Appeal Nos. 23-1512, -1513, -1514

United States Court of Appeals

for the

Federal Circuit

ALIVECOR, INC.

Appellant,

v.

APPLE INC.

Appellee.

On Appeal from the United States Patent and Trademark Office,
Patent Trial and Appeal Board
Nos. IPR2021-00970, IPR2021-00971, and IPR2021-00972

OPENING BRIEF OF APPELLANT ALIVECOR, INC.

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LANGUAGE OF EXEMPLARY PATENT CLAIMS

U.S. Patent No. 9,572,499
1. A method of determining a presence of an arrhythmia of a first user, said method comprising sensing a heart rate of said first user with a heart rate sensor coupled to said first user; transmitting said heart rate of said first user to a mobile computing device, wherein said mobile computing device is configured to sense an electrocardiogram; determining, using said mobile computing device, a heart rate variability of said first user based on said heart rate of said first user; sensing an activity level of said first user with a motion sensor; comparing, using said mobile computing device, said heart rate variability of said first user to said activity level of said first user; and alerting said first user to sense an electrocardiogram of said first user, using said mobile computing device, in response to an irregularity in said heart rate variability of said first user.
7. The method of claim 1, further comprising determining a presence of said arrhythmia using a machine learning algorithm.

U.S. Patent No. 10,595,731
1. A smart watch to detect the presence of an arrhythmia of a user, comprising: a processing device; a photoplethysmography ("PPG") sensor operatively coupled to the processing device; an ECG sensor, comprising two or more ECG electrodes, the ECG sensor operatively coupled to the processing device; a display operatively coupled to the processing device; and a memory, operatively coupled to the processing device, the memory having instructions stored thereon that, when executed by the processing device, cause the processing device to: receive PPG data from the PPG sensor; detect, based on the PPG data, the presence of an arrhythmia; receive ECG data from the ECG sensor; and confirm the presence of the arrhythmia based on the ECG data.
3. The smart watch of claim 2, wherein to detect the presence of the arrhythmia, the processing device is configured to input the PPG data into a machine learning algorithm trained to detect arrhythmias.

U.S. Patent No. 10,638,941
1. A method of cardiac monitoring, comprising: sensing an activity level of a user with a first sensor on a smartwatch worn by the user; when the activity level is resting, sensing a heart rate parameter of the user with a second sensor on the smartwatch; determining, by a processing device, that a discordance is present between the activity level value and the heart rate parameter; based on the presence of the discordance, indicating to the user, using the smartwatch, a possibility of an arrhythmia being present; and receiving electric signals of the user from an electrocardiogram sensor ("ECG") on the smartwatch to confirm a presence of the arrhythmia, wherein the ECG sensor comprises a first electrode and a second electrode.

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 23-1512, 23-1513, 23-1514

Short Case Caption AliveCor, Inc. v. Apple Inc.

Filing Party/Entity AliveCor, Inc.

Instructions:

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Date: 05/26/2023 Signature: /s/ Sean S. Pak

Name: Sean S. Pak

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	**2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2).	**3. Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. ☑ None/Not Applicable	Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. ☐ None/Not Applicable
AliveCor, Inc.		OMROM Corp.

☐ Additional pages attached

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

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5. Related Cases. Other than the originating case(s) for this case, are there related or prior cases that meet the criteria under Fed. Cir. R. 47.5(a)?

☑ Yes (file separate notice; see below) ☐ No ☐ N/A (amicus/movant)

If yes, concurrently file a separate Notice of Related Case Information that complies with Fed. Cir. R. 47.5(b). **Please do not duplicate information.** This separate Notice must only be filed with the first Certificate of Interest or, subsequently, if information changes during the pendency of the appeal. Fed. Cir. R. 47.5(b).

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

☑ None/Not Applicable ☐ Additional pages attached

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STATEMENT OF RELATED CASES

This consolidated appeal may affect or be affected by AliveCor's (No. 23-1509) and Apple's (No. 23-1553) pending appeals from the International Trade Commission's decision involving the same patents. Those appeals have also been consolidated with themselves and have been made companion cases with this consolidated appeal. *See* Dkt. 16.

