monitoring, longer spans may be appropriate at night or periods of decreased activity and shorter spans may be appropriate during the day or periods of increased activity. The duration of spans 505, 510, 515, 520, 525, 605, 610, 615, 620, 625 can also be adjusted based on an attribute of biological signal 200. For example, in cardiac monitoring, the duration of spans 505, 510, 515, 520, 525, 605, 610, 615, 620, 625 can include a fixed number of beats rather than a fixed time period.

FIGS. 7 and 8 show data structures 700, 800 that associate one or more sample events with a span. Data structures 700, 800 can be used together or separately as alternative approaches to associating events with a span. Data structure 700 includes an event field 705 and a time stamp field 710. Event field 705 includes data describing a portion of a biological signal that has been identified as an event. Event field 705 can include raw data drawn from the biological signal or event field 705 can include an episode of an event to describe the event. An episode is a collection of information that summarizes the relevance of the event to the purpose for which the event is monitored. For example, an episode can be a redacted portion of an event (e.g., the first three minutes worth of the event). Time stamp field 710 includes data describing the time when the event described in event field 705 occurred. Time stamp field 710 can thus associate the event with a span by identifying a time that falls within the time span.

Data structure 800 is shown as a table of attribute-value pairs but other data structures (including, for example, records, files, lists, and other data structures) that associate similar information can be used. Data structure 800 includes an event category information field 805, span identification information field 810, and allocation information fields 815, 820, 825. Event category information field 805 describes one or more event categories that are allocable to data structure 800. An event category can be described by name, by an associated identification number or other token, or by a pointer or other description of a memory location that includes such information. Span identification information field 810 describes the time span from which events of a category identified in event category information field 805 are allocable to data structure 800. The time span can be described directly using, e.g., a start and stop time stamp, or the time span can be described indirectly by a pointer or other description of a memory location that includes such information. Each instance of data structure 800 can be specific to a single span.

Allocation information fields 815, 820, 825 each describe a certain event that is allocated to data structure 800. An event can be allocated to data structure 800 when the event is of a category described in event category information field 805 and when the event occurred in a time span described in span identification information field 810. Such allocations thus associate the event with the described category and time span. Allocation information fields 815, 820, 825 can describe an event by including an event field and a time stamp field, such as fields 705, 710 of data structure 700 (FIG. 7).

Data structure 800 can include one or more allocation information fields. Single allocation fields decrease the size of data structure 800 and may facilitate handling. Multiple allocation fields increase the number of events associated with the span identified by span identification information field 810 and may provide more complete information when data structure 800 is handled.

FIG. 9 shows a process 900 in which events are associated with a time span. Events can be associated with a time span by allocation to a data structure such as data structures 700, 800. The process 900 can be performed by one or more data processing devices that perform data processing activities. The activities of process 900 can be performed in accordance with the logic of a set of machine-readable instructions, a hardware assembly, or a combination of these and/or other instructions. The device performing process 900 can be deployed at any of a number of different positions in a system in which a biological signal is monitored. For example, in system 100 (FIG. 1), the device performing process 900 can be deployed at instrumentation 110 or at receiver 120.

The device performing process 900 receives the biological signal at 905. The biological signal can be received in raw form or after signal processing. The biological signal can be received in digital or analog format. The receiving device can identify and classify one or more events in the biological signal at 910. Events can be identified and classified based on one or more attributes of the biological signal, such as the identifying characteristics described in Table 1.

The device performing process 900 can also determine a measure of the merit of identified events at 915. A measure of the merit of an event is a valuation of an event when applied to a particular purpose. For example, when the biological signal is monitored for diagnostic medical purposes, the measure of the merit of an event can describe the diagnostic value of the information content of the event. The measure of the merit of an event can be based on a number of factors, including whether or not the event is representative of the biological signal or of other events of the same category in the biological signal, the quality (e.g., noise or signal dropout) associated with the event, and even the category of the event itself.

The device performing process 900 can determine if the measure of the merit of an event identified at 910 is greater than the measure of the merit of the least meritorious event of the same category currently associated with the time span that includes the identified event at decision 920. The least meritorious event of the same category can be associated with the time span in a data structure such as data structures 700, 800 (FIGS. 7 and 8). The determination can be made by comparing the measure of the merit of the identified event with the measure of the merit of the associated, least meritorious event of the same category. If the identified event is not as meritorious, the device performing process 900 can discard the identified event at 925.

On the other hand, if the identified event is more meritorious than the associated, least meritorious event of the same category, then the device performing process **900** can discard the latter at **930** and associate the more meritorious event identified at **910** with the time span at **935**. For example, the device performing process **900** can allocate the more meritorious event identified at **910** to the appropriate of fields **715**, **805**, **810** in data structures **700**, **800** (FIGS. **7** and **8**).

The device performing process **900** can determine if the end of a time span in the biological signal has been reached at decision **940**. If the end of the span has not been reached, the process **900** returns to **910** to identify and classify any additional event(s) in the biological signal. If the end of the span has been reached, the process proceeds to handle the allocated events at **945**. The events can be handled alone or in association with other information, including duration and classification information, prior and subsequent events of the same or different categories, and additional information retrieved from other biological signals.

TABLE 3

Event Category	Event Grade
VFIB	1
Long Pause/ Asystole	1
VTACH	1
Patient initiated event	1
Severe Tachycardia	1
Severe Bradycardia	1
Atrial Fibrillation/ Flutter with High HR	2
Pause	2
Atrial Fibrillation/ Flutter onset	2
Moderate Bradycardia	2
Moderate Tachycardia	2

FIG. **10** shows a process **1000** for determining a measure of the merit of an event. A data processing device can perform the process **1000** in isolation or as part of a larger process. For example, the process **1000** can be performed within process **900** at **915** (FIG. **9**). The device performing process **1000** can determine the severity of an event at **1005**. The severity of an event is a measure of the gravity of the event to the purpose for which the biological signal is monitored. For example, when the biological signal is monitored for diagnostic medical purposes, the severity of an event can be indicative of the individual's physical discomfort or hardship associated with a diagnosis that can be made using the event. Severity can be graded on a discrete scale or on a continuous scale. Table 3 shows example discrete grades of the severity of various cardiac events when cardiac monitoring is performed for prophylactic and diagnostic purposes. In Table 3, events are graded on a two point scale, with an event grade of "1" indicating that the event is more severe and an event grade of "2" indicating that the event is less severe (e.g., a moderately sever event). For example, event grade "1" can indicate an acute medical condition that requires immediate medical attention, whereas event grade "2" can indicate a chronic or other medical condition that does not require immediate medical attention.

Another approach to determining the severity of an event involves comparing characteristics of the biological signal during the event with threshold values relating to various physiological conditions associated with the events. For example, for a tachycardia event as described in Table 2, the severity of a tachycardia event can be determined using Equation 1:

$$\text{Tachy Severity} = (\text{Heart Rate} - \text{Low Heart Rate})/(\text{High Heart Rate} - \text{Low Heart Rate}) \quad \text{Equation 1}$$

Similarly, the severity of a Bradycardia event, and Atrial Fibrillation Event, and a Pause event can be determined using the appropriate of Equations 2-4:

$$\text{Brady Severity} = (\text{High Heart Rate} - \text{Low Heart Rate})/(\text{High Heart Rate} - \text{Low Heart Rate}) \quad \text{Equation 2}$$

$$\text{AFIB Severity} = \text{Heart Rate}/\text{Atrial Fibrillation High Heart Rate} \quad \text{Equation 3}$$

$$\text{Pause Severity} = (\text{Pause Duration} - \text{Low Threshold})/(\text{High Threshold} - \text{Low Threshold}) \quad \text{Equation 4}$$

The device performing process **1000** can also determine the quality of the event at **1010**. The quality of the event is a measure of the likelihood that the event is suited to the purpose for which the biological signal is monitored. One factor that can impact quality is the amount or type of noise in the biological signal during the event. For example, when the biological signal is a cardiac signal monitored for diagnostic medical purposes, noise can be determined using approaches such as those described in Wang, J. Y. "A New Method for Evaluating ECG Signal Quality for Multi-lead Arrhythmia Analysis," appearing in Proceedings of IEEE Computers in Cardiology Conference 2002, pp. 85-88 and U.S. Pat. No. 5,967,994 to Jyh-Yun Wang, the contents of both of which are incorporated herein by reference. Quality can be graded on a discrete scale or on a continuous scale.

TABLE 4

Severity	Noise	Quality
Low	High	Lowest
Low	Medium	Low
Low	Low	Low
Medium	High	Low
Medium	Medium	Medium
Medium	Low	High
High	High	Low
High	Medium	High
High	Low	High

The device performing process **1000** can determine the measure of the merit of an event based at least in part on the severity and quality of the event at **1015**. The measure of the merit can be graded on a discrete scale or on a continuous scale. The measure of the merit can be determined using any of a number of different approaches. Table 4 includes examples of various discrete merit grades (lowest, low, medium, and high) that can be assigned to an event when an event is determined to have the corresponding severity and quality.

The handling of allocated events, such as those allocated during a process such as process **900**, can involve any of a number of different activities. For example, event handling can include notifying medical personnel about the event. Such notification can be performed in response to the identi-

fication of an event associated with an acute medical condition, such as those events graded level "1" in Table 3. Event handling can also include the assembly of more complex data structures, the transmission of allocated events to, for example, a receiver such as receiver **120** (FIG. **1**), or the storage of allocated events (for example, in anticipation of assembly into more complex data structures or transmission). Such data structure assembly, transmission, and storage can be performed with events associated with medical conditions that do not require immediate medical attention, such as those graded level "2" in Table 3.

FIG. **11** shows a data structure **1100** that can result from handling of events associated with time spans. The events and time spans can be associated by repeated performance of process **900** by a data processing device. Data structure **1100** includes a data assembly **1105**, a series of associated events **1110**, and a series of discarded events **1115**. Data assembly **1105** includes a collection of time span records, including time span records **1120**, **1125**, and **1130**. Time span records **1120**, **1125**, **1130** can include information identifying the duration of an associated time span. For example, time span record **1120** can include information identifying that span record **1120** lasts from 12 AM to 6 AM, whereas time span record **1130** can include information identifying that span record **1130** lasts from 4 PM to 6 PM. Time span records **1120**, **1125**, **1130** can include information identifying one or more categories of events associated with time span records **1120**, **1125**, **1130**, as well as a severity of any associated category of events. For example, data structure **1100** can be devoted to events of a certain severity, such as level **2** events as discussed above.

Associated events **1110** includes a collection of event records of one or more categories, including event records **1135**, **1140**, **1145**, **1150**. Associated events **1110** can be allocated to the time spans in data assembly **1105** by allocation to an appropriate time span record. Event records can include data describing the event (such as raw data from the relevant portion of biological signal **200**). Associated events **1110** can be allocated to the appropriate time span records through a series of pointers **1155**. For example, event records **1135**, **1140**, **1145** are allocated to time span record **1120** through a first pointer **1155**, whereas event record **1150** is associated with time span record **1125** through a second pointer **1155**. A time span record need not have an associated event record. For example, no event record is associated with time span record **1130**. This lack can reflect that no appropriate event was identified within the time span associated with time span record **1130**.

Discarded events **1115** includes a collection of event records of one or more categories. Discarded events **1115** are not associated with the time spans in data assembly **1105** or with any of allocated events **1110**.

FIG. **12** shows another data assembly, namely a data collection **1200**, that can result from handling of events associated with time spans. Data collection **1200** includes a data collection title **1205**, data collection metadata **1210**, and a series of data structures **1215**. Data collection title **1205** can include information identifying data collection **1200**. Data collection metadata **1210** can include information about the data in collection **1200**, such as the subject of the biological signal, parameters regarding the instrument used to generate the biological signal, and date and location information regarding the data generation process.

Series of data structures **1215** includes data structures **1220**, **1225**, **1230**. Each data structure **1220**, **1225**, **1230** can result from associating events of different categories with time spans and can include one or more events of different categories. For example, each data structure **1220**, **1225**, **1230** can include a data structure such as data structure **1100**. Since each data structure **1220**, **1225**, **1230** can include events from different categories selected for high information content, data collection **1200** can include a relatively large amount of information regarding a biological signal but yet retain a high density of information content.

FIGS. **13** and **14** illustrate another way that events associated with time spans are handled, namely by transmission to a receiver in a system such as receiver **120** in system **100**. In particular, as shown in FIG. **13**, data can be gathered and events can be allocated at instrumentation **110** to form one or more of assemblies of data such as data structures **700**, **800**, **1100** and data collection **1200**. In response to a trigger, data assemblies can be relayed over path **115** to receiver **120**, where they are received as shown in FIG. **14**. Example triggers include the passage of a predetermined period of time, user input indicating that transmission is appropriate, or the identification of an event of sufficient severity to warrant immediate transmission.

FIG. **15** shows one implementation of system **100** in which a biological signal derived from an individual is monitored for medical purposes. System **100** includes individual **105**, instrumentation **110**, signal path **115**, and receiver **120**.

Instrumentation **110** can be adapted for electrocardiographic monitoring of individual **105**. Instrumentation **110** can include a sensor module **1505** and a monitor module **1510**. Sensor module **1505** can include three ECG leads with electrodes, as well as a two channel ECG signal recorder and a wireless and/or wired data output. Sensor module **1505** can also include a clip for attaching sensor module to a belt, a neckpiece, or other item worn by individual **105**. Monitor module **1510** includes a data input that is adapted to receive data output from sensor module **1505** as well as one or more wireless and/or wired data outputs for data communication over signal path **115**. Monitor module **1510** also includes a data processing device that performs data processing activities in accordance with the logic of a set of machine-readable instructions. The instructions can be realized in digital electronic circuitry, integrated circuitry, specially designed ASICs (application specific integrated circuits), computer hardware, firmware, software, and/or combinations thereof. The instructions can describe how to identify and/or handle events in accordance with one or more of the techniques described herein. In one implementation, monitor module **1510** also includes an input/output device for interaction with a user (such as an event trigger input with which a user can manually trigger the start of an event.

Signal path **115** can include one or both of a wired data link **1515** and a wireless data link **1520** coupled to a data network **1525** to place instrumentation **110** in data communication with receiver **120**. Wired data link **1515** includes a public network portion **1530** and a private or virtual private network portion **1535** bridged by a server **1540**. Public network portion **1530** provides for data communication between instrumentation **110** and server **1540** over a wired data link such as a telephone network. Private network portion **1535** provides for private or virtually private data communication from server **1540** to receiver **120**. Server **1540** can interface for data communication with both portions **1530**, **1535**. For example, server **1540** can communicate directly with receiver **120** using the peer-to-peer protocol (PPP).

Wireless data link **1545** can include one or more wireless receivers and transmitters **1550** such as a WiFi receiver, a cellular phone relay station, and/or other cellular telephone infrastructure to place instrumentation **110** in data communi-

cation with data network **1525**. In turn, data network **1525** communicates with receiver **120**.

Receiver **120** includes a receiver server **1555**, a data storage device **1560**, a call router **1565**, a communications server **1570**, and one or more application servers **1575** that are all in data communication with one another over one or more data links **1580**. Receiver server **1555** is a data processing device that receives and transmits communications over signal path **115** and relays incoming communications to data storage device **1560** and call router **1565** in accordance with the logic of a set of machine-readable instructions. Data storage device **1560** is a device adaptable for the storage of information. Data storage device **1560** can be a volatile and/or non-volatile memory that records information electrically, mechanically, magnetically, and/or optically (such as a disk drive). Call router **1565** is a data processing device that, in accordance with the logic of a set of machine-readable instructions, identifies the content of an incoming communication and directs the communication to one or more appropriate application servers **1575** based on that content. Communications server **1570** is a data processing device that relays communications between call router **1565** and one or more application servers **1575** over an external network. Application servers **1575** are data processing devices that interact with a user or operate in isolation to provide one or more monitoring services in accordance with the logic of a set of machine-readable instructions. Data links **1580** can be part of a local area and/or private network or part of a wide area and/or public network.

In operation, sensor module **1505** can sense, amplify, and record electrical signals relating to the activity of the heart. Sensor module **1505** can also relay all or a portion of those signals to monitor module **1510** where they can be managed. For example, monitor module **1510** can manage the signals in accordance with one or more of processes **900** and **1000** (FIGS. **9-10**). As part of the management, monitor module **1510** can transmit the signals to receiver **120**. The signals can be transmitted in association with a time span. For example, the signals can be transmitted in one or more of data structures **700**, **800**, **1100**, **1200** (FIGS. **7-8** and **11-12**).

The transmitted signals pass along data link **115** over one or more of wired data link **1515** and wireless data link **1520** to receiver **120**. At receiver **120**, the signals are received by server **1555** which causes at least a portion of the incoming signals to be stored on data storage device **1560** and relayed to call router **1565**. The incoming signals stored on data storage device **1560** can be stored in one or more of data structures **700**, **800**, **1100**, **1200** (FIGS. **7-8** and **11-12**).

The incoming signals relayed to call router **1565** are directed to one or more appropriate application servers **1575** based on the content of the signals. For example, when the signal relates to a certain category of cardiac event, the signal can be directed to a certain application server **1575** that is accessible to a cardiologist having expertise with that certain category of event. As another example, when the signal originates with an individual who is under the care of a particular physician, the signal can be directed to a certain application server **1575** that is accessible to that physician. As yet another example, when the signal relates to a certain category of cardiac event, the signal can be directed to a certain application server **1575** that accesses an expert system or other set of instructions for diagnosing and/or treating that category of event. When appropriate, a signal can be routed to communications server **1570** which in turn relays the signal to the appropriate application server **1575** over an external network.

Communications can also be relayed from receiver **120** back to individual **105** or to other individuals. For example, when a physician or expert system identifies that care is needed, a message requesting that the individual seek care can be returned to individual **105** over data link **115**. In urgent care situations, third parties such as medical personnel can be directed to individual **105**, either by receiver **120** or by instrumentation **110**.

Various implementations of the systems and techniques described here can be realized in digital electronic circuitry, integrated circuitry, specially designed ASICs (application specific integrated circuits), computer hardware, firmware, software, and/or combinations thereof. These various implementations can include one or more computer programs that are executable and/or interpretable on a programmable system including at least one programmable processor, which may be special or general purpose, coupled to receive data and instructions from, and to transmit data and instructions to, a storage system, at least one input device, and at least one output device.

These computer programs (also known as programs, software, software applications or code) may include machine instructions for a programmable processor, and can be implemented in a high-level procedural and/or object-oriented programming language, and/or in assembly/machine language. As used herein, the term "machine-readable medium" refers to any computer program product, apparatus and/or device (e.g., magnetic discs, optical disks, memory, Programmable Logic Devices (PLDs)) used to provide machine instructions and/or data to a programmable processor, including a machine-readable medium that receives machine instructions as a machine-readable signal. The term "machine-readable signal" refers to any signal used to provide machine instructions and/or data to a programmable processor.

To provide for interaction with a user, the systems and techniques described here can be implemented on a computer having a display device (e.g., a CRT (cathode ray tube) or LCD (liquid crystal display) monitor) for displaying information to the user and a keyboard and a pointing device (e.g., a mouse or a trackball) by which the user can provide input to the computer. Other kinds of devices can be used to provide for interaction with a user as well; for example, feedback provided to the user can be any form of sensory feedback (e.g., visual feedback, auditory feedback, or tactile feedback); and input from the user can be received in any form, including acoustic, speech, or tactile input.

The systems and techniques described here can be implemented in a computing environment that includes a back-end component (e.g., as a data server), or that includes a middleware component (e.g., an application server), or that includes a front-end component (e.g., a client computer having a graphical user interface or a Web browser through which a user can interact with an implementation of the systems and techniques described here), or any combination of such back-end, middleware, or front-end components. The components of the environment can be interconnected by any form or medium of digital data communication (e.g., a communication network). Examples of communication networks include a local area network ("LAN"), a wide area network ("WAN"), and the Internet.

The computing environment can include clients and servers. A client and server are generally remote from each other and typically interact through a communication network. The relationship of client and server arises by virtue of computer programs running on the respective computers and having a client-server relationship to each other.

A number of implementations have been described. Nevertheless, it will be understood that various modifications may be made. For example, information included in any of the data structures can be handled as meta data describing the

data structures themselves and hence still associated with the data structures. An event can be associated with a time span based on the merit of the event exceeding a certain threshold. All events that exceed such a threshold can remain associated with the time span, rather than be discarded. Accordingly, other implementations are within the scope of the following claims.

What is claimed is:

1. A method of monitoring a cardiac biological signal using electrocardiographic monitoring instrumentation, comprising:

receiving, at the electrocardiographic monitoring instrumentation, the cardiac biological signal that includes information describing events, wherein events comprise periods in time when an information content of the cardiac biological signal is of increased relevance to a particular purpose and the events are demarcated by periods of time that are not of increased relevance to the particular purpose;

at the electrocardiographic monitoring instrumentation, classifying the events into two or more categories based on cardiac conditions indicated by the information describing each event;

at the electrocardiographic monitoring instrumentation, determining a measure of merit of the information describing each event, wherein the measure of merit embodies a severity of the cardiac condition associated with the event and an amount of noise in the information describing the event;

comparing, at the electrocardiographic monitoring instrumentation, the measure of merit of information describing each event with a first merit criterion;

transmitting, for medical purposes, information describing a first proper subset of the events in a first of the categories that have merits meeting the first merit criterion from the electrocardiographic monitoring instrumentation to a remote medical receiver, wherein the remote medical receiver is not located at the same site at the electrocardiographic monitoring instrumentation;

at the electrocardiographic monitoring instrumentation, discarding information describing a second proper subset of the events in the first of the categories that have measures of merit that fail to meet the first merit criterion;

comparing, at the electrocardiographic monitoring instrumentation, the measure of merit of information describing each event with a second merit criterion;

transmitting, for medical purposes, information describing a third proper subset of the events in a second of the categories that have measures of merit meeting the second merit criterion from the electrocardiographic monitoring instrumentation to the remote medical receiver, wherein the second category differs from the first category and the second merit criterion differs from the first merit criterion; and

at the electrocardiographic monitoring instrumentation, discarding information describing a fourth proper subset of the events in the second of the categories that have measures of merit that fail to meet the second merit criterion.

2. The method of claim **1**, wherein the first merit criterion is based on measures of merit of other events in the first of the categories.

3. The method of claim **1**, wherein transmitting the information describing the first proper subset comprises transmitting the information describing events that have measures of merit among a certain number of the most meritorious in the first of the categories.

4. The method of claim **1**, wherein:

the first proper subset of the events comprises events that occur within a certain time span and excludes events occurring outside the certain time span.

5. The method of claim **4**, wherein:

the first proper subset of the events comprises events that occur within a predetermined time span and excludes events occurring outside the predetermined time span.

6. The method of claim **1**, wherein receiving the cardiac biological signal comprises receiving a measurement of electrical potential.

7. The method of claim **1**, wherein classifying the events comprises classifying the events as one or more of an asystole event, a tachycardia event, a bradycardia event, and an atrial fibrillation/flutter event based on identifying characteristics of these events.

8. The method of claim **1**, wherein classifying the events comprises classifying the events based on a frequency of heart beats.

9. The method of claim **1**, further comprising associating information describing each event in the first proper subset with information describing a time span in which the event occurred.

10. The method of claim **9**, wherein associating the information describing each event in the first proper subset with the information describing the time span comprises associating the information describing each event in the first proper subset with the information describing the time span when the event measure of merit is among a predetermined number of the most meritorious events in the first of the categories.

11. The method of claim **9**, wherein associating the information describing each event in the first proper subset with the information describing the time span comprises generating a data structure having a time stamp associated with the information describing the event.

12. The method of claim **9**, wherein associating information describing each event in the first proper subset comprises associating raw data drawn from an electrocardiogram with information describing the time span in which the event occurred.

13. The method of claim **9**, wherein the cardiac biological signal comprises a stream of information describing a state of a heart of a biological system.

14. The method of claim **1**, further comprising comparing a first measure of merit of information describing a first event with a second measure of merit of information describing a second event to identify a more meritorious event.

15. The method of claim **14**, further comprising creating an episode describing the more meritorious event.

16. The method of claim **15** wherein creating the episode comprises summarizing a relevance of the information describing the more meritorious event.

17. The method of claim **1**, wherein the cardiac biological signal comprises an electrocardiogram signal.

18. The method of claim **1**, wherein:

a first event described in the cardiac biological signal has a first duration;

a second event described in the cardiac biological signal has a second duration; and

the first duration is not equal to the second duration.

19. The method of claim **1**, wherein classifying the events comprises classifying a first event as a tachycardia event.

20. The method of claim **1**, wherein classifying the events comprises classifying a first event as a bradycardia event.

21. The method of claim 1, wherein classifying the events comprises classifying a first event as an atrial fibrillation/flutter event.

22. A method of monitoring a cardiac biological signal using electrocardiographic monitoring instrumentation, comprising:

receiving a cardiac biological signal that includes information describing events at the electrocardiographic monitoring instrumentation, wherein events comprise periods in time when an information content of the cardiac biological signal is of increased relevance to a particular purpose and the events are demarcated by periods of time that are not of increased relevance to the particular purpose;

determining, at the electrocardiographic monitoring instrumentation, a measure of merit of information describing each event, wherein the measure of merit embodies both the severity of the cardiac condition indicated by the information describing the event and an amount of noise in the information describing the event;

comparing, at the electrocardiographic monitoring instrumentation, the measure of merit of information describing each event with a merit criterion;

transmitting, for medical purposes, information describing a first proper subset of the events that have measures of merit meeting the merit criterion from the electrocardiographic monitoring instrumentation to a remote medical receiver; and

discarding information describing a second proper subset of the events that have measures of merit that fail to meet the merit criterion at the electrocardiographic monitoring instrumentation.

23. The method of claim 22, wherein determining the measure of merit of the information describing each event comprises determining the amount of noise in the information describing the event.

24. The method of claim 22, wherein determining the measure of merit of the information describing each event comprises determining a signal dropout during the event.

25. An article comprising one or more machine-readable media storing instructions operable to cause one or more machines to perform operations for monitoring a cardiac biological signal using electrocardiographic monitoring instrumentation, the operations comprising:

receiving the cardiac biological signal that includes information describing events, wherein events comprise periods in time when an information content of the cardiac biological signal is of increased relevance to a particular purpose and the events are demarcated by periods of time that are not of increased relevance to the particular purpose;

classifying the events into two or more categories based on cardiac conditions indicated by the information describing each event;

determining a measure of merit of the information describing each event, wherein the measure of merit embodies a severity of the cardiac condition associated with the event and a an amount of noise in the information describing the event;

comparing the measure of merit of information describing each event with a first merit criterion;

transmitting, for medical purposes, information describing a first proper subset of the events in a first of the categories that have merits meeting the first merit criterion to a remote medical receiver, wherein the remote medical receiver is not located at the same site at the electrocardiographic monitoring instrumentation;

discarding information describing a second proper subset of the events in the first of the categories that have measures of merit that fail to meet the first merit criterion;

comparing the measure of merit of information describing each event with a second merit criterion;

transmitting, for medical purposes, information describing a third proper subset of the events in a second of the categories that have measures of merit meeting the second merit criterion to the remote medical receiver, wherein the second category differs from the first category and the second merit criterion differs from the first merit criterion; and

discarding information describing a fourth proper subset of the events in the second of the categories that have measures of merit that fail to meet the second merit criterion.

26. The article of claim 25, wherein the first merit criterion is based on measures of merit of other events in the first of the categories.

27. The article of claim 25, wherein the operations further comprise associating information describing each event in the first proper subset with information describing a time span in which the event occurred.

28. The article of claim 27, wherein associating the information describing each event in the first proper subset with the information describing the time span comprises associating the information describing each event in the first proper subset with the information describing the time span in which the event measure of merit is among a predetermined number of the most meritorious events in the first of the categories.

29. The article of claim 27, wherein associating the information describing each event in the first proper subset with the information describing the time span comprises generating a data structure having a time stamp associated with the information describing the event.

30. The article of claim 25, wherein the operations further comprise creating an episode describing the more meritorious event.

31. The article of claim 30, wherein creating the episode comprises summarizing a relevance of the information describing the more meritorious event.

32. The article of claim 25, wherein the cardiac biological signal comprises an electrocardiogram signal.

33. The article of claim 25, wherein:

a first event described in the cardiac biological signal has a first duration;

a second event described in the cardiac biological signal has a second duration; and

the first duration is not equal to the second duration.

34. The article of claim 25, wherein classifying the events comprises classifying a first event as a tachycardia event.

35. The article of claim 25, wherein classifying the events comprises classifying a first event as a bradycardia event.

36. The article of claim 25, wherein classifying the events comprises classifying a first event as an atrial fibrillation/flutter event.

37. An article comprising one or more machine-readable media storing instructions operable to cause one or more machines to perform operations for monitoring a cardiac biological signal using electrocardiographic monitoring instrumentation, the operations comprising:

receiving a cardiac biological signal that includes information describing events, wherein events comprise periods in time when an information content of the cardiac biological signal is of increased relevance to a particular

purpose and the events are demarcated by periods of time that are not of increased relevance to the particular purpose;

determining a measure of merit of information describing each event, wherein the measure of merit embodies both the severity of the cardiac condition indicated by the information describing the event and an amount of noise in the information describing the event;

comparing the measure of merit of information describing each event with a merit criterion;

transmitting, for medical purposes, information describing a first proper subset of the events that have measures of merit meeting the merit criterion to a remote medical receiver; and

discarding information describing a second proper subset of the events that have measures of merit that fail to meet the merit criterion.

38. The article of claim **37**, wherein determining the measure of merit of the information describing each event comprises determining the amount of noise in the information describing the event.

39. The article of claim **37**, wherein determining the measure of merit of the information describing each event comprises determining a signal dropout during the event.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 7,587,237 B2
APPLICATION NO. : 10/770702
DATED : September 8, 2009
INVENTOR(S) : Korzinov et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

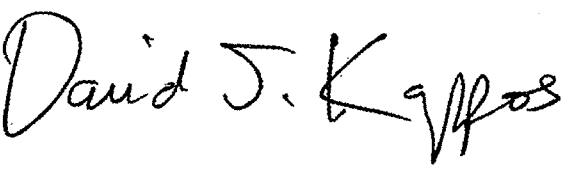
On the Title Page:

The first or sole Notice should read --

Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 487 days.

Signed and Sealed this

Twenty-first Day of September, 2010



David J. Kappos
Director of the United States Patent and Trademark Office

EXHIBIT K

US007941207B2

(12) **United States Patent**
Korzinov

(10) **Patent No.: US 7,941,207 B2**
(45) **Date of Patent: *May 10, 2011**

(54) **CARDIAC MONITORING**

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(52) **U.S. Cl.** **600/518**

(58) **Field of Classification Search** 600/509–521; 607/25

See application file for complete search history.

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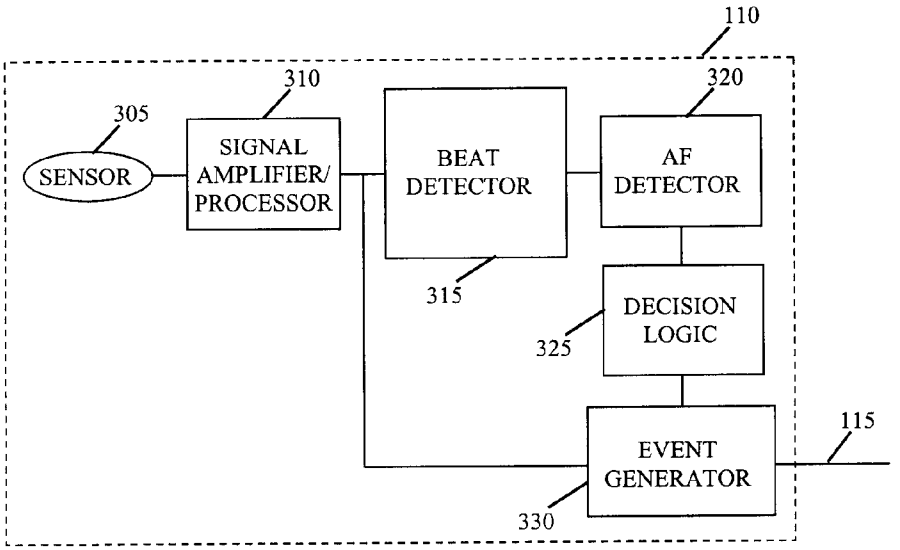
(74) *Attorney, Agent, or Firm* — Fish & Richardson P.C.

(57) **ABSTRACT**

Systems and techniques for monitoring cardiac activity. In one aspect, a method includes collecting information describing the variability in heart rate over a series of beats, designating variability at a lower end of physiological values as being largely irrelevant to atrial fibrillation, designating variability in a midrange of physiological values as being indicative of atrial fibrillation, designating variability in an upper range of physiological values as being negatively indicative of atrial fibrillation, and determining a relevance of the variability described in the collection to atrial fibrillation.

25 Claims, 7 Drawing Sheets



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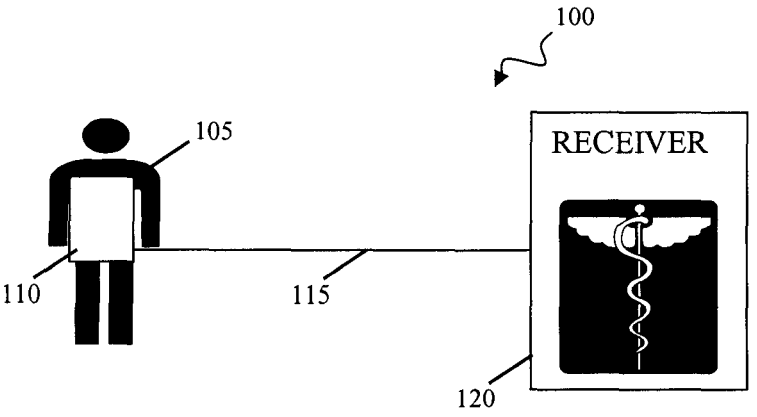


FIG. 1

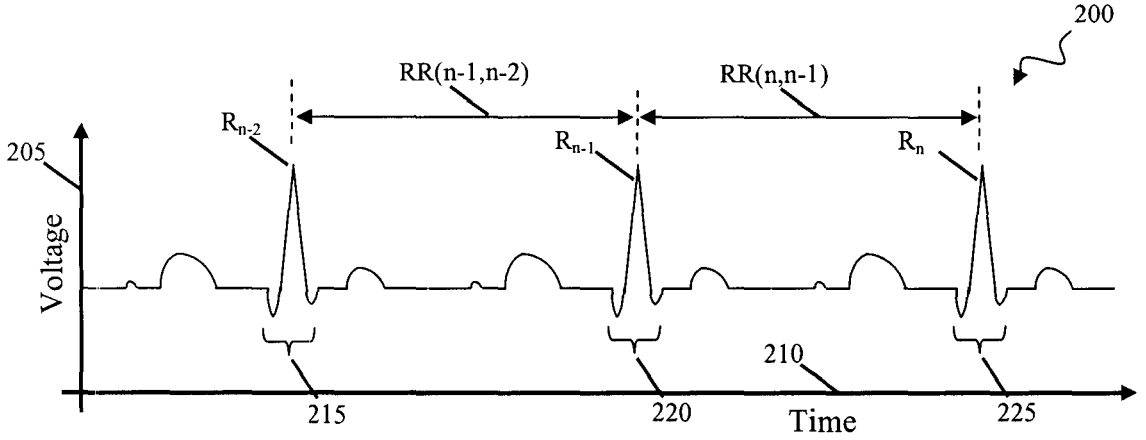


FIG. 2

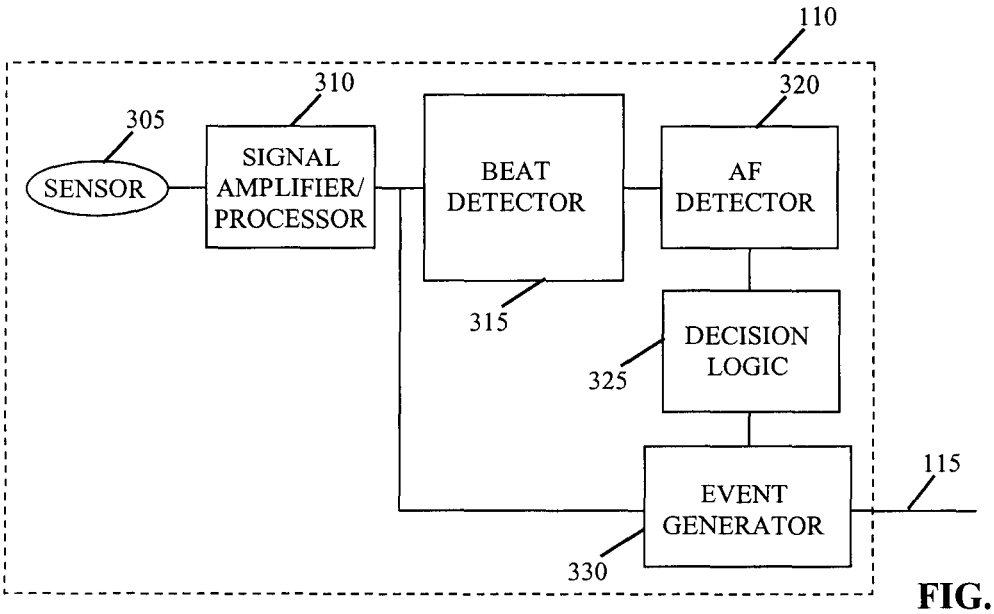


FIG. 3

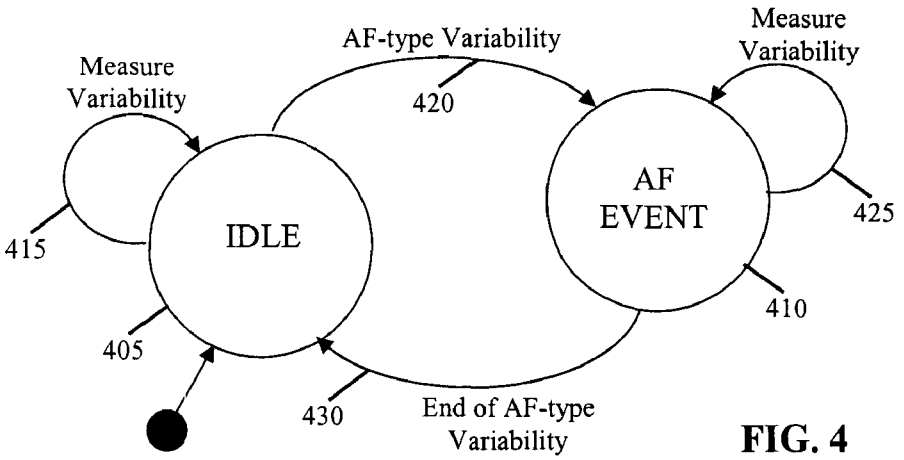


FIG. 4

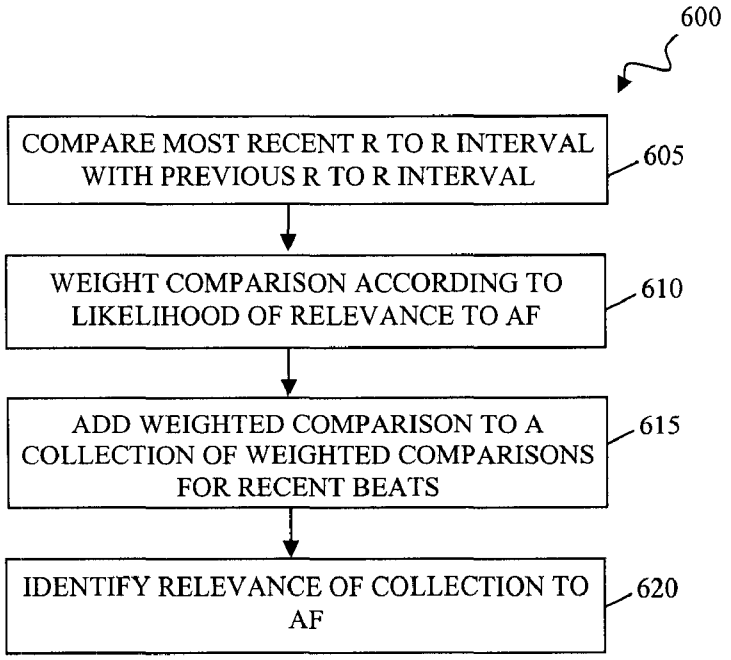


FIG. 6A

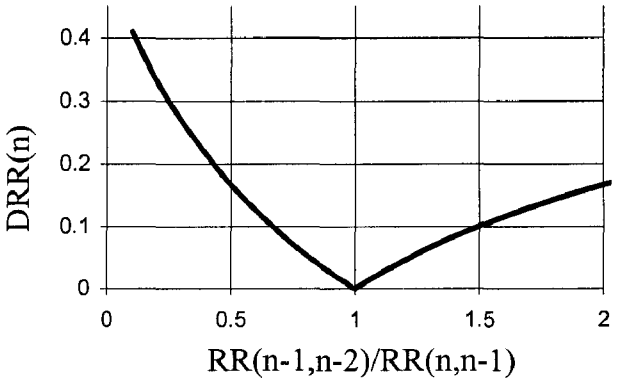


FIG. 6B

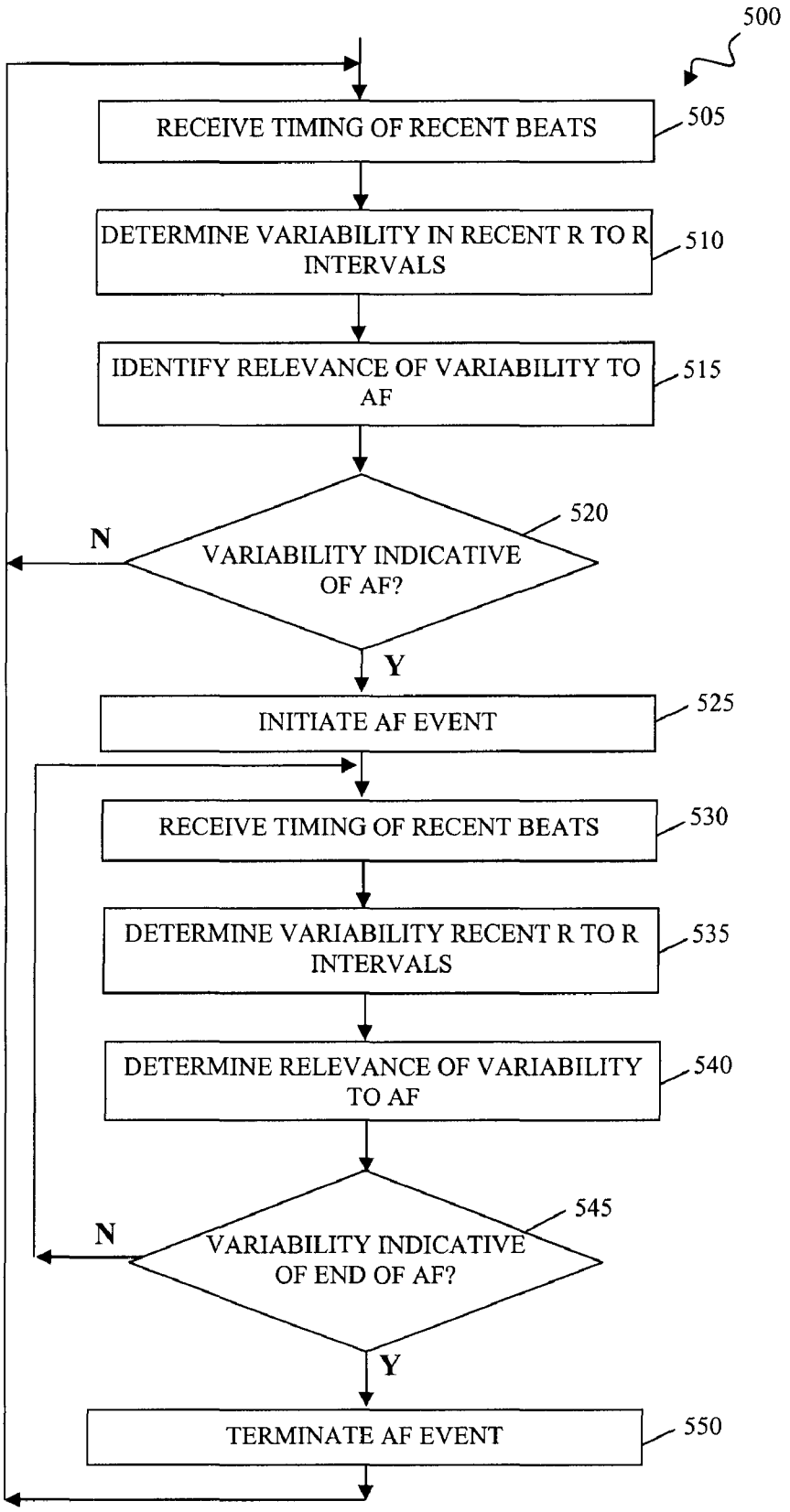

500
RECEIVE TIMING OF RECENT BEATS
505
DETERMINE VARIABILITY IN RECENT R TO R INTERVALS
510
IDENTIFY RELEVANCE OF VARIABILITY TO AF
515
VARIABILITY INDICATIVE OF AF?
520
N
Y
INITIATE AF EVENT
525
RECEIVE TIMING OF RECENT BEATS
530
DETERMINE VARIABILITY RECENT R TO R INTERVALS
535
DETERMINE RELEVANCE OF VARIABILITY TO AF
540
VARIABILITY INDICATIVE OF END OF AF?
545
N
Y
TERMINATE AF EVENT
550

FIG. 5

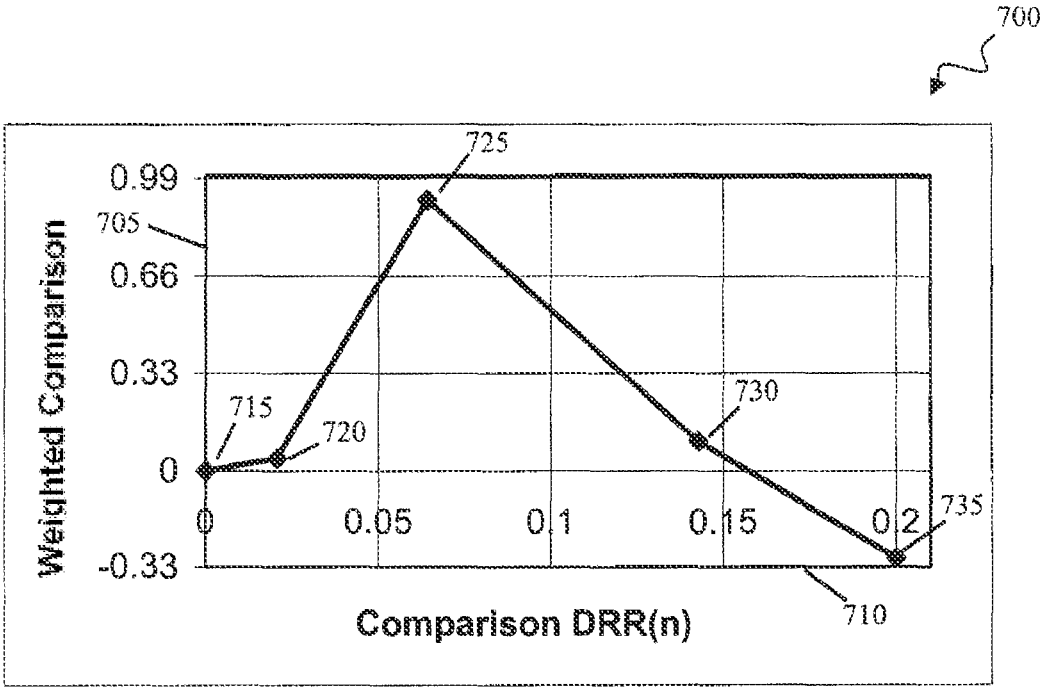

700
725
0.99
705
0.66
0.33
715
720
730
0
0
0.05
0.1
0.15
0.2
735
-0.33
Weighted Comparison
Comparison DRR(n)
710

FIG. 7

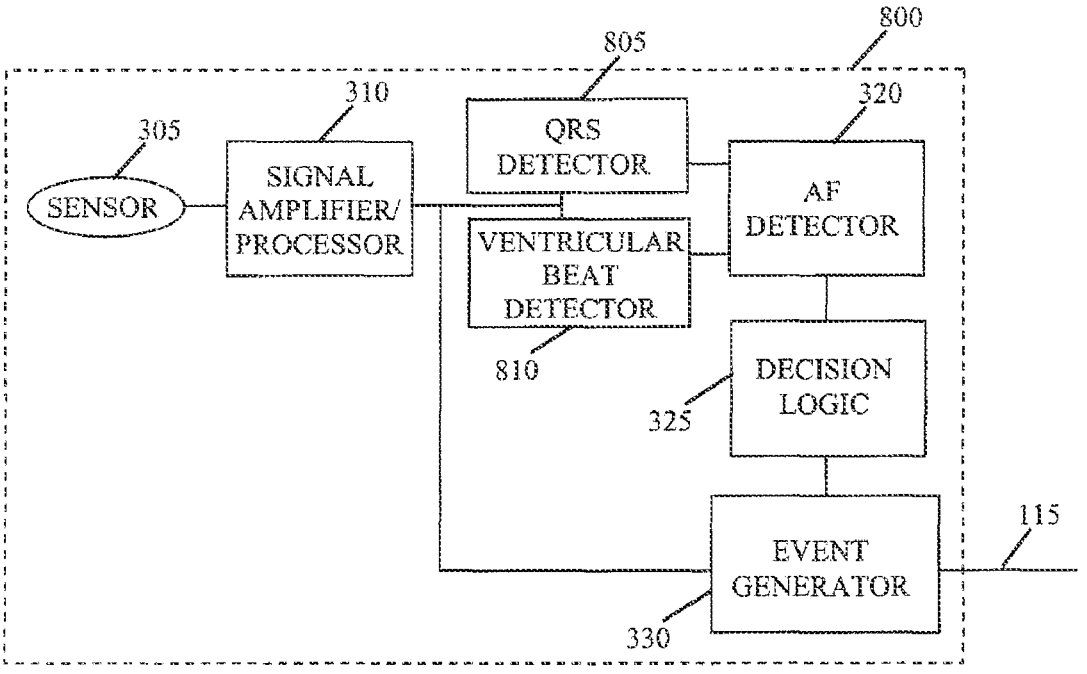

800
805
310
320
305
QRS DETECTOR
SENSOR
SIGNAL AMPLIFIER/ PROCESSOR
AF DETECTOR
VENTRICULAR BEAT DETECTOR
810
DECISION LOGIC
325
115
EVENT GENERATOR
330

FIG. 8

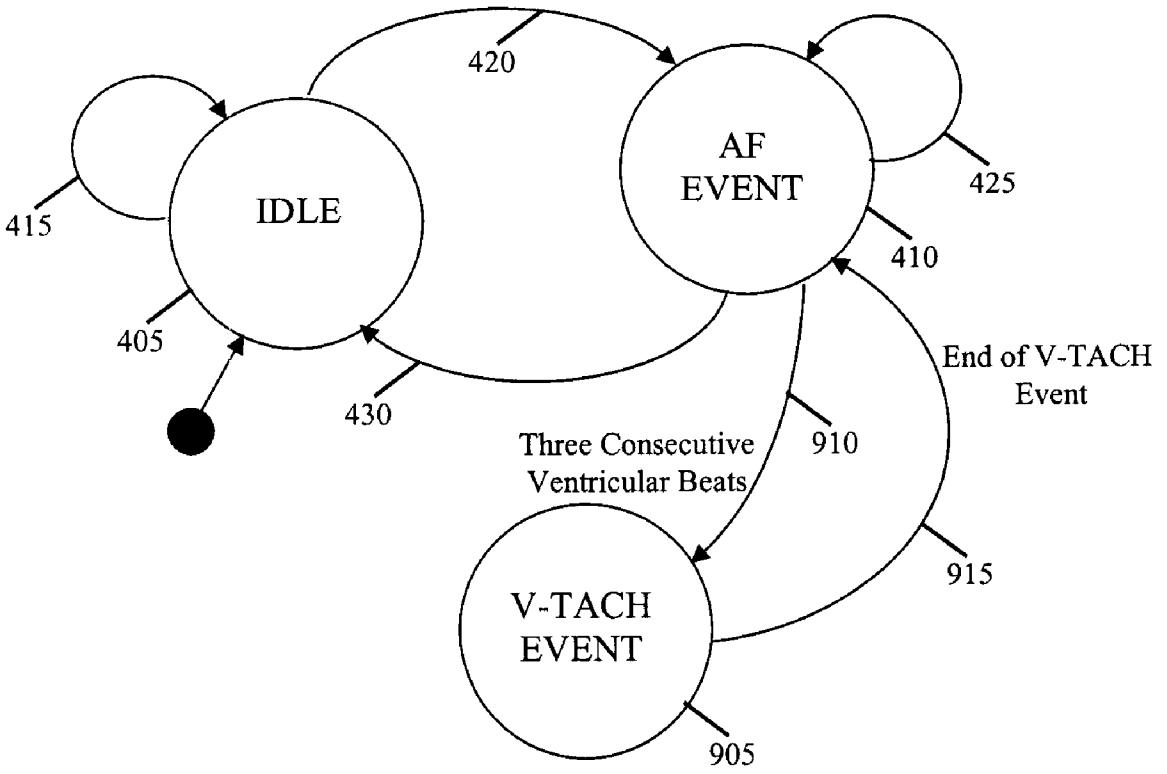

420
AF
EVENT
425
IDLE
415
410
405
End of V-TACH
Event
430
Three Consecutive
Ventricular Beats
910
915
V-TACH
EVENT
905

FIG. 9

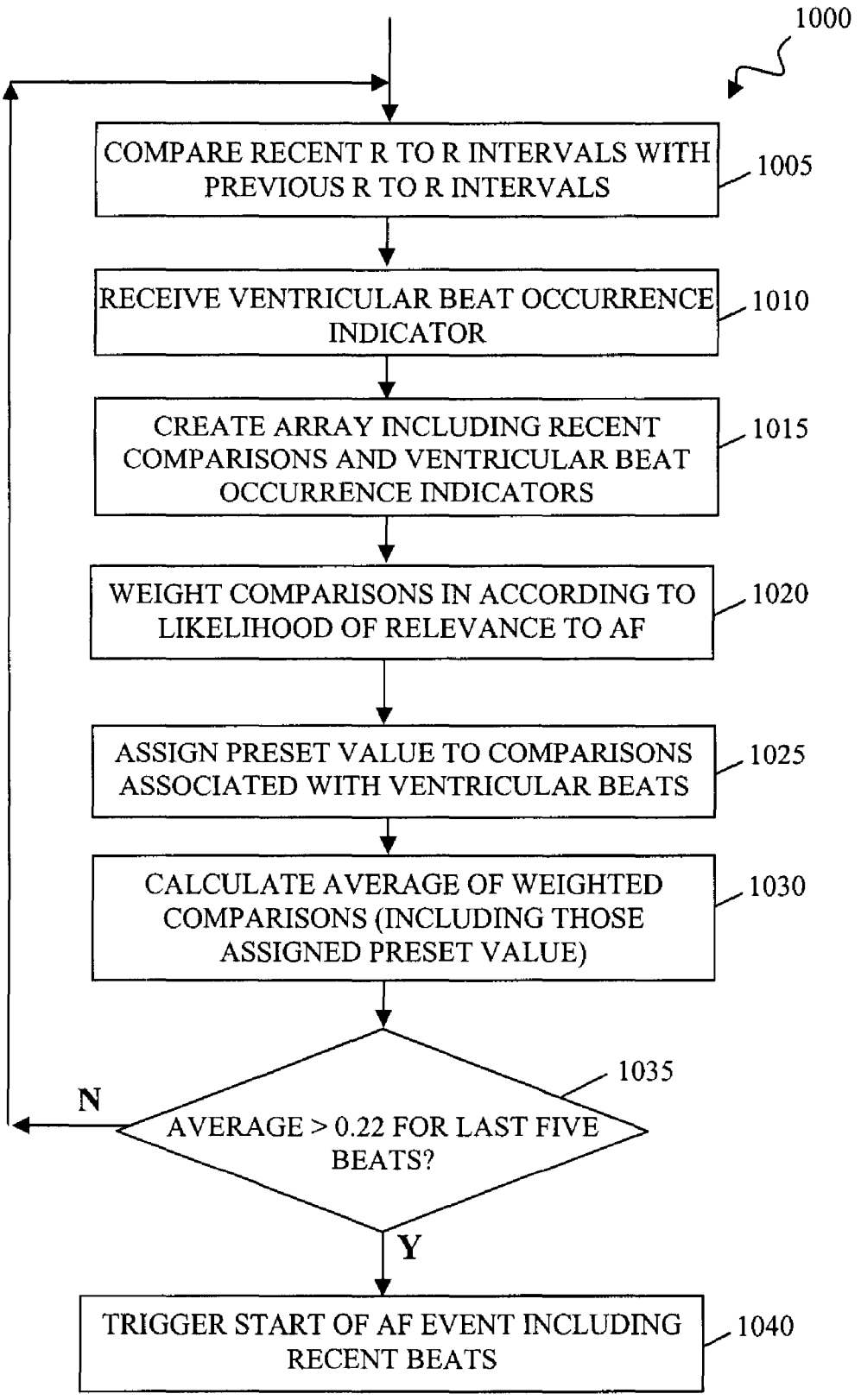

1000
COMPARE RECENT R TO R INTERVALS WITH PREVIOUS R TO R INTERVALS
1005
RECEIVE VENTRICULAR BEAT OCCURRENCE INDICATOR
1010
CREATE ARRAY INCLUDING RECENT COMPARISONS AND VENTRICULAR BEAT OCCURRENCE INDICATORS
1015
WEIGHT COMPARISONS IN ACCORDING TO LIKELIHOOD OF RELEVANCE TO AF
1020
ASSIGN PRESET VALUE TO COMPARISONS ASSOCIATED WITH VENTRICULAR BEATS
1025
CALCULATE AVERAGE OF WEIGHTED COMPARISONS (INCLUDING THOSE ASSIGNED PRESET VALUE)
1030
1035
N
AVERAGE > 0.22 FOR LAST FIVE BEATS?
Y
TRIGGER START OF AF EVENT INCLUDING RECENT BEATS
1040

FIG. 10

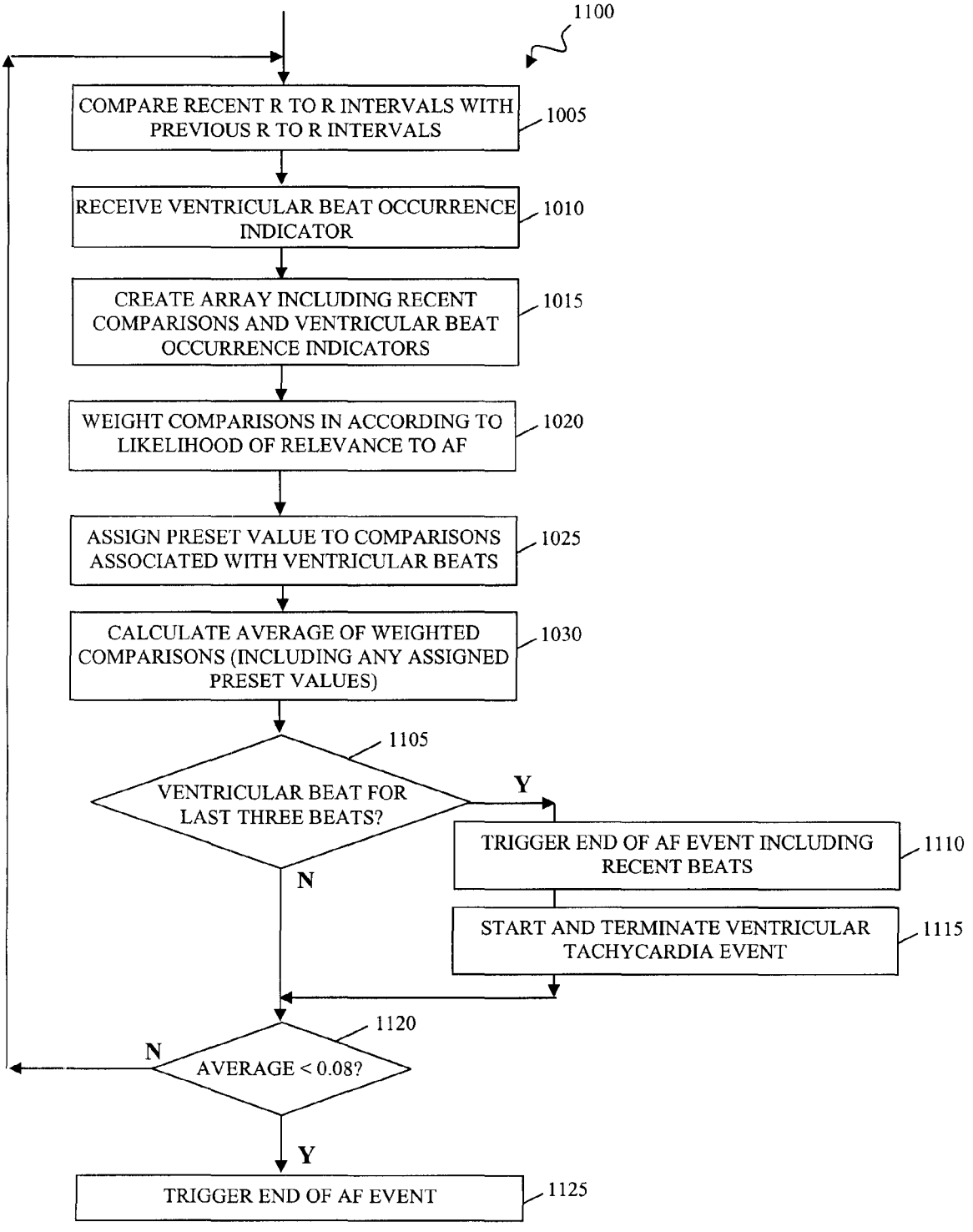

1100
COMPARE RECENT R TO R INTERVALS WITH PREVIOUS R TO R INTERVALS
1005
RECEIVE VENTRICULAR BEAT OCCURRENCE INDICATOR
1010
CREATE ARRAY INCLUDING RECENT COMPARISONS AND VENTRICULAR BEAT OCCURRENCE INDICATORS
1015
WEIGHT COMPARISONS IN ACCORDING TO LIKELIHOOD OF RELEVANCE TO AF
1020
ASSIGN PRESET VALUE TO COMPARISONS ASSOCIATED WITH VENTRICULAR BEATS
1025
CALCULATE AVERAGE OF WEIGHTED COMPARISONS (INCLUDING ANY ASSIGNED PRESET VALUES)
1030
1105
VENTRICULAR BEAT FOR LAST THREE BEATS?
Y
N
TRIGGER END OF AF EVENT INCLUDING RECENT BEATS
1110
START AND TERMINATE VENTRICULAR TACHYCARDIA EVENT
1115
1120
AVERAGE < 0.08?
N
Y
TRIGGER END OF AF EVENT
1125

FIG. 11

CARDIAC MONITORING

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims the priority of U.S. application Ser. No. 10/762,887, filed on Jan. 21, 2004, now U.S. Pat. No. 7,194,300 as a continuation application. The contents of U.S. application Ser. No. 10/762,887 are incorporated herein by reference.

BACKGROUND

The following description relates to cardiac monitoring, for example, by monitoring cardiac electrical activity.

The electrical activity of the heart can be monitored to track various aspects of the functioning of the heart. Given the volume conductivity of the body, electrodes on the body surface or beneath the skin often display potential differences related to this activity. Anomalous electrical activity can be indicative of disease states or other physiological conditions that can range from benign to deadly.

One example of such a physiological condition is atrial fibrillation. Atrial fibrillation involves the loss of synchrony between the atria and the ventricles. In complex atrial fibrillation, long-lived wavelets of depolarization travel along circular paths in the atria. This can lead to irregular ventricular beating as well as blood stagnation and clotting in the atria.

Atrial fibrillation is among the most common forms of cardiac arrhythmia and may affect more than two million people annually. Atrial fibrillation has been associated with stroke, congestive heart failure, and cardiomyopathy.

Another example of such a physiological condition is atrial flutter. Atrial flutter also involves the loss of synchrony between the atria and the ventricles. In atrial flutter, multiple atrial waveforms reach the atrioventricular (AV) node during each ventricular beat due to, e.g., atrial scars, an atrial infarction, or a re-entrant circuit encircling a portion of the right atrium.

Atrial flutter is less common than atrial fibrillation but is also associated with stroke, congestive heart failure, and cardiomyopathy.

SUMMARY

The cardiac monitoring systems and techniques described here may include various combinations of the following features.

A method can include determining a beat-to-beat variability in cardiac electrical activity; determining a relevance of the variability to one of atrial fibrillation and atrial flutter using a non-linear statistics, identifying one of an atrial fibrillation event and an atrial flutter event based on the determined relevance. The event is a period in time when the information content of the cardiac electrical activity is of increased relevance.

The end of the event can be identified based on the determined relevance. An event state associated with atrial fibrillation can be transitioned into in response to identification of the event. The event can be transmitted to a remote receiver from an ambulatory patient. The relevance of the variability to atrial fibrillation can be determined by receiving information identifying a ventricular beat and assigning a preset value indicating that the variability is negatively indicative of atrial fibrillation.

A ventricular tachycardia event can be identified based at least in part on the information identifying the ventricular beat. The relevance of the variability to atrial fibrillation can be determined by determining an average relevance of variability in a collection of R to R intervals.

The beat-to-beat variability can be determined in a series of successive beats, e.g., by determining the variability in an interval between successive R-waves. The event can be identified by comparing the relevance of the variability to a first predetermined amount of relevance. Further, the relevance of the variability in the event can be compared to a second predetermined amount of relevance to identify the end of the event. The second predetermined amount can be lower than the first predetermined amount.

A method can include collecting information describing the variability in heart rate over a series of beats, designating variability at a lower end of physiological values as being largely irrelevant to atrial fibrillation, designating variability in a midrange of physiological values as being indicative of atrial fibrillation, designating variability in an upper range of physiological values as being negatively indicative of atrial fibrillation, and determining a relevance of the variability described in the collection to atrial fibrillation.

The variability can be designated by multiplying the information describing the variability by a weighting factor. Information describing a variability in R to R intervals over a series of beats can be collected. The collected information can be a function of a ratio of a first R to R interval and an immediately preceding R to R interval, such as information related to factor DRR(n) as given by

$$DRR(n) = \mathrm{ABS}\left(\frac{RR(n, n-1)}{RR(n, n-1) + RR(n-1, n-2)} - \frac{1}{2}\right).$$

The variability at the lower end of physiological values can be designated as being largely irrelevant by designating information related to factors DRR(n) less than about 0.0.2 as being largely irrelevant. The variability at the midrange of physiological values can be designated as being indicative of atrial fibrillation by designating information related to factors DRR(n) greater than about 0.02 and less than about 0.15 as being indicative of atrial fibrillation. The variability at the upper range of physiological values can be designated as being negatively indicative of atrial fibrillation by designating information related to factors DRR(n) greater than about 0.157 as being negatively indicative of atrial fibrillation.

Information describing the variability can be collected by collecting the variability in heart rate over a series of between 20 and 200 of the recent R to R intervals. The determined relevance of the variability can be the relevance of the variability to sustained atrial fibrillation. The series of R to R intervals can be a continuous series of R to R intervals.

A method can include comparing recent R to R intervals with preceding R to R intervals to yield a collection of comparisons, weighting the comparisons according to a likelihood that the comparisons are relevant to atrial fibrillation, and determining the average relevance of the collection to atrial fibrillation. The weighting can include identifying a first of the recent beats as a ventricular beat and assigning a preset value to weight the first beat in the collection. The preset value can be negatively indicative of atrial fibrillation.

The comparisons can be weighted by designating variability at a lower end of physiological values as being largely irrelevant to atrial fibrillation and designating variability in a midrange of physiological values as being indicative of atrial fibrillation. The comparisons can also be weighted by designating variability in an upper range of physiological values as

being negatively indicative of atrial fibrillation. A ventricular tachycardia event can be identified based at least in part on the identification of the ventricular beat. Recent R to R intervals can be compared with immediately preceding R to R intervals to yield a collection of comparisons.

The cardiac monitoring systems and techniques may provide one or more of the following advantages. Atrial fibrillation ("AFib") and/or atrial flutter ("AFlut," with "AF" referring to either) can be distinguished from other types of cardiac arrhythmia, such as the normal sinus rhythm irregularity, irregularity from various types of heart blocks, and the irregularity associated with premature ventricular contractions. The described systems and techniques are a practical approach to calculating the beat-to-beat irregularity while providing improved positive predictability of AF. Moreover, the described systems and techniques are able to identify sustained AF episodes, where AF continues for more that approximately 20 beats and has an increased clinical significance.

For example, when the systems and techniques described here were used to analyze the MIT-BIH arrhythmia database, available from MIT-BIH Database Distribution, MIT Room E25-505A, Cambridge, Mass. 02139, USA, a sensitivity to AF in excess of 90% and a positive predictivity in excess of 96% were obtained.

The described systems and techniques are well-adapted to monitoring cardiac signals of ambulatory patients who are away from controlled environments such as hospital beds or treatment facilities. The cardiac signals obtained from to ambulatory patients may be noisier and otherwise strongly impacted by the patients' heightened levels of activity. Thus, improved monitoring systems and techniques, such as those described herein, are required for ambulatory patients.

The described systems and techniques are also well-adapted to real-time monitoring of arrhythmia patients, where minimal delays in distinguishing between different types of cardiac arrhythmia can speed the delivery of any urgent medical care. The described systems and techniques also require minimal computational resources. Further, the described systems and techniques do not require training before different types of cardiac arrhythmia can be distinguished.

The details of one or more implementations of the invention are set forth in the accompanying drawings and the description below. Other features, objects, and advantages will be apparent from the description and drawings, and from the claims.

DESCRIPTION OF DRAWINGS

FIG. **1** shows a system in which a cardiac signal is monitored for medical purposes.

FIG. **2** shows an example of a cardiac signal.

FIG. **3** shows an example of instrumentation for cardiac monitoring using a cardiac signal.

FIG. **4** shows an example state diagram of a cardiac monitoring system during cardiac monitoring.

FIG. **5** shows a process for cardiac monitoring for the detection of an AF event.

FIG. **6**A shows a process for determining the variability in the recent R to R intervals and identifying if the variability is relevant to either the onset or termination of AF.

FIG. **6**B shows a graph of factor DRR(n) as a function of RR(n−1,n−2)/RR(n,n−1).

FIG. **7** shows a transformation function for weighting the variability in the timing of recent beats.

FIG. **8** shows an example of instrumentation for cardiac monitoring using an electrocardiogram trace.

FIG. **9** shows an example state diagram of a cardiac monitoring system that accommodates the variability caused by ventricular beats.

FIG. **10** shows a process for determining the variability of recent R to R intervals and identifying if the variability is relevant to the onset of AF while accommodating the variability caused by ventricular beats.

FIG. **11** shows a process for determining the variability in recent R to R intervals and identifying if the variability is relevant to the termination of AF while accommodating the variability caused by ventricular beats.

Like reference symbols in the various drawings indicate like elements.

DETAILED DESCRIPTION

FIG. **1** shows a system **100** in which a cardiac signal is monitored for medical purposes. System **100** includes an individual **105**, instrumentation **110**, a signal path **115**, and a receiver **120**. Individual **105** can be a patient or a healthy individual for whom monitoring of one or more biological signals is deemed to be appropriate. Instrumentation **10** can include one or more sensing, calibration, signal processing, control, data storage, and transmission elements suitable for generating and processing the cardiac signal, as well as relaying all or a portion of the cardiac signal over path **115**. Path **115** can be any suitable medium for data transmission, including wired and wireless media suitable for carrying optical and/or electrical signals. The receiver **120** can include a receiver element for receiving the transmitted signal, as well as various data processing and storage elements for extracting and storing the information carried by the transmission regarding the state of individual **105**. The receiver **120** can be a medical system in that receiver **120** presents information to medical personnel or to a medical expert system for analysis. The receiver **120** either can reside remotely from instrumentation **110** in that receiver **120** is not located at the same site as instrumentation **110** (e.g., at the same hospital, nursing home, or other medical care facility) or the receiver **120** can reside within the same general area or vicinity as instrumentation **110** (e.g., within the same room, building, or health care facility).

FIG. **2** shows an example of a cardiac signal, namely the trace of a scalar electrocardiogram **200**. Electrocardiogram trace **200** follows a potential difference **205** measured between two points on the body surface of an individual. Potential difference **205** changes with time **210** in a manner characteristic of the physiology and function of an individual's heart.

Electrocardiogram trace **200** generally includes features characteristic with particular aspects of cardiac activity. For example, trace **200** includes a series of QRS complexes **215**, **220**, **225** associated with activation of the ventricles. QRS complex **225** includes an R-wave R_n, QRS complex **220** includes an R-wave R_{n-1}, and QRS complex **215** includes an R-wave R_{n-2}. The time between successive R-waves can be referred to as the R to R interval. In particular, the R to R interval between R-wave R_n and R-wave R_{n-1} is RR(n,n−1) and the R to R interval between R-wave R_{n-1} and R-wave R_{n-2} is RR(n−1,n−2).

FIG. **3** shows an example of instrumentation **110** for cardiac monitoring using a cardiac signal such as electrocardiogram trace **200**. Instrumentation **110** includes a sensor **305**, a signal amplifier/processor **310**, a beat detector **315**, an atrial fibrillation/atrial flutter (AF) detector **320**, decision logic **325**,

and an event generator **330**. Sensor **305** can include two or more electrodes subject to one or more potential differences that yield a voltage signal such as electrocardiogram trace **200**. The electrodes can be body surface electrodes such as silver/silver chloride electrodes and can be positioned at defined locations to aid in monitoring the electrical activity of the heart. Sensor **305** can also include leads or other conductors that form a signal path to signal amplifier/processor **310**. Signal amplifier/processor **310** can receive, amplify, and/or process the voltage signals. The processing can include filtering and digitization. The amplification and remainder of the processing can occur before or after digitization. Signal amplifier/processor **310** can provide the amplified and/or processed signal to beat detector **315**.

Beat detector **315** is a device such as a circuit or other arrangement that identifies the time period between ventricular contractions. For example, beat detector **315** can be a QRS detector in that it identifies successive QRS complexes (or an equivalent indicator of ventricular activity) and determines the beat-to-beat timing from the time between complexes. The beat-to-beat timing can be determined by measuring times between successive R-waves, such as RR(n,n−1) and RR(n−1,n−2) in electrocardiogram trace **200** (FIG. **2**). Beat detector **315** can provide information regarding the time period between ventricular contractions to AF detector **320**.

AF detector **320** is a data processing device that analyzes information regarding the time period between ventricular contractions to detect AF. The detection of AF can include distinguishing AF from other sources of ventricular irregularity, such as premature ventricular contraction, heart blocks, and normal sinus rhythm irregularity. The detection of AF can also include distinguishing between short AF episodes and sustained AF episodes. Short AF episodes generally include between two and 20 beats and may or may not have clinical significant, whereas sustained AF episodes generally include more than 20 beats and may have relatively greater clinical significance. The detection of AF can also include the detection of other types of irregularity caused by random refractory periods of the ventricles.

AF detector **320** can analyze information regarding the time period between ventricular contractions to detect AF using non-linear statistical approaches. Non-linear statistics treats the relationship between variables as something other than a linear function. Detail regarding an example non-linear statistical approach to detecting AF is given below. AF detector **320** can provide information regarding the detection of AF to decision logic **325**

Decision logic **325** is a set of instructions for determining when the AF detected by AF detector **320** has commenced and terminated. For example, decision logic **325** can be embodied in a circuit or decision logic **325** can be executed by a data processing device such as AF detector **320**. Decision logic **325** can also trigger the generation of an AF event by event generator **230**.

Event generator **330** is a device such as a data processing device that prepares an AF event for handling. An AF event is a period in time when the information content of the signal sensed by sensor **305** is deemed to be of increased relevance to the monitoring of AF. AF events need not be of equal or predetermined duration. For example, an event associated with an sustained AF episode may have a longer duration than an event associated with a short AF episode.

Event generator **330** can prepare an AF event for handling by collecting information that summarizes the relevance of the event to the detection and/or monitoring of AF. For example, event generator **330** can excise data associated with the period identified as AF from the amplified and processed signal output from signal amplifier/processor **310**. Event generator **330** can also redact such data (e.g., by selecting the first three minutes worth when generating the event). Handling the AF event can include transmitting the AF event over data link **115** or storing the AF event in a data storage device.

FIG. **4** shows an example state diagram **400** of a cardiac monitoring system during cardiac monitoring. For example, state diagram **400** can relate to the operation of an assembly such as AF detector **320** and decision logic **325** in instrumentation **110** (FIG. **3**). State diagram **400** includes an idle state **405** and an AF event state **410**. Idle state **405** originates a reflexive transition **415** and a state transition **420**. AF event state **410** originates a reflexive transition **425** and a state transition **430**. Reflexive transition **415** is associated with a series of variability measurements. State transition **420** is triggered by the onset of AF-type variability as detected by such measurements. Reflexive transition **425** is associated with another series of variability measurements. State transition **430** is triggered by the end of AF-type variability as detected by such measurements.

In operation, a cardiac monitoring system can start in idle state **405** and measure the variability of a cardiac signal. For example, the system can measure the variability in the beat-to-beat timing of successive R-waves, such as the variability between RR(n,n−1) and RR(n−1,n−2) in electrocardiogram trace **200** (FIG. **2**). Once the variability has been identified as AF-type variability, the system transitions to AF event state **410** where the system continues to measure the variability of the cardiac signal. In AF event state **410**, once the AF-type variability has ended, the system returns to idle state **405**.

FIG. **5** shows a process **500** for cardiac monitoring, e.g., for the detection of an AF event. Process **500** can be performed by one or more data processing devices that perform data processing activities. The activities of process **500** can be performed in accordance with the logic of a set of machine-readable instructions, a hardware assembly, or a combination of these and/or other instructions. The activities in process **500** can be performed at any of a number of different elements in a system in which a biological signal is monitored. For example, in instrumentation **110** (FIG. **3**), the activities in process **900** can be performed at AF detector **320**, decision logic **325**, and event generator **330**.

The device performing process **500** receives information regarding the timing of recent beats it **505**. The timing information can be received in discrete amounts (e.g., on a beat-to-beat basis) or in a collection that includes such information. Using the received timing information, the system determines the variability in the recent R to R intervals at **510**. The variability in the R to R intervals can reflect the beat-to-beat change in heart rate over a set period or over a set number of beats.

The system can also identify the relevance of such variability to AF at **515**. The variability is relevant to AF when it is associated with a high probability that an individual undergoes AF at or near the time of the recent beats. Relevance can be identified by comparing the variability to a predetermined amount of variability or to an amount identified as typical for the monitored patient.

The system can also determine if the identified relevance of the variability is indicative of the monitored individual undergoing AF at decision **520**. If not, the system returns to **505**. This return can correspond to the system remaining in idle state **405** along reflexive transition **415** in state diagram **400** (FIG. **4**). If the system determines that the results of the monitoring are indicative of the individual undergoing AF, the system initiates an AF event at **525**. This initiation of the AF event can correspond to the system transitioning to AF

event state **410** in state diagram **400** (FIG. **4**). The initiation of such an event can include various activities that lead to the generation of an event, such as triggering an event generator to add markers to a data stream such as electrocardiogram trace **200** or excising a relevant portion of the data stream.

The system can continue to receive information regarding the timing of recent beats at **530**. Using the received timing information, the system determines the variability in the recent R to R intervals at **535**. The system can also identify the relevance of such variability to the end of AF at **540**. The variability is relevant to the end of AF when it is associated with an increased probability that AF has halted. Relevance can be identified by comparing the variability to a predetermined amount of variability or to an amount identified as typical for the monitored patient.

The system can also determine if the identified relevance of the variability indicates that AF has ended in the monitored individual at decision **545**. If not, the system returns to **530**. This return can correspond to the system remaining in AF event state **410** along reflexive transition **425** in state diagram **400** (FIG. **4**). If the system determines that AF has ended in the monitored individual, the system returns to **555**. This return can correspond to the system transitioning to idle state **405** in state diagram **400** (FIG. **4**).

FIG. **6**A shows a process **600** for determining the variability in the recent R to R intervals and identifying if the variability is relevant to either the onset or termination of AF. Process **600** can be performed independently or process **600** can be performed as part of a larger collection of activities. For example, process **600** can be performed as part of process **500**, namely as steps **510**, **515** or as steps **535**, **540** (FIG. **5**). Various activities in process **600** can also be performed to trigger state transitions **420**, **430** in state diagram **400** (FIG. **4**).

The system performing process **600** can compare the most recent R to R interval (e.g., RR(n,n−1) of FIG. **2**) with the immediately preceding R to R interval (e.g., RR(n−1,n−2) of FIG. **2**) at **605**. Such a comparison can yield a factor that reflects the beat-to-beat variability in heart rate. For example, a factor DRR(n), given by the expression

$$DRR(n) = \mathrm{ABS}\left(\frac{RR(n, n-1)}{RR(n, n-1) + RR(n-1, n-2)} - \frac{1}{2}\right) \qquad \text{Equation 1}$$

can reflect the beat-to-beat variability in R to R interval and in heart rate. A graph of factor DRR(n) as a function of RR(n−1,n−2)/RR(n,n−1) is shown in FIG. **6**B.

The system performing process **600** can also weight the comparison of the most recent R to R interval with the immediately preceding R to R interval according to the likelihood that the results of the comparison are indicative of AT at **610**. The weighting can determine a role that the comparison will play in subsequent processing cardiac monitoring activities. For example, the weighting can include the whole or partial exclusion of a certain comparisons from subsequent cardiac monitoring activities.

One technique for weighting the comparison is through the use of a transformation, such as transformation function **700** shown in FIG. **7**. Transformation function **700** provides weights that are multiplied by the value of a comparison (e.g., factor DRR(n)) to reflect the relevance of the comparison to AF. The weights provided in transformation function **700** can be multiplied by the value of every comparison or by a selected subset of the comparisons. One technique for selecting such a subset is discussed further below.

Transformation function **700** is adapted to the factor DRR(n) given in equation 1. In particular, transformation function **700** is adapted to overweight factor DRR(n) when factor DRR(n) is in a midrange of potential physiological values (e.g., when DRR(n) is greater than about 0.02 and less than about 0.15). Transformation function **700** is adapted to weight factor DRR(n) as being negatively indicative of AF when factor DRR(n) is at the upper range of potential physiological values (e.g., when DRR(n) is greater than about 0.157). Transformation function **700** is adapted to weight factor DRR(n) as being largely irrelevant to AF when factor DRR(n) is at the lower range of potential physiological values (e.g., when DRR(n) is less than about 0.0.2). Transformation function **700** includes a scalar weighted comparison **705** that varies as a function of the comparison factor DRR(n) **710**. In particular, weighted comparison **705** varies linearly between points **715**, **720**, **725**, **730**, **735**. The values of points **715**, **720**, **725**, **730**, **735** are given in Table 1.

TABLE 1

Point	Comparison DRR(n)	Weight Comparison
715	0	0
720	0.0206	0.0417
725	0.0642	0.9178
730	0.1427	0.1005
735	0.2	−0.3

In operation, weighted comparison **705** for any value of the factor DRR(n) can be determined by linear interpolation between the weighted comparisons of points **715**, **720**, **725**, **730**, **735**. The interpolation can be performed for each value of the factor DRR(n) as it arises or the results of a certain number of such interpolations can be stored in a look up table. For any value of the factor DRR(n) above 0.2, a weighted comparison of −0.3 can be assigned.

Returning to FIG. **6**A, the system performing process **600** can also add a weighted comparison to a collection of weighted comparisons for recent beats at **615**. For example, the system can form a FIFO stack or an array of weighted comparisons having a separate data element for each of between 10 and 200 (e.g., 100) of the most recent beats. The system can also determine the relevance of the collection of weighted comparisons for recent beats to AF at **620**. The collection of weighted comparisons can be relevant to either the onset or termination of AF.

To determine the relevance, the system can sum the weighted comparisons to arrive at a number that represents the average relevance of the weighted comparisons in the collection. The system can calculate such sums for several beats in a row before determining that the beat-to-beat variability is indicative of the onset or termination of AF. In one implementation, the system calculates the average of the weighted comparisons of the beats in the collection and compares this average with a first predetermined threshold to determine if the variability is indicative of the onset of AF and with a second predetermined threshold to determine if the variability is indicative of the termination of AF. In general, the first, onset threshold may be higher than the second, termination threshold. The difference between the onset and termination thresholds can introduce hysteresis into the state transitions to stabilize any system performing process **600**.

FIG. **8** shows an example of instrumentation for cardiac monitoring using an electrocardiogram trace, namely instrumentation **800**. In addition to sensor **305**, signal amplifier/processor **310**, AF (AF) detector **320**, decision logic **325**, and event generator **330**, instrumentation **800** also includes a QRS

detector **805** and a ventricular beat detector **810**. QRS detector **805** and ventricular beat detector **810** can both receive an amplified and processed signal from signal amplifier/processor **310**. QRS detector **805** is a device such as a circuit or other arrangement that identifies the time period between successive QRS complexes. QRS detector **805** can provide information regarding the time period between successive QRS complexes to AF detector **320**

Ventricular beat detector **810** is a device such as a circuit or other arrangement that identifies ventricular beats. Ventricular beats (i.e., premature ventricular beats) are irregular beats that interrupt the normal heart rhythm. Ventricular beats generally arise from a ventricular focus with enhanced automaticity. Ventricular beats may also result from reentry within the His-Purkinje system. The occurrence of ventricular beats is generally unrelated to AF. For example, the occurrence of ventricular beats can be used to identify ventricular tachycardia (e.g., when there are three or more consecutive ventricular beats). Ventricular beats may be precipitated by factors such as alcohol, tobacco, caffeine, and stress. Ventricular beat detector **810** can monitor an electrocardiogram trace to identify ventricular beats. Various systems and techniques for identifying ventricular beats can be used. For example, the Mortara VERITAS Analysis Algorithm, available from Mortara Instrument, Inc. (Milwaukee, Wis.), can be used. Ventricular beat detector **810** can also provide information regarding the occurrence of ventricular beats to AF detector **320**.

Ventricular beat detector **810** can be housed together with QRS detector **805**. An example of such a joint device is the ELI 250TM Electrocardiograph available from Mortara Instrument, Inc. (Milwaukee, Wis.).

Approaches for determining the variability in recent R to R intervals and identifying if the variability is relevant to either the onset or termination of AF can accommodate the variability caused by ventricular beats. FIG. **9** shows an example state diagram **900** of a cardiac monitoring system that accommodates the variability caused by ventricular beats. In addition to idle state **405** and AF event state **410**, state diagram **900** also includes a ventricular tachycardia (V-TA CH) event state **905**. Ventricular tachycardia is a rapid succession of ventricular contractions (e.g., between 140 and 220 per minute) generally caused by an abnormal focus of electrical activity in a ventricle. Ventricular tachycardia can last from a few seconds to several days and can be caused by serious heart conditions such as a myocardial infarction. AF event state **410** originates a state transition **910** that is triggered by the occurrence of three consecutive ventricular beats. V-TACH event state **905** originates a state transition **910** that is triggered by the end of a V-TACH event. The end of a V-TACH event can be identified, e.g., when the rate of ventricular contractions falls below a predetermined value (e.g., a value between 100 and 200 bpm).

FIG. **10** shows a process for determining the variability in recent R to R intervals and identifying if the variability is relevant to the onset of AF while accommodating the variability caused by ventricular beats, namely a process **1000**. Process **900** can be performed independently or process **1000** can be performed as part of a larger collection of activities. For example, process **1000** can be performed as part of process **500**, namely as steps **510**, **515** (FIG. **5**). Various activities in process **1000** can also be performed to trigger state transition **420** in state diagram **900** (FIG. **9**).

The system performing process **1000** can compare the recent R to R intervals with the respective, immediately-preceding R to R intervals at **1005** using, e.g., the expression in Equation 1 to reflect the beat-to-beat variability in heart rate. The system performing can also receive an indicator of the occurrence of a ventricular beat at **1010**. Such an indicator can be received, e.g., from a ventricular beat detector.

The system can create an array or other data structure that includes both the ventricular beat indicators and the R to R interval comparisons at **1015**. The array can include the ventricular beat indicators and the R to R interval comparisons for between 10 and 200 (e.g., 100) of the most recent beats. The system can also weight the comparisons according to the likelihood that the R to R interval comparisons are relevant to AF at **1020** using, e.g., transformation function **700** (FIG. **7**).

The system can also assign a preset value to the R to R interval comparisons associated with ventricular beats at **1025**. The preset value can be a penalty value in that the preset value reflects a decreased likelihood that the variability is indicative of an AF event. The preset value can be selected in light of the approaches used to compare the R to R intervals and to weight such comparisons. For example, when the R to R intervals are compared using Equation 1 and the resulting comparisons are weighted using transformation function **700** (FIG. **7**), R to R interval comparisons associated with ventricular beats can be assigned a preset value of −0.06 and R to R intervals comparisons associated with the R to R intervals immediately succeeding ventricular beats can be assigned a preset value of zero.

Using both the weighted and preset timing comparisons, the system can calculate the average value of an entry in the array of the most recent beats at **1030**. If the system determines that the average is greater than 0.22 for the last five beats at decision **1035**, then the system triggers the start of an AF event in the recent beats at **1040**. On the other hand, if the system determines that the average is less than or equal to 0.22 for the last five beats, then the system returns to compare the recent R to R intervals with the previous R to R interval at **1005**.

FIG. **11** shows a process for determining the variability in the recent R to R intervals and identifying if the variability is relevant to the termination of AF while accommodating the variability caused by ventricular beats, namely a process **1100**. Process **1100** can be performed independently or process **1100** can be performed as part of a larger collection of activities. For example, process **1100** can be performed as part of process **500**, namely as steps **535**, **540** (FIG. **5**). Various activities in process **1100** can also be performed to trigger state transitions **430**, **910**, **915** in state diagram **900** (FIG. **9**).

The system performing process **1100** can perform the activities at **1005**, **1010**, **1015**, **1020**, **1025**, **1030** as in process **1000**. The system can also determine if the last three beats have been ventricular beats at decision **1105**. For example, the system can determine if the last three beats are marked with a ventricular beat occurrence indicator such as that received at **1010**.

If the system determines that the last three beats have been ventricular beats, the system triggers the end of the AF event at **1110** and, when appropriate, terminates a ventricular tachycardia event at **1115**. The start and termination of the ventricular tachycardia event can transition the state of a system into and out of a V-TACH event, much like transitions **910**, **915** in state diagram **900** (FIG. **9**).

When the V-TACH event has been terminated at **1115** or when the system determines that the last three beats have not been ventricular beats at **115**, the system then determines if the average of both the weighted and preset timing comparisons in the array of the most recent beats has dropped below 0.08 at decision **1120**. If the average has not dropped below 0.08, the system returns to compare the recent R to R intervals with the previous R to R interval at **1005**. On the other hand,

when the average has dropped below 0.08, the system triggers the end of the AF event at **1125**. This triggering can transition the state of a system out of an AF event, much like transition **430** in state diagram **900** (FIG. **9**).

Various implementations of the systems and techniques described here can be realized in digital electronic circuitry, integrated circuitry, specially designed ASICs (application specific integrated circuits), computer hardware, firmware, software, and/or combinations thereof. These various implementations can include one or more computer programs that are executable and/or interpretable on a programmable system including at least one programmable processor, which may be special or general purpose, coupled to receive data and instructions from, and to transmit data and instructions to, a storage system, at least one input device, and at least one output device.

These computer programs (also known as programs, software, software applications or code) may include machine instructions for a programmable processor, and can be implemented in a high-level procedural and/or object-oriented programming language, and/or in assembly/machine language. As used herein, the term "machine-readable medium" refers to any computer program product, apparatus and/or device (e.g., magnetic discs, optical disks, memory, Programmable Logic Devices (PLDs)) used to provide machine instructions and/or data to a programmable processor, including a machine-readable medium that receives machine instructions as a machine-readable signal. The term "machine-readable signal" refers to any signal used to provide machine instructions and/or data to a programmable processor.

To provide for interaction with a user, the systems and techniques described here can be implemented on a computer having a display device (e.g., a CRT (cathode ray tube) or LCD (liquid crystal display) monitor) for displaying information to the user and a keyboard and a pointing device (e.g., a mouse or a trackball) by which the user can provide input to the computer. Other kinds of devices can be used to provide for interaction with a user as well; for example, feedback provided to the user can be any form of sensory feedback (e.g., visual feedback, auditory feedback, or tactile feedback); and input from the user can be received in any form, including acoustic, speech, or tactile input.

The systems and techniques described here can be implemented in a computing environment that includes a back-end component (e.g., as a data server), or that includes a middleware component (e.g., an application server), or that includes a front-end component (e.g., a client computer having a graphical user interface or a Web browser through which a user can interact with an implementation of the systems and techniques described here), or any combination of such back-end, middleware, or front-end components. The components of the environment can be interconnected by any form or medium of digital data communication (e.g., a communication network). Examples of communication networks include a local area network ("LAN"), a wide area network ("WAN"), and the Internet.

The computing environment can include clients and servers. A client and server are generally remote from each other and typically interact through a communication network. The relationship of client and server arises by virtue of computer programs running on the respective computers and having a client-server relationship to each other.

A number of implementations have been described. Nevertheless, it will be understood that various modifications may be made. Cardiac signals other than scalar electrocardiograms such as heart sounds can be monitored. Other weighting approaches and transformation functions can be used, depending upon the manner in which the timing of beats is compared. Weight **705** can be interpolated in any of a number of different ways such as a cubic spline between points **715**, **720**, **725**, **730**, **735**. Cardiac monitoring can be performed in real time or delayed. The values of different parameters can be changed and useful results still obtained. For example, in FIG. **7**, point **735** can be repositioned to a comparison factor DRR(n) value above 0.2. Accordingly, other implementations are within the scope of the following claims.

What is claimed is:

1. A device, comprising:
- a beat detector to identify a beat-to-beat timing of cardiac activity;
- a ventricular beat detector to identify ventricular beats in the cardiac activity;
- variability determination logic to determine a variability in the beat-to-beat timing of a collection of beats;
- relevance determination logic to identify a relevance of the variability in the beat-to-beat timing to at least one of atrial fibrillation and atrial flutter; and
- an event generator to generate an event when the variability in the beat-to-beat timing is identified as relevant to the at least one of atrial fibrillation and atrial flutter in light of the variability in the beat-to-beat timing caused by ventricular beats identified by the ventricular beat detector.

2. The device of claim **1**, wherein the relevance determination logic is to accommodate variability in the beat-to-beat timing caused by ventricular beats by weighting ventricular beats as being negatively indicative of the one of atrial fibrillation and atrial flutter.

3. The device of claim **1**, wherein the variability determination logic is to compare times between R-waves in three successive QRS complexes to determine the variability in the beat-to-beat timing.

4. The device of claim **1**, wherein:
- the variability determination logic is to represent the variability in the beat-to-beat timing as a factor that is lowest when a first time between beats is close to a second time between beats; and
- the first time immediately proceeds the second time.

5. The device of claim **4**, wherein the variability determination logic is to represent the variability in the beat-to-beat timing as a factor that increases non-linearly when the absolute difference between the first time the second time grows.

6. The device of claim **4**, wherein the variability determination logic is to represent the variability in the beat-to-beat timing as a factor that increases more rapidly when the first time grows less than the second time than when the first time grows greater than the second time.

7. The device of claim **1**, wherein the event generator is to generate an event by performing operations comprising:
- collecting data associated with the collection of beats; and
- transmitting the data associated with the collection of beats to a remote receiver.

8. The device of claim **1**, wherein the relevance determination logic comprises weighting logic to:
- weight variability at a lower end of physiological values as being substantially irrelevant to the one of atrial fibrillation and atrial flutter;
- weight variability in a midrange of physiological values as being positively indicative of the one of atrial fibrillation and atrial flutter; and
- weight variability in an upper range of physiological values as being negatively indicative of the one of atrial fibrillation and atrial flutter.

9. The device of claim 8, wherein the weighting logic is also to weight a beat identified as a ventricular beat as being negatively indicative of the one of atrial fibrillation and atrial flutter.

10. The device of claim 1, wherein the relevance determination logic comprises logic to identify the relevance of the variability using a non-linear function of a beat-to-beat interval.

11. The device of claim 1, wherein the beat detector comprises a QRS detector.

12. The device of claim 1, further comprising a sensor that includes two or more body surface electrodes subject to one or more potential differences related to cardiac activity.

13. A method comprising:

receiving information describing a timing of heart beats of an individual;

determining a first time between a first heart beat and a second heart beat of the individual, wherein the second heart beat follows immediately after the first heart beat;

determining a second time between the second heart beat and a third heart beat of the individual, wherein the third heart beat follows immediately after the second heart beat;

determining a factor reflecting the difference between the first time and the second time, wherein

the factor is lowest when the first time is close to the second time, and

the factor increases non-linearly when the absolute difference between the first time the second time grows; and

identifying at least one of an atrial fibrillation event and an atrial flutter event of the individual based on the factor.

14. The method of claim 13, wherein the factor increases more rapidly when the first time grows less than the second time than when the first time grows greater than the second time.

15. The method of claim 13, wherein:

the method further comprises weighting the factor to reflect a relevance of the factor to one of atrial fibrillation and atrial flutter; and

the identifying of the at least one of the atrial fibrillation event and the atrial flutter event is based on the weighted factor.

16. The method of claim 15, wherein weighting the factor comprises:

weighting the factor at a lower end of physiological values as being substantially irrelevant to the one of atrial fibrillation and atrial flutter;

weighting the factor in a midrange of physiological values as being positively indicative of the one of atrial fibrillation and atrial flutter; and

weighting the factor in an upper range of physiological values as being negatively indicative of the one of atrial fibrillation and atrial flutter.

17. The method of claim 13, wherein:

the method further comprise repeating the determining of the first time, the determining of the second time, and the determining of the factor for additional heart beats to generate additional factors; and

the identifying of the at least one of the atrial fibrillation event and the atrial flutter event is based on the additional factors.

18. The method of claim 17, wherein identifying the at least one of the atrial fibrillation event and the atrial flutter event of the individual based on the additional factors comprises identifying the at least one of the atrial fibrillation event and the atrial flutter event of the individual based on between 19 and 199 additional factors.

19. The method of claim 13, wherein determining the factor comprises determining DRR(n) as given by

$$DRR(n) = \mathrm{ABS}\left(\frac{RR(n, n-1)}{RR(n, n-1) + RR(n-1, n-2)} - \frac{1}{2}\right).$$

20. An article comprising one or more machine-readable media storing instructions operable to cause one or more machines to perform operations, the operations comprising:

determining a beat-to-beat variability in cardiac electrical activity;

determining a relevance of the variability over a collection of beats to one of atrial fibrillation and atrial flutter using a non-linear function of a beat-to-beat interval; and

identifying one of an atrial fibrillation event and an atrial flutter event based on the determined relevance, the event being a period in time when the information content of the cardiac electrical activity is of increased relevance to the one of atrial fibrillation and atrial flutter.

21. The article of claim 20, wherein determining the relevance comprises:

weighting variability at a lower end of physiological values as being substantially irrelevant to the one of atrial fibrillation and atrial flutter;

weighting variability in a midrange of physiological values as being positively indicative of the one of atrial fibrillation and atrial flutter;

weighting variability in an upper range of physiological values as being negatively indicative of the one of atrial fibrillation and atrial flutter; and

determining a relevance of the weighted variability to the one of atrial fibrillation and atrial flutter.

22. The article of claim 20, determining the relevance comprises:

identifying a beat of the collection as a ventricular beat, and

weighting the beat as being negatively indicative of the one of atrial fibrillation and atrial flutter.

23. The article of claim 20, wherein:

determining the beat-to-beat variability comprises determining a factor reflecting the difference between a first time between a first heart beat and a second heart beat and a second time between a second heart beat and a third heart beat;

the second heart beat follows immediately after the first heart beat; and

the third heart beat follows immediately after the second heart beat.

24. The article of claim 23, wherein:

the factor is lowest when the first time is close to the second time; and

the factor increases non-linearly when the absolute difference between the first time the second time grows.

25. The article of claim 24, wherein the factor increases more rapidly when the first time grows less than the second time than when the first time grows greater than the second time.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

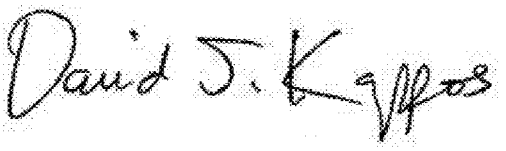
CERTIFICATE OF CORRECTION

PATENT NO.	: 7,941,207 B2
APPLICATION NO.	: 11/674053
DATED	: May 10, 2011
INVENTOR(S)	: Lev Korzinov

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Col. 12, Claim 5, line 46, delete "difference between the first time the second time grows." and insert -- difference between the first time and the second time grows. --

Signed and Sealed this
Second Day of August, 2011



David J. Kappos
Director of the United States Patent and Trademark Office

EXHIBIT L

REDACTED IN ITS ENTIRETY

EXHIBIT M

REDACTED IN ITS ENTIRETY

EXHIBIT N

REDACTED IN ITS ENTIRETY

EXHIBIT O

REDACTED IN ITS ENTIRETY