IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

CARDIONET, LLC, et al.,	:	
Plaintiffs,	:	**CIVIL ACTION**
v.	:	**NO. 12-2516**
THE SCOTTCARE CORPORATION, et al.,	:	
Defendants.	:	

MEMORANDUM

Tucker, J. **July__11___, 2019**

In the present motion, Defendants, The ScottCare Corporation and Ambucor Health Solutions, Inc., ask that the Court grant their Motion for Judgment On The Pleadings Or, In The Alternative, Summary Judgment ("Motion") (Doc. 211) with respect to Plaintiffs' asserted claims of United States Patent Nos. 7,587,237 (the "'237 Patent") and 7,941,207 (the "'207 Patent"). For the reasons set forth more fully below, Defendants' Motion is GRANTED.

I. FACTUAL AND PROCEDURAL BACKGROUND

Plaintiffs, CardioNet, LLC and Braemar Manufacturing, LLC[1] (collectively, "Plaintiffs" or "CardioNet") bring this patent infringement action against Defendants, The ScottCare Corporation and Ambucor Health Solutions, Inc. (collectively, "Defendants" or "ScottCare"), alleging that Defendants are infringing five patents originally owned by CardioNet, which

[1] CardioNet, LLC moved to amend its First Amended Complaint to add Braemar Manufacturing, LLC as co-party to the present action. Braemar Manufacturing, LLC was added to this suit on May 10, 2013. During the Markman Hearing, the only parties present were CardioNet, LLC and ScottCare Corporation.

CardioNet assigned to Braemer Manufacturing, LLC.[2] Pls.' Second Am. Compl., Doc. 58. The patents-in-suit[3]—two of which are the subject of the pending motion[4]—are directed to multiple aspects of an electrocardiographic ("ECG") telemetry device and its software. Pls.' Second Am. Compl., Doc. 58. The ECG telemetry device uses a monitor to record and transmit the electrical activity of the heart over a period of time. Pls.' Second Am. Compl., Ex. C, Doc. 58. This device helps medical professionals monitor a patient's cardiac activity and detect cardiac irregularities. Pls.' Second Am. Compl., Ex. C, Doc. 58. The cardiac data recorded by the ECG telemetry device is transmitted to a remote location where medical technicians review the information. Pls.' Second Am. Compl., Ex. C, Doc. 58. This information can then be sent to a medical professional for further review and diagnosis. Pls.' Second Am. Compl., Ex. C, Doc. 58.

Plaintiffs allege that Defendants have infringed and are continuing to infringe their patents by making, using, selling, and/or offering for sale ScottCare's TeleSentry Mobile Cardiac Telemetry System, which consists of a device that records and processes a patient's ECG signal and a monitoring service whereby personnel at Ambucor evaluate the cardiac data transmitted by the device. Pls.' Second Am. Compl., Doc. 58.

A. Overview of CardioNet's Mobile Cardiac Outpatient Telemetry ("MCOT™") Device

CardioNet LLC, a corporation having its principal place of business in Conshohocken, Pennsylvania, provides continuous, real-time ambulatory "outpatient management solutions for

[2] On December 31, 2012, CardioNet assigned all rights, title, and interest in the five patents-in-suit to Braemar Manufacturing, LLC, and Braemar Manufacturing, LLC granted CardioNet an exclusive license to make, use, offer to sell, sell, import, license, and exploit the patents-in-suit. Pls.' Second Am. Compl. 3, Ex. L, Doc. 58.
[3] U.S. Patent Nos. 7,212,850 (the "'850 Patent"), 7,907,996 (the "'996 Patent"), 6,569,095 (the "'095 Patent"), '237 Patent, and the '207 Patent.
[4] The '237 and '207 Patents.

monitoring clinical information regarding an individual's health." Pls.' Second Am. Compl. 1, Doc. 58. CardioNet LLC, through its MCOT™ device, focuses on the diagnosis and monitoring of cardiac arrhythmias, or heart rhythm disorders. Pls.' Opp'n To Defs.' Mot. J. Pleadings 5, Doc. 224. A cardiac arrhythmia is a disorder of the heart rate or rhythm—i.e. a person's heart beats too quickly, too slowly, or with an irregular pattern. Pls.' Opp'n To Defs.' Mot. J. Pleadings 2, Doc. 224. A physician can diagnose an arrhythmia remotely by monitoring a patient's heart rhythm. *See* Pls.' Opp'n To Defs.' Mot. J. Pleadings 4–5, Doc. 224. If done remotely, an ambulatory cardiac monitoring device will record the patient's heart rate either intermittently or continuously. *See* Pls.' Opp'n To Defs.' Mot. J. Pleadings 4–5, Doc. 224.

The MCOT™ device enables heartbeat-by-heartbeat ECG monitoring, analysis, and response, at home or away, 24 hours a day, 7 days a week, 365 days a year. Pls.' Opp'n To Defs.' Mot. J. Pleadings 5, Doc. 224. The MCOT™ device includes a patient-worn sensor attached to electrodes that capture two-channel ECG data, measuring electrical activity of the heart and communicating wirelessly with a company-handheld-monitor. Pls.' Second Am. Compl., Ex. J, Doc. 58. The monitor analyzes incoming heartbeat-by-heartbeat information from the sensor on a real-time basis by applying algorithms designed to detect abnormal heart "events"—i.e. arrhythmias. *See* Pls.' Opp'n To Defs.' Mot. J. Pleadings 4–5, Doc. 224. When the monitor detects an arrhythmia, "it automatically transmits [ECG] information to [] CardioNet['s] monitoring center for analysis and response." Pls.' Opp'n To Defs.' Mot. J. Pleadings 5, Doc. 224.

B. Overview of the '237 Patent (Patent No. 7,587,237)

The '237 Patent—entitled "Biological Signal Management"—relates to systems and techniques for analyzing and handling a patient's biological signal for medical purposes,

including notifying cardiac monitoring technicians when an arrhythmia has been detected by the device. ’237 Patent, Abstract, Ex. A[5]. Biological signals are electrical or optical streams that, in the medical context, include information relating to the physiological state of an organism which can be used to diagnose and treat disease. ’237 Patent, 1:7–11, Ex. A. The handling of biological signals includes notifying medical personnel at a remote location when an “event,” such as atrial fibrillation or atrial flutter (collectively “AF”), is identified. An event is a period in time when the information content of the cardiac electrical activity is of increased relevance. ’237 Patent, 4:19–23, Ex. A.

The claimed method of the’237 Patent involves receipt of cardiac biological signals involving events; determining a measure of merit for each identified event; comparing the measure of merit to a merit criterion; transmitting information of the events meeting the merit criterion to a remote medical receiver; and discarding information of the events that do not meet the merit criterion. ’237 Patent, Abstract, Ex. A. The ’237 Patent describes a method of analyzing biological signals before handling to reduce data clutter and handling costs. ’237 Patent, 2:43–50, Ex. A. By analyzing the biological signal before handling and only transmitting meritorious events to the monitoring center for review, the volume of data that is handled by the system is reduced, including the volume of data that is reviewed by medical technicians. ’237 Patent at 2:46–50, Ex. A. “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.” ’237 Patent, 2:46–50, Ex. A.

[5] Attached hereto as Exhibit A.

C. Overview of the ’207 Patent (Patent No. 7,941,207)

The ’207 Patent—entitled “Cardiac Monitoring”—relates to “[s]ystems and techniques for monitoring cardiac activity.” ’207 Patent, Abstract, Ex. B.[6] The systems and techniques collect information describing variability in heart beats and determine whether that variability is indicative of AF. Pls.’ Second Am. Compl. Ex. K, Doc. 58. The patented method accomplishes this by: (1) “determining a beat-to-beat variability in cardiac electrical activity,” (2) “determining a relevance of the variability to one of atrial fibrillation and atrial flutter,” and (3) “identifying . . . an atrial fibrillation [] and atrial flutter event based on the determined relevance.” ’207 Patent, 1:49-56, Ex. B.

D. Overview of the Pending Motion

On September 11, 2018, Defendants filed the instant Motion arguing that the ’237 and ’207 Patents are directed to abstract ideas and that the asserted claims do not contain inventive concepts, thereby rendering the Patents ineligible under 35 U.S.C. § 101 (“§ 101”). Defs.’ Mot. for J. On The Pleadings, Or In The Alternative Summ. J. 1, Doc. 211. Defendants further allege that Plaintiffs are collaterally estopped from asserting infringement of claims 1, 2, 8, 9, 10, 21, 22, and 23 of the ’207 Patent because Judge Talwani of the District Court for the District of Massachusetts (“Massachusetts District Court”) found the ’207 Patent ineligible under § 101. *CardioNet, LLC v. InfoBionic, Inc.*, 348 F. Supp. 3d 87 (D. Mass. 2018); Defs.’ Reply in Supp. of Mot. for J. On The Pleadings, Or In The Alternative Summ. J. 2, Doc. 228.

Plaintiffs respond that the ’237 Patent focuses on a specific method, not an abstract idea and the asserted claims recite an inventive concept for analyzing ECG data. Pls.’ Opp’n To Defs.’ Mot. J. Pleadings 11–16, Doc. 224. Regarding the ’207 Patent, Plaintiffs claim that

[6] Attached hereto as Exhibit B.

collateral estoppel does not apply because the Massachusetts District Court did not adjudicate identical issues. Pls.' Opp'n To Defs.' Mot. J. Pleadings 17, Doc. 224. Plaintiffs further argue that the '207 Patent is a specific device rather than an abstract idea and the claims recite inventive concepts that improve AF diagnosis. Pls.' Opp'n To Defs.' Mot. J. Pleadings 21–24, Doc. 224.

II. STANDARD OF REVIEW

Under Federal Rule of Civil Procedure 12(c), a party may move for judgment on the pleadings after the pleadings are closed, as long as the party does so early enough not to delay the trial. Fed. R. Civ. P. 12(c). Courts in this Circuit construe motions for judgment on the pleadings that assert failure to state a claim under the same standard as motions to dismiss made pursuant to Rule 12(b)(6). *Katzenmoyer v. City of Reading*, 158 F. Supp. 2d 491, 496 (E.D. Pa. 2001). "The only notable difference between these two standards is that the court in a motion on the pleadings reviews not only the complaint but also the answer and written instruments attached to the pleadings." *Sprague v. Neil*, No. 1:05-CV-1605, 2007 WL 3085604, at *2 (M.D. Pa. Oct. 19, 2007).

To survive a motion to dismiss under Rule 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 554, 570 (2007)). A complaint is plausible on its face when its factual allegations allow a court to draw a reasonable inference that a defendant is liable for the harm alleged. *Santiago v. Warminster Twp.*, 629 F.3d 121, 128 (3d Cir. 2010). A court must accept as true all factual allegations contained in a complaint and interpret them in the light most favorable to the plaintiff. *Argueta v. U.S. Immigration & Customs Enf't*, 643 F.3d 60, 74 (3d Cir. 2011). "While as a general rule, a

court ma[]y not consider anything beyond the four corners of the complaint on a motion to dismiss pursuant to 12(b)(6), the Third Circuit has held that a court may consider certain narrowly defined types of material without converting the motion to dismiss [to one for summary judgment pursuant [to] Rule 56]." *Nasdaq, Inc. v. IEX Group, Inc.*, 2019 WL 102408, at *2 (D. N.J. 2019) (citing *In re Rockefeller Ctr. Props. Sec. Litig.*, 184 F.3d 280, 287 (3d Cir. 1999). "[D]ocument[s] integral to or explicitly relied upon in the complaint may be considered." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997) (internal quotations omitted).

III. DISCUSSION

In its Motion, Defendants argue that the '237 and '207 Patents are ineligible under § 101 because they are directed to an abstract idea and the asserted claims do not contain an inventive concept. Defs.' Mot. for J. On The Pleadings, Or In The Alternative Summ. J. 2, Doc. 211. Defendants further argue that Plaintiffs are collaterally estopped from alleging infringement of the asserted claims of the '207 Patent. Defs.' Reply in Supp. of Mot. for J. On The Pleadings, Or In The Alternative Summ. J. 2, Doc. 228. For the reasons that follow, the Court agrees and, therefore, Defendants' Motion is GRANTED.

A. Patent Eligibility Under § 101

A patent may be obtained for "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." 35 U.S.C. § 101. "Laws of nature, natural phenomena, and abstract ideas[, however,] are not patentable." *Ass'n. for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2116 (2013) (internal brackets omitted) (quoting *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 70 (2012)). The Supreme Court has established a two-step framework through which courts assess patent

eligibility under § 101. *See Alice Corp. Pty. Ltd. v. CLS Bank Int'l.*, 134 S. Ct. 2347, 2354–55 (2014).

First, a court must determine whether the claims at issue are directed to a patent-ineligible concept—i.e. laws of nature, natural phenomena, or abstract ideas. *Id.* at 2355. Second, if the claims are directed to a patent-ineligible concept, a court then examines whether "the additional elements transform the nature of the claim into a patent-eligible application." *Id.* (internal quotations omitted). To transform an abstract idea into a patent-eligible application, the claims must do "more than simply stat[e] the abstract idea while adding the words 'apply it.'" *Id.* at 2357. Stated otherwise, a court must determine whether the elements of the claim, considered "both individually and as an ordered combination," contain an "inventive concept." *Id.* at 2355 (internal quotations omitted). The presence of an inventive concept will "'transform the nature of the claim' into a patent-eligible application." *Id.* (internal quotations omitted).

B. The '237 Patent

i. Claims 25 and 37 are Representative of All Asserted Claims of the '237 Patent

District courts are not required to assess each asserted claim of infringement where a patent's claims are substantially similar to the representative claims and linked to the same abstract idea. *See Content Extraction & Transmission LLC v. Wells Fargo Bank, Nat'l Ass'n*, 776 F.3d 1343, 1348 (Fed. Cir. 2014) (holding that where all of the claims are directed to the same abstract idea, "addressing each of the asserted patents . . . [is] unnecessary"); *Planet Bingo, LLC v. VKGS LLC*, 576 F. App'x 1005, 1007 (Fed. Cir. 2014) (affirming district court's finding that "[t]he system claims recite the same basic process as the method claims, and the dependent claims recite only slight variations of the independent claims."). The '237 Patent asserts four (4)

independent claims—1, 22, 25, and 37—and six (6) dependent claims—4, 6, 11, 17, 29, and 32. Claims 25 and 37 are representative of the asserted claims of the ’237 Patent.

The ‘237 patent is generally directed to methods of filtering information into different groups based on identifying characteristics and transmitting a portion of this information to the cardiac monitoring center for review by medical technicians. ’237 Patent, Abstract, Ex. A. Claims 1, 22, 25, and 37 explain how information is classified into groups based on certain attributes that relate to specific cardiac conditions; given a measure of merit; and then transmitted or discarded based on a comparison between the measure of merit and merit criterion. ’237 Patent, 15:10–62; 17:4–32; 17:40–18, 18:59–20–3, Ex. A.