In addition, this appeal may affect the pending district-court litigation in which AliveCor has asserted against Apple the same patents at issue in this appeal. *See AliveCor, Inc. v. Apple Inc.*, No. 20-cv-1112 (W.D. Tex.). That litigation is stayed pending resolution of the appeals from the International Trade Commission's decision. *See id*., Order, Dkt. 26 (May 6, 2021).

PRELIMINARY STATEMENT

This consolidated appeal by Patent Owner-Appellant AliveCor, Inc. arise from three Final Written Decisions ("FWDs") of the Patent Trial and Appeal Board (the "Board") in favor of Petitioner-Appellee Apple Inc., ruling on *inter partes* review that certain claims of AliveCor's U.S. Patent Nos. 9,572,499 ("the '499 patent"), 10,595,731 ("the '731 patent"), and 10,638,941 ("the '941 patent") are obvious over a number of prior art references.

The inventors of the AliveCor patents developed a device that could detect one of the most prevalent types of cardiovascular disease: arrhythmia. Arrhythmia is a condition where the heartbeat is irregular or beats slower or faster than normal. At the time of AliveCor's inventions, arrhythmia detection typically required using an ECG device in a clinical setting, where multiple independent leads or electrodes are attached to a patient's chest. The inventors recognized that while the less-intrusive PPG measurement was also available, that measurement was significantly less accurate at detecting arrhythmias. The inventors devised a novel solution: ***detecting*** an arrhythmia using PPG, which is measured continuously, and ***confirming*** the arrhythmia using ECG, which requires user interaction and is thus measured with less frequency but yields a more accurate result. This novel combination is found nowhere in the prior art.

The Board erred in its unpatentability determination for several reasons. *First*, the Board erroneously concluded that the machine learning dependent claims of AliveCor's '499 and '731 patents are obvious over the Li 2012 and Hu 1997 prior art, based on the testimony of Apple's expert Dr. Chaitman, submitted with its petition. Dr. Chaitman, however, is not qualified to opine on machine learning—he conceded a complete lack of knowledge regarding various kinds of machine learning, including what terms like "support vector machines" mean. Because Dr. Chaitman lacks any experience or even a basic understanding of machine learning, his testimony regarding the obviousness of those claims is unreliable and irrelevant as a matter of law. And because his testimony is the sole basis on which obviousness is based, the Board's decisions as to the '499 and '731 patents should be reversed on this basis alone.

Moreover, neither Li 2012 nor Hu 1997 prior art supports a *prima facie* case of obviousness given that the Board only found that a person of ordinary skill in the art ("POSITA") would have been motivated to use machine learning to ***confirm*** an arrhythmia, not to ***detect*** it as required by the claims. Moreover, neither reference teaches using machine learning ***on PPG data alone without the use of ECG data***. Rather, both references concern applying machine learning to data collected in an intensive care unit, where measurements from multiple data sources can be taken in a clinical setting. Li 2012—the reference used for the machine learning claims of

the ’731 patent—teaches using machine learning with a dataset ***including ECG*** and other data in addition to PPG data, but not using machine learning with PPG data alone. And while Li 2012 does teach a PPG-only embodiment, this embodiment does *not* use machine learning, as the Board correctly found. Hu 1997—the reference used for the machine learning claims of the ’499 patent—teaches ECG data only with no mention of PPG data. But one point of novelty of the AliveCor patents is applying machine learning to the inferior PPG measurement to more accurately detect an arrhythmia using PPG and thereby avoid triggering the user to take an ECG unnecessarily. If the Board’s reliance on Dr. Chaitman’s testimony alone does not warrant reversal on the machine learning claims of the ’499 and ’731 patents, the Board’s failure to find that all elements in the claims are obvious over the prior art does.

Second, the Board erroneously concluded that the Shmueli prior art renders obvious “confirming” a PPG detection of an arrhythmia using an ECG measurement, as required by the independent claims of the ’731 and ’941 patents. Shmueli detects an arrhythmia using a PPG sensor, and while Shmueli teaches the use of an ECG sensor, data from that sensor is ***not*** used to confirm; rather, the ECG data is analyzed only to identify “search correlations” used to “update detection parameters.” With no teachings in the prior art on which to rely, Apple led the Board into a hindsight-based reconstruction of the claims, pulling implications from Shmueli’s limited

teachings out of thin air to find confirmation obvious. The Board's decisions regarding the claims of the '731 and '941 patents should be reversed for this reason as well.

Third, the Board's decisions were based on an incomplete record because Apple violated its self-executing and self-enforcing obligation under the Board's rules to produce documents inconsistent with its allegations that the claims of the AliveCor patents are invalid as obvious. Despite the initial determination of the International Trade Commission ("ITC") in parallel proceedings ***upholding*** the validity of the claims based on secondary indicia evidence issuing prior to the FWDs, Apple deliberately opted not to produce any of that evidence in the IPR proceedings. Instead, Apple pitted these two agencies against each other, leveraging the ITC's stringent protective order to prevent AliveCor from even requesting production of the ITC secondary indicia evidence, thus preventing the Board from having a complete record on obviousness. Had the Board been privy to the secondary indicia evidence that played a significant role at the ITC, including before both the ALJ and the full Commission, the Board may very well have found, like the ITC, that the AliveCor patents are non-obvious. These divergent outcomes based on different sets of evidence warrant remand.

JURISDICTIONAL STATEMENT

The Board had jurisdiction over the underlying IPRs pursuant to 35 U.S.C. §§ 6(c) and 311. On February 7, 2023, AliveCor timely filed notices of appeal from the Board's three FWDs, each of which had issued on December 6, 2022. Appx914; Appx1474; Appx2016. This Court has jurisdiction pursuant to 35 U.S.C. § 319 and 28 U.S.C. § 1295(a)(4)(A).

STATEMENT OF THE ISSUES

1. Whether the Board erred in determining that claims 7-9 and 17-19 of the '499 patent and claims 3, 5, 6, 19, 21, and 22 of the '731 patent, which recite the application of machine learning to PPG data, are invalid as obvious, where the Board only found it would have been obvious to use machine learning to ***confirm*** an arrhythmia, not ***detect*** it as required by the claims.

2. Whether the Board erred in determining that claims 1-30 of the '731 patent and claims 1-23 of the '941 patent, which recite "confirm[ing] the presence of the arrhythmia" based on ECG data, are invalid as obvious, where the principal prior art reference (Shmueli) only teaches ***detecting*** irregular heart conditions using PPG data.

3. Whether the Board's decisions should be vacated where Apple withheld evidence of secondary indicia of non-obviousness despite its ongoing

obligation under Board rules to produce evidence inconsistent with its position that the AliveCor patents are obvious.

STATEMENT OF THE CASE

A. Cardiac Monitoring

1. Arrhythmias

The AliveCor patents teach systems and methods that allow for increased efficacy and convenience of heart monitoring for arrhythmias. Appx226 (2:17-38). The parties agreed in the proceedings below that an arrhythmia is "a cardiac condition in which the electrical activity of the heart is irregular or is faster or slower than normal." Appx7434. Arrhythmias can occur either continuously or intermittently (Appx249 (1:34-35)) and, while continuous arrhythmias are relatively easy to diagnose (because a diagnostic technique applied at any time will capture the continuously occurring arrhythmia), intermittent arrhythmias are more problematic because the diagnostic technique must be applied at the moment the user is experiencing the intermittent arrhythmia (which is unpredictable) (Appx249 (1:35-53)). Due to this unpredictability, continuous monitoring is necessary to detect intermittent arrhythmias. Appx249 (1:34-53).

There are many kinds of arrhythmias including "atrial or junctional premature beat;" "ventricular premature beat"; "atrial fibrillation / atrial flutter"; "supraventricular tachycardia intermittent"; "sick sinus syndrome"; "sinus tachycardia"; and "sinus bradycardia." Appx4116. Here, "tachycardia" refers to a

heartbeat rate that is faster than normal, while "bradycardia" refers to a heartbeat rate that is slower than normal. Appx194 (1:31-33).

One of the most common forms of cardiac arrhythmia is ***atrial fibrillation***, referred to as AFib, which occurs when electrical conduction through the atria of the heart is irregular and disorganized, leading to irregular activation of the ventricles. Appx194 (1:35-38). AFib is associated with atrial blood clot formation, which can lead to clot migration and stroke. Appx194 (1:40-42). AFib is a major contributor to cardiovascular diseases, a leading cause of death worldwide. Appx194 (1:25-26).

2. PPG

Of the two cardiac monitoring sensors described in the AliveCor patents, the simpler of the two is photoplethysmography (PPG). PPG sensors measure "a pulse pressure signal" from a user. Appx8464. PPG monitoring can reliably measure oxygen saturation and average heart rate, but is less reliable in detecting arrhythmias, especially atrial arrhythmias, such as atrial fibrillation, as compared to ECG. *See* Appx8472 (noting in 2017 that while "PPG can be an alternative to ECG for AF detection, it remains that in real-world applications, PPG-based AF detection could be limited by a number of factors").

One advantage of PPG is that it "only requires attaching a single sensor to the hand of the user." Appx3411. PPG sensors thus can fit easily into portable devices, permitting a user's cardiac health to be monitored at all times by having a single

sensor contact the user's hand. Appx3819 (teaching "***continuously*** measuring SpO_2 at least one of a wrist and a finger of the subject") (emphasis added).

3. ECG/EKG

ECG (also commonly referred to as EKG) is the "gold standard" for arrhythmia detection. Appx8138 (62:9-21); *see* Appx3874 (table 1); Appx8466. ECG measurements require more equipment than PPG and generally are more intrusive for a user, requiring connecting multiple electrodes to a patient. Appx4116. Thus, unlike PPG, ECG requires multiple points of contact and cannot be measured continuously on a portable device in a manner that is not cumbersome to a user.

As a result, however, ECG has many advantages for arrhythmia detection. "[E]lectrical activity of the heart" "show[s] up as five distinct waves on [an] ECG readout." Appx60 n.7. These are the "P-wave, Q-wave, R-wave, S-wave, and T-wave." Appx60 n.7. These waves, with the exception of the R-wave, are not present in PPG data. *See* Appx3410-3411 (¶ 32) (Apple's expert Dr. Chaitman testifying that only "the physiological information derived from RR intervals of ECG data can … be derived from the pulse period of a PPG reading."). However, certain kinds of arrhythmias, such as atrial fibrillation—the most common kind of arrhythmia—can only be detected using the P-wave, which is not visible on PPG. Appx233 (15:18-21).

B. AliveCor's Patents

The novel solution claimed in AliveCor's patents allows detection of an arrhythmia via the less-intrusive, continuously-monitored PPG sensor and confirmation when appropriate using the more accurate but more burdensome ECG sensor, combined with activity monitoring using the tools available on a smartphone or smartwatch. Appx7138-7139 (¶¶ 46-47). As discussed in greater detail below, the AliveCor patents teach application of machine learning algorithms to the PPG sensor to train and improve its ability to detect arrhythmias, before alerting the user to take a second measurement using the ECG sensor.

Pertinent to this appeal, the '499 and '731 patents include claims directed to machine learning, while the '731 and '941 patents include claims directed to "confirming" a presence of an arrhythmia.[1]

1. The Claims Of The '731 And '941 Patents Requiring Separate "Detection" And "Confirmation"

One point of novelty of the '731 and '941 patents is the requirement of ***separate*** "detection" and "confirmation" steps.[2] An arrhythmia condition is first

[1] The '499 patent is the great-grandparent of the '731 patent, and the two patents share the same specification. *See* Appx208-209. The '941 patent, while part of a different patent family, is directed to the same subject matter. Appx240; Appx257 (claim 1 reciting "cardiac monitoring" including indicating "a possibility of an arrhythmia being present" and taking an ECG).

[2] The '499 patent does not claim confirmation. Instead, it claims "alerting" a user to perform an ECG, which precedes analysis of the ECG to confirm the presence of the arrhythmia. Appx206.

detected using PPG data, and then is later confirmed with ECG data. *See* Appx64 ('731 patent, claim 1: "detect, based on the PPG data, the presence of an arrhythmia" and "confirm the presence of the arrhythmia based on the ECG data"); Appx123 ('941 patent, claim 1: "indicating to the user, using the smartwatch, a possibility of an arrhythmia being present" and "receiving electric signals of the user from an electrocardiogram sensor ('ECG') on the smartwatch to confirm a presence of the arrhythmia"). In the context of the machine learning dependent claims for the '731 patent, the Board ruled "that 'confirm' and 'confirming' are discrete requirements from 'detect.'" Appx85. The Board did not construe "confirm" or "confirming" in the context of the '941 patent. Appx143. In parallel proceedings before the ITC, Apple conceded the claims of both patents follow this multi-step process with separate detection and confirmation steps. *See* Appx7445 ("Respondent argues that 'one must first detect … before one can confirm' the arrhythmia's presence.").

The separate detection and confirmation steps are a core component of AliveCor's invention. As discussed above, one significant advantage of PPG is that it requires only a single sensor and can be measured continuously and non-invasively. Appx3411; Appx3819. But this ease of use comes with a downside: Although PPG is more convenient than ECG, PPG data is significantly less detailed than ECG data and therefore is less useful for detecting arrhythmias. *E.g.*, Appx3410-3411 (¶ 32); *see also* Appx8466 ("ECG remains the gold standard for the

electrophysiological definition and recognition of arrhythmias, including AF diagnosis."). Thus, the inventors developed a novel solution, marrying the more convenient but less accurate PPG sensor for initially detecting arrhythmias with the more intrusive but significantly more detailed ECG sensor for confirming that there is, in fact, an arrhythmia present. By putting both of these sensors on a portable device like a smartwatch, the user is able to realize the best of both worlds, with continuous PPG monitoring and accurate ECG confirmation of PPG-detected arrhythmias.

2. The Claims Of The '499 And '731 Patents Requiring Application Of Machine Learning To PPG Data At The "Detection" Step

The '499 and '731 patents explain that machine learning algorithms are used "to identify atrial fibrillation or other conditions such as arrhythmias." Appx230 (9:67-10:3). Machine learning relates to "algorithms capable of learning and/or adapting their structure (e.g., parameters) based on a set of observed data, with adaptation done by optimizing over an objective or cost function." Appx4670. Machine learning is used to "improv[e] the sensitivity and/or specificity of detection and diagnosis of disease." Appx4670; *see* Appx4669 (machine learning can "improv[e] detection, diagnosis, and therapeutic monitoring of disease"). The patents describe a number of specific types of machine learning algorithms that could be used for this purpose: "decision tree learning such as with a random forest,

association rule learning, artificial neural network, inductive logic programming, support vector machines, clustering, Bayesian networks, reinforcement learning, representation learning, similarity and metric learning, sparse dictionary learning, or the like." Appx230 (10:3-9).

The machine learning algorithms in AliveCor's patents improve the arrhythmia-detection ability of AliveCor's devices using PPG data. The machine learning claims of the '731 patent recite "input[ting] ***the PPG data*** into a machine learning algorithm trained to ***detect*** arrhythmias." Appx238-239 (emphasis added); *see* Appx238 (claim 5, reciting HRV data, which is derived from PPG data); Appx239 (claim 21) (same). The '499 patent's claims recite "***determining*** a presence of said arrhythmia using a machine learning algorithm." Appx206-207 (claims 7, 17) (emphasis added). And they do so using a "heart rate sensor," another name for a PPG sensor. Appx206 (claim 1, "determining, using said mobile computing device, a heart rate variability of said first user based on said heart rate of said first user"). Accordingly, the claims of the '499 patent require that the machine learning algorithm be applied to ***PPG data*** for arrhythmia detection.

Moreover, because the machine learning in the '499 and '731 patents is applied to ***detection***, it is necessarily applied to ***PPG data***. In both patents, the ECG sensor is ***not*** used during the detection process. In the '499 patent, "an irregularity in … heart rate variability" is determined using a PPG sensor that triggers an alert

to a user to perform the more accurate ECG measurement in order to confirm the presence of an arrhythmia detected by the PPG sensor. Appx206 (claim 1). And in the '731 patent, the "presence of the arrhythmia" detected using PPG is confirmed "based on … ECG data." Appx238 (claim 1).

C. The IPR Proceedings Below

Apple filed the IPR petitions at issue in this appeal in June 2021. IPR2021-00970 challenged claims 1-20 of the '499 patent based on (1) Shmueli in view of Osorio;[3] and (2) Shmueli in view of Osorio and Hu 1997. IPR2021-00971 challenged claims 1-30 of the '731 patent based on, *inter alia*, (1) Shmueli alone; (2) Shmueli in view of Osorio; and (3) Shmueli in view of Osorio and Li 2012. IPR2021-00972 challenged claims 1-23 of the '941 patent based on, *inter alia*, Shmueli in view of Osorio. There are other grounds in the IPRs addressing dependent claims not at issue here.

1. The Pertinent Cited Art

(a) Shmueli

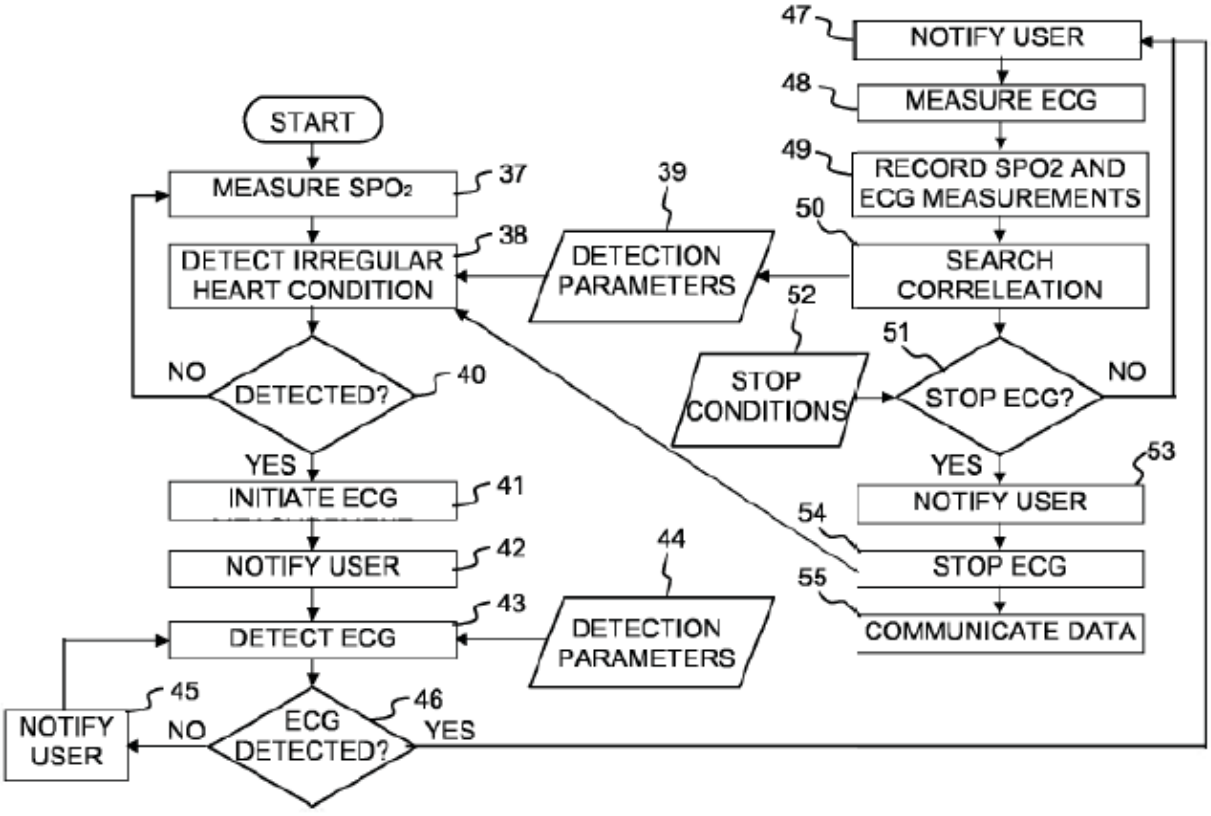
Shmueli is titled "Pulse Oximetry Measurement Triggering ECG Measurement." Appx3817. Shmueli discloses a "method and a system for triggering the measurement of electrocardiogram (ECG) signal of a user" by

[3] The issues in this appeal do not implicate the Osorio prior art, and it is therefore not discussed herein.

"continuously measuring SpO_2 at the wrist of the user, detecting an irregular heart condition from the SpO_2 measurement, notifying the user to perform an ECG measurement, and initiating the ECG measurement at least partially at the wrist." Appx3817. In the context of Shmueli for purposes of this appeal, SpO_2 and PPG are interchangeable.

In Figure 7, Shmueli depicts a "simplified flow chart" of the software it describes:

Fig. 7



Appx3843. In elements 37 and 38, Shmueli describes performing an SpO_2 measurement (PPG) and detecting an irregular heart condition from that

measurement. Appx3829. If an irregular condition is detected, the software "initiates [an] ECG measurement" by "operating ECG measuring unit 31" and notifying the user to perform an ECG at element 42. Appx3829. Once an ECG signal is detected using the ECG detection parameters (element 44), the software proceeds to element 47 to notify the user that the ECG signal is detected. Appx3829. At this point, the software "proceeds to element 48 to perform the ECG measurement" and "to element 49 to record the SpO_2 and the ECG measurements." Appx3830. The SpO_2 and ECG signals are "correlated and stamped with a time stamp." Appx3830.

Shmueli teaches that in element 50 the software "search[es] for correlations between the SpO_2 signal and the ECG signal to produce new detection parameters, or modify existing detection parameters, so as to enhance the detection algorithms of the irregular heart conditions." Appx3830. Once a "stop condition" terminates the ECG measurement, Shmueli transmits the ECG and SpO_2 data to a remote server that "further analyzes the data and distributes it and/or derived medical information to physicians, paramedics, or any other healthcare specialists." Appx3831. The AliveCor patents seek to avoid precisely this clinical analysis.

(b) Li 2012

Li 2012 describes analysis of "[f]alse cardiac monitor alarms in the intensive care unit (ICU)." Appx3873. Li 2012 describes a dataset using all the information

available in an ICU setting—PPG, arterial blood pressure ("ABP,") SpO_2, and ECG—and applying machine learning to this ***combined*** dataset. Appx3874. Li 2012 teaches that removing even one of the data sources, such as ABP, undermines the utility of its false alarm suppression algorithm. Appx3878-3879 (Tables 6-7 (removing one data source reduced false alarm suppression (the goal of Li 2012) from 30% to 20%)).

Li 2012 also teaches an embodiment using only PPG data. Appx3875. The PPG-only embodiment of Li 2012, however, does not utilize machine learning, but instead employs a rule-based heuristic algorithm. Appx3875. A rule-based algorithm is not a machine learning algorithm. Appx109 n.23.

(c) Hu 1997

Hu 1997 describes an ECG "beat classifier" for improving the performance of ECG processing. Appx4801. Hu 1997 teaches this beat classification in the context of "a clinical setting, such as an intensive care unit." Appx4801. While Hu 1997 does teach machine learning, it does not mention PPG. *See* Appx4801-4810.

2. Apple's IPR Prior Art Expert

Dr. Bernard Chaitman was Apple's sole prior art expert in the IPR proceedings, and Apple's machine learning arguments for both the '731 and '499 patents were built entirely on his testimony. Dr. Chaitman is a "well-respected cardiologist with 'extensive experience working with tools for detecting cardiac

conditions,'" and the Board found that he is a POSITA with respect to the AliveCor patents in general. *See* Appx83. Dr. Chaitman is not, however, an expert in machine learning and by his own admission does not know the meaning of machine learning terminology used in the patents to describe AliveCor's innovations. Indeed, Dr. Chaitman conceded in deposition that he "doesn't know" what the machine learning terminology recited in the patents, like "support vector machines," means. *See* Appx8017 (108:18-20) (conceding he has "never designed any support vector machines"); Appx8017 (108:12-14) (conceding he has "never designed any neural networks"); Appx8018 (109:5-8) ("I don't know exactly what each of these terms [means], the exact translation of that term, what the definition is, without doing further study on it."); Appx8018 (109:12-16) (conceding he "couldn't tell … exactly what [support vector machine] machines without having done that study").

3. The Final Written Decisions

The Board held a consolidated oral hearing on the three IPRs in September 2022. On December 6, 2022, the Board issued FWDs in each proceeding, finding all claims invalid on all grounds Apple had asserted. Appx1-55; Appx56-115; Appx116-169.

(a) IPR2021-00970 ('499 Patent)

As to the '499 patent, the Board found in Apple's favor on all asserted grounds, largely adopting Apple's arguments and reasoning in reply and rejecting AliveCor's counterarguments.

Regarding Ground 1, the combination of Shmueli and Osorio, the Board first addressed the teachings of Apple's primary reference, Shmueli. The Board found that Shmueli's disclosure of "irregular heart conditions" encompasses arrhythmias; that Shmueli's SpO_2 sensor is a reference to a PPG sensor; and that Shmueli "combines the ease of use of the PPG sensor with a less convenient, but confirmatory, ECG." Appx28-36. The Board concluded that "one of ordinary skill in the art would have understood Shmueli to teach or disclose methods and systems for 'determining the presence of an arrhythmia,' as required by the challenged claims." Appx35-36 (citing Appx3171 (¶ 30); Appx3184-3185 (¶ 52)).

Regarding Ground 2, which adds Hu 1997 to the combination of Shmueli and Osorio, the Board again adopted Apple's arguments in full. Appx42-51. Relying on Dr. Chaitman, the Board first addressed Apple's "PPG Data Machine Learning Theory," finding that "although Hu 1997 exemplifies the detection of arrhythmia using ECG data," the fact that the heart rate parameters come from PPG "would not have deterred a [POSITA] from applying machine learning to them" given the advantages of machine learning in improving detection accuracy. Appx46 (citing

Appx710; Appx3190-3192 (¶¶ 60-63)). The Board recognized that Hu 1997 teaches that the application of machine learning to ***ECG*** data is straightforward. Appx47-48. Next, the Board addressed Apple's "ECG Data Machine Learning Theory," acknowledging AliveCor's argument that Hu 1997 teaches only applying machine learning to ECG data. Appx49. The Board, however, found that the machine learning claims were not limited to PPG data. Appx50-51 ("[W]e read claim 7 as encompassing the application of machine learning to ECG data collected in response to the last step of claim 1, which does not require the analysis of PPG data.").

(b) IPR2021-00971 ('731 Patent)

The Board agreed with all of Apple's arguments for the '731 patent as well. *First*, the Board accepted Apple's arguments that Shmueli alone (Ground 1) and the combination of Shmueli and Osorio (Ground 2) render the claims obvious. Appx85-104). The Board's rationale that "Shmueli teaches or suggests 'analyz[ing] ECG data to detect (and confirm) irregular heart conditions'" (Appx94 (citing Appx1368)) mirrored its rationale for Ground 1 for the '499 patent (*see* Appx28-36), notwithstanding that the '731 patent includes claim limitations not found in the '499 patent, most notably "confirm[ing] the presence of the [detected] arrhythmia based on the ECG data" (Appx238 (claim 1)). The Board also noted that Shmueli's teaching of a "stop condition" wherein the ECG measurement continues until the

irregular heart condition is no longer detected supported the obviousness of the "confirm" aspect of the claims. Appx94-96.

Second, as to the '731 patent's machine learning claims, the Board found that a POSITA would have been motivated to combine Li 2012 with Shmueli and Osorio because of the "many advantages" machine learning has for "increas[ing] detection accuracy" of arrhythmias. Appx105. Despite recognizing that Li 2012 discloses applying machine learning to a combined dataset including both ECG as well as PPG data, the Board agreed with Apple that Li 2012 "could easily be adapted" to use fewer types of data than the full dataset it describes. Appx109. And the Board did so despite finding that Li 2012 ***does*** include an alternative PPG-only embodiment (a more natural read to the claims of the '731 patent, which expressly recite applying machine learning to PPG data) in which machine learning is ***not used***. Appx109 n.23. Resting its decision on Dr. Chaitman's testimony, the Board found that "those of ordinary skill in the art had a both [*sic*] interest and success in adapting machine learning to various biomedical applications." Appx110 (citing Appx3467-3468 (¶ 117); Appx3527 (¶ 259)). The Board then concluded that "it would have been obvious to ***confirm*** arrhythmia detection using a machine learning algorithm based on the PPG data, motion sensor data, and/or ECG data." Appx111 (quotation omitted; emphasis added). The Board did not find that it would have been obvious to use machine learning to ***detect*** an arrhythmia as required by the claims.

(c) IPR2021-00972 ('941 Patent)

As to the '941 patent, despite slightly different claim language, the Board's findings regarding Shmueli and Osorio overlap with its findings as to the other patents. *See* Appx144-162.

D. The Parallel ITC Proceedings

In April 2021, months before Apple filed its IPRs, AliveCor filed a complaint in the ITC alleging violations of Section 337 of the Tariff Act of 1930 based on Apple's infringement of the '499, '731, and '941 patents. When Apple filed its IPRs in June 2021, it put the two agencies on a parallel track, with both the Board's IPR decisions and the Commission's final determination (discussed below) issuing in December 2022. The Commission's final determination followed an initial determination by the ALJ that issued in June 2022. *See In the Matter of Certain Wearable Electronic Devