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Filed on behalf of: InfoBionic, Inc.

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INFOBIONIC, INC.
Petitioner,

v.

BRAEMAR MANUFACTURING, LLC
Patent Owner.

Patent No. 7,212,850

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 7,212,850

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LISTING OF EXHIBITS[1]

Exhibit	Description
Ex. 1001	U.S. Patent No. 7,212,850 to Prystowsky et al.
Ex. 1002	Declaration of Robert T. Stone, Ph.D.
Ex. 1003	Prosecution History of U.S. Patent No. 7,212,850
Ex. 1004	U.S. Provisional Application No. 60/525,386
Ex. 1005	U.S. Patent No. 6,490,479 to Bock
Ex. 1006	U.S. Patent No. 7,490,085 to Walker et al.
Ex. 1007	U.S. Patent No. 4,531,527 to Reinhold, Jr. et al.
Ex. 1008	ACC/AHA Guidelines for Ambulatory Electrocardiography, Journal of the American College of Cardiology, Vol. 34, No. 3, September 1999, pp. 912-948 ("*ACC Guidelines*")
Ex. 1009	U.S. Patent No. 6,470,210 to Chen et al.
Ex. 1010	Plaintiff Cardionet, Inc.'s Opening Claim Construction Memorandum in CardioNet, Inc. v. MedNet Healthcare Technologies, Inc. et al., Civil Action 12-cv-2517 (JS), United States District Court Eastern District of

[1] Citations to non-patent publications are to the exhibit page numbers and citations to patent publications are to column:line number of the patents.

	Pennsylvania, dated January 9, 2013.
Ex. 1011	Memorandum Opinion in CardioNet, Inc., et al. v. The Scottcare Corporation and Ambucor Health Solutions, Inc., Civil Action No. 2:12-cv-2516, United States District Court Eastern District of Pennsylvania, dated October 8, 2014.
Ex. 1012	Plaintiff Cardionet, Inc.'s Opening Claim Construction Memorandum in CardioNet, Inc. v. The Scottcare Corporation and Ambucor Health Solutions, Inc., Civil Action No. 12-cv-2516 (PBT), United States District Court Eastern District of Pennsylvania, dated March 13, 2013.
Ex. 1013	Memorandum in CardioNet, Inc., et al. v. MedNet Healthcare Technologies, Inc., et al., Civil Action No. 12-2517, United States District Court Eastern District of Pennsylvania, dated November 15, 2013.
Ex. 1014	Definitions of "correlation" and "measure" from Merriam-Webster's Collegiate Dictionary, Tenth Edition, Copyright 2001, pages 260, 719.

I. INTRODUCTION

On behalf of InfoBionic, Inc. ("InfoBionic" or "Petitioner") and in accordance with 35 U.S.C. § 311 and 37 C.F.R. § 42.100, Petitioner requests *inter partes* review (IPR) of claims 1-9, 20, 21, 31-34, 37, and 38 of U.S. Patent No. 7,212,850 to Prystowsky et al. ("the '850 patent," Ex. 1001). This Petition establishes that there is a reasonable likelihood that Petitioner will prevail with respect to at least one of the challenged claims. This Petition also establishes by a preponderance of evidence that claims 1-9, 20, 21, 31-34, 37, and 38 of the '850 patent are unpatentable under 35 U.S.C. § 103(a). Accordingly, these claims should be cancelled.

II. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8(a)(1)

Real Party-in-Interest: Pursuant to 37 C.F.R. § 42.8(b)(1), Petitioner, InfoBionic, Inc., is the real party-in-interest.

Related Matters: Per 37 C.F.R. § 42.8(b)(2), Petitioner identifies related matters. Braemar Manufacturing, LLC ("Braemar" or "Patent Owner"), the alleged owner by assignment of the '850 patent, and CardioNet LLC ("CardioNet"), the alleged exclusive licensee of the '850 patent, have asserted the '850 patent and U.S. Patent Nos. 7,907,996 ("the '996 patent"), 6,225,901 ("the '901 patent"), and 6,940,403 ("the '403 patent") against Petitioner in a civil action titled *CardioNet, LLC et al. v. InfoBionic, Inc.*, Case No. 1:15-cv-11803, at the

United States District Court, District of Massachusetts. This action is currently pending. Petitioner is concurrently filing petitions for *inter partes* review of the '996 patent, the '901 patent, and the '403 patent.

The '850 patent and '996 patent have also been asserted in two additional patent litigation actions in the Eastern District of Pennsylvania: (1) *CardioNet, Inc. et al. v. The Scottcare Corp. et al.*, Case No. 2:12-cv-2516 (pending); and (2) *CardioNet, Inc. et al. v. MedNet Healthcare Tech. Inc. et al.*, Case No. 2:12-cv-02517 (terminated).

U.S. Patent Application No. 14/593,237 claims priority to the '850 patent and is pending before the Patent Office.

Counsel and Service Information: Lead counsel is Leslie Bookoff (Reg. No. 38,084) and back-up counsel are Dinesh Melwani (Reg. No. 60,670), and Biju Chandran (Reg. No. 63,684). Addresses for hand and postal delivery of service is: Bookoff McAndrews, PLLC, 2401 Pennsylvania Ave., NW, Suite 450, Washington, DC 20037. Addresses for electronic mail delivery of service are: docketing@bookoffmcandrews.com, lbookoff@bookoffmcandrews.com, dmelwani@bookoffmcandrews.com, and bchandran@bookoffmcandrews.com. Petitioner consents to electronic service. The lead and backup counsel can be reached by phone at (202) 808-3494 and by facsimile at (202) 450-5538.

III. NOTICE OF FEES PAID UNDER 37 C.F.R. § 42.15(a)

Petitioner submits the required fees with this petition. Please charge any additional fees required for this proceeding to Deposit Account No. 50-5906.

IV. CERTIFICATION OF GROUNDS FOR STANDING UNDER 37 C.F.R. § 42.104(a)

Petitioner certifies that the '850 patent is available for *inter partes* review, and that the Petitioner is not barred or estopped from requesting such review of the '850 patent on the grounds identified in this Petition.

V. IDENTIFICATION OF CHALLENGE AND RELIEF REQUESTED UNDER 37 C.F.R. § 42.104(b)(1)-(3)

As described in more detail in Section IX, claims 1-9, 20, 21, 31-34, 37, and 38 of the '850 patent are unpatentable in view of the references and grounds listed below. Therefore, it is respectfully requested that these claims be cancelled.

Reference 1: U.S. Patent No. 6,490,479 ("*Bock* "), filed December 28, 2000, and issued December 3, 2002, qualifies as prior art to the '850 patent under 35 U.S.C § 102(e). Ex. 1005 .

Reference 2: U.S. Patent No. 7,490,085 ("*Walker*"), filed December 18, 2002, and issued February 10, 2009, qualifies as prior art to the '850 patent under 35 U.S.C § 102(e). Ex. 1006.

Reference 3: ACC/AHA Guidelines for Ambulatory Electrocardiography, ACC/AHA Practice Guidelines ("*ACC Guidelines*"), Journal of the American

College of Cardiology, Vol. 34, No. 3, September 1999, pp. 912-948. Ex. 1008. The *ACC Guidelines* qualifies as prior art to the '850 patent under 35 U.S.C § 102(b).

Reference 4: U.S. Patent No. 4,531,527 ("*Reinhold*"), issued July 30, 1985, qualifies as prior art to the '850 patent under 35 U.S.C § 102(b). Ex. 1007.

Reference 5: U.S. Patent No. 6,470,210 ("*Chen*"), issued October 22, 2002, qualifies as prior art to the '850 patent under 35 U.S.C § 102(b). Ex. 1009.

Ground 1: Claims 1, 2, 5, 6, 8, 20, 21, 31-34, 37, and 38 are unpatentable over *Bock* in view of *Walker* and the *ACC Guidelines* under 35 U.S.C. § 103(a).

Ground 2: Claims 3, 4, and 7 are unpatentable over *Bock* in view of *Walker* and the *ACC Guidelines* and further in view of *Reinhold* under 35 U.S.C. § 103(a).

Ground 3: Claim 9 is unpatentable over *Bock* in view of *Walker* and the *ACC Guidelines* and further in view of *Chen* under 35 U.S.C. § 103(a).

VI. BACKGROUND

1. Disclosure of the '850 Patent

The '850 patent describes systems and techniques for processing arrhythmia events (e.g., atrial fibrillation "AF" events) from physiological data and "selectively presenting atrial fibrillation events to a medical practitioner." Ex. 1001 at 1:18-21. With reference to FIG. 1 reproduced below, the '850 patent discloses a monitoring system 109 that communicates, via devices 101 and 102,

physiologic data to monitoring center 104. *Id.* at 2:27-30. Monitoring center 104 includes a monitoring (or display) station 105 and a processing system 106. *Id.* at 2:55-56. A cardiovascular technician (CVT) uses monitoring station 105 to evaluate the physiological data received at the monitoring station 105 to identify arrhythmia events, such as AF events. *Id.* at 2:57-61. The CVT reports assessments of the physiological data to processing system 106 which also receives information related to the arrhythmia events identified by monitoring system 109. *Id.* at 2:61-64. Processing system 106 analyzes the human-assessed data from the CVT and the data reported by monitoring system 109 and determines whether to generate a graph related to these events based on a correlation analysis of the human-assessed data and the data reported from monitoring system 109. *Id.* at 2:65 – 3:2; Ex. 1002 at ¶ 16, 17.

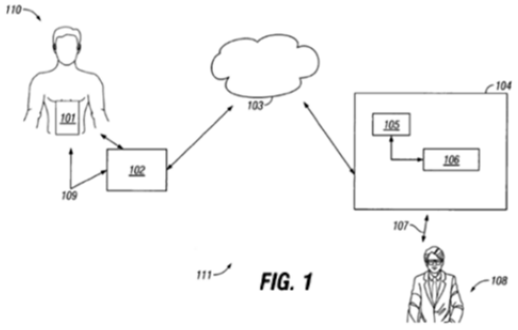


FIG. 1

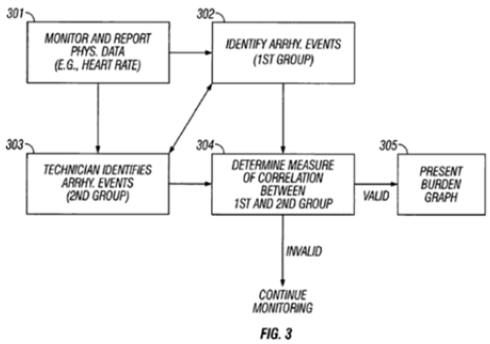


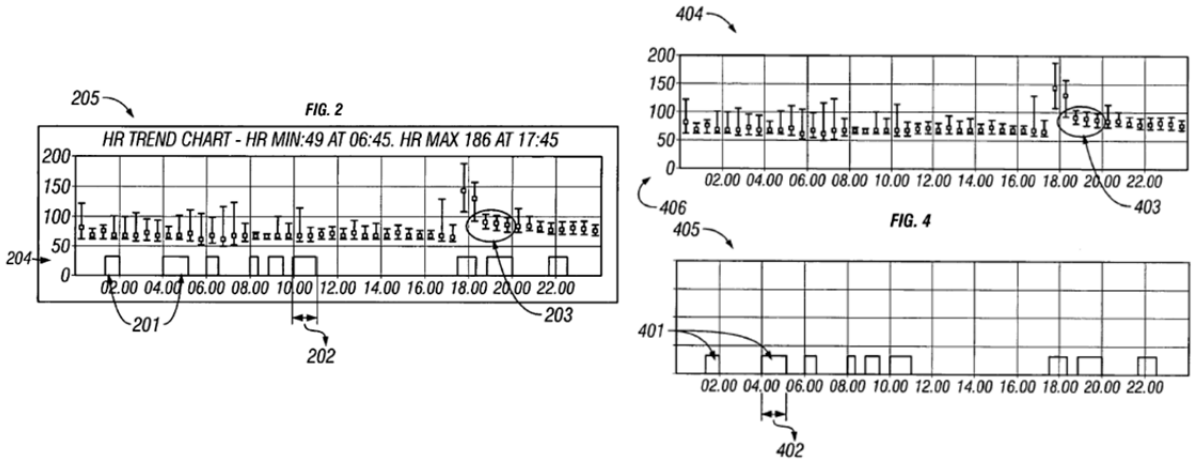
FIG. 3

In one embodiment (*see* FIG. 3 reproduced above), monitoring system 109 monitors and reports physiologic data to monitoring center 104 at step 301. Ex. 1001 at 3:12-14; 2:36-39. Monitoring center 104 analyzes the received

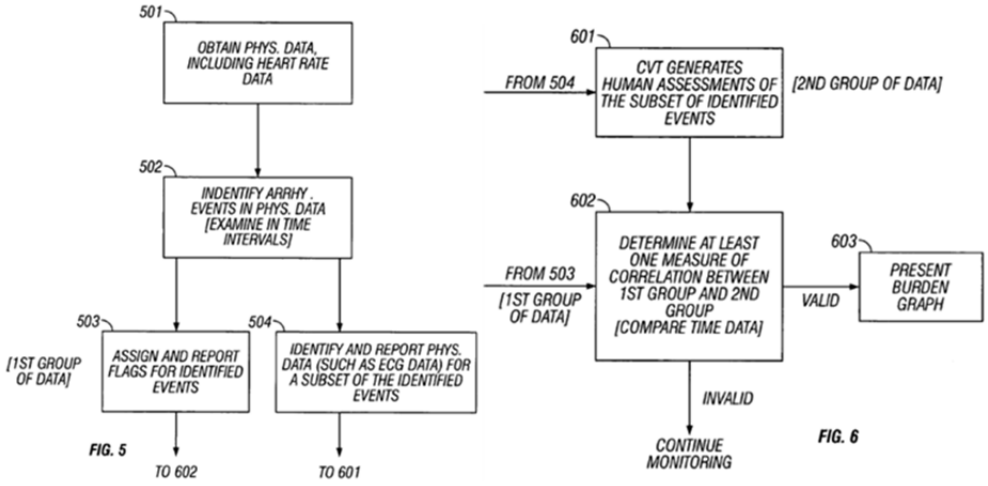
physiologic data at step 302 and identifies arrhythmia events. *Id.* at 3:14-17; 2:38. These events constitute a first group of data. *Id.* at 3:18-19. At step 303, a CVT uses station 105 to evaluate the data received from steps 301 and/or 302 and identifies arrhythmia events (human-assessed events). *Id.* at 3:25-28. These human-assessed events constitute a second group of data. *Id.* at 3:28-30; Ex. 1002 at ¶ 18.

At step 304, processing system 106 analyzes both the first and second groups of data and determines a measure of correlation between them. Ex. 1001 at 3:33-35. That is, processing system 106 compares the software identified arrhythmia events to the human-assessed events. If this correlation analysis indicates that the arrhythmia events are valid, the system generates a report including the heart rate trend and arrhythmia events such as the graph shown in FIG. 2 or FIG. 4 at step 305. *Id.* at 3:35-44. If there is insufficient correlation, the system does not generate a report and continues monitoring the patient. *Id.* at 3:43-45; Ex. 1002 at ¶ 19.

FIGS. 2 and 4, reproduced below, illustrate "example[s] of how to pictographically present [ ] heart rate trend and atrial fibrillation burden on a common time scale." Ex. 1001 at 4:4-6, 18-20. The information can be presented using one graph (FIG. 2) or two graphs (FIG. 4). *Id.* at 4:18-22; Ex. 1002 at ¶ 20.



FIGS. 5 and 6, reproduced below, illustrate another embodiment of presenting data based on a correlation analysis. Ex. 1001 at 4:30-31. At steps 501, 502 monitoring system 109 obtains physiologic data and identifies the presence of arrhythmia events (e.g., AF events). *Id.* at 4:31-36. At step 503, the system assigns flags indicating the presence of arrhythmia events and reports those flags (first group of data) to the processing system. *Id.* at 4:36-39. At step 504, the system identifies and reports physiological data, such as ECG data, for a subset of the events identified at 502 and reported at 503. *Id.* at 4:39-41. At step 601, the CVT analyzes this data to determine whether arrhythmia events have occurred, thereby generating a second group of data (human-assessed events). *Id.* at 4:46-48. The system then determines a measure of correlation between the two groups of data, and if enough human-assessed events reported at 601 match, the events reported at step 503 are pictographically presented as FIG. 2 or FIG. 4. *Id.* at 4:48-58; Ex. 1002 at ¶ 21.



In all of the disclosed implementations of the ’850 patent, cardiac data is evaluated both by an algorithm and by a human to identify arrhythmia events such as AF events. *See* steps 302 and 303 in FIG. 3 (Ex. 1001 at 3:14-17, 25-27) and steps 502 and 601 in FIGS. 5 and 6 (*Id.* at 4:33-36, 46-48). The algorithm-identified and human-identified arrhythmia events are then compared. *See* step 304 in FIG. 3 (*Id.* at 3:32-35) and step 602 in FIGS. 5 and 6 (*Id.* 4:48-51). And, if the algorithm-detected arrhythmia event is validated or corroborated by the human assessment, it is presented. *Id.* at 3:39-45; 4:52-56; *See* also Ex. 1004. at p. 8; Ex. 1002 at ¶ 22.

2. Prosecution History of the ’850 Patent

The ’850 patent, which issued from U.S. Patent Application No. 10/760,122 (“the ’122 application”), filed on January 16, 2004, allegedly claims priority to Provisional Application No. 60/525,386 (Ex. 1004) filed on November 26, 2003.

As filed, the ’122 application included application claims 1, 11, 21, 24, 27, 29, 31, 33, 35, 37, 39, 41, 43, and 45 in independent form. Ex. 1003 at pp. 81-93. As-filed, independent application claim 1 recited:

> 1. A machine-implemented method comprising:
>
> identifying atrial fibrillation events in physiological data obtained for a living being;
>
> obtaining heart rate data for the living being; and
>
> pictographically presenting, using a common time scale, information regarding the heart rate data during a defined time period and regarding duration of atrial fibrillation activity, according to the identified atrial fibrillation events, during the defined time period such that heart rate trend is presented with atrial fibrillation burden.

Id. at p. 81. Independent application claims 21 and 39 included substantially similar limitations. *Id.* at pp. 84, 91. In a first Office Action, the Examiner rejected independent application claims 1, 21, and 39 (and several of its dependent claims) as being obvious over U.S. Patent No. 6,937,887 to Bock (Bock ’887), a reference which is a continuation of, and shares the same specification as the *Bock* reference used in the counts of this Petition. *Id.* at p. 56. Dependent application claims 9 and 23 (depending from independent application claims 1 and 21 respectively) were, however, indicated to include allowable subject matter. These claims recited:

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

Id. at pp. 82, 84. Application claims 11-20, 24-38, and 41-46 were also allowed, of which the independent application claims included similar limitations related to human-assessment of atrial fibrillation/arrhythmia events. *Id.* at pp. 57, 82, 85-93. In Response to the Office Action, without contesting the rejection of the base claims over Bock '887, the Patent Owner amended the rejected independent application claims (1, 21, and 39) to include the limitations of claims 9 and 23. *Id.* at p. 50. All of the claims were subsequently allowed with application claims 1, 21, and 39 renumbered as patent claims 1, 20, and 37 respectively. *Id.* at pp. 30, 33. Thus, during prosecution of the '850 patent, the Examiner believed, and the Patent Owner implicitly acknowledged, that Bock '887 (and *Bock* because it shares a specification with Bock '887) taught all aspects of the claims except the aspects related to human assessment.

VII. CLAIM CONSTRUCTION

During an IPR, claim terms should be given their broadest reasonable interpretation in view of the specification in which they appear.[2] *See* 37 C.F.R. §

[2] Given the different claim construction standards used by the PTO and district courts, Petitioner reserves the right to argue different claim constructions in

42.100(b); Ex. 1002 at ¶ 23. The United States Court of Appeals for the Federal Circuit recently concluded that the Patent Office properly adopted that standard for construing claims in an IPR. *In re Cuozzo Speed Technologies, LLC.*, No. 2014-1301 (February 4, 2015). Any claim terms not construed herein should be "given their ordinary and customary meaning," which is the meaning that the term would have to a person of ordinary skill in the art ("POSITA").[3] *See In re Translogic Tech Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007) (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312, 1313 (Fed. Cir. 2005) (en banc)).

1. "Measure of Correlation"

Independent claims 1, 20, and 37 recite presenting information "based on a measure of correlation between [ ] identified atrial fibrillation events and human-assessments of at least a portion of the identified atrial fibrillation events." Under the BRI standard, "measure of correlation" should be construed to mean "an

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litigation. Petitioner also reserves all other arguments, such as 35 U.S.C § 112 arguments, for litigation.

[3] For the purposes of this Petition, a person of ordinary skill in the art (or POSITA) is someone who would have had at least a bachelor's degree in electrical or mechanical engineering, or equivalent proficiency, and at least two to three years of experience in the research and/or development of remote patient monitoring systems, such as cardiac remote patient monitoring systems.

amount or degree of relationship between things or variables." Ex. 1002 at ¶ 24. The proposed construction is consistent with the plain language of the claims, the '850 patent, Patent Owner's statements in related district court litigations, and findings by the court.

The plain meaning of the term "measure" is an "amount" or a "degree," and the plain meaning of the term "correlation" is "a relation existing between phenomena or things or between mathematical or statistical variables which tend to vary, be associated, or occur together in a way not expected on the basis of chance alone." Ex. 1014 at pp. 4, 3. Therefore, the plain meaning of the phrase "measure of correlation" is "an amount or degree of relationship between things or variables." Ex. 1002 at ¶ 25. This is consistent with the '850 patent. The specification of the '850 patent does not define the term "measure of correlation," and at most provides that a correlation "indicat[es] a high positive predictively for the identification of AF events." Ex. 1001 at 3:55-56; Ex. 1002 at ¶ 25.

Indeed, Patent Owner has argued in related district court litigations that the phrase "measure of correlation" does not require construction because these are common terms with plain meanings. Ex. 1010 at pp. 14-15; Ex. 1012 at pp. 19-20. The Patent Owner has further argued that this phrase should be interpreted to include any "measure of correlation" between the two events, and that such a construction is consistent with the plain meaning of the term and the use of the

phrase throughout the intrinsic record. *Id.* While the Scottcare court ultimately construed this phrase as "a numerical value representing a comparison between the first data set and a second data set" (Ex. 1011 at p. 11-13), the MedNet court declined to construe the phrase observing that the plain and ordinary meaning refers to "an amount or degree of relationship between two things or variables" (Ex. 1011 at pp. 7-10). Consistent with these findings, the term "measure of correlation" should be "an amount or degree of relationship between things or variables" under the BRI standard for purposes of this IPR proceeding.

2. "Selectively Presenting"

Claims 1, 20, and 37 recite "selectively presenting [ ] information based on a measure of correlation." Under the BRI standard, "selectively presenting" should be construed to mean "selecting what information is presented, how information is presented, or if information is presented." Ex. 1002 at ¶ 26. The proposed construction is consistent with the plain language of the claims, the '850 patent, Patent Owner's statements in related district court litigations, and findings by the court. Ex. 1002 at ¶ 27.

The Patent Owner argued in the related litigations that the term "selectively presenting" should be understood, consistent with its plain and ordinary meaning, to cover all types of selecting. Ex. 1010 at pp. 16-18; Ex. 1012 at pp. 20-22. The

Patent Owner stated that the plain meaning of "selectively presenting" is consistent with the '850 patent:

> Th[e] broad understanding of "selectively presenting" is supported by the specification. For example, the specification clearly states that selectively presenting may encompass determining ***what*** information to present and ***how*** it is presented, in addition to ***whether*** it is presented. (*See* [Ex. 1001] at Fig. 2; Fig. 4; 3:1-2 (determining 'whether to generate a graph (or other similar presentation)'); 3:39-46 (explaining that information may be presented 'such as the graph shown in FIG. 2 or the graphs shown in FIG. 4.'); 4:4-5 ('FIG. 2 represents one example of how to pictographically present …'); 4:18-20 ('Like FIG. 2, FIG. 4 represents an example of how to pictographically present …'); 5:57-61 ('[T]he graphs of FIG. 2 and 4 could be modified …).') (*See* [Ex. 1001] at Fig. 2, Fig. 4 (two different examples of ***how to*** pictographically present information).).

Ex. 1012 at pp. 21-22. (emphasis in original). While the Scottcare court ultimately construed this phrase to mean "determining whether to present information or not present information based on a numerical value" (Ex. 1011 at pp. 13-15), the MedNet court agreed with the Patent Owner that the phrase need not be construed and observed that "selectively presenting the information" under its plain meaning refers to "selecting what information is presented, selecting how the information is presented, and/or selecting whether information is presented at all" (Ex. 1013 at p.

10-13). Consistent with these findings, the term "measure of correlation" should be "an amount or degree of relationship between things or variables" under the BRI standard for purposes of this IPR proceeding.

3. Means-Plus-Function Terms

Several claims of the '850 patent include means-plus-function claim terms. The specification does not identify particular structure corresponding to the function of each means-plus-function claim term. However, as required by 37 C.F.R § 42.104 (b)(3), and without conceding sufficiency of the claims under 35 U.S.C. § 112, ¶ 6, Petitioner identifies what Patent Owner may argue is the corresponding "structure."[4]

a. "Monitoring Means"

Independent claim 33 recites "monitoring means for processing and reporting physiological data, including heart[ ] rate data, for a living being and for identifying arrhythmia events from the physiological data." The term "monitoring means" is a means-plus-function limitation. The recited function is: (a)

[4] Because the IPR procedure does not permit challenges under 35 U.S.C. § 112, Petitioner has not included any indefiniteness arguments here. Petitioner reserves the right, however, to raise such arguments and/or argue different constructions during litigation.

"processing and reporting physiological data," and (b) "identifying arrhythmia events from the physiological data."

The '850 patent describes a monitoring system 109 that communicates physiologic data to monitoring center 104 and detects arrhythmia events from the data. Ex. 1001 at 2:27-30, 38. The '850 patent states that monitoring system 109 includes devices 101 and 102. *Id.* at 2:27-39. Device 101 is an implantable medical device (such as a cardiac defibrillator or a pacemaker with a transceiver) or a device that a patient wears to obtain physiological data. *Id.* at 2:30-34. Device 102 is a processing device that detects arrhythmia events and sends the data to monitoring center 104. *Id.* at 2:34-39. Patent Owner may argue that processing device 102 performs the recited functions of the "monitoring means." Patent Owner may also argue that the '850 patent states that devices 101 and 102 may be in a single device such as, for example, the commercially available CardioNet Mobile Cardiac Outpatient Telemetry (MCOT) device. *Id.* at 2:39-44. Further, Patent Owner may point out that the system and all of its functions "can be implemented in digital electronic circuitry, or in computer hardware, firmware, software, or in combinations of the forgoing." *Id.* at 4:65 – 5:2. The '850 patent states that an example of a software product is a computer program and that hardware can include microprocessors. *Id.* at 5:2-9, 20-30.

Thus, for purposes of this proceeding Petitioner has assumed the corresponding structures for the identified function of "processing and reporting physiological data" and "identifying arrhythmia events from the physiological data" are: the MCOT device; digital electronic circuitry; and/or a computer system with software/hardware configured to perform the recited functions; or equivalents thereof. Ex. 1002 at ¶ 28.

b. "Display Means"

Independent claim 33 recites "display means for receiving the physiological data from the monitoring means and for displaying the physiological data to a human user." The term "display means" is a means-plus-function limitation. The recited function is: (a) "receiving the physiological data from the monitoring means," and (b) "displaying the physiological data to a human user,"

The '850 patent describes that a cardiovascular technician (CVT) uses monitoring station 105 to analyze physiological data received from monitoring system 109 and identify and report arrhythmic events such as AF events. Ex. 1001 at 2:56-61. The '850 patent states that, to interact with a CVT "the system can be implemented on a computer system having a display device such as a monitor or LCD (liquid crystal display) screen for displaying information to the user." *Id.* at 5:41-44. Patent Owner may argue that monitoring station 105 performs the recited functions of the "display means." Patent Owner may also point out that the '850

patent states that the system and all its functions "can be implemented in digital electronic circuitry, or in computer hardware, firmware, software, or in combinations of the forgoing." *Id.* at 4:65 – 5:2. The '850 patent states that an example of a software product is a computer program and that hardware can include microprocessors. *Id.* at 5:2-9, 20-30.

Thus, for purposes of this proceeding Petitioner has assumed the corresponding structures for the identified functions of "receiving the physiological data from the monitoring means" and "displaying the physiological data to a human user" are: digital electronic circuitry; and/or a computer system with a monitor or LCD screen and software/hardware (e.g., microprocessor) configured to perform the recited functions; or equivalents thereof; Ex. 1002 at ¶ 29.

c. "Processing Means"

Independent claim 33 recites "processing means for receiving arrhythmia information from the monitoring system and for receiving human-assessed arrhythmia information from the display means." The term "processing means" is a means-plus-function limitation. The recited function is: (a) "receiving arrhythmia information from the monitoring system," and (b) "receiving human-assessed arrhythmia information from the display means."

The '850 patent describes that the cardiovascular technician (CVT) assesses physiological data using monitoring station 105 and "reports these assessments of

the physiological data to the processing system 106, which also receives information related to the arrhythmia events identified by monitoring system 109." Ex. 1001 at 2:57-64. Patent Owner may argue that processing system 106 performs the recited functions of the "processing means." Patent Owner may also point out that the '850 patent states that the system and all its functions "can be implemented in digital electronic circuitry, or in computer hardware, firmware, software, or in combinations of the forgoing." *Id.* at 4:65 – 5:2. The '850 patent states that an example of a software product is a computer program and that hardware can include microprocessors. *Id.* at 5:2-9, 20-30.

Thus, for purposes of this proceeding Petitioner has assumed the corresponding structures for the identified functions of "receiving arrhythmia information from the monitoring system" and "receiving human-assessed arrhythmia information from the display means" are: digital electronic circuitry; and/or a computer system with software/hardware configured to perform the recited functions; or equivalents thereof. Ex. 1002 at ¶ 30.

d. "Means for Identifying Atrial Fibrillation Events"

Independent claim 37 recites "means for identifying atrial fibrillation events in physiological data obtained for a living being." This is a means-plus-function limitation with the function of "identifying atrial fibrillation events in physiological data."

The ’850 patent describes monitoring system 109 with devices 101 and 102. Ex. 1001 at 2:27-30. The ’850 patent states that “monitor processing device 102 … can detect arrhythmia events (such as atrial fibrillation events)” from physiologic data. *Id.* at 2:36-39. The ’850 patent also states that “a cardiovascular technician (CVT) can use [a] monitoring station 105 to evaluate physiological data received from monitoring system 109, [and] identify[] and report[ ], among other things, arrhythmia events (such as atrial fibrillation events).” *Id.* at 2:57-61. Patent Owner may argue that each of monitor processing device 102 and the monitoring station 105 performs the function of “identifying atrial fibrillation events in physiological data.”

The Patent Owner may also argue that devices 101 and 102 may be in a single device such as, for example, the “CardioNet Mobile Cardiac Outpatient Telemetry (MCOT) device.” *Id.* at 2:39-44. Patent Owner may also point out that the ’850 patent states that the system and its functions “can be implemented in digital electronic circuitry, or in computer hardware, firmware, software, or in combinations of the forgoing.” *Id.* at 4:65 – 5:2. The ’850 patent states that an example of a software product is a computer program and that hardware can include microprocessors. *Id.* at 5:2-9, 20-30.

Thus, for purposes of this proceeding Petitioner has assumed the corresponding structures for the identified function of “identifying atrial fibrillation

events in physiological data" are: the MCOT device; digital electronic circuitry; and/or a computer system with software/hardware configured to perform the recited function; or equivalents thereof. Ex. 1002 at ¶ 31.

e. "Means for Obtaining Heart Rate Data"

Claim 37 recites "means for obtaining heart rate data for the living being." This is a means-plus-function limitation with the recited function of "obtaining heart rate data for the living being."

In the '850 patent, monitoring system 109 receives physiologic data (including heart rate data) from the patient and sends the data to monitoring center 104. Ex. 1001 at 2:27-38; 1:51-53; 3:12-14. A technician using monitoring station 105 assesses the physiological data received from monitoring system 109 and reports these assessments to the processing system 106. *Id.* at 2:57-62. The '850 patent states that processing system 106 "generates a report relating to both heart rate trend and the arrhythmia events," based on a correlation analysis. *Id.* at 3:33-44. Patent Owner may argue that each of monitoring system 109, monitoring station 105, and processing system 106 performs the recited function of "obtaining heart rate data for the living being." Patent Owner may also point out that the '850 patent states that monitoring system 109, monitoring station 105, and processing system 106 may be implemented as "digital electronic circuitry, or in computer hardware, firmware, software, or in combinations of the forgoing." *Id.* at 4:65 –

5:2. The ’850 patent states that an example of a software product is a computer program and that hardware can include microprocessors. *Id.* at 5:2-9, 20-30. The ’850 patent also states that the monitoring system 109 may be the “CardioNet Mobile Cardiac Outpatient Telemetry (MCOT) device.” *Id.* at 2:39-44.

Thus, for purposes of this proceeding Petitioner has assumed the corresponding structures that perform the identified function of “obtaining heart rate data for the living being” are: the MCOT device; digital electronic circuitry; and/or a computer system with software/hardware configured to perform the recited function; or equivalents thereof. Ex. 1002 at ¶ 32.

f. “Means for Pictographically Presenting”

Claim 37 recites “means for pictographically presenting, using a common time scale, information regarding the heart rate data during a defined time period and regarding duration of atrial fibrillation activity, according to the identified atrial fibrillation events, during the defined time period such that heart rate trend is presented with atrial fibrillation burden.” This is a means-plus-function limitation with the function of “pictographically presenting” the recited data.

In the ’850 patent, processing system 106 performs a correlation analysis, and “[i]f, based on the correlation analysis, the information related to the arrhythmia events is determined to be valid, then the system generates a report relating to both heart rate trend and the arrhythmia events at 305, such as the graph

shown in FIG. 2 or the graphs shown in FIG. 4." Ex. 1001 at 3:33-44. FIGS. 2 and 4 illustrate examples of "how to pictographically present both heart rate trend and atrial fibrillation burden on a common time scale." *Id.* at 4:4-6, 18-20. Patent Owner may argue that processing system 106 performs the function of "pictographically presenting" the recited data.

Patent Owner may also point out that the '850 patent states that the system and all its functions "can be implemented in digital electronic circuitry, or in computer hardware, firmware, software, or in combinations of the forgoing." *Id.* at 4:65 – 5:2. The '850 patent states that an example of a software product is a computer program and that hardware can include microprocessors. *Id.* at 5:2-9, 20-30. The '850 patent also states that the disclosed system can be implemented on a computer system with a monitor or an LCD screen. *Id.* at 5:2-8, 41-47.

Thus, for purposes of this proceeding Petitioner has assumed the corresponding structures for the identified function of "pictographically presenting" data are: digital electronic circuitry; and/or a computer system with a monitor or an LCD screen and software/hardware configured to perform the recited functions; or equivalents thereof. Ex. 1002 at ¶ 33.

g. "Means for Selectively Presenting"

Claim 37 recites that "the means for pictographically presenting information comprises means for selectively presenting the information based on a measure of

correlation between the identified atrial fibrillation events and human-assessments of at least a portion of the identified atrial fibrillation events." This is a means-plus-function limitation with the function of "selectively presenting [ ] information."

As explained above, in the '850 patent, processing system 106 performs a correlation analysis, and if the information related to the arrhythmia event is determined to be valid based on the correlation analysis, a report relating to both heart rate trend and the arrhythmia events is generated. Ex. 1001 at 3:33-44; FIGS. 2, 4; *see supra* Section VII.3.f. Patent Owner may argue that processing system 106 performs the function of "selectively presenting" the recited data. Thus, for the purposes of this proceeding, Petitioner has assumed that corresponding structure that performs the function of "pictographically presenting" also performs the function of "selectively presenting" (i.e., digital electronic circuitry; and/or a computer system with a monitor or an LCD screen and software/hardware configured to perform the recited functions; or their equivalents). *See supra* Section VII.3.f; Ex. 1002 at ¶ 34.

VIII. PETITIONER'S ARGUMENTS RE: APPLIED ART DO NOT CONTRADICT NOR REHASH ANY OF THE EXAMINER'S ASSERTIONS

This Petition relies on previously unapplied combinations. While a reference that shares the same specification as *Bock* (*Bock* '887) was considered

during prosecution, the combination of *Bock* and the *ACC Guidelines* and *Walker*, both of which were not cited or considered by the Examiner, demonstrate that the claimed features were known in and obvious from the prior art. As discussed above in Section VI.2, the claims of the '850 patent were allowed after the feature requiring human-assessment of identified atrial fibrillation events was added to the claims rejected over *Bock*. This feature was known, described in, and practiced in the art well before the '850 patent as evidenced by the *ACC Guidelines*, which explains that human-assessment of algorithm-detected arrhythmias was critical to ensure accuracy (*see* Ex. 1008 at 913, 914, 917), and *Walker*, which teaches incorporating human-assessment into an algorithm-based arrhythmia detection system such as *Bock* (*see generally* Ex. 1006). Additionally, this Petition is supported by the declaration of Robert Stone (Ex. 1002), an expert in the field of the prior art and the '850 patent. Thus, the arguments presented in this petition establish a reasonable likelihood that the Petitioner will prevail with respect to at least one challenged claim and should not preclude institution of this IPR. *See e.g.*, *Fresenius-Kabi USA LLC*, v. *Cubist Pharmaceuticals, Inc.*, IPR2015-00223, Paper No. 13 (instituting IPR based on a ground applying the same prior art reference that a patent owner had successfully argued over during prosecution). *See also* IPR2015-00227; IPR2014-01043; IPR2013-00066.

IX. DETAILED DISCUSSION OF UNPATENTABILITY

A. Ground 1 - Claims 1, 2, 5, 6, 8, 20, 21, 31-34, 37, and 38 are obvious over *Bock* in view of *Walker* and *ACC Guidelines*

1. Independent Claim 1

i. "A machine-implemented method comprising:"

Bock discloses methods to detect irregularities, such as arrhythmias and atrial fibrillation ("AF") in a heartbeat. Ex. 1005 at 1:6-10. *Bock* states that the method may "be implemented in software running on a computer." *Id.* at 3:66-67. That is, the method of *Bock* is "machine-implemented." Ex. 1002 at ¶ 36.

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

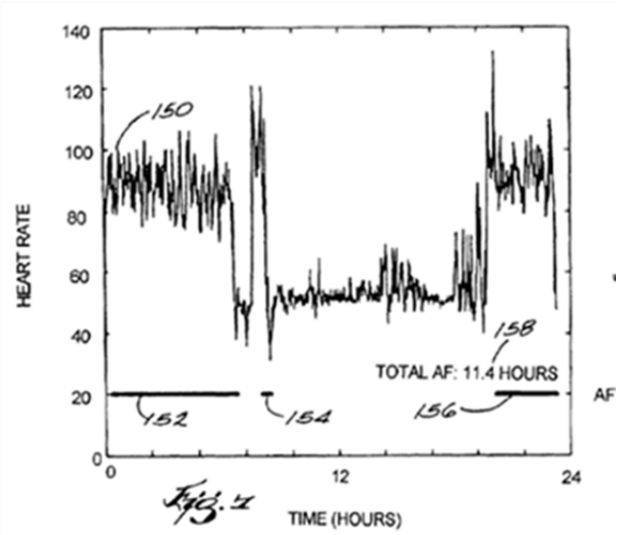
In *Bock*, AF events are identified in ECG data obtained from a living being. Ex. 1005 at 1:6-10, 55; 2:41-44; 5:16-17; 6:6-10. Specifically, *Bock* states that "system 20 receives physiological information in the form of ECG" and outputs "a state variable, which indicates the alarm state of AF and a minute-by-minute trend variable of the state of AF." *Id.* at 5:16-17; 11:36-38; Ex. 1002 at ¶ 37.

iii. "obtaining heart rate data for the living being; and"

In *Bock*, heart rate data (e.g., RR interval) of the living being is obtained. Ex. 1005 at Abstract; 1:6-7; 2:41-44; Ex. 1002 at ¶ 38.

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

Bock discloses graphically presenting the trend of heart rate (*see* y-axis) over time (*see* x-axis) for a defined time period (24 hrs). Ex. 1005 at 11:45-49; *see* FIG. 7 reproduced to the right. In the FIG. 7 graph, "portions of the waveform during which an AF condition exists are [ ] [also] marked with horizontal bars 152, 154, and 156." *Id.* That is, in FIG. 7, the duration of the identified AF events are presented along with heart rate trend on common time scale. Ex. 1002 at ¶ 39.



The '850 patent defines "atrial fibrillation burden" as "the overall amount of time that a patient is in atrial fibrillation (or arrhythmia) over a specified time period, taking into account the number and duration of episodes." Ex. 1001 at 3:61-65; *see also* 4:4-6, 18-20, FIGS. 2 and 4 (showing examples "of how to pictographically present both heart rate trend and atrial fibrillation burden on a common time scale"). In FIGS. 2 and 4, the width of each bar represents the duration of an AF event. *Id.* at 4:9, 24. The only way of obtaining the "overall amount of time that a patient is in atrial fibrillation" for the illustrated time period (i.e., AF burden) from FIGS. 2 and 4 is by adding the durations of each identified

AF event. Ex. 1002 at ¶ 40. Similarly, adding the durations (or width) of the bars 152, 154, and 156 will yield AF burden from FIG. 7 of *Bock*. *Id*. The total AF time 158 for the time period (24 hrs.) is displayed in FIG. 7 ("158" in FIG. 7). Ex. 1005 at 11:48-49, FIG. 7. Therefore, in *Bock*, heart rate trend is presented with atrial fibrillation burden. Ex. 1002 at ¶ 40.

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

As explained earlier, "selectively presenting" information means "selecting what information is presented, how information is presented, or if information is presented." *Supra* Section VII.2. And, "measure of correlation" means "an amount or degree of relationship between things or variables." *Supra* Section VII.1. Therefore, the claimed presenting step includes selecting what or how or if the recited information is presented, taking into account an amount/degree of relationship between identified AF events and human-assessments of at least a portion of the AF events. Ex. 1002 at ¶ 41.

State evaluation module 50 of *Bock* selectively presents the recited information discussed above (in *supra* Section IX.A.1.iv.), taking into account the degree of relationship between AF events identified by engine 40 and information regarding assessments of these AF events from module 30. Ex. 1005 at 2:44-49;

5:46-51; 6:6-9, 43-47, 53-55; 9:25-26; 10:41-46. Specifically, *Bock* states that engine 40 detects atrial fibrillation and "outputs a state variable having one of two possible states: AF or NOT AF." *Id.* at 2:41-44; 6:53-55. The "state variable … is provided to the contextual analysis module 30 and the state evaluation module 50." *Id.* at 6:36-38. Module 30 performs multiple tests to check if the AF state detected by engine 40 is a true AF event or a false alarm. *Id.* at 2:46-52; 9:41-46; Ex. 1002 at ¶ 42. In one test, module 30 compares the signals associated with the detected AF state with common beat patterns (or block maps) that appear irregular but are not as a result of an AF event. *Id.* at 9:41-46. The results of these tests are provided to the state evaluation module 50. *Id.* at 2:64-67; 5:58-65; 6:42-47; *see* also *id.* at 2:46-54; 6:42-43. "[M]odule 50 uses the outputs of the probability analysis module 40, [and] the contextual analysis module 30, … to determine whether an AF condition exists. If the state variable of the probability engine 40 indicates an AF condition … and contextual analysis module[ ] output[s] negative results, then the state evaluation module 50 determines that an AF condition is present." Ex. 1005 at 6:6-13; *see* also 10:64 – 11:35. Therefore, module 50 determines if an AF state identified by engine 40 is a true AF event or not by taking into account the degree of relationship between the AF states identified by engine 40 (i.e., state variable) and assessments of these AF states by module 30. *Id.* at 11:8-16; Ex. 1002 at ¶ 42.

If the AF states identified by engine 40 are validated by module 30, an AF event is indicated by state evaluation module 50 and output on a display. Ex. 1005 at 6:9-13, 42-46; 11:36-39. If the tests performed by module 30 indicate that an AF state identified by engine 40 does not represent a true AF event, module 50 does not indicate an AF state. *Id.* at 9:63-10:2, 20-24; 11:8-11. For example, "[i]f the current state is NOT AF and the [ ] engine 40 outputs an AF indication, … [i]f the refractory period has been enabled from interval similarity or rhythm patterns [by module 30], then the current state remains NOT AF." *Id.* at 11:8-13. When the state variable indicates NOT AF, an AF state identified by module 40 is not output on the display. Ex. 1002 at ¶ 43. Thus, module 50 determines what information is presented, and if information is presented on the display based on a measure of correlation between the AF state identified by engine 40 and assessment of these AF states by module 30. *Id*. *Bock* also states that "trending data could be displayed in other ways, such as bar graphs and the like." Ex. 1005 at 11:49-51. Therefore, module 50 also determines how information is presented. Ex. 1002 at ¶ 43. In the Scottcare litigation, the Patent Owner admitted that determining how to present information (such as FIG. 2 or FIG. 4 of the '850 patent) is "selectively presenting." Ex. 1012 at p. 21.

Module 30 of *Bock* performs an algorithm-based assessment of the AF states identified by engine 40. However, it would have been obvious to a POSITA to

have the AF states identified by engine 40 assessed by a technician based on preexisting knowledge in the art and *Walker*'s disclosure. Ex. 1002 at ¶ 44. At the time of the alleged invention, a POSITA was well aware that it was important for arrhythmic events (such as, AF) detected by computer algorithms to be validated by medical professionals or technicians to ensure accuracy of the computer-based diagnosis. *Id*. For instance, the *ACC Guidelines* explain that, for arrhythmias detected by computer algorithms, "[i]t is critical that each classification of arrhythmia morphology and each ischemic episode be reviewed by an experienced technician or physician to ensure accurate diagnosis because AECG [ambulatory electrocardiography] recordings during routine daily activities frequently have periods of motion artifact of baseline wander that may distort the [ ] QRS morphology." Ex. 1008 at 913, 914, 917. Thus, based at least on these 1999 *ACC Guidelines*, at the time of the alleged invention (in late 2003), a POSITA would have known that it was "critical" to have algorithm-detected arrhythmias validated by an experienced technician for accuracy of diagnosis especially when *Bock*'s method is used for ambulatory electrocardiography (AECG) recordings during Holter monitoring (*see* Ex. 1005 at 1:59-61). Ex. 1002 at ¶ 44.

In addition, *Walker* discloses techniques for "enhancing performance of computer-assisted data operating algorithms in a medical context." Ex. 1006 at Abstract. In *Walker*, diagnosis made by a computer algorithm is improved by

modifying the algorithm based on validation and feedback from human experts. *Id.* In *Walker*, physiological data (such as ECG data) from sensors 114 on a patient is processed and transmitted to a processing module 120 for analysis and then to a display/user interface 122 for output. *Id.* at 16:5-9, 18-31; 17:29-32; FIG. 9. Algorithms are used for analysis of the data in module 120. *Id.* at 46:35-44; Ex. 1002 at ¶ 45.

In *Walker*, with reference to FIG. 26 reproduced to the right, both an expert (step 400) and the algorithm (step 404) analyze patient data (such as ECG data) for diagnosis (e.g., detect arrhythmias). Ex. 1006 at. 3:15-17; 71:60-62; 72:9-12; 11:3-6, 18-23; 17:55-67; 6:5-7. After analysis, the expert produces a dataset D1 (step 402) and the algorithm produces a dataset D2 (step 406). *Id.* at 72:3-5, 21-23. The expert produced dataset D1 may be verified by an algorithm (step 408) to produce dataset D3 (step 410) and the algorithm produced dataset D2 may be verified by an expert (step 412) to produce dataset D4 (step 414). *Id.* at 72:24-28, 45-46, 51-54, 62-63. The discrepancies between datasets D3 (produced by the expert) and D4 (produced by the algorithm)

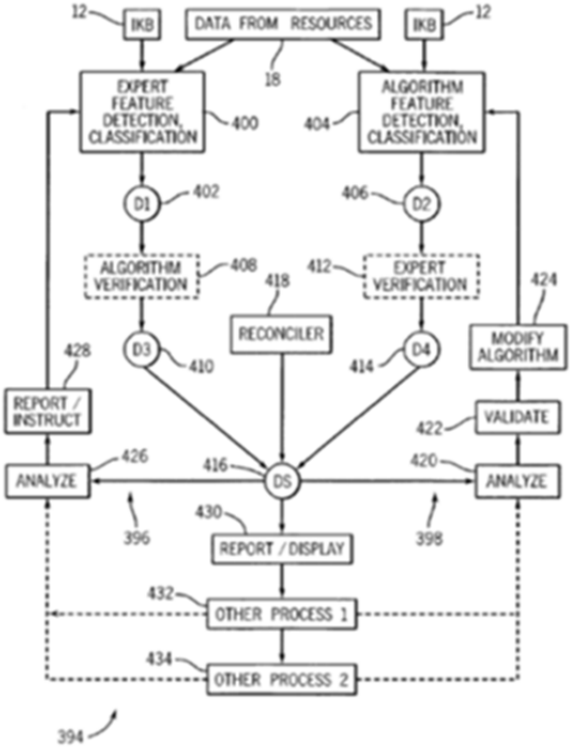


FIG. 26

are then resolved by a reconciler 418 (a medical professional) to produce a dataset D5 (step 416) which is then reported and displayed (step 430). *Id.* at. 73:1-2, 5-7, 10-14, 61-63. The changes made by the expert in the algorithm produced results (in steps 412 and 418) are then used to modify parameters of the algorithm to improve future diagnosis. *Id.* at 73:15-28; Ex. 1002 at ¶ 46. *Walker* states that, using this iterative approach, the algorithm "may be specifically tailored for [a] patient by altering parametric settings to enhance the utility of future application of the algorithm." Ex. 1006 at 74:25-27.

In *Walker*, dataset D4 (and D5) includes diagnosis that takes into consideration the degree of relationship between algorithm-identified diagnosis (dataset D2) and human-assessments of the algorithm-identified diagnosis (in steps 412 and 418). Ex. 1002 at ¶ 47. *Walker* states that datasets D4 and D5 may be annotated to indicate features identified by the algorithm and changes made to the identification by the expert. Ex. 1006 at 72:64-67; 73:2-5. Thus, in steps 412 and 418, *Walker* determines how the information is presented taking into consideration the degree of relationship between the algorithm and the human diagnoses. Ex. 1002 at ¶ 47. Since parts of the dataset D2 that the expert does not agree with, or has changed (Ex. 1006 at 72:65-66; 73:4-5), are not included in datasets D4 and D5, they are not reported in step 430. Therefore, *Walker* also selects if information is presented, and what information is presented, based on the degree of relationship

between algorithm and the human diagnoses. Ex. 1002 at ¶ 47. Thus, *Walker* selectively presents information based on a measure of correlation between algorithm-identified diagnosis and human-assessments of at least a portion of the algorithm-identified diagnosis. *Id*.

Based on the teachings of *Walker* and the *ACC Guidelines*, it would have been obvious to POSITA to modify *Bock* by incorporating the human-assessment feature of *Walker* in *Bock* to improve diagnosis of AF. *Id*. at ¶ 48. *Bock* recognizes the difficulty of identifying AF over other irregular heart rhythms using computer algorithms, and the importance of ensuring accurate AF diagnosis. Ex. 1005 at 2:4-17. The *ACC Guidelines* teach the importance of having algorithm-detected arrhythmias validated by an experienced technician to ensure accuracy of diagnosis especially during ambulatory cardiac monitoring. Ex. 1008 at 913, 914, 917. *Walker* teaches a technique of using human assessment to improve the accuracy of the diagnosis made by computer algorithms and to tailor the computer based diagnosis to specific patients. Ex. 1006 at 2:16-22; 7:21-29. Based on the teachings of one or both of the *ACC Guidelines* and *Walker*, a POSITA would have recognized that modifying *Bock* to include human-assessment will assist in improving the accuracy of diagnosis especially during Holter monitoring in which ECG of an ambulatory patient is monitored. *See* Ex. 1005 at 1:59-61; Ex. 1002 at ¶ 48. Moreover, a POSITA also would have recognized that incorporating the

human-assessment feature in *Bock* would assist in distinguishing AF rhythms in the physiological data from other irregular rhythms and to specifically tailor AF diagnosis for different patients (*id*.), and would have amounted to nothing more than the use of a known technique to improve a similar device that yields nothing more than predictable results. *See KSR Int'l. Co. v. Teleflex, Inc.*, 550 U.S. 398, 417 (2007).

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

In FIG. 7 of *Bock*, "portions of the waveform during which an AF condition exists are [ ] marked with horizontal bars 152, 154, and 156, respectively." Ex. 1005 at 11:46-48; FIG. 7. Thus, bars 152, 154, 156 indicate the incidence of AF events. The bar widths indicate the duration of the identified AF events. Ex. 1002 at ¶ 49. For example, the width of bar 152 indicates that the duration of this AF event is approximately 7.2 hours (based on a rough measurement of the x-axis). *Id*. Thus, bars 152, 154, 156 indicate information on both incidence and duration of AF events during the defined time period of 24 hrs. *Id*.

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

In FIG. 7 of *Bock*, heart rate trend (waveform 150) is presented side-by-side with the atrial fibrillation burden (bars 152, 154, 156, and total AF 158). *See* Ex. 1005 at FIG. 7; Ex. 1002 at ¶ 50.

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

FIG. 7 of *Bock* presents heart rate trend and atrial fibrillation burden on the same graph. *See* Ex. 1005 at FIG. 7, 11:45-48; Ex. 1002 at ¶ 51.

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

In system 20 of *Bock*, ECG data is input into a classification module 22 "where the beats are detected and correlated to templates based on morphology." Ex. 1005 at 5:15-21, FIG. 2. A beat refers to an ECG signal from one complete heartbeat. Ex. 1002 at ¶ 52. "The beat classification module determines whether the heart beat being analyzed falls within classifications that are suitable for use in analyzing whether an AF condition exists. If the beat falls within a class suitable for analysis, the ECG information is fed to an interval calculator [24]." Ex. 1005 at 2:33-38. "The interval calculator determines the time interval between successive R waves (the 'RR interval')." *Id.* at 2:38-39; *see* also 5:29-30. The RR

interval output from interval calculator 24 is provided to a probability engine 40 and to a contextual analysis module 30. *Id.* at 2:29-41. Engine 40 "receives the beat classification data and RR interval value generated by modules 22 and 24 and calculates a probability that the current beat or rhythm is an AF arrhythmia" and outputs a state variable indicating whether or not AF is present in that beat. *Id.* at 5:46-53; 6:53-55. That is, system 20 identifies AF events by examining ECG data in multiple time intervals (i.e., multiple beats), and identifies intervals (beats) in which at least one AF event has occurred. Ex. 1002 at ¶ 52.

FIG. 7 illustrates how the AF events identified by system 20 are presented. In FIG. 7, the time intervals at which AF events are identified by system 20 are presented (bars 152, 154, 156) in alignment with the information regarding the heart rate data on a common time scale. Ex. 1005 at 11:44-49, FIG. 7; *see also supra* Section IX.A.1.iv; Ex. 1002 at ¶ 53.

6. Independent Claim 20

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

Bock discloses methods to detect heart beat irregularities. Ex. 1005 at 1:6-10. *Bock* states that the method "is intended to be implemented in software running on a computer … capable of executing instructions and having such common hardware components as a [ ] memory." *Id.* at 3:66 – 4:2. A memory of

the computer that stores this software is the recited "article comprising a machine-readable medium." Ex. 1002 at ¶ 54.

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

As discussed with claim 1, *Bock* teaches this limitation. Ex. 1005 at 1:8-10, 52-55; 5:16-17; 11:36-38; *supra* Section IX.A.1.ii; Ex. 1002 at ¶ 55.

iii. "obtaining heart rate data for the living being; and"

As discussed with claim 1, *Bock* teaches this limitation. Ex. 1005 at Abstract; 1:6-7, 54-55; 2:38-39; FIG. 7; *supra* Section IX.A.1.iii; Ex. 1002 at ¶ 56.

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

As discussed with claim 1, *Bock* teaches this limitation. Ex. 1005 at 11:45-49; FIG. 7; *supra* Section IX.A.1.iv; Ex. 1002 at ¶ 57.

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

As discussed with claim 1, *Bock* as modified by *Walker* and the *ACC Guidelines* teaches this limitation. *Supra* Section IX.A.1.v; Ex. 1002 at ¶ 58.

7. Claim 21 - "The article of claim 20, wherein identifying atrial fibrillation events comprises examining the physiological data in time intervals, and identifying the intervals in which at least one

atrial fibrillation event has occurred, and wherein presenting information comprises displaying the identified intervals in alignment with the information regarding the heart rate data on the common time scale."

As discussed with claim 8, *Bock* as modified by *Walker* and the *ACC Guidelines* teaches this limitation. *Supra* Section IX.A.5; Ex. 1002 at ¶ 59.

8. Independent claim 31

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

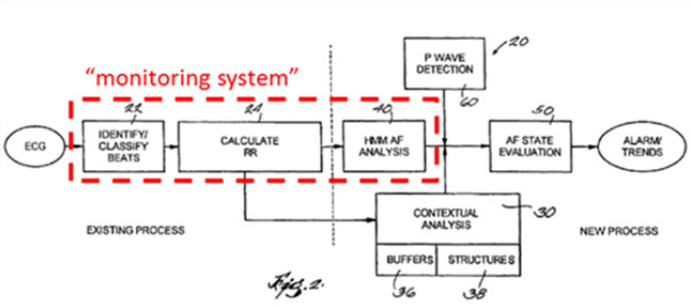
Bock discloses methods and devices to detect arrhythmias and atrial fibrillation (AF). Ex. 1001 at 1:6-10. In *Bock*, information related to the arrhythmias is reported as a graph. Ex. 1005 at 11:45-49; FIG. 7; Ex. 1002 at ¶ 60.

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

FIG. 2 of *Bock* is reproduced below and annotated with a dashed box to indicate the "monitoring system." Ex. 1002 at ¶ 61. As illustrated in this FIG. 2, classification module 22, interval calculator 24, and probability engine 40 of system 20 form the recited "monitoring system" that is configured to process and report physiological data, including "heart rate data" (RR intervals), for a living being and configured to identify arrhythmia events from the physiological data.

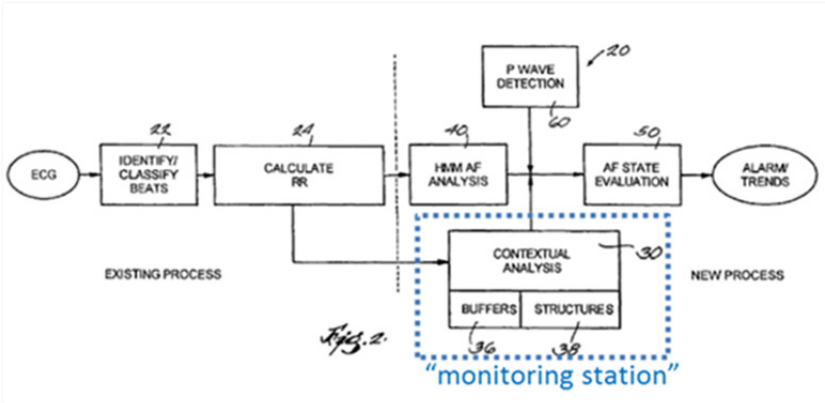
In system 20, ECG data is input into classification module 22 which determines whether the heart beat is suitable for use in analyzing whether an AF

condition exists. Ex. 1005 at 2:33-36. If it is, the ECG information is directed to interval calculator 24. *Id.* at 2:36-38. "The interval calculator determines the time interval between successive R waves (the 'RR interval')," and provides the RR interval output to probability engine 40 and contextual analysis module 30. *Id.* at 2:38-41. Engine 40 "receives the beat classification data and RR interval value generated by modules 22 and 24 and calculates a probability that the current beat or rhythm is an AF arrhythmia" and outputs a state variable indicating whether or not an AF event is present in that beat. *Id.* at 5:47-52; 6:53-55. AF is a form of arrhythmia. Ex. 1002 at ¶ 62; *see also* Ex. 1005 at 1:6-10. The components of FIG. 2 may be software components or hard-wired circuits. Ex. 1005 at 3:65 – 4:5.



iii. "a monitoring station for receiving the physiological data from the monitoring system;"

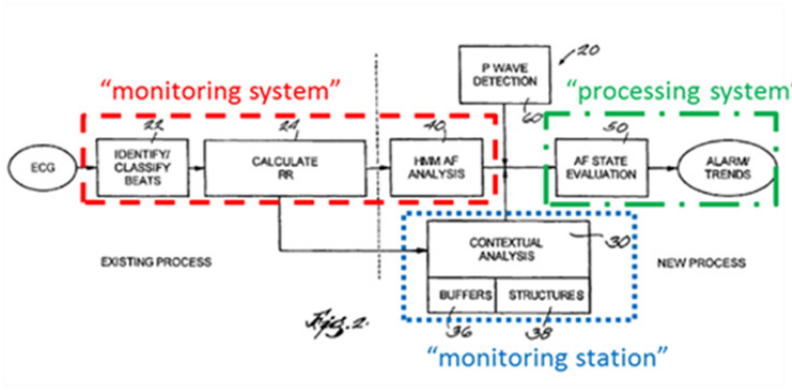
FIG. 2 of *Bock* is reproduced to the right and annotated with a dashed box to indicate the "monitoring station." As just discussed above, classification module 22, interval calculator 24, and



probability engine 40 form the recited "monitoring system." The AF detected by engine 40 and the RR interval values from calculator 24 are output to module 30. *Id.* at 6:32-38. "[M]odule matches predefined maps to the running map of the current ECG information. The contextual analysis module also determines the similarity between consecutive RR intervals." *Id.* at 2:46-49. Contextual analysis module 30 is the recited "monitoring station" that receives the physiological data from the monitoring system. Ex. 1002 at ¶ 63.

iv. "a processing system configured to receive arrhythmia information from the monitoring system and configured to receive human-assessed arrhythmia information from the monitoring station wherein the human-assessed arrhythmia information derives from at least a portion of the physiological data and"

FIG. 2 of *Bock* reproduced to the right is annotated with dashed boxes to indicate the "monitoring station," "monitoring system," and "processing system."



With reference to this figure, state evaluation module 50 receives the state variable that indicates whether an AF condition is present from probability engine 40. Ex. 1005 at 2:41-45; 5:51-52; 6:53-55. That is, module 50 is configured to receive arrhythmia information from

the "monitoring system" (classification module 22, interval calculator 24, and probability engine 40). Ex. 1002 at ¶ 64.

Contextual analysis module 30 performs multiple tests to check if the AF state detected by engine 40 is a true AF event or a false alarm. Ex. 1005 at 2:46-52; 9:41-45. In one test, module 30 compares the physiological signal associated with the detected AF state with common beat patterns (or block maps) that appear irregular but are not as a result of an AF event. *Id.* at 9:42-45. The results of these tests are provided to module 50. *Id.* at 6:43-44; *see also* 2:46-54; 6:42-43; 9:63 – 10:28. Therefore, module 50 is also configured to receive arrhythmia information, derived from at least a portion of ECG data, from the "monitoring station" (module 30). Thus, module 50 is the recited "processing system." Ex. 1002 at ¶ 65.

Module 30 performs an algorithm-based assessment of the AF states identified by engine 40. Ex. 1002 at ¶ 66. However, As discussed with claim 1, it would have been obvious for a POSITA to have the assessment performed by a human in light of the knowledge of one of ordinary skill in the art and the disclosures of *Walker* and the *ACC Guidelines* to improve the accuracy of *Bock*'s algorithm-based diagnosis. *See supra* Section IX.A.1.v; Ex. 1002 at ¶ 66.

v. "wherein the processing system is capable of pictographically presenting, using a common time scale, information regarding the heart rate data during a defined time period and regarding duration of arrhythmia event activity, according to the identified arrhythmia events, during the defined time period such that heart rate trend is presented with arrhythmia event burden."

In *Bock*, module 50 ("processing system") "determines AF state and trend information that is delivered to a display or other output device" as illustrated in FIG. 7. Ex. 1005 at 6:43-47; 11:36-46; FIG. 7; Ex. 1002 at ¶ 67. As discussed with claim 1, FIG. 7 graphically presents heart rate trend and duration of AF activity for a defined time period on a common time scale and presents heart rate trend with AF burden. Ex. 1005 at 11:46-48; FIG. 7; *supra* Section IX.A.1.iv.

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

As discussed with claim 8, the "monitoring system" of *Bock* is capable of examining ECG data in multiple time intervals (i.e., multiple beats), and identifying intervals (beats) in which at least one AF event has occurred (*see* Ex. 1005 at 5:15-21, 46-53), and the "processing system" is capable of displaying the time intervals at which AF events are identified by system 20 in alignment with the information regarding the heart rate data on a common time scale. *Id.* at 6:43-47; 11:45-48; FIG. 7; *see supra* Section IX.A.5; Ex. 1002 at ¶ 68.

10. Independent claim 33

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

As discussed above with respect to claim 31, *Bock* discloses a system to detect and report arrhythmias. Ex. 1005 at 11:44-48; FIG. 7; *supra* Section IX.A.8.i; Ex. 1002 at ¶ 69.

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

As discussed with claim 31, in *Bock*, classification module 22, interval calculator 24, and probability engine 40 are configured to process and report physiological data, including "heart rate data" (RR intervals), for a living being and to identify arrhythmia events from the data. Ex. 1005 at 1:6-10; 2:33-41; 5:47-52; 6:53-55; *see supra* Section IX.A.8.ii. *Bock* discloses that system 20 (including module 22, interval calculator 24, and probability engine 40) can "be implemented in software running on a computer … capable of executing instructions and having such common hardware components as a central processor," or may be "created using hard-wired circuits." *Id.* at 3:66 – 4:9. The structures of module 22, interval calculator 24, and engine 40 of *Bock* form the recited "monitoring means" as construed above. *See supra* Section VII.3.a.; Ex. 1002 at ¶ 70.

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

As described with reference to claim 31, the AF events detected by probability engine 40 and the RR interval values from interval calculator 24 are

output to state evaluation module 50 and contextual analysis module 30, and module 30 compares the patterns in the received ECG information with predefined maps and sends information regarding the identified AF events to module 50. Ex. 1005 at 2:46-54; 6:9-13, 42-43; *see supra* Section IX.A.8.iii. Thus, module 30 receives physiological data from the "monitoring means." Ex. 1002 at ¶ 71.

If module 30 is not configured for "displaying the physiological data to a human user," it would have been obvious for a POSITA to incorporate such a feature in module 30 in light of the knowledge of one of ordinary skill in the art and the disclosure of *Walker* and the *ACC Guidelines*. Ex. 1002 at ¶ 72. As discussed with claim 1, based at least on the teachings of these references, it would have been obvious for a POSITA to incorporate the human-assessment feature of *Walker* in *Bock* to improve the accuracy of *Bock*'s algorithm-based arrhythmia detection. *See Supra* section IX.A.1.v; Ex. 1002 at ¶ 72. In *Walker*, the human expert uses a computer to review the physiological data (step 400) and the algorithm produced results (step 412). Ex. 1006 at 6:51-55; 71:60-66; 72:3-6; *see also* at 17:61-63. This computer receives and displays the physiologic data to the expert. Ex. 1002 at ¶ 72.

In *Bock* as modified by *Walker* and the *ACC Guidelines*, contextual analysis module 30 performs the recited functions of "receiving the physiological data from the monitoring means," and "displaying the physiological data to a human user."

Bock discloses that system 20 (including module 30) can "be implemented in software running on a computer … capable of executing instructions and having such common hardware components as a central processor," or may be "created using hard-wired circuits." Ex. 1005 at 3:66 – 4:9. The structures of module 30 of *Bock* form the recited "display means" as construed above. *See supra* Section VII.3.b; Ex. 1002 at ¶ 73.

iv. "processing means for receiving arrhythmia information from the monitoring system and for receiving human-assessed arrhythmia information from the display means wherein the human-assessed arrhythmia information derives from at least a portion of the physiological data and"

As discussed with claim 31, state evaluation module 50 is configured to receive arrhythmia information from the monitoring system (module 22, interval calculator 24, and probability engine 40). *See supra* Section IX.A.8.iv. Module 50 also receives information from module 30 regarding the arrhythmia information derived from at least a portion of the physiological data. Ex. 1005 at 2:47-54; 5:58-65; 6:6-9, 42-43. In *Bock* as modified by *Walker* and the *ACC Guidelines* (as discussed above, *supra* Section IX.10.iii.), module 50 receives human-assessed arrhythmia information derived from physiological data from module 30. Thus, in *Bock* as modified by *Walker*, module 50 performs the recited functions of "receiving arrhythmia information from the monitoring system," and "receiving human-assessed arrhythmia information from the display means." Ex. 1002 at ¶

74. *Bock* discloses that system 20 (including module 50) can "be implemented in software running on a computer … capable of executing instructions and having such common hardware components as a central processor," or may be "created using hard-wired circuits." Ex. 1005 at 3:66 – 4:9. The structures of module 50 of *Bock* form the recited "processing means" as construed above. *See supra* Section VII.3.c; Ex. 1002 at ¶ 74.

v. "wherein the processing means is capable of pictographically presenting, using a common time scale, information regarding the heart rate data during a defined time period and regarding duration of arrhythmia event activity, according to the identified arrhythmia events, during the defined time period such that heart rate trend is presented with arrhythmia event burden."

As discussed with claim 31, state evaluation module 50 ("processing means") is capable of pictographically presenting heart rate data and duration of arrhythmic event activity for a defined time period using a common time scale such that heart rate trend is presented with arrhythmic event burden. Ex. 1005 at 6:43-47; 11:36-38; FIG. 7; *see supra* Section IX.A.8.v; Ex. 1002 at ¶ 75.

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

As discussed with claim 8, module 22, calculator 24, and engine 40 of *Bock* ("monitoring means") are capable of examining ECG data in multiple time

intervals (i.e., multiple beats), and identifying intervals (beats) in which at least one AF event has occurred (*see* Ex. 1005 at 11:8-9), and module 50 ("processing means") is capable of displaying the time intervals at which AF events are identified in alignment with the information regarding the heart rate data on a common time scale. *Id.* at 7:42-47;11:45-48; FIG. 7; *see supra* Section IX.A.5; Ex. 1002 at ¶ 76.

12. Independent Claim 37

i. "An apparatus comprising:"

Bock discloses an apparatus to detect irregular heart activity of a patient. Ex. 1005 at Abstract; 1:6-10, 55; Ex. 1002 at ¶ 77.

ii. "means for identifying atrial fibrillation events in physiological data obtained for a living being;"

As discussed with claim 1, system 20 of *Bock* receives ECG data from a patient and outputs a state variable which indicates the state of AF (atrial fibrillation). Ex. 1005 at 1:55, 44-45; 5:16-17; 11:36-39; *supra* Section IX.A.1.ii. Thus, system 20 of *Bock* performs the recited function of "identifying atrial fibrillation events in physiological data obtained for a living being." Ex. 1002 at ¶ 78. *Bock* discloses that system 20 can "be implemented in software running on a computer … having such common hardware components as a central processor," or may be "created using hard-wired circuits." Ex. 1005 at 3:66 – 4:9. The structures of system 20 of *Bock* form the recited "means for identifying atrial

fibrillation events" as construed above. *See supra* Section VII.3.d; Ex. 1002 at ¶ 78.

iii. "means for obtaining heart rate data for the living being; and"

In *Bock*, heart rate of the living being is obtained. Ex. 1005 at Abstract; 1:6-7; 2:41-44; *supra* Section IX.A.1.iii. Specifically, *Bock* states that "[t]he interval calculator 24 determines intervals between R waves and outputs an RR interval value," to contextual analysis module 30. Ex. 1005 at 5:29-32. "The probability engine 40 also receives [ ] the RR interval value." *Id.* at 5:42-43; *see* also 6:32-36. Thus both contextual analysis module 30 and probability engine 40 of *Bock* perform the recited function of "obtaining heart rate data for the living being." *Bock* discloses that system 20 (including module 30 and engine 40) can "be implemented in software running on a computer … having such common hardware components as a central processor," or may be "created using hard-wired circuits." *Id.* at 3:66 – 4:9. The structures of module 30 and engine 40 of *Bock* form the recited "means for obtaining heart rate data" as construed above. *See supra* Section VII.3.e; Ex. 1002 at ¶ 79.

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

Bock discloses that state evaluation module 50 of system 20 determines AF state and trend information that is delivered to a display or another output device. Ex. 1005 at. 6:42-47. This output of system 20 is illustrated in FIG. 7. *Id.* at 11:36-45. As disclosed with reference to claim 1, FIG. 7 graphically presents heart rate trend and duration of atrial fibrillation (AF) activity for a defined time period on a common time scale and presents heart rate trend with AF burden as recited in this limitation. *Id.* at 11:46-48; FIG. 7; *supra* Section IX.A.1.iv. Thus, module 50 performs the function of "pictographically presenting" in the recited manner. Ex. 1002 at ¶ 80. *Bock* discloses that system 20 (including module 50) can "be implemented in software running on a computer … having such common hardware components as a central processor," or may be "created using hard-wired circuits." Ex. 1005 at 3:66 – 4:9. The structures of module 50 of *Bock* form the recited "means for pictographically presenting" as construed above. *See supra* Section VII.3.f; Ex. 1002 at ¶ 80.

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

As explained with reference to claim 1, in *Bock* as modified *Walker*, the state evaluation module 50 selectively presents the information (heart rate trend and duration of AF) based on a measure of correlation between the identified AF

events and human-assessments of at least a portion of the identified AF events. *Supra* Section IX.A.1.v; Ex. 1002 at ¶ 81. Thus, the state evaluation module 50 ("means for pictographically presenting") of *Bock* comprises the "means for selectively presenting." As discussed in the claim construction section, in the '850 patent, the same structures perform the functions of "pictographically presenting" and "selectively presenting." *Supra* Section VII.3.g. As explained above, the structure for the "means for pictographically presenting" in the '850 patent and the structure for module 50 of *Bock* are the same or equivalent. *See supra* Section IX.A.12.v. Therefore, the same or equivalent structures perform the function of "selectively presenting" in *Bock* and the '850 patent. Ex. 1002 at ¶ 81.

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

As discussed above with respect to claim 37, module 50 of *Bock* presents information regarding AF events and heart rate data during a defined time period using a common time scale. *See supra* Section IX.A.12.iv; FIG. 7. Module 50 presents this information if the degree of relationship between AF events identified by engine 40 and the information from module 30 indicates that an AF event has occurred. Ex. 1005 at 5:64-65; 6:6-9; Ex. 1002 at ¶ 82.

Engine 40 determines the probability of an AF condition using a model and outputs one of two states AF or not AF. Ex. 1005 at 5:46-47, 54-55; 6:53-55. When the model indicates a high probability that the ECG signal indicates an AF, a state of AF is output to module 50 and module 30. *Id.* at 8:43-45. Module 30 performs several additional checks to validate this identification of an AF event by probability engine 40. *Id.* at 6:36-38; Ex. 1002 at ¶ 83.

First, module 30 determines if the rhythm associated with an AF event is a result of a pathology other than AF. Ex. 1005 at 6:58-61; 9:41-46, 63-65. If it is, the output from module 30 to module 50 indicates that the rhythm is not as a result of AF. *Id.* at 9:63 – 10:2. Module 30 then performs a percent similarity test to determine if the RR interval values indicate an AF. *Id.* at 10:2-7. If they do not, the output to module 50 indicates that AF is not present. *Id.* at 10:20-24; 11:11-13. Module 30 then performs an additional test to determine if the rhythm indicates an AF event. *Id.* at 10:4-6, 24-25. Thus, module 30 performs three separate tests to check the validity of an AF event detected by engine 40; Ex. 1002 at ¶ 84.

State evaluation module 50 outputs a state of AF only when both engine 40 and information from module 30 indicates an AF event. Ex. 1005 at 6:6-9; 11:8-14. Since engine 40 identifies an AF event only when there is a high probability of AF, and since this identified AF event is further validated using multiple tests by module 30, module 50 presents the recited information if the degree of relationship

between the two outputs (engine 40 and module 30) indicate a high positive predictivity for the identification of AF. Ex. 1002 at ¶ 85.

B. Ground 2 - Claims 3, 4, and 7 are obvious over *Bock*, *Walker*, and the *ACC Guidelines* and further in view of *Reinhold*

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

As discussed with reference to claim 1, *Bock* discloses graphically presenting heart rate data and duration of atrial fibrillation over time. Ex. 1005 at 11:45-48; FIG. 7; *see supra* Section IX.A.1.iv. While the heart rate values listed along the Y-axis of FIG. 7 are consistent with heart rate in beats per minute ("BPM"), *Bock* does not expressly state that the heart rate is presented in BPM. If the heart rate presented in FIG. 7 of *Bock* is not already in BPM, as considered by the Examiner during prosecution, it would have been obvious for a POSITA to graphically present the heart rate in BPM based on common knowledge in the art, and also from the teachings of *Reinhold*. *See Ex*. 1003 at p. 56, 57; *Ex*. 1002 at ¶ 86.

Reinhold discloses a remote cardiac monitoring system for monitoring patients using patient-worn units and remotely located office units. Ex. 1007 at Abstract. The patient-worn unit acquires the patient's physiological data and analyzes the data in real time to determine heart rate and other arrhythmias. *Id.* at Abstract; 27:55-66. The analyzed data is sent by telemetry to the remotely located

an office unit. *Id.* at Abstract; 24:55-56. The office unit prepares a patient report for a physician. *Id.* at Abstract; *See* "Patient Report" at 29:60 – 32:15. This patient report includes FIG. 8 reproduced to the right. *Id.* at 30:49; Ex. 1002 at ¶ 87.

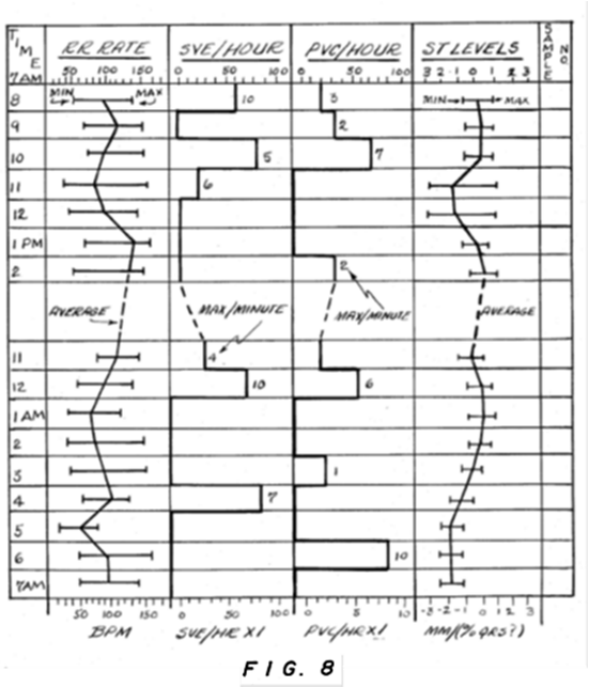


FIG. 8

FIG. 7 of *Bock* plots the heart rate (*see* "R-R Rate" on the x-axis) in BPM and the frequency of arrhythmic events (such as, supraventricular extrasystole (SVE), premature ventricular contraction (PVC), etc.) which were recorded over the monitored time. Ex. 1007 at FIG. 8; 26:1-26; 27:55-66; 31:35-54; Ex. 1002 at ¶ 88. If the heart rate in FIG. 7 of *Bock* is not already in BPM, based at least on the teachings of *Reinhold*, it would have been obvious for a POSITA to modify FIG. 7 to present the heart rate data in BPM to enable a physician to easily understand the heart rate data and render treatment. A POSITA would have known that heart rate is the speed of the patient's heartbeat per unit of time and is commonly expressed in BPM. Ex. 1002 at ¶ 88. Thus, a POSITA would have known that presenting heart rate in BPM in FIG. 7 of *Bock* would be beneficial to certain physicians, who may be used to seeing heart rate

expressed in its common unit of measurement, BPM. Ex. 1002 at ¶ 88; *see KSR*, 550 U.S. at 417.

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

As discussed above with respect to claim 3, it would have been obvious for a POSITA to modify the heart rate data presented in FIG. 7 of *Bock* based on the presentation of heart rate data in FIG. 8 of *Reinhold*. *See supra* Section IX.B.1. In FIG. 8 of *Reinhold*, the heart rate is presented in average beats-per-minute and also shows the minimum ("MIN") and maximum ("MAX") heart rates. Ex. 1007 at FIG. 8. Standard deviation is a measure of how spread out the heart rate measurements are. Ex. 1002 at ¶ 89. The presented MIN and MAX in FIG. 8 correspond to "information regarding standard deviation of heart rate." A POSITA would have recognized that presenting heart rate as an average over a desired time window and indicating the maximum and minimum heart rate for this time window provide certain benefits including enabling the reviewing physician to quickly visualize the heart rate and its variability from the graph. Ex. 1002 at ¶ 89. A POSITA would have recognized that, due to the noisy appearance of the heart rate waveform in *Bock* (*see* Ex. 1005 at FIG. 7), a physician would have to spend time and effort to determine the patient's heart rate at any particular time. Ex. 1002 at ¶ 89. For example, the POSITA would have known that it would be difficult for the

physician to quickly determine the patient's heart rate at, for example, 2.4 hours after monitoring began (i.e., at the first indicator mark on the x-axis to the right of time = 0) because the heart rate in this region appears to vary from about 80-100. *Id*. Based at least on the teaching of *Reinhold*, a POSITA would have recognized that presenting the heart rate as an average value and showing its minimum and maximum values (as in FIG. 8 of *Reinhold*) will allow the physician to quickly determine the patient's average heart rate and its variability. *Id*. A POSITA would have known that variability of the heart rate is an indicator of cardiac health (*see* Ex. 1008 at p. 918) and therefore would have been motivated to present, not only the average heart rate, but also a standard deviation in FIG. 7 of *Bock* which would yield nothing but predictable results. Ex. 1002 at ¶ 89; *see KSR*, 550 U.S. at 417.

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

As discussed above with claim 1, FIG. 7 of *Bock* pictographically presents heart rate trend and AF burden. *See supra* Section IX.A.1.iv. Based at least on the teachings of *Reinhold*, it would have been obvious for a POSITA to show the heart rate trend and atrial fibrillation burden on different graphs. Ex. 1002 at ¶ 90.

As discussed with reference to claim 3, *Reinhold* discloses a remote cardiac monitoring system which produces a patient report with illustrations as shown in FIG. 8. Ex. 1007 at Abstract; 29:59; 30:48-52; *see supra* Section IX.B.1. FIG. 8

plots the heart rate of the patient for a time period (24 hrs – 7AM to 7AM) and arrhythmic events such as (the frequencies of supraventricular extrasystole (SVE), premature ventricular contraction (PVC), etc.) for the same time period on a common time scale (*see* Y-axis). Ex. 1007 at FIG. 8; 26:1-26; 27:55-66; *see supra* Section IX.B.1; Ex. 1002 at ¶ 91. In FIG. 8, the heart rate and the observed arrhythmic events are plotted as different graphs (*see* different x-axes scales for heart rate, SVE/hour and PVC/hour) using a common time scale on the Y-axis. *See* Ex. 1007 at FIG. 8.

Based at least on this teaching of *Reinhold*, it would have been obvious for a POSITA to modify FIG. 7 of *Bock* to show heart rate trend and atrial fibrillation burden on different graphs for better readability. Ex. 1002 at ¶ 92. A POSITA would have known that showing different types of arrhythmic events (e.g., atrial irregularities, ventricular irregularities, ischemias, etc.) experienced by the patient during the monitored time period in different graphs (as in *Reinhold*) will enable the physician to get a better idea of the cardiac condition of the patient and thus help in diagnosis and treatment. *Id*. A POSITA would also have known that showing such different types of arrhythmic events on the same graph as the heart rate trend will make the graph cluttered and hard for the physician to read. *Id*. A POSITA would have recognized that showing the heart rate trend and the observed

arrhythmic events in different graphs will make it easier for the physician to review the graph. *Id*.

C. Ground 3 – Claim 9 is obvious over *Bock*, *Walker*, and the *ACC Guidelines* and further in view of *Chen*.

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

As discussed above with respect to claim 1, FIG. 7 of *Bock* pictographically presents heart rate trend and atrial fibrillation burden for a defined time period of 24 hours. Ex. 1005 at FIG. 7; *see supra* Section IX.A.1.iv. If the method of *Bock* does not include receiving an input specifying this defined time period, based at least on the teachings of *Chen*, it would have been obvious for a POSITA to modify *Bock* to enable a physician to evaluate the effect of a treatment on the patient's cardiac data. Ex. 1002 at ¶ 93.

Chen discloses a method of detecting atrial arrhythmias in a patient using an implantable system 20. Ex. 1009 at Abstract; 4:45-49. In the method of *Chen*, system 20 detects the occurrence of arrhythmia from cardiac rhythms for a monitored time period and determines the duration of time associated with each arrhythmia. *Id.* at 1:53-55, 57-60. Trend data is then produced by summing the time durations to determine a cumulative time duration for each observed arrhythmia during the monitored time period. *Id.* at 1:63 – 2:4. An output is then produced which lists information (start time, duration, etc.) regarding the observed

arrhythmias for the monitored time period. *Id.* at 11:5-12; FIG. 8. In *Chen*, the monitored time period may be selected by a physician using an external programmer "by inputting a beginning date/time and an ending date/time to define a time span of interest." *Id.* at 11:20-23. The physician uses the output in *Chen* to determine "reductions or increases in AF rhythms over time, such as before and after a time at which AF therapy was delivered." *Id.* at 12:1-8; Ex. 1002 at ¶ 94. *Chen* states that "[t]his data may be used by the physician when evaluating a patient's condition and when developing or administering a treatment program for the patient." Ex. 1009 at 12:13-16. Based at least on these teachings of Chen, a POSITA would have known that enabling a physician (or a technician) to specify the time period for presenting heart rate trend and atrial fibrillation burden information in *Bock* will allow the physician to gauge the effect of treatment on the patient's heart rate and/or AF occurrence and duration. Ex. 1002 at ¶ 94. A POSITA would also have recognized that, due to the noisy appearance of the heart rate waveform in *Bock* (*see* Ex. 1005 at FIG. 7), a physician would have to spend time and effort to determine the patient's heart rate at any particular time. For example, the person or ordinary skill in the art would have known that it would be difficult for the physician to quickly determine the patient's heart rate at, for example, 2.4 hours after monitoring began (i.e., at the first indicator mark on the x-axis to the right of time = 0) because the heart rate in this region of FIG. 7 appears

to vary from about 80-100. *See id.* at FIG. 7; Ex. 1002 at ¶ 94. A POSITA would have known that allowing the physician to modify the time period (or the x-axis range of FIG. 7) of the information presented in *Bock* would enable the physician to plot the graph for a smaller time window (e.g., between 1.2 and 3.6 hrs. on the x-axis), and thus make it easier to obtain the heart rate 2.4 hours after monitoring the heart rate waveform and would amount to nothing more than applying known techniques to a known method to yield predictable results. *See* Ex. 1002 at ¶ 94; *KSR*, 550 U.S. at 417.

IX. CONCLUSION

For all of the foregoing reasons, the Petition for *Inter Partes* Review should be granted.

Respectfully submitted,

Dated: August 10, 2015

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Certificate of Service

Pursuant to 37 C.F.R. §§ 42.6(e) and 42.105(a), I hereby certify that on August 10, 2015, I caused to be served a true and correct copy of the foregoing "PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 7,212,850" and INFOBIONIC EXHIBITS 1001-1014 by Priority Express Mail on the Patent Owner at the following correspondence address of record for Patent No. 7,212,850, and at the following correspondence address for Patent Owner's litigation counsel:

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