Claims 1[i] and 25[ii] are substantially similar in that they provide the same procedure, except that Claim 25 is directed to the software for performing the steps of Claim 1. *Compare* ’237 Patent, 15:10–62, Ex. A *with* 17:40–18:17, Ex. A. Likewise, Claim 22[iii] mirrors the procedure of Claim 37,[iv] except that Claim 37 is directed to the software for performing the steps of Claim 22. *Compare* ’237 Patent, 17:4–32, Ex. A *with* 18:59–20–3, Ex. A. The method claims—Claims 1 and 22—are no different from the software claims—Claims 25 and 37—in substance; each are directed to the same abstract idea of collecting, classifying, or otherwise filtering cardiac data. *See Alice*, 134 S. Ct. at 2360. The method claims recite the abstract idea of “monitoring a cardiac biological signal using [ECG] monitoring instrumentation” while the software claims recite programming instructions “to cause one or more machines to perform [the] operations for monitoring a cardiac biological signal using [ECG] monitoring instrumentation.” ’237 Patent, 15:10–62; 17:4–32; 17:40–18, 18:59–20–3, Ex. A. Accordingly, Claims 25 and 37 accurately represent the asserted independent claims of the ’237 Patent. *See Alice*, 134 S. Ct. at 2360.

The dependent claims—Claims 4, 6, 11, 17, 29, and 32—"recite only slight variations of the independent claims." *Planet Bingo*, 576 F. App'x at 1007. Claims 4,[v] 6,[vi] and 17,[vii] depend on Claim 1 and Claim 11[viii] depends on Claim 9,[ix] which in turn depends on Claim 1. '237 Patent, 16:4–57, Ex. A. Claim 29[x] depends on Claim 27,[xi] which, in turn, depends on Claim 25; and Claim 32[xii] depends on Claim 25. '237 Patent, 18:32–37; 18:44–45, Ex. A. Dependent Claims 4, 6, 11, 17, 29, and 32 define further particulars of Claims 1 and 25, including: (1) using the same filtering process over a certain time span, and excluding events occurring outside of that certain time span; (2) providing that the cardiac biological signal will comprise of a measurement of electrical potential; (3) providing that the information will have a time stamp; and (4) providing that the cardiac biological signal will comprise an ECG signal. '237 Patent, 16:4–57, 18:32–37; 18:44–45, Ex. A. The dependent claims merely provide additional information relating to Claims 1 and 25 by "recit[ing] only slight variations." *Planet Bingo*, 576 F. App'x at 1007. Because Claim 25 is representative of Claim 1, Claim 25 accurately represents the asserted dependent claims of the '237 Patent.

Accordingly, Claims 25 and 37 accurately represent the asserted claims—Claims 1, 4, 6, 11, 17, 22, 29, and 32—of the '237 Patent.

ii. *Alice* Step One Analysis: Patent-Ineligible Concepts

When determining whether computerized technology is directed to an abstract idea, courts "ask whether the focus of the claims is on the specific asserted improvement in computer capabilities . . . or, instead, on a process that qualifies as an 'abstract idea' for which computers are merely invoked as a tool." *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1335–36 (Fed. Cir. 2016), *see also In re TLI Commc'ns LLC Patent Litig.*, 823 F.3d 607, 612 (Fed. Cir. 2016) ("[A] relevant inquiry at step one is to ask whether the claims are directed to an improvement to

computer functionality versus being directed to an abstract idea.") (internal citation omitted) (internal quotations omitted). If "the plain focus of the claim is on an improvement to computer functionality itself, not on economic or other tasks for which a computer is used in its ordinary capacity," it is not directed to an abstract idea. *Enfish*, 822 F.3d at 1336. Conversely, if the claims "are directed to a[n] abstract idea of organizing information through mathematical correlations with recitation of only generic gathering and processing activities," or "recite[] a purely conventional computer implementation of a mathematical formula," it is directed to an abstract idea. *Id*. at 1338–39. Additionally, "[w]here every aspect of the patented method could be carried out manually, courts tend to find that the method is too abstract to be patentable." *SkillSurvey, Inc. v. Checkster, LLC*, 178 F. Supp. 3d 247, 256 (E.D. Pa. 2016).

Patent claims that "merely collect, classify, or otherwise filter data" are patent-ineligible under § 101. *Intellectual Ventures I LLC v. Erie Indem. Co.*, 850 F.3d 1315, 1327 (Fed. Cir. 2017); *see also TLI*, 823 F.3d at 611 (concluding that the patent was directed to the abstract idea of classifying and storing digital images in organized manner); *Content Extraction*, 776 F.3d at 1347 (concluding that the patent was "drawn to the abstract idea of 1) collecting data, 2) recognizing certain data within the collected data set, and 3) storing that recognized data in a memory"); *Bascom Glob. Internet Servs., Inc. v. AT&T Mobility LLC*, 827 F.3d 1341, 1348–49 (Fed. Cir. 2016) (concluding that "content filtering system for filtering content retrieved from an [i]nternet computer network" was directed to an abstract idea); *Cyberfone Sys., LLC v. CNN Interactive Grp., Inc.*, 558 F. App'x 988, 992 (Fed. Cir. 2014) ("the well-known concept of categorical data storage, i.e., the idea of collecting information in classified form, then separating and transmitting that information according to its classification, is an abstract idea that is not patent-eligible.").

a. The asserted claims of the ’237 Patent are directed to an abstract idea.

Defendants argue that the asserted claims of the ’237 Patent are “directed to the abstract idea of organizing human behavior.” Defs.’ Mot. for J. On The Pleadings, Or In The Alternative Summ. J. 16, Doc. 211. Specifically, Defendants contend that the asserted claims are “analogous to a medical professional checking a patient’s physiological heart data, looking for changes and similarities in the data, filtering the data the medical professional deems most valuable, and storing that data for later use.” Defs.’ Mot. for J. On The Pleadings, Or In The Alternative Summ. J. 14, Doc. 211.

Plaintiffs counter that the asserted claims of the ’237 Patent are not directed to an abstract idea because “each claim recites a detailed, computer-implemented method governing the flow and analysis of information between an ECG monitoring instrumentation . . . and a remote medical receiver.” Pls.’ Opp’n To Defs.’ Mot. J. Pleadings 11, Doc. 224.

The asserted claims of the ’237 Patent recite systems and techniques for monitoring “a cardiac biological signal.” ’237 Patent, Abstract, Ex. A. This includes determining a “measure of merit” for each monitored cardiac event. ’237 Patent, 1:28–30, Ex. A. The measure of merit encompasses both the severity of the cardiac condition related to the event and the amount of noise in the information describing the event. ’237 Patent, 1:35–37, Ex. A. The measure of merit for each event is subsequently compared with a merit criterion. ’237 Patent, 1:56–61, Ex. A. Events that have measures of merit meeting the merit criterion are transmitted to a remote medical receiver for review by medical technicians; events that have measures of merit that fail to meet the merit criterion are discarded. ’237 Patent, 1:56–61, Ex. A.

Representative Claims 25 and 37 do not focus “on an improvement to computer functionality itself,” rather the asserted claims are directed to the abstract idea of merely

collecting, classifying, or otherwise filtering data into different groups based on identifying characteristics and transmitting relevant information for review. ’237 Patent, Abstract, Ex. A. Courts have found these types of patent claims to be abstract ideas. *Intellectual Ventures*, 850 F.3d at 1327; *Content Extraction*, 776 F.3d at 1351; *Bascom Glob.*, 827 F.3d at 1348–49; *Cyberfone Sys.*, 558 F. App’x at 990–92.

In *Content Extraction*, the Federal Circuit found the asserted claims invalid as patent ineligible under § 101. *Content Extraction*, 776 F.3d at 1351. The claims asserted methods of “extracting data from hard copy documents using an automated digitizing unit such as a scanner,” “recognizing specific information from the extracted data,” and “storing that information in a memory.” *Id.* at 1344. In conducting step one of its *Alice* analysis, the Federal Circuit determined that the claims of the asserted patent were generally directed to “the abstract idea of 1) collecting data, 2) recognizing certain data within the collected data set, and 3) storing that recognized data in a memory.” *Id.* at 1347. The court explained that “[t]he concept of data collection, recognition, and storage is undisputedly well-known,” and emphasized that “humans have always performed these functions.” *Id.* The court rejected Plaintiff’s argument that the claims were patent eligible because they required hardware to perform functions that humans cannot—processing and recognizing the stream of bits output by the scanner. *Id*. Comparing the asserted claims to “the computer-implemented claims in *Alice*,” the court concluded that the claims were “drawn to the basic concept of data recognition and storage,” even though they recited a scanner. *Id.*

Like the Plaintiff in *Content Extraction*, Plaintiffs have failed to show that the focus of the asserted claims of the ’237 Patent are directed to an improvement in computer functionality, as opposed to generic gathering and processing activities that can be carried out manually.

Representative Claims 25 and 37 reflect analysis that medical professionals have performed. As Plaintiffs explain, "the asserted claims of the '237 Patent . . . enable accurate, automatic review of a large volume of cardiac monitoring data *that was previously reviewed manually by trained technicians*. The claims save physicians or other trained medical personnel from performing costly review of less clinically-significant data." Pls.' Opp'n To Defs.' Mot. J. Pleadings 12, Doc. 224 (emphasis added). The asserted claims of the '237 Patent are directed to the abstract idea of collecting, classifying, and selectively transmitting relevant data. Having made this determination, the Court proceeds to the second step of the *Alice* analysis.

iii. *Alice* Step Two Analysis: Inventive Concept

An abstract idea does not, in and of itself, render it patent ineligible. *Alice*, 134 S. Ct. at 2354. A patent that contains an inventive concept will transform the claimed abstract idea into a patent-eligible application. *Id.* at 2357. To constitute an inventive concept, the claimed abstract idea must be more than "well-understood, routine, conventional activity." *Mayo*, 566 U.S. at 79. "[G]eneric computer implementation" is insufficient to transform an abstract idea into a patent-eligible invention. *Alice*, 134 S. Ct. at 2352, 2357.

a. Use of generic computer technology does not render this otherwise abstract idea inventive.

Defendants argue that the asserted claims of the '237 Patent add nothing inventive to the underlying abstract idea because they "merely automate or otherwise make more efficient, traditional methods or techniques existing in the medical field." Defs.' Mot. for J. On The Pleadings, Or In The Alternative Summ. J. 19, Doc. 211.

Plaintiffs contend that the asserted claims of the '237 Patent "do not merely computerize conventional techniques," but instead recite an inventive concept by "creat[][ing] a combined measurement of the severity of adverse cardiac events together with the signal noise level, to

automatically identify less clinically-significant events." Pls.' Opp'n To Defs.' Mot. J. Pleadings 16, Doc. 224. Plaintiffs further argue that the asserted claims of the '237 Patent are inventive under the "machine-or-transformation" test because the claims are "tied to a particular machine or apparatus, namely [ECG] monitoring instrumentation." Pls.' Opp'n To Defs.' Mot. J. Pleadings 17, Doc. 224.

In *Bascom Glob.*, the Federal Circuit found that patent claims directed to "filtering Internet content" were patent-eligible under § 101. *Bascom Glob.*, 827 F.3d at 1355. Although the Federal Circuit found the asserted claims to be directed to the abstract idea of filtering content, the court determined that the asserted claims contained an inventive concept that transformed the abstract idea into patent-eligible subject matter. *Id.* at 1350–52. In so doing, the Federal Circuit determined that the asserted claims do not: 1) "merely recite the abstract idea of filtering content along with the requirement to perform it on the Internet, or to perform it on a set of generic computer components," and (ii) "preempt all ways of filtering content on the Internet" or on generic computer components performing conventional activities. *Id.* at 1350. The court focused on the technical aspect of the claimed invention and stated that while "[f]iltering content on the Internet was already a known concept, [] the patent describes how its particular arrangement of elements is a technical improvement over prior art . . . filters [that] were either susceptible to hacking and dependent on local hardware and software, or confined to an inflexible one size-fits-all scheme." *Id.* at 1350. The Federal Circuit stated that "[b]y taking a prior art filter solution (one-size fits-all filter at the ISP server) and making it more dynamic and efficient (providing individualized filtering at the ISP server) the claimed invention represents a software-based invention[ ] that improve[s] the performance of the computer system itself." *Id.* at 1351.

Unlike the claims in *Bascom Glob.*, representative Claims 25 and 37 add nothing inventive to the abstract idea of collecting, classifying, and selectively transmitting relevant data. The claim elements, individually or collectively, recite performing the abstract idea with conventional technology and fail to provide any specific, inventive technological improvement.

Claims 25 and 37 describe "[a]n article comprising one or more machine-readable storing instructions operable to cause one or more machines to perform operations for monitoring a cardiac biological signal using [ECG] instrumentation." '237 Patent, 17:40–44; 18:59–63, Ex. A. Notably, a "machine-readable medium" is described as "any computer program product, apparatus and/or device . . . used to provide machine instructions and/or data to a programmable processor" and the term "'machine-readable signal' refers to any signal used to provide machine instructions and/or data to a programmable processor." '237 Patent, 14:17–31, Ex. A. The claims do not provide any specific, inventive technological improvement, but rather provide processing instructions for use on any type of "machine-readable medium." The '237 Patent discloses that a "vari[ety] of implementations of systems and techniques" can be used to implement the Patent's claimed process. '237 Patent, 14:6–57, 14:32–57, Ex. A. Reciting such conventional computer components is insufficient to transform an abstract idea into a patent-eligible invention. *Alice*, 134 S. Ct. at 2352, 2357.

i. The asserted claims of the '237 Patent do not satisfy the machine-or-transformation test.

Under the machine-or-transformation test, a claimed process is patent eligible under § 101 if "it is tied to a particular machine or apparatus" and "the use of a specific machine or transformation of an article . . . impose meaningful limits on the claim's scope." *SiRF Tech., Inc. v. Int'l Trade Com'n*, 601 F.3d 1319, 1332 (Fed. Cir. 2010) (internal citation omitted). "In order for the addition of a machine to impose a meaningful limit on the scope of a claim, it must play a

significant part in permitting the claimed method to be performed, rather than function solely as an obvious mechanism for permitting a solution to be achieved more quickly." *Id.* at 1333. "[S]imply implementing a mathematical principle on a physical machine, namely a computer, [i]s not a patentable application" of an otherwise abstract idea. *Alice*, 134 S. Ct. at 2357 (internal citation omitted).

In *SiRF Tech.*, the Federal Circuit held that certain patents related to global positioning systems ("GPS") were patent-eligible under § 101. *SiRF Tech.*, 601 F.3d at 1333. The patent claims were directed to a method of "estimating a plurality of states associated with a satellite signal receiver" and "forming a dynamic model relating the plurality of states, the dynamic model operative to compute position of the satellite signal receiver." *Id.* at 1332. In concluding that the patents satisfied the machine-or-transformation test, the court found that the "GPS receiver" was held to be a "particular machine" that was "integral to each of the claims at issue." *Id.* The court emphasized that the "methods at issue could not be performed without the use of a GPS receiver," and there was no evidence that "the calculations [ ] c[ould] be performed entirely in the human mind." *Id.* at 1332–33. Because the claimed method could not be "performed without a" GPS receiver, the receiver was indispensable to the patented process. *Id.*

For the reasons stated above, the '237 Patent fails under the machine-or-transformation test. Unlike the claims in *SiRF Tech.*, Plaintiffs' claims are not tied to any particular machine that is integral to the claimed systems and techniques for monitoring cardiac biological signals. The asserted claims merely recite conventional computer components for "permitting a solution to be achieved more quickly" through a machine-readable medium that can be "any computer program product, apparatus and/or device." *SiRF Tech.*, 601 F. 3d at 1333. Because the asserted claims of the '237 Patent are not directed to a specific machine, they do not contain an inventive concept

sufficient to transform the abstract idea into patent-eligible subject matter. For these reasons, the ’237 Patent is directed to an abstract idea and the asserted claims do not add an inventive element. Accordingly, the asserted claims of the ’237 Patent are patent-ineligible under § 101.

C. The ’207 Patent

Defendants argue that Plaintiffs are collaterally estopped from alleging infringement of claims 1, 2, 8, 9, 10, 21, 22, and 23 of the ’207 Patent following the Massachusetts District Court’s decision in *CardioNet, LLC v. InfoBionic, Inc.* 348 F. Supp. 3d 87 (D. Mass. 2018); Defs.’ Reply in Supp. of Mot. for J. On The Pleadings, Or In The Alternative Summ. J. 2, Doc. 228. In that case, in ruling on defendant’s motion to dismiss, Judge Talwani determined that claims 1, 2, 3, 7, 10, 11, 12, and 22 of the ’207 Patent were ineligible under § 101. *InfoBionic*, 348 F. Supp. at 89. Judge Talwani concluded that “the ’207 patent is directed to an abstract idea and the asserted claims do not add [] inventive elements.” *Id.* at 98.

With respect to unadjudicated claims 8, 9, 21, and 23, Defendants maintain that “they present identical issues” and are representative of Claim 1, which was previously invalidated in *InfoBionic*. Defs.’ Reply in Supp. of Mot. for J. On The Pleadings, Or In The Alternative Summ. J.6, Doc. 228.

Plaintiffs argue that collateral estoppel does not apply to the asserted claims of the ’207 Patent because the Massachusetts District Court did not adjudicate claims 8, 9, 21, and 23 of the ’207 Patent. Pls.’ Opp’n To Defs.’ Mot. J. Pleadings 17, Doc. 224. Plaintiffs further argue that “the Massachusetts court based a substantial portion of its opinion on the alleged breadth of [] claims [1, 2, 3, 7, 10, 11, 12, and 22]—a rationale that cannot apply to claims 8, 9, 21, and 23.” Pls.’ Opp’n To Defs.’ Mot. J. Pleadings 17, Doc. 224. Finally Plaintiffs contend that collateral

estoppel should not apply because an appeal is pending. Pls.' Opp'n To Defs.' Mot. J. Pleadings 18–19, Doc. 224.

i. Collateral Estoppel

The doctrine of collateral estoppel—also known as issue preclusion—precludes a party from litigating an issue that has previously been decided in a former judicial proceeding. *Scooper Dooper, Inc. v. Kraftco Corp.*, 494 F.2d 840, 844 (3d Cir. 1974). In *Blonder-Tongue*, the Supreme Court unanimously held that where a patent has been declared invalid in a prior adjudication, an unrelated defendant in a subsequent action for infringement may assert a collateral estoppel defense based on the previous judgment. *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 350 (1971); *Kaiser Indus. Corp. v. Jones & Laughlin Steel Corp.*, 515 F.2d 964, 976 (3d Cir. 1975). In its ruling, the Supreme Court created "a pragmatic formula that harmonized considerations of due process and judicial economy. It was aimed at producing substantial justice while avoiding needlessly repetitious litigation." *Kaiser Indus. Corp.*, 515 F.2d at 976–77.

To invoke the doctrine of collateral estoppel as a defense, a defendant must establish that: (1) the identical issue was previously adjudicated; (2) the issue was actually litigated; (3) the previous determination of the issue was necessary to the decision; and (4) the party being precluded from relitigating the issue was fully represented in the prior action. *Stone v. Johnson*, 608 F. App'x 126, 127 (3d Cir. 2015). The Third Circuit has also considered whether the issue was determined by a final and valid judgment. *Jean Alexander Cosmetics, Inc. v. L'Oreal USA, Inc.*, 458 F.3d 244, 249 (3d Cir. 2006).

ii. Claims 1, 2, 10, and 22

In light of the Supreme Court's holding in *Blonder-Tongue*, this Court finds that Plaintiffs are collaterally estopped from alleging infringement of claims 1, 2, 10, and 22 of the '207 Patent because Judge Talwani of the Massachusetts District Court ruled that these claims are patent ineligible under § 101. *InfoBionic*, 348 F. Supp. 3d at 98. With respect to claims 1, 2, 10, and 22, the only element of collateral estoppel that Plaintiffs dispute is whether the *InfoBionic* decision constitutes a final judgment. Thus, the Court's discussion focuses on this element.

a. The issue was determined by a final judgment.

There is no bright-line rule regarding what constitutes a "final judgment" for issue preclusion purposes. *Free Speech Coal., Inc. v. AG of the United States*, 677 F.3d 519, 541 (3d Cir. 2012). However, "a prior adjudication of an issue in another action must be sufficiently firm to be accorded conclusive effect." *Id.* (internal quotations omitted). When determining whether a prior ruling was sufficiently firm for preclusion purposes, courts consider the following factors: (1) whether the parties were fully heard; (2) whether a reasoned opinion was filed; and (3) whether that decision could have been, or was, appealed. *Id.* None of these factors alone are determinative. *Id.*

The Court finds that the Massachusetts District Court's decision—concluding that Plaintiffs' asserted claims in the '207 Patent are patent-ineligible—constitutes a final judgment for collateral estoppel purposes; the parties were fully heard on the issues, the Massachusetts District Court issued a well-reasoned opinion, and Plaintiffs had a full and fair opportunity to litigate their claims.

First, Plaintiffs were fully heard regarding claims 1, 2, 10, and 22 of the ’207 Patent. Plaintiffs were represented by competent counsel before the Massachusetts District Court and had a full opportunity to brief the issues and present oral argument. Second, the Massachusetts District Court issued a well-reasoned opinion in support of its decisions. The Massachusetts District Court conducted its *Alice* analysis and clearly articulated its basis for concluding that claims 1, 2, 10, and 22 of the ’207 Patent are patent-ineligible because “Plaintiffs’ asserted claims are not directed to any improvement in the computer technology itself, but rather seek to improve cardiac monitoring instead through the abstract idea of measuring the variability of heartbeats.” *InfoBionic*, 348 F. Supp. 3d at 98. Third, Plaintiffs have appealed the Massachusetts District Court’s decision to the Federal Circuit. *In re Brown*, 951 F.2d 564, 569 (3d Cir. 1991) (internal citation omitted) (“In determining whether the resolution was sufficiently firm, the second court should consider whether . . . that decision could have been, or actually was, appealed.”).

Plaintiffs’ contention that collateral estoppel should not apply because the issues have been appealed is unpersuasive. Pls.’ Opp’n To Defs.’ Mot. J. Pleadings 18–19, Doc. 224. The collateral estoppel effect of a prior district court decision is not impacted by the fact that an appeal has been taken from the decision. *See Pharmacia & Upjohn Co. v. Mylan Pharm., Inc.*, 170 F.3d 1373, 1380–81 (Fed. Cir. 1999) (“[T]he law is well settled that the pendency of an appeal has no effect on the finality or binding effect of a trial court’s holding.”); *Rice v. Dep’t of the Treasury*, 998 F.2d 997, 999 (Fed. Cir. 1993); *SSIH Equip. S.A. v. U.S. Int’l Trade Comm’n*, 718 F.2d 365, 370 (Fed. Cir. 1983).

The Court is satisfied that the Massachusetts District Court conducted an appropriate assessment of Plaintiffs' claims. Accordingly, the Court finds that the Massachusetts District Court's order granting defendant's motion to dismiss constitutes a final judgment.

b. The remaining elements of the collateral estoppel analysis are satisfied.

Although Plaintiffs' have not contested the remaining elements of collateral estoppel, the Court has determined that Defendants have satisfied each of the remaining elements. In addition to finality, the doctrine of collateral estoppel requires that the issue in the present litigation is identical to the issue previously adjudicated; the issue to have been actually litigated; the previous determination of the issue to have been necessary to the decision; and the party being precluded from relitigating the issue to have been fully represented in the prior action. *Johnson*, 608 F. App'x at 127.

First, in the prior litigation, the Massachusetts District Court was asked to determine whether claims 1, 2, 3, 7, 10, 11, 12, and 22 of the '207 Patent were patent-ineligible under § 101. *See InfoBionic*, 348 F. Supp. 3d at 89–92. This is precisely the same issue that this Court has been asked to adjudicate with respect to Claims 1, 2, 10, and 22 of the '207 Patent. Second, the Massachusetts District Court's adjudication came after the parties had a full and fair opportunity to brief and argue the issues; thus, the issues were actually litigated. Third, the Massachusetts District Court's decision granting defendant's motion to dismiss was premised on the court's determination that Claims 1, 2, 3, 7, 10, 11, 12, and 22 were patent-ineligible because they "are not directed to any improvement in the computer technology itself, but rather seek to improve cardiac monitoring instead through the abstract idea of measuring the variability of heartbeats." *InfoBionic*, 348 F. Supp. 3d at 98. Therefore, the determination that Claims 1, 2, 10, and 22 were patent-ineligible was necessary to the Massachusetts District Court's decision in

granting defendant's motion to dismiss. Fourth, Plaintiffs, against whom collateral estoppel is asserted in this matter, were the same plaintiffs in the prior litigation. Plaintiffs were represented before the Massachusetts District Court by competent counsel and had a full opportunity to brief the issues. Therefore, the Court finds that Plaintiffs were fully represented in the prior action.

For the reasons stated above, the Court finds that Plaintiffs had a full and fair opportunity to present Claims 1, 2, 3, 7, 10, 11, 12, and 22 of the '207 Patent in the prior litigation. Accordingly, Plaintiffs are collaterally estopped from litigating Claims 1, 2, 10, and 22 of the '207 Patent in the present matter.

iii. Claims 8, 9, 21, and 23

Collateral estoppel is not limited to identical patent claims; it may apply to patent claims that were not previously adjudicated because "[i]t is the issues litigated, not the specific claims around which issues were framed, that is determinative." *Westwood Chem., Inc. v. United States*, 525 F.2d 1367, 1372 (Ct. Cl. 1975). "If the difference between the unadjudicated patent claims and adjudicated patent claims do not materially alter the question of invalidity, collateral estoppel applies." *Ohio Wilson Wood Co. v. Alps South, LLC*, 735 F.3d 1333, 1342 (Fed. Cir. 2013). In this case, Plaintiffs contest Defendants' assertion that the differences between unadjudicated claims 8, 9, 21, and 23 and adjudicated claims 1, 2, 3, 7, 10, 11, 12 and 22 do not materially alter the question of validity under § 101.

As discussed in Section I.C., the '207 Patent discloses devices and techniques for monitoring cardiac activity, in particular, collecting information describing the variability in heart beats, and determining whether that information is indicative of an AF event. '207 Patent, Abstract, 3:7–9, Ex. B. Claims 8, 9, 21, and 23—like previously adjudicated Claims 1, 2, 3, 7, 10, 11, 12 and 22—involve various aspects concerning the variability in beat-to-beat timing; the

relevance of this variability to AF; and the identification of an event when the variability is identified as relevant.

Claim 1 of the '207 Patent, an independent claim, 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 [] 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.

'207 Patent, 12:12–27, Ex. B. Claims 2, 3, 7, 10, 11, and 12 depend on Claim 1, and read as follows:

> 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.
> . . . .
>
> 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.
> . . . .
>
> 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.

'207 Patent, 12:28–36; 12:52–56; 13:5–13, Ex. B. Claim 22 depends upon unasserted Claim 20[xiii] and reads as follows:

> 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.

'207 Patent, 14:39–43, Ex. B. Applying the *Alice* framework to the '207 Patent, Judge Talwani in *InfoBionic* answered the first step in the affirmative. In reaching this conclusion, Judge Talwani stated that:

> Review of the '207 patent shows that the claims add conventional computer components to the abstract idea that AF can be distinguished by focusing on the variability of the irregular heartbeat. The specifications describe systems and techniques with various methods for monitoring that variability. The patent claims at issue in this case thus appear to be similarly directed to collecting and analyzing information to detect particular anomalies, and notifying the user when the anomaly is detected . . . . The idea of using a machine to monitor and analyze heart beat variability and interfering beats so as to alert the user of potential AF events may well improve the field of cardiac telemetry, but Plaintiffs do not identify improvements to any particular computerized technology. Thus, the '207 patent is directed to an abstract idea.

InfoBionic, 348 F. Supp. 3d at 93 (D. Mass. 2018) (internal quotations omitted).

At the second phase of the analysis, Judge Talwani examined and found no innovation in the individual steps of the asserted claims. Judge Talwani explained that Claims 1, 2, 3, 7, 10, 11, 12 and 22 do not "impose[] a meaningful limit on the abstract idea of identifying AF by looking at the variability in time between heartbeats and taking into account ventricular beats." *Id.* at 97.

Judge Talwani emphasized that "Plaintiffs' asserted claims are not directed to any improvement in the computer technology itself, but rather seek to improve cardiac monitoring instead through the abstract idea of measuring the variability of heartbeats." *Id.* at 98. Judge Talwani wrote:

> The 'determination logic' cited by Plaintiffs is not a limitation set forth in the '207 patent. Instead, the 'determination logic' is undefined and unspecified. Claim 1 broadly claims the use of components with 'variability determination logic to determine a variability in the beat-to-beat timing of a collection of beats,' without specifying any limitations to that logic. '207 Patent 16 col. 12:17-18 [# 25-1]. In claim 2, the 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.' *Id.* at col. 12:29-32. In claim 3 '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.' *Id.* at col. 12:33-36. And, in claim 10 'the relevance determination logic comprises logic to identify the relevance of the variability using a non-linear function of a beat-to-beat interval.' *Id.* at 17 col. 13:5-8. The innovation of the '207 patent may be to use computer equipment and logic to monitor the variability of beats, but nothing in these claims places any limitation on that abstract idea.

Id. at 97. While Judge Talwani agreed that Claims 2, 3, 10 and 22 add additional information relating to the variability or determination logic, she determined that they "provide no meaningful details on *how* to implement it, and [,]thus[,] add nothing inventive." *Id.*

Judge Talwani's invalidity analysis regarding Claims 1, 2, 3, 7, 10, 11, 12 and 22 applies to unadjudicated Claims 8, 9, 21, and 23.

Claims 8

Claim 8 depends on invalidated Claim 1. Claim 8 reads as follows:

> 8. The device of claim 1, wherein 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.

'207 Patent, 12:57–67, Ex. B. Claim 1 broadly claims the use of components with "relevance determination logic to identify a relevance of the variability in the beat-to-beat timing to at least one of the atrial fibrillation and atrial flutter." '207 Patent, 12:19–21, Ex. B. Claim 8 merely adds additional information relating to relevance determination logic.

In holding in *InfoBionic* that dependent Claim 2—which is dependent on Claim 1—was patent-ineligible, Judge Talwani stated that the additional information that "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," '207 Patent, 12:28–32, Ex. B, "provided no meaningful details on how to implement it, and thus added nothing inventive." *InfoBionic*, 348 F. Supp. 3d at 98. That Claim 8 also contains further information on weighting ventricular beats does not materially detract from Judge Talwani's invalidity analysis. Simply classifying weight variabilities as "substantially irrelevant," "positively indicative," or "negatively indicative" of AF based on physiological values does not provide any information on how to implement determination or weighting logic. Therefore, like invalidated Claims 2, 10, and 22, Claim 8 provides additional information relating to determination and/or weighting logic, but is void of any details on how to implement it. Accordingly, Claim 8 does not materially alter the question of invalidity that Judge Talwani performed with respect to invalidated Claims 2, 10, and 22.

Claim 9

Claim 9, which depends on Claim 8—which in turn depends on invalidated Claim 1—merely contains the limitation of weighting ventricular beats "as being negatively indicative of the one of atrial fibrillation and atrial flutter." '207 Patent, 13:1–4, Ex. B.

> 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.

'207 Patent, 13:1–4, Ex. B. Claim 9 is not patentably distinct from Claim 2 under the *InfoBionic* analysis; the claims recite substantially similar language. Claim 2 recites the device of Claim 1 as "weighting ventricular beats as being negatively indicative of the one of atrial fibrillation and atrial flutter." '207 Patent, 12:28–36, Ex. B. Claim 9 recites the device of Claim 8—which is the device of Claim 1—as also weighting a "ventricular beat as being negatively indicative of the one of atrial fibrillation and atrial flutter." '207 Patent, 13:1–4, Ex. B. As articulated above, Judge Talwani determined that Claim 2 provided no meaningful details for implementing determination logic. *InfoBionic*, 348 F. Supp. 3d at 97–98. Claim 9 similarly provides no meaningful details for implementing determination logic or determining the weighting factor. Therefore, the further narrowing of Claim 9 does not materially alter the question of invalidity that Judge Talwani performed with respect to invalidated Claims 2, 10, and 22.

Claim 21

Claim 21,[xiv] which depends on unasserted Claim 20, is directed to the software for Claim 8. *Compare* '207 Patent, 12:57–67, Ex. B *with* 14:25–38, Ex. B.

> 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.

'207 Patent, 14:25–38, Ex. B. That Claim 21 is written in terms of "operations" performed by an "article comprising one or more machine-readable media storing instructions" and includes "determining a relevance of the weighted variability to the one of atrial fibrillation and atrial flutter" does not alter the analysis that the Court conducted for Claim 8. *See Alice*, 134 S. Ct. at 2360 (stating that "media claims rise or fall with its method claims").

When confronted with method and system claims that were like one another, the Supreme Court stated:

> [T]he system claims are no different from the method claims in substance. The method claims recite the abstract idea implemented on a generic computer; the system claims recite a handful of generic computer components configured to implement the same idea. This Court has long "warn[ed] . . . against" interpreting § 101 "in ways that make patent eligibility 'depend simply on the draftsman's art.'" Holding that the system claims are patent eligible would have exactly that result.

Alice, 134 S. Ct. at 2360 (internal citations omitted). Here, there is no difference in substance between Claims 8 and 21. Both claims classify weight variabilities as "substantially irrelevant," "positively indicative," or "negatively indicative" of AF based on physiological values. Accordingly, because there is no meaningful difference in substance between Claims 8 and 21, the analysis for Claim 8 applies equally to the analysis for Claim 21. Therefore, like invalidated Claims 2, 10, and 22, Claim 21 provides additional information relating to determination logic, but is void of any details on how to implement it. Accordingly, Claim 21 does not materially

alter the question of invalidity that Judge Talwani performed with respect to Claims 2, 10, and 22.

Claim 23

Claim 23,[xv] which depends on unasserted Claim 20, is directed to determining beat-to-beat variability.

> 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 heartbeat and a second heartbeat and a second time between a second heartbeat and a third heartbeat;
> the second heart beat follows immediately after the first heartbeat; and
> the third heartbeat follows immediately after the second heartbeat.

'207 Patent, 14:44–53, Ex. B. As the '207 Patent specification explains:

> 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.

'207 Patent, 2:4–12, Ex. B.

In examining Claim 3, Judge Talwani found that comparing "times between R waves in three successive QRS complexes" did not explain how to implement variability logic. *InfoBionic*, 348 F. Supp. 3d at 98. "The time period between successive R-waves can be referred to as the R to R interval." '207 Patent, 4:58–59, Ex. B. Three successive QRS complexes include an R-wave R_n, R-wave R_{n-1}, and R-wave R_{n-2}. '207 Patent, 4:54–58, Ex. B. 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). '207 Patent, 4:59–62. This can be illustrated as follows:

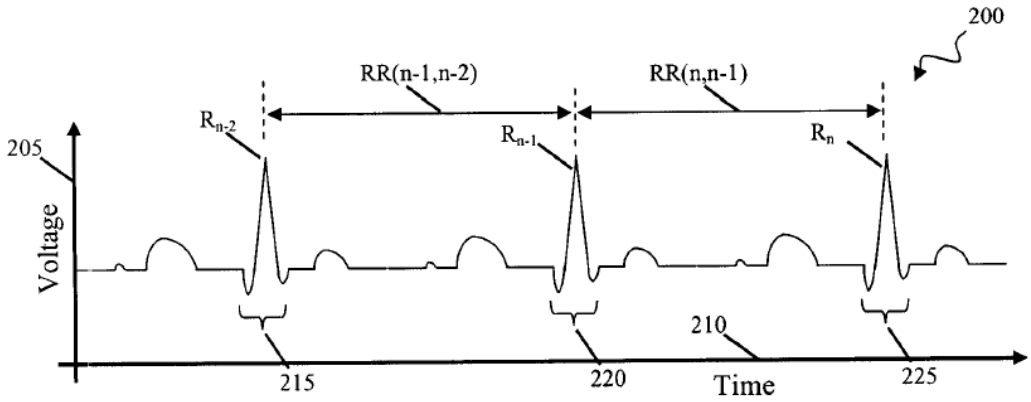

FIG. 2

'207 Patent, Fig. 2, Ex. B.

Like Claim 3, Claim 23 broadly relates to Claim 1 in determining the variability in beat-to-beat timing. Claim 23 is directed to the factor DRR(n) given in Equation 1 of the '207 Patent.

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

'207 Patent, 7:40–45. Equation 1 incorporates the times between successive R-waves—RR(n, n-1) and RR(n-1, n-2)—as a function of a ratio of the first R to R interval and an immediately preceding R to R interval. That Claim 23 determines beat-to-beat variability by "determining a factor reflecting the difference between a first time between a first heartbeat and a second heartbeat and a second time between a second heartbeat and a third heartbeat" is no different than determining beat-to-beat variability by measuring times between R waves in successive

QRS complexes. Claims 3 and 23 both provide information describing a variability in R to R intervals over a series of beats.

Although Claims 3 and 23 recite additional information relating to variability logic, they do not explain how to implement variability logic. Claim 23 does not provide information on how to determine a factor "reflecting the difference between a first time between a first heartbeat and a second heartbeat and a second time between a second heartbeat and a third heartbeat." '207 Patent, 14:44–53, Ex. B. Claim 23 merely recites generic information that is expressed as Equation 1. Equation 1 is merely an algorithm and like Claim 3, does not explain how to ascertain the R-waves—i.e. RR(n, n-1) and RR(n-1, n-2). Accordingly, Claim 23 does not materially alter the analysis that Judge Talwani performed with respect to Claim 3. Claim 23 offers no additional inventive aspect to what was disclosed in Claim 1 and 3 regarding beat-to-beat variability.

Because the Court determined that asserted Claims 8, 9, 21, and 23 do not materially differ from Judge Talwani's analysis of Claims 1, 2, 10, and 22, the Court's collateral estoppel analysis of Claims 1, 2, 10, and 22 applies equally to Claims 8, 9, 21, and 23. Accordingly, Plaintiffs are collaterally estopped from asserting Claims 8, 9, 21, and 23 of the '207 Patent.

iv. *Alice* Step One Analysis: Patent-Ineligible Concepts

Even if collateral estoppel did not apply to Claims 8, 9, 21, and 23, the '207 Patent is directed to an abstract idea and the asserted claims do not add an inventive element thereby rendering it patent-ineligible.

As articulated in Section III.B.ii, when determining whether computerized technology is directed to an abstract idea, courts "ask whether the focus of the claims is on the specific asserted improvement in computer capabilities . . . or, instead, on a process that qualifies as an 'abstract

idea' for which computers are merely invoked as a tool." *Enfish*, 822 F.3d at 1335–36, *see also In re TLI Commc'ns LLC Patent Litig.* 823 F.3d at 612 ("[A] relevant inquiry at step one is to ask whether the claims are directed to an improvement to computer functionality versus being directed to an abstract idea.") (internal citation omitted) (internal quotations omitted). If "the plain focus of the claim is on an improvement to computer functionality itself, not on economic or other tasks for which a computer is used in its ordinary capacity," it is not directed to an abstract idea. *Enfish*, 822 F.3d at 1336. Conversely, if the claims are "directed to a[n] abstract idea of organizing information through mathematical correlations with recitation of only generic gathering and processing activities," or "recite[] a purely conventional computer implementation of a mathematical formula," it is directed to an abstract idea. *Id*. at 1338.

a. The asserted claims of the '207 Patent are directed to an abstract idea.

Defendants contend that the '207 Patent claims "are directed to the abstract idea of identifying common medical conditions—[AF]—by looking at the variability in time between heartbeats and taking into account any ventricular beats." Defs.' Mot. for J. On The Pleadings, Or In The Alternative Summ. J. 20, Doc. 211. Defendants argue that because the '207 Patent claims to automatically identify AF by looking at the "loss of synchrony between the atria and the ventricles [] leading to 'irregular' heartbeats," it "improperly attempts to claim automatically identifying [AF] in the same way doctors have always done." Defs.' Mot. for J. On The Pleadings, Or In The Alternative Summ. J. 20, Doc. 211.

Plaintiffs dispute that the '207 Patent is directed to an abstract idea and argue instead that the focus of the claims is on a specific device, rather than an abstract idea. Pls.' Opp'n To Defs.' Mot. J. Pleadings 21, Doc. 224. Plaintiffs maintain that "[a] device comprising a beat detector, ventricular beat detector, heart beat variability determination logic, and an event generator for

reporting [AF] does not qualify" under any definition as an abstract idea. Pls.' Opp'n To Defs.' Mot. J. Pleadings 21, Doc. 224.

Here, the claims at issue are directed to collecting and analyzing information to detect and notify a user of an AF event. However, "merely presenting the results of abstract process of collecting and analyzing information, without more . . . is abstract as an ancillary part of such collection and analysis." *See FairWarning IP, LLC v. Latric Sys., Inc.*, 839 F.3d 1089, 1093 (Fed. Cir. 2016). The Federal Circuit has "treated collecting information, including when limited to particular content (which does not change its character as information), as within the realm of abstract ideas." *Elec. Power Grp., LLC v. Alstom S.A.*, 830 F.3d 1350, 1353.

In *FairWarning IP, LLC v. Latric Sys., Inc.*, the asserted patent was directed to ways of "detect[ing] fraud and misuse by identifying unusual patterns in user access of sensitive data." *FairWarning IP*, 839 F.3d at 1092. The claimed systems and methods "record[ed] audit log data concerning user access of digitally stored patient health information (PHI)," "analyze[d] it against a rule, and provide[d] a notification if the analysis detect[ed] misuse." *Id.* In finding that the asserted claims were directed to an abstract concept, the Federal Circuit explained that the use of an enumerated rule to analyze log data did not make the claims patent-eligible. *Id.* at 1095. Although plaintiff purported to accelerate the process of analyzing audit log data, the court found that this came from the capabilities of a general-purpose computer, not from the patented method itself. Id. at 1096–97. The court found that the asserted claims were directed "to the broad concept of monitoring audit log data" and did not "propose a solution or overcome a problem 'specifically arising in the realm of computer [technology].'" *Id.* at 1097.

Here, the claims of the '207 Patent recite conventional computer components for detecting AF by examining the variability of heartbeats. The particular claims seek to identify

AF by: (1) "determining a beat-to-beat variability in cardiac electrical activity," (2) "determining a relevance of the variability to one of atrial fibrillation and atrial flutter," and (3) "identifying . . . . an atrial fibrillation [] and atrial flutter event based on the determined relevance." '207 Patent, 1:49–56, Ex. B. Like the claims in *FairWarning*, the claims here merely use a device and software to achieve its intended purpose. The focus of the asserted claims "is not on . . . an improvement in computers as tools, but on certain independently abstract ideas that use computers as tools." *Elec. Power Grp.*, 830 F.3d at 1354. Accordingly, the asserted claims of the '207 Patent are directed to an abstract idea.

v. *Alice* Step Two Analysis: Inventive Concept

Since the Court has determined that that the asserted claims of the '207 Patent are directed to an abstract idea, the Court will now consider whether "the elements of each claim both individually, and as an ordered combination . . . transform the nature of the claim into a patent-eligible application." *Alice*, 134 S. Ct. at 2355 (internal citation omitted).

a. The asserted claims of the '207 Patent do not recite an inventive concept.

Defendants argue that the asserted claims of the '207 Patent "add nothing inventive to the abstract idea of identifying [AF] with conventional technology." Defs.' Mot. for J. On The Pleadings, Or In The Alternative Summ. J. 23, Doc. 211. Defendants maintain that "[t]he asserted claims do not provide any specific or inventive technological improvement" and "say nothing about how to program the standard equipment to accomplish the claimed function." Defs.' Mot. for J. On The Pleadings, Or In The Alternative Summ. J. 23, Doc. 211.

Plaintiffs respond that the claims are not generic and conventional. Pls.' Opp'n To Defs.' Mot. J. Pleadings 22, Doc. 224. Plaintiffs argue that the '207 Patent "explains how to put the

claimed components to a new use to improve cardiac monitoring technology." Pls.' Opp'n To Defs.' Mot. J. Pleadings 22, Doc. 224.

Dependent Claims 8, 9, 21, and 23 add nothing inventive to the abstract idea that AF can be determined by examining the variability of heartbeats by collecting and analyzing information to detect and notify a user of an AF event. The claim elements, individually or collectively, recite performing the abstract idea with conventional technology and fail to provide any specific, inventive technological improvement. *See Intellectual Ventures I LLC v. Symantec Corp.*, 838 F.3d 1307, 1315 (Fed. Cir. 2016) (finding no inventive concept where the claimed method of filtering emails for computer viruses and spam did not "improve the functioning of the computer itself," but rather "used generic computers to perform generic computer functions.").

Claims 8, 9, and 21 relate to relevance determination logic. As discussed in Section III.C.iii., Claims 8, 9, and 21 do not impose any meaningful limitation on determination logic. These claims provide no details for determining relevance. Claim 8 merely classifies weight variabilities as "substantially irrelevant," "positively indicative," or "negatively indicative" of AF based on physiological values. Claim 9 simply contains the limitation of weighting ventricular beats "as being negatively indicative of the one of atrial fibrillation and atrial flutter." And Claim 21 is directed to the software for Claim 8. Claim 21 is written in terms of "operations" performed by an "article comprising one or more machine-readable media storing instructions" and includes "determining a relevance of the weighted variability to the one of atrial fibrillation and atrial flutter." Individually, or collectively, none of these claims contain information regarding how to implement "weighting logic" to determine relevance.

Claim 23 relates to beat-to-beat variability. As discussed in Section III.C.iii., Claim 23 provides additional information relating to variability logic, but does not impose any meaningful

limitation. Claim 23 does not provide information on how to determine a factor "reflecting the difference between a first time between a first heartbeat and a second heartbeat and a second time between a second heartbeat and a third heartbeat." '207 Patent, 14:44–53, Ex. B. Although Claim 23 is related to the factor DRR(n) given in Equation 1[7] of the '207 Patent, this does not transform the asserted claims into patent-eligible subject matter. *Alice*, 134 S. Ct. at 2357 ("simply implementing a mathematical principle on a physical machine, namely a computer, [i]s not a patentable application" of an otherwise abstract idea.) (internal citation omitted).

In *Gottschalk v. Benson*, the Supreme Court determined that an algorithm implemented on "a general-purpose digital computer" was an abstract idea that did not contain an inventive concept because the process could be "carried out in existing computers long in use." 409 U.S. 63, 67 (1972). The Court "held that simply implementing a mathematical principle on a physical machine, namely a computer, was not a patentable application of that principle." *Mayo*, 566 U.S. at 84–85 (citing *Benson*, 409 U.S. at 64). The Court explained that a patent cannot cover all possible uses of a mathematical procedure or equation within a computer.

Here, the '207 Patent specification explains that a "vari[ety] of implementations of" conventional computer hardware/software can be used to implement the claimed functions of the '207 Patent. *See* '207 Patent, 9:22–23, Ex. B; 11:5–9, Ex. B. Specifically, a patient's ventricular beats and the beat-to-beat timing can be determined using "components that can be purchased off-the-shelf such as a QRS detector and the Mortara VERITAS analysis Algorithm or the ELI 250YM Electrocardiograph." Defs.' Mot. for J. On The Pleadings, Or In The Alternative Summ.

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

7

J. 8, Doc. 211. Equation 1 of the ’207 Patent “can be carried out in existing computers” and therefore, like the algorithm in *Gottschalk*, does not transform the asserted claims into patent-eligible subject matter. Equation 1 is not limited to any particular machinery or equipment and instead can be used on any type of conventional computer hardware/software. Further, the “machine-readable medium” referenced in Claim 21 is described as “any computer program product, apparatus and/or device . . . used to provide machine instructions and/or data to a programmable processor.” ’207 Patent, 11:17–30, Ex. B. The ’207 Patent does not claim any new or improved approach in computer technology. As Defendants maintain the ’207 Patent “describes performing the steps in functional terms, using conventional, pre-existing medical and computer technology.” Defs.’ Mot. for J. On The Pleadings, Or In The Alternative Summ. J. 8, Doc. 211.

Plaintiffs’ asserted claims individually, or collectively, are not directed to an improvement in computer technology, but seek to improve cardiac monitoring through the abstract idea of measuring the variability of heartbeats by collecting and analyzing data. Accordingly, the ’207 Patent is directed to an abstract idea and the asserted claims do not add an inventive element.

IV. CONCLUSION

For the reasons stated above, the Court finds that the ’237 and ’207 Patents are directed to abstract ideas and the asserted claims do not add an inventive element thereby rendering the patents ineligible under § 101. The Court also finds that Plaintiffs are collaterally estopped from asserting infringement of Claims 1, 2, 8, 9,10, 21, 22, and 23 of the ’207 Patent. Accordingly, Defendants’ Motion is GRANTED. An order consistent with this memorandum follows.

[i] Claim 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.

’237 Patent, 15:10–62, Ex. A.

[ii] Claim 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 [] 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.

'237 Patent, 17:40–18:17, Ex. A.

[iii] Claim 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.

'237 Patent, 17:4–32, Ex. A.

[iv] Claim 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.

'237 Patent, 18:59–20:3, Ex. A.

[v] Claim 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.

'237 Patent, 16:4–7, Ex. A.

[vi] Claim 6 –The method of claim 1, wherein receiving the cardiac biological signal comprises receiving a measurement of electrical potential. '237 Patent, 16:12–14, Ex. A.

[vii] Claim 17 –The method of claim 1, wherein the cardiac biological signal comprises an electrocardiogram signal. '237 Patent, 16:56–57, Ex. A.

[viii] Claim 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. '237 Patent, 16:34–38, Ex. A.

[ix] Claim 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. '237 Patent, 16:23–26, Ex. A.

[x] Claim 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. '237 Patent, 18:32–37, Ex. A.

[xi] Claim 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. '237 Patent, 18:21–24, Ex. A.

[xii] Claim 32 –The article of claim 25, wherein the cardiac biological signal comprises an electrocardiogram signal. ’237 Patent, 18:43–44, Ex. A.

[xiii] Claim 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.

’207 Patent, 14:12–24, Ex. B.

[xiv] Claim 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.

’207 Patent, 14:25–38, Ex. B.

[xv] Claim 23 – The article of claim 20, wherein:

determining the beat-to-beat variability comprises deter mining a factor reflecting the difference between a first time between a first heartbeat and a second heartbeat and a second time between a second heartbeat and a third heartbeat;

the second heart beat follows immediately after the first heartbeat; and

the third heartbeat follows immediately after the second heartbeat.

’207 Patent, 14:44–53, Ex. B.

Exhibit A

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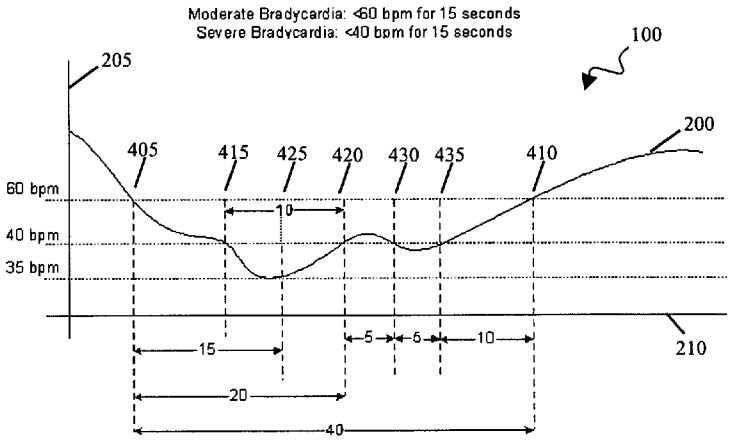
Primary Examiner—Mark W Bockelman
Assistant Examiner—Eric D Bertram
(74) *Attorney, Agent, or Firm*—Fish & Richardson P.C.

(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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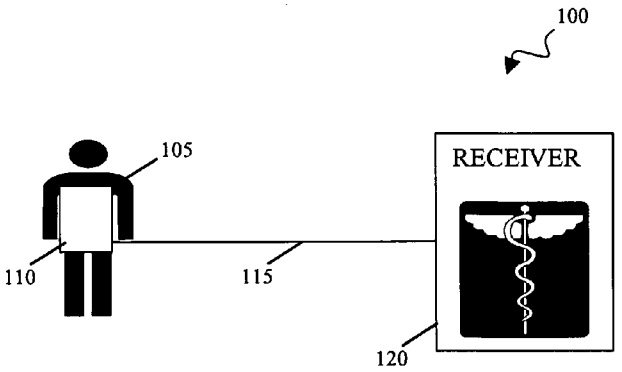


FIG. 1

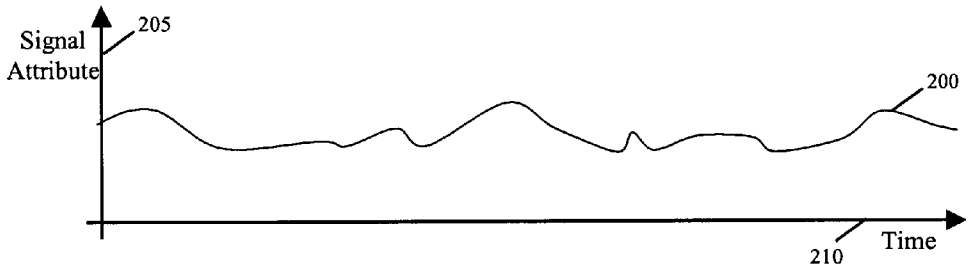


FIG. 2

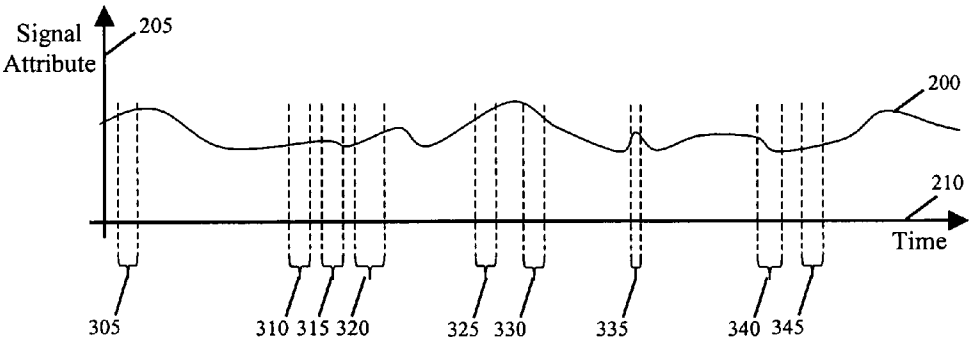


FIG. 3

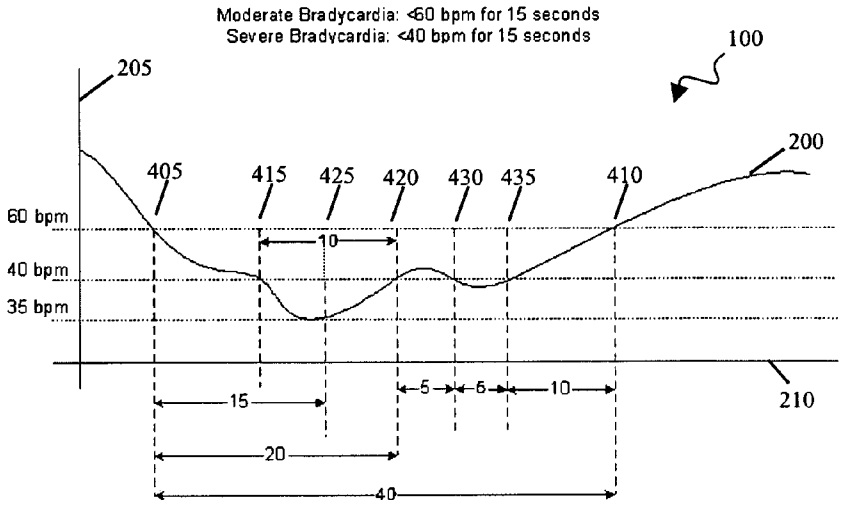

Moderate Bradycardia: <60 bpm for 15 seconds
Severe Bradycardia: <40 bpm for 15 seconds
100
205
200
405
415
425
420
430
435
410
60 bpm
40 bpm
35 bpm
10
15
5
6
10
20
40
210

FIG. 4

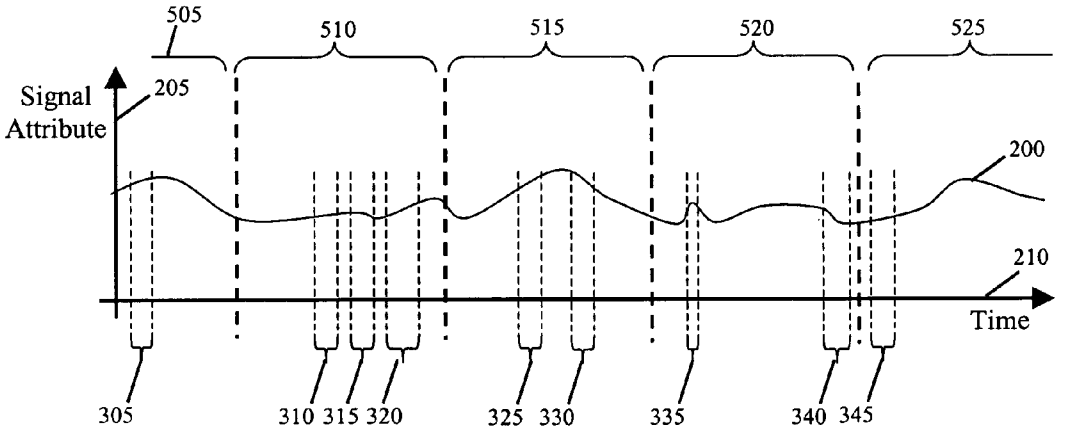

505
510
515
520
525
Signal Attribute
205
200
210
Time
305
310 315 320
325 330
335
340 345

FIG. 5

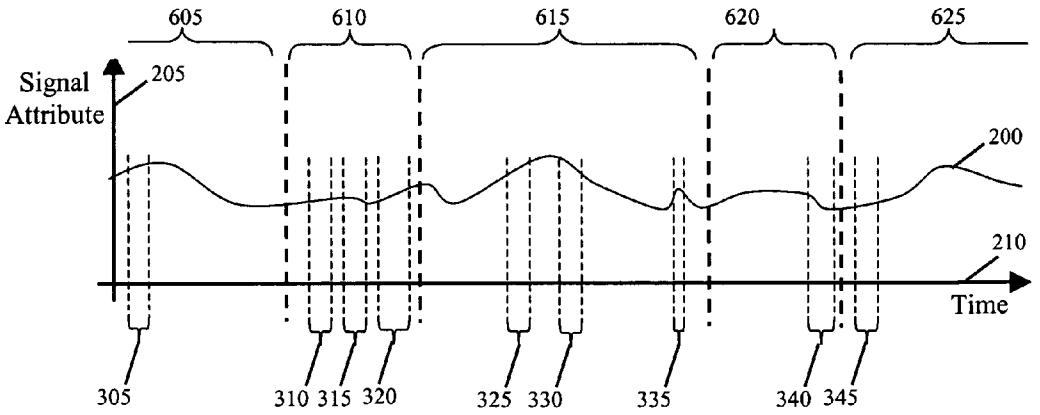


FIG. 6

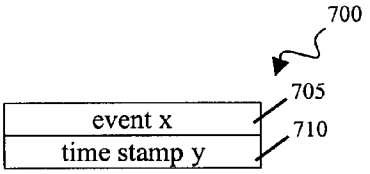


FIG. 7

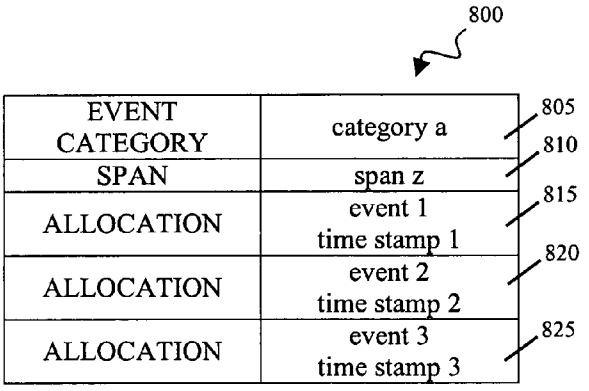


FIG. 8

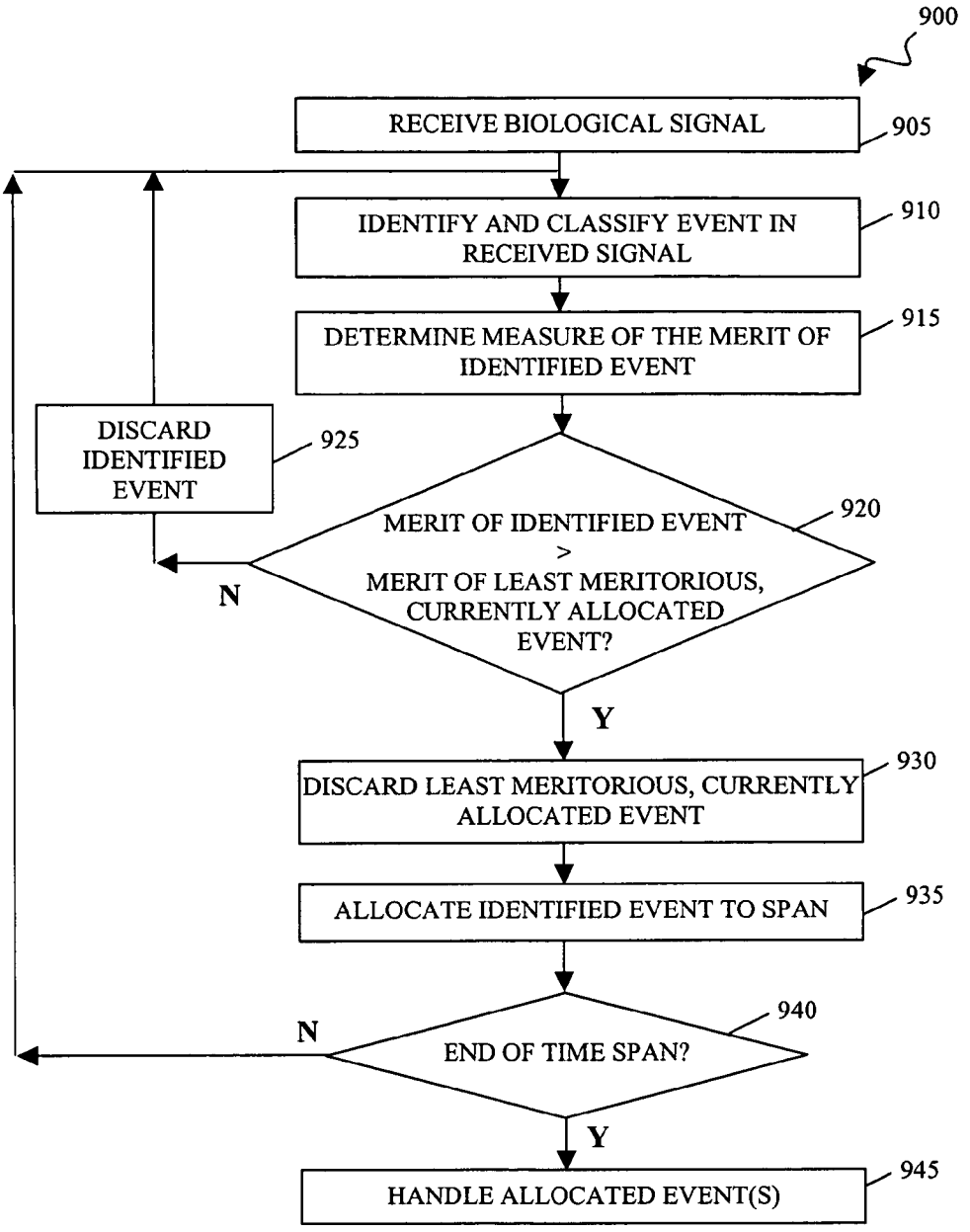

900
RECEIVE BIOLOGICAL SIGNAL
905
IDENTIFY AND CLASSIFY EVENT IN RECEIVED SIGNAL
910
DETERMINE MEASURE OF THE MERIT OF IDENTIFIED EVENT
915
DISCARD IDENTIFIED EVENT
925
MERIT OF IDENTIFIED EVENT > MERIT OF LEAST MERITORIOUS, CURRENTLY ALLOCATED EVENT?
920
N
Y
DISCARD LEAST MERITORIOUS, CURRENTLY ALLOCATED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

FIG. 9

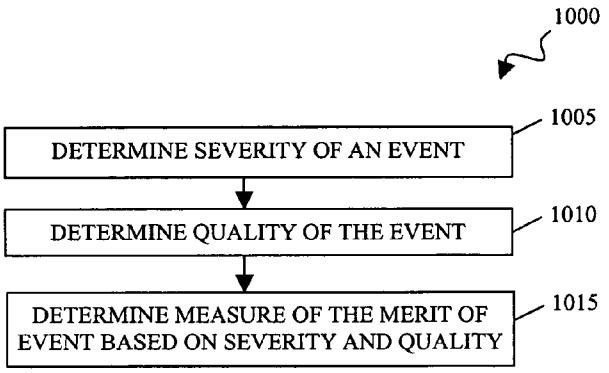
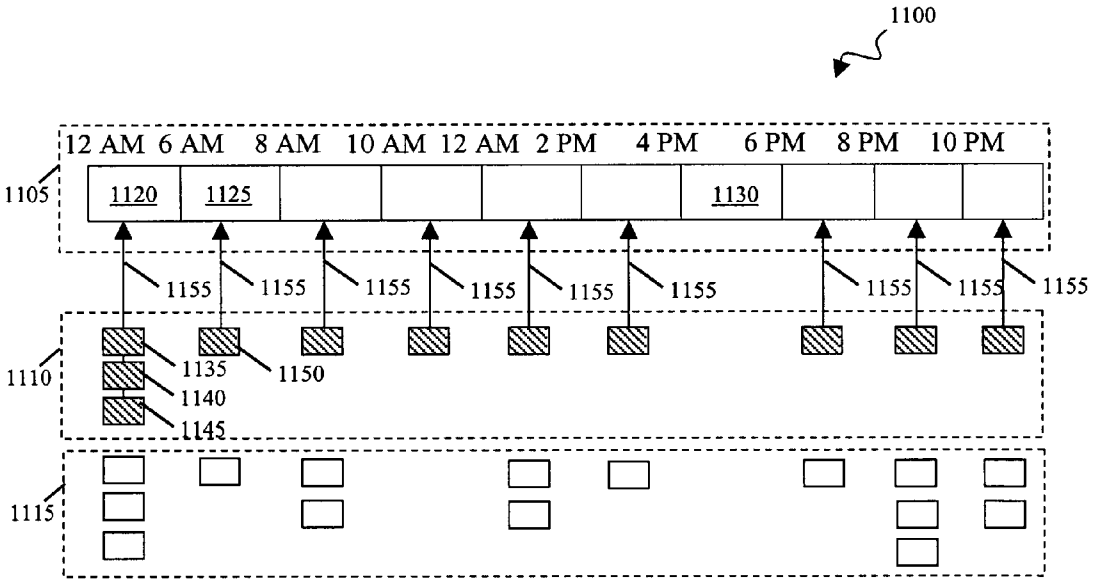

1000
1005
DETERMINE SEVERITY OF AN EVENT
1010
DETERMINE QUALITY OF THE EVENT
1015
DETERMINE MEASURE OF THE MERIT OF EVENT BASED ON SEVERITY AND QUALITY

FIG. 10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1120
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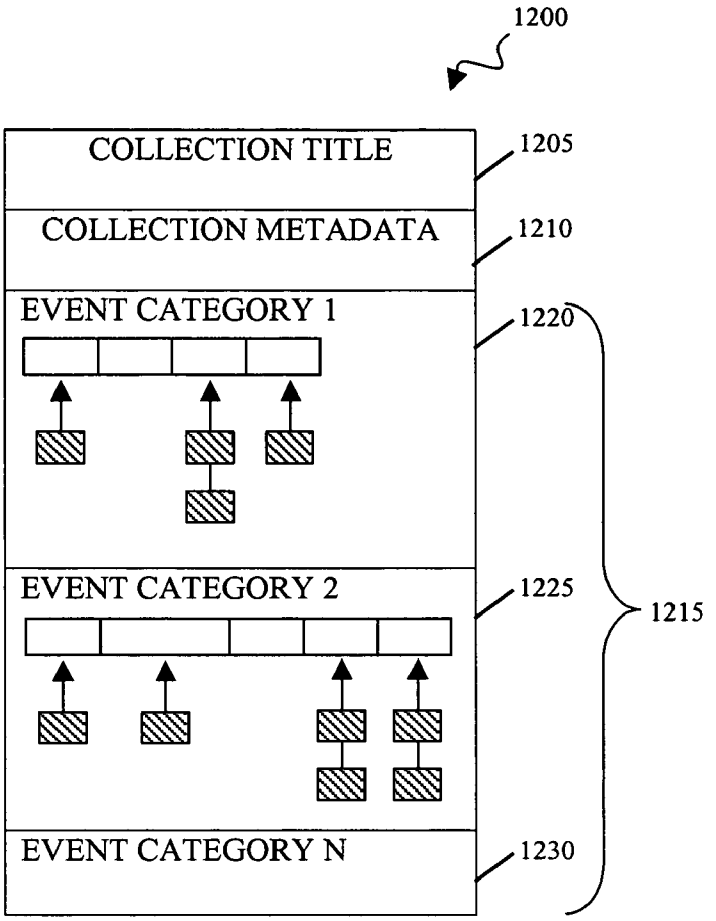
1150
1115

FIG. 11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COLLECTION TITLE
1205
COLLECTION METADATA
1210
EVENT CATEGORY 1
1220
EVENT CATEGORY 2
1225
1215
EVENT CATEGORY N
1230

FIG. 12

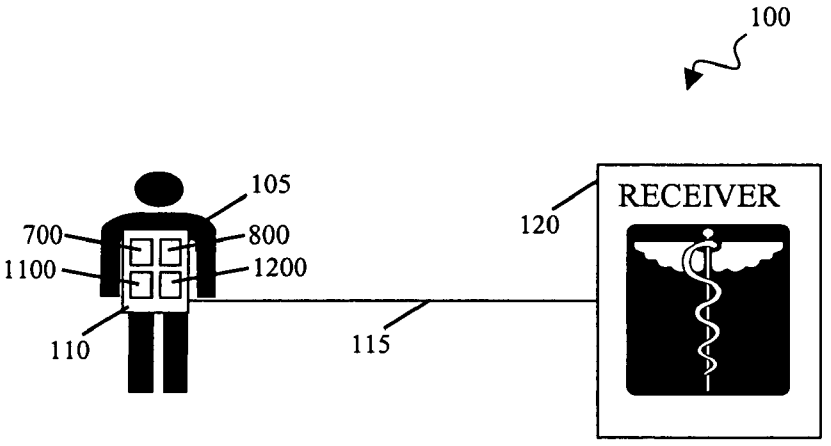

100
105
700
800
1100
1200
110
115
120
RECEIVER

FIG. 13

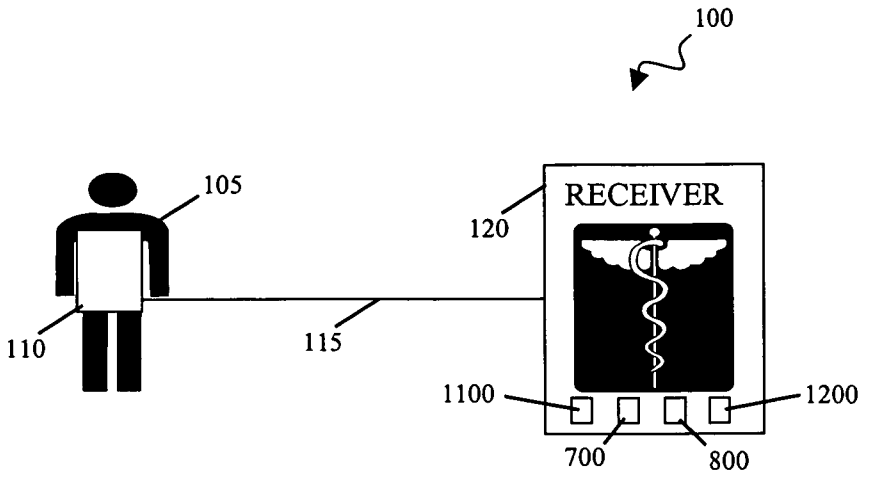

100
105
RECEIVER
120
110
115
1100
1200
700
800

FIG. 14

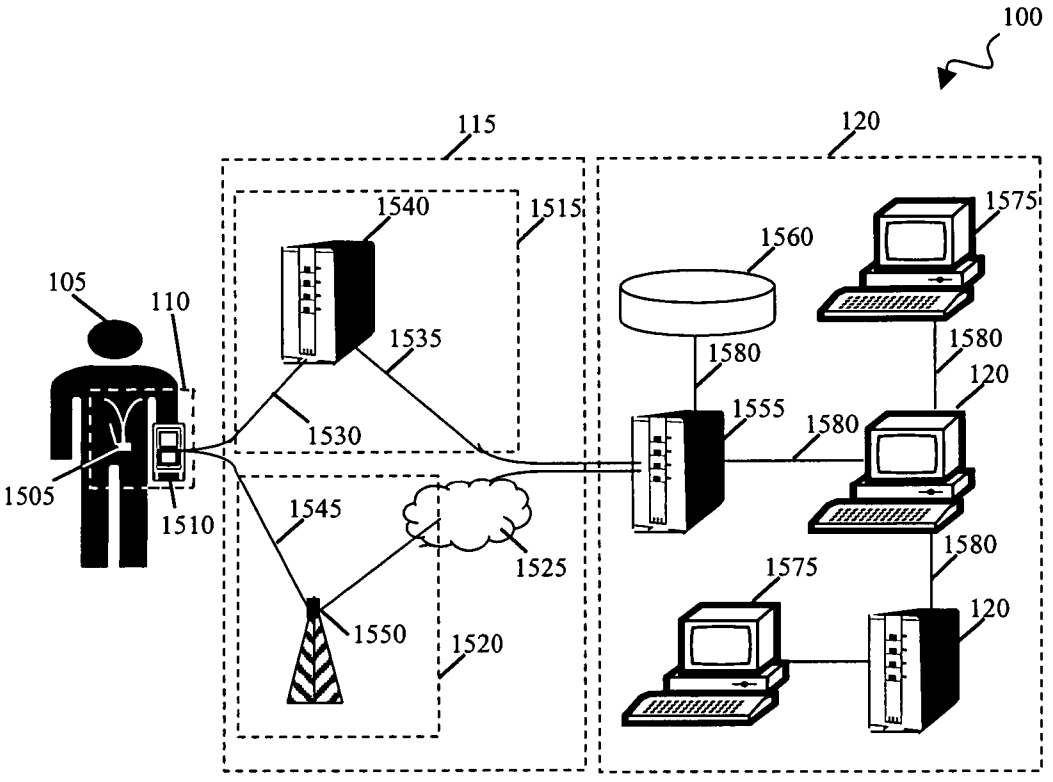

100
115
120
1540
1515
1575
1560
105
110
1535
1580
1580
120
1555
1530
1580
1505
1510
1545
1525
1580
1575
1550
1520
120

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:

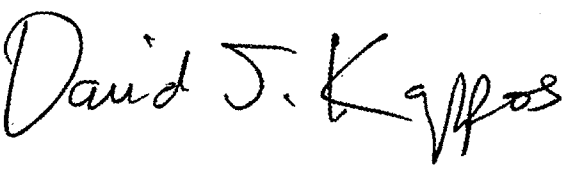
On the Title Page:

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 B

US007941207B2

(12) **United States Patent**
Korzinov

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

(54) **CARDIAC MONITORING**

(75) Inventor: **Lev Korzinov**, 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 1104 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **11/674,053**

(22) Filed: **Feb. 12, 2007**

(65) **Prior Publication Data**

US 2007/0129642 A1 Jun. 7, 2007

Related U.S. Application Data

(63) Continuation of application No. 10/762,887, filed on Jan. 21, 2004, now Pat. No. 7,194,300.

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

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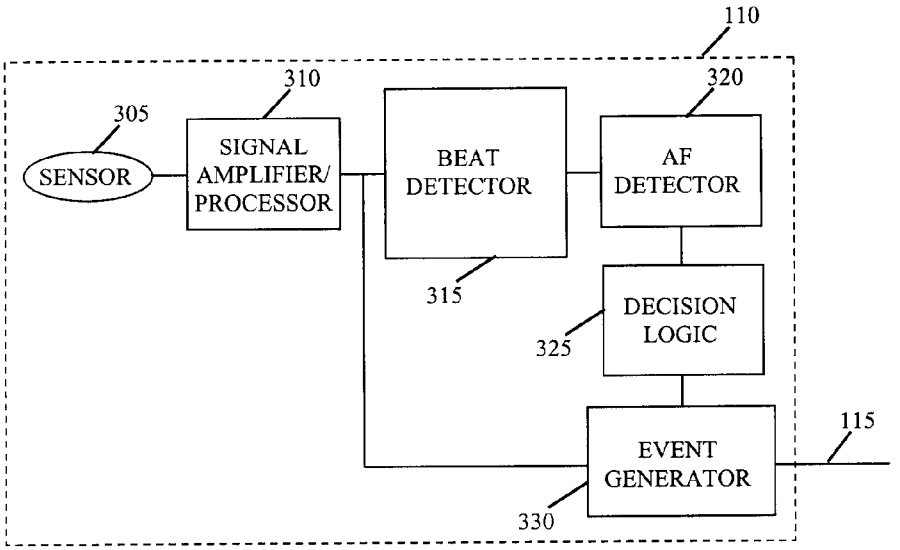
Primary Examiner — George Manuel
(74) *Attorney, Agent, or Firm* — Fish & Richardson P.C.

(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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Machine translation of JP 10-234688 from Patent Abstracts of Japan (7 pages).

* cited by examiner

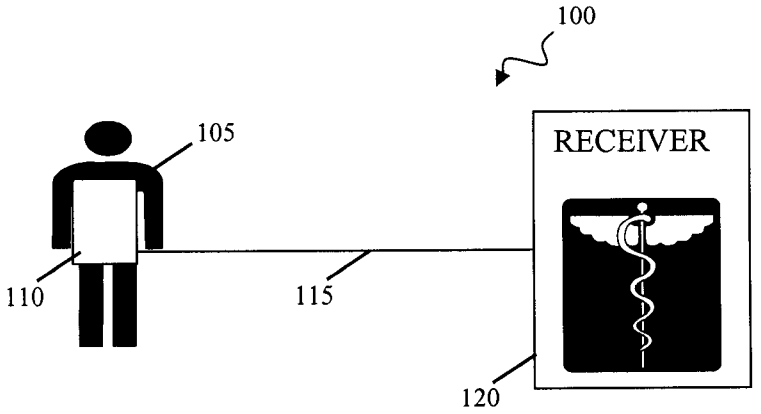

FIG. 1

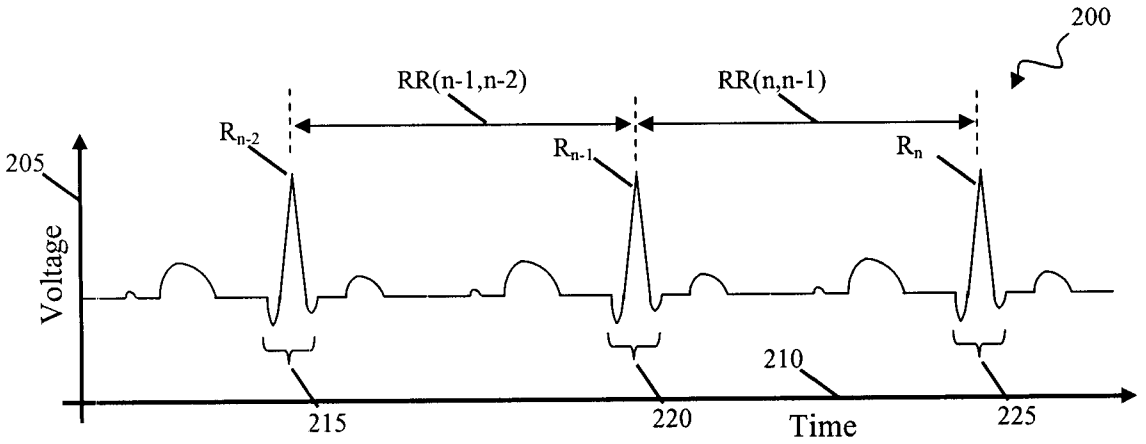

FIG. 2

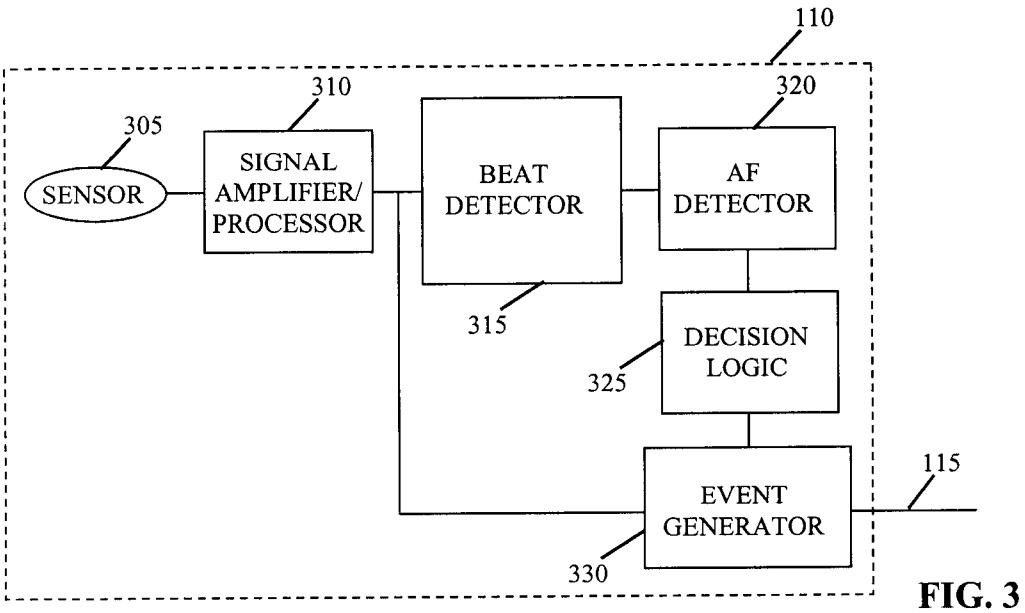

FIG. 3

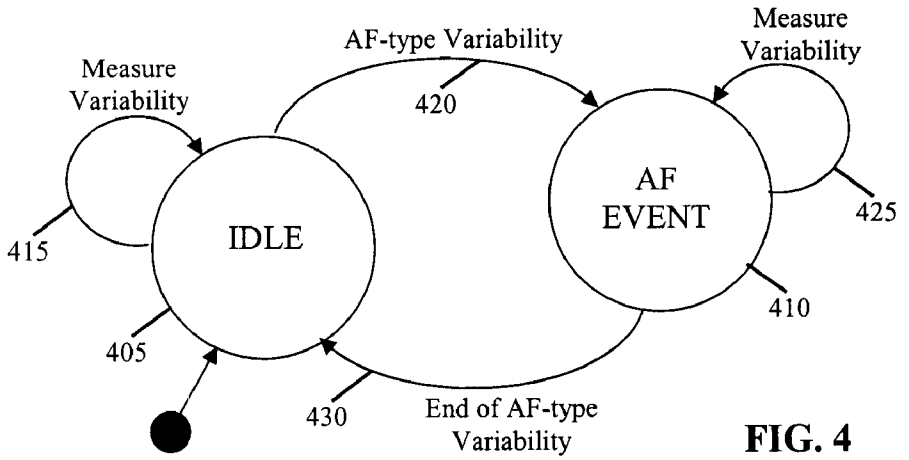

FIG. 4

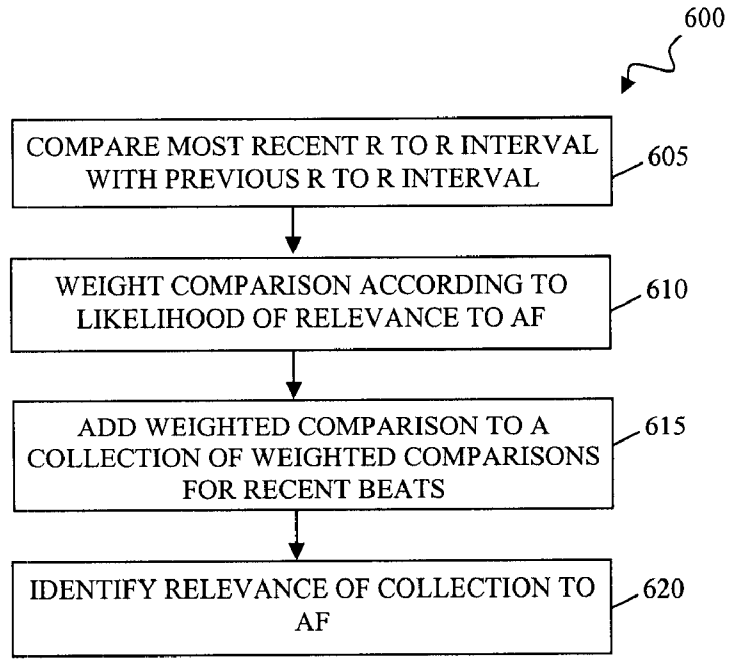

FIG. 6A

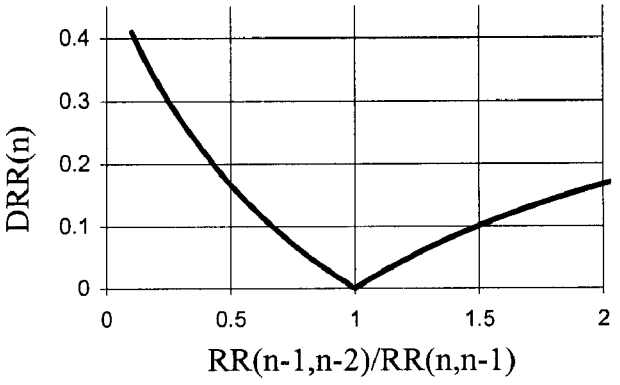

FIG. 6B

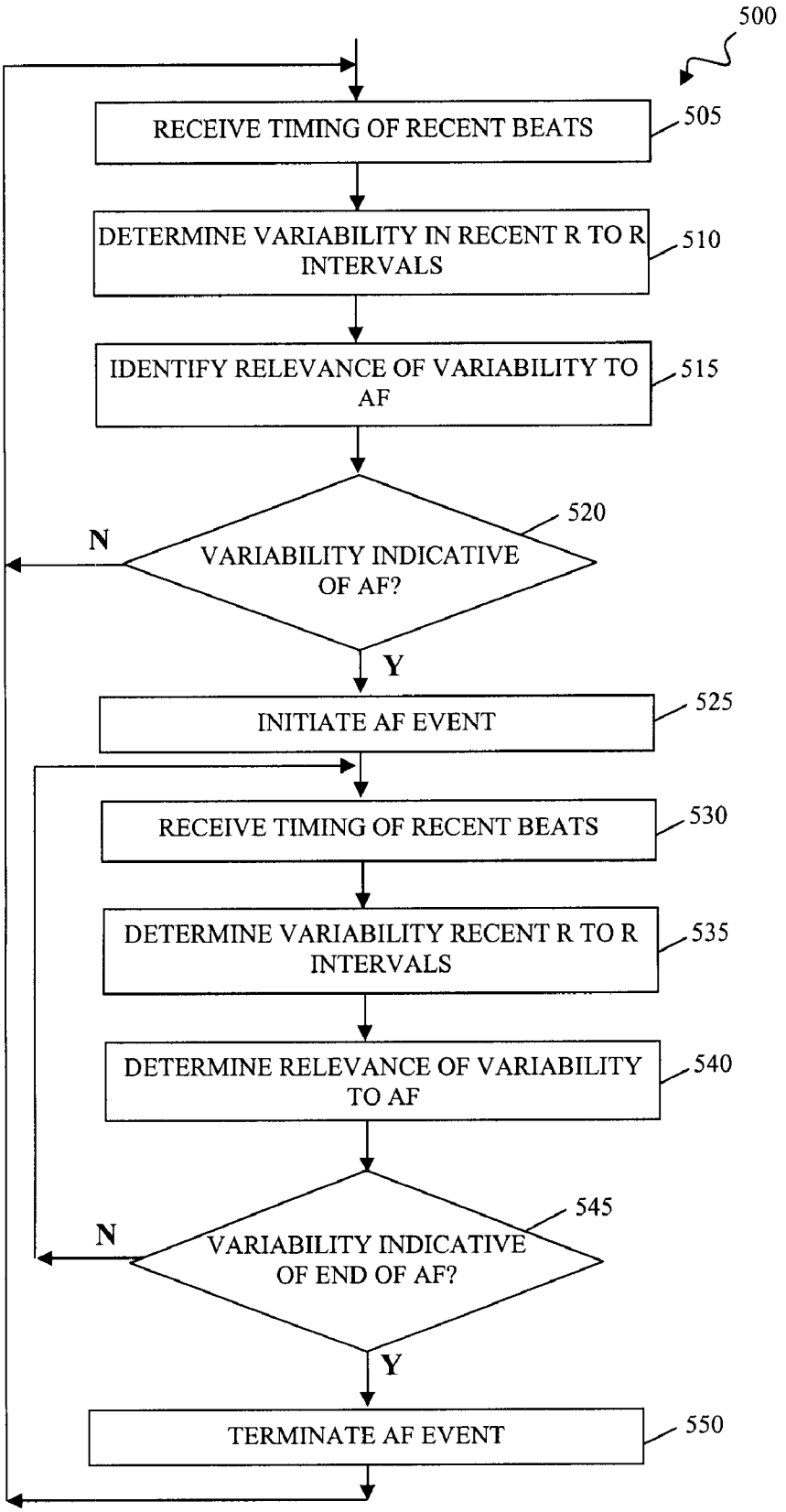
500
RECEIVE TIMING OF RECENT BEATS
505
DETERMINE VARIABILITY IN RECENT R TO R INTERVALS
510
IDENTIFY RELEVANCE OF VARIABILITY TO AF
515
VARIABILITY INDICATIVE OF AF?
520
N
Y
INITIATE AF EVENT
525
RECEIVE TIMING OF RECENT BEATS
530
DETERMINE VARIABILITY RECENT R TO R INTERVALS
535
DETERMINE RELEVANCE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

FIG. 5

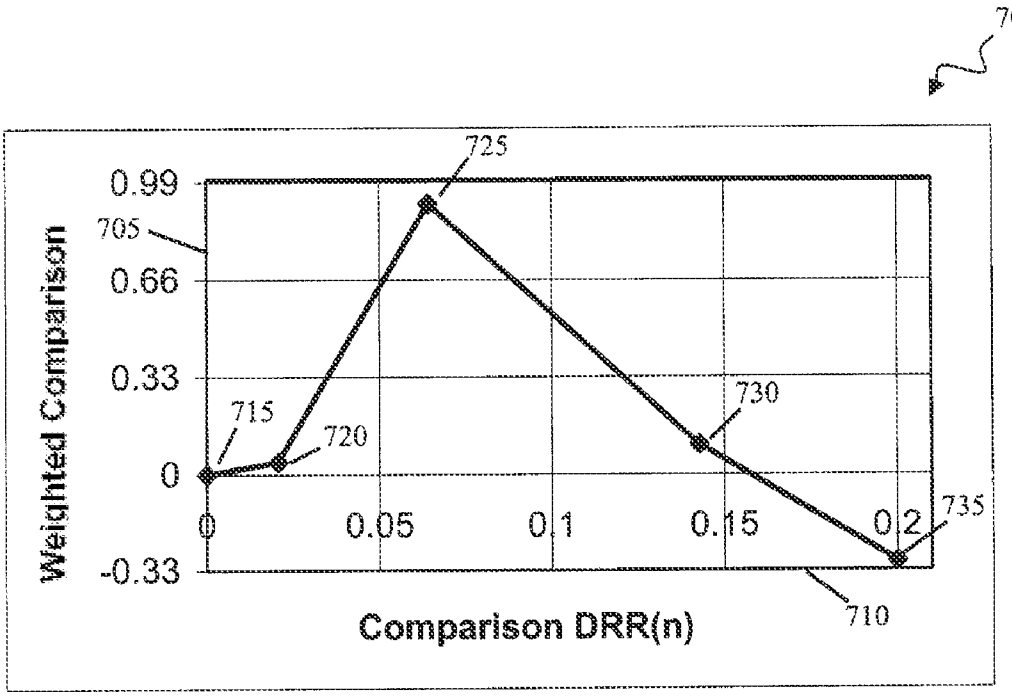
700
725
705
0.99
0.66
0.33
0
-0.33
715
720
730
735
710
0
0.05
0.1
0.15
0.2
Weighted Comparison
Comparison DRR(n)

FIG. 7

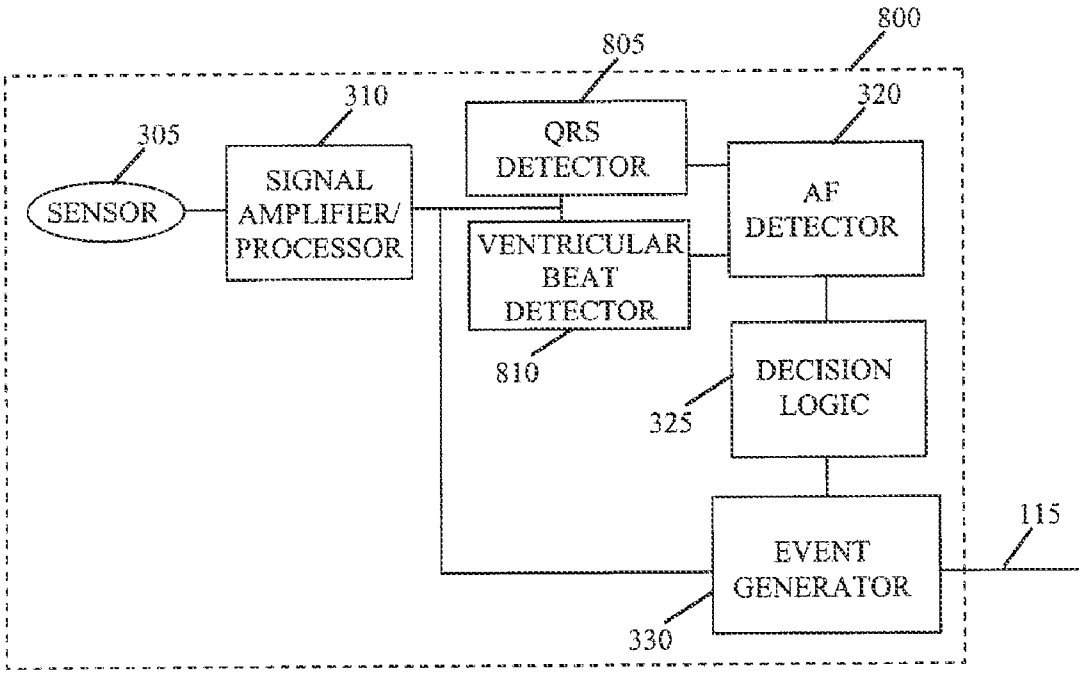
800
805
310
320
305
SENSOR
SIGNAL AMPLIFIER/ PROCESSOR
QRS DETECTOR
AF DETECTOR
VENTRICULAR BEAT DETECTOR
810
DECISION LOGIC
325
EVENT GENERATOR
330
115

FIG. 8

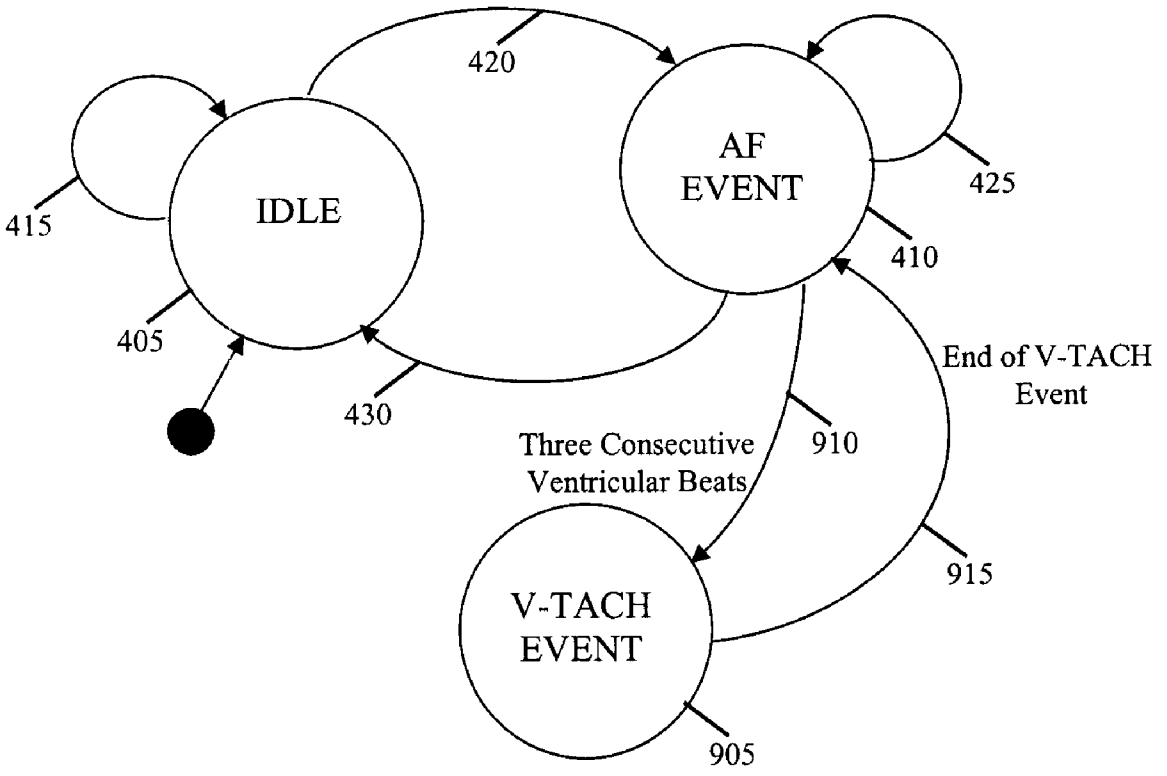
420
AF
EVENT
425
IDLE
415
410
405
End of V-TACH
Event
430
Three Consecutive
Ventricular Beats
910
915
V-TACH
EVENT
905

FIG. 9

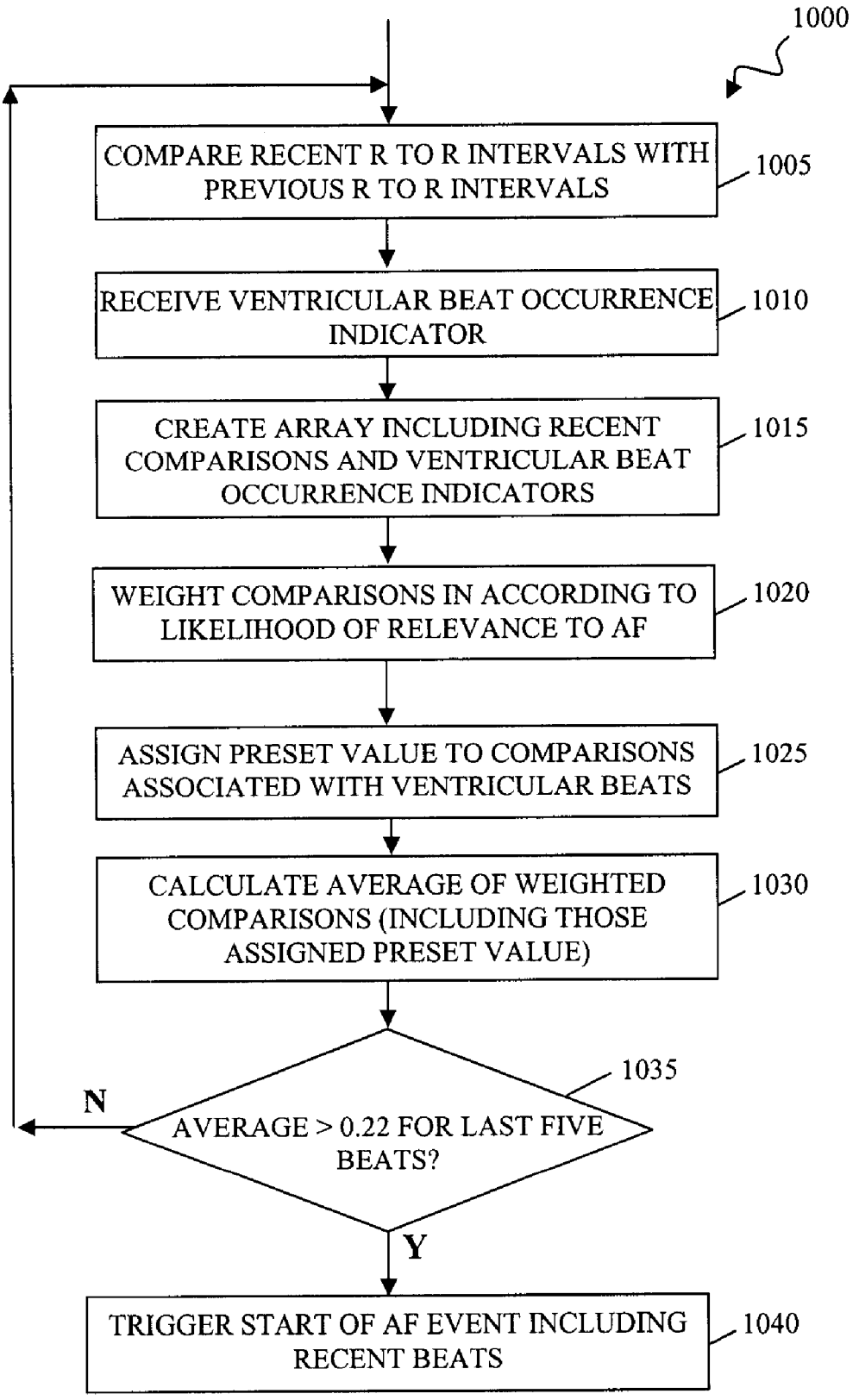
1000
COMPARE RECENT R TO R INTERVALS WITH PREVIOUS R TO R INTERVALS
1005
RECEIVE VENTRICULAR BEAT OCCURRENCE INDICATOR
1010
CREATE ARRAY INCLUDING RECENT COMPARISONS AND VENTRICULAR BEAT OCCURRENCE INDICATORS
1015
WEIGHT COMPARISONS IN ACCORDING TO LIKELIHOOD OF RELEVANCE TO AF
1020
ASSIGN PRESET VALUE 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

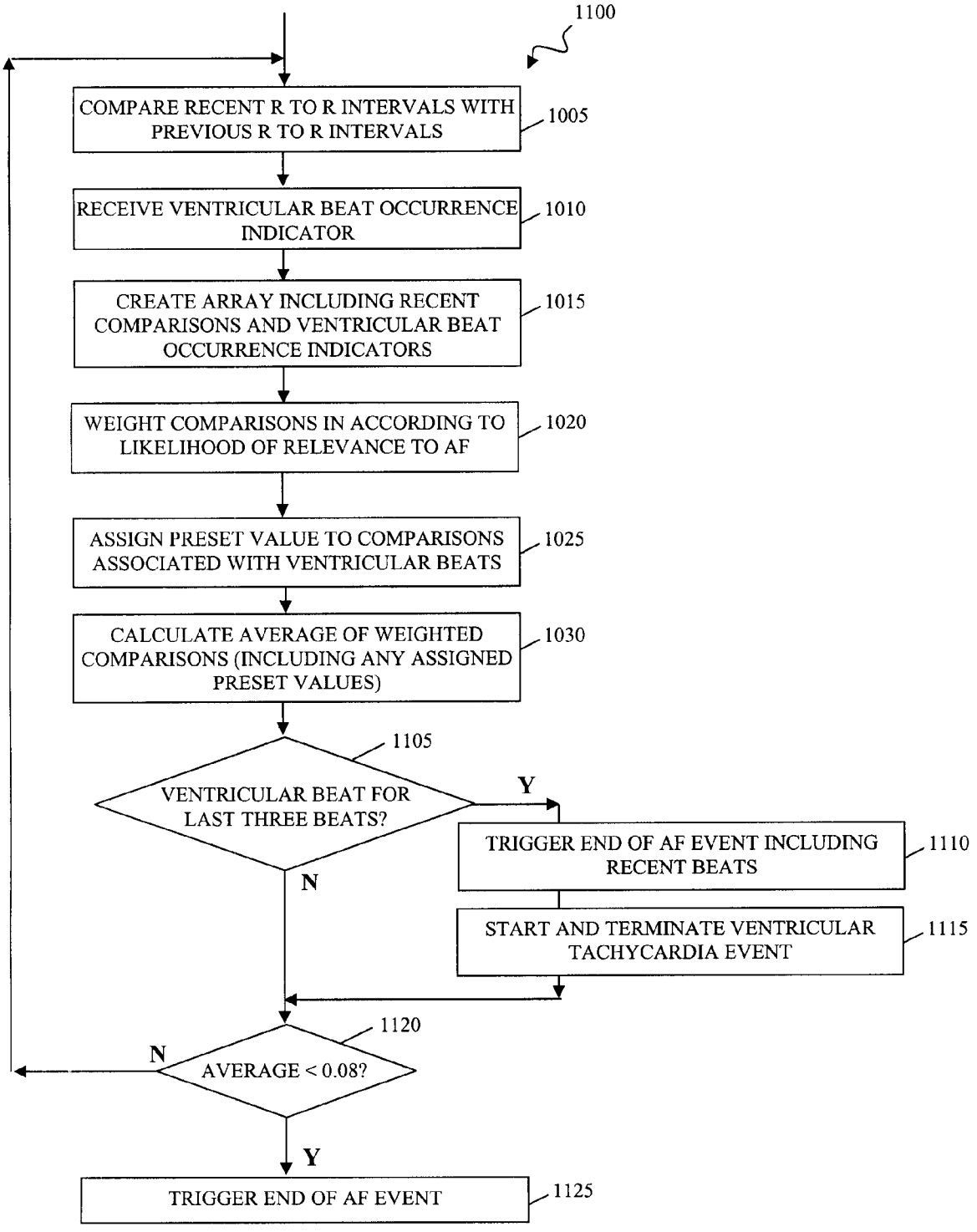
1100
COMPARE RECENT R TO R INTERVALS WITH PREVIOUS R TO R INTERVALS
1005
RECEIVE VENTRICULAR BEAT OCCURRENCE INDICATOR
1010
CREATE ARRAY INCLUDING RECENT COMPARISONS AND VENTRICULAR BEAT OCCURRENCE INDICATORS
1015
WEIGHT COMPARISONS IN ACCORDING TO LIKELIHOOD OF RELEVANCE TO AF
1020
ASSIGN PRESET VALUE 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

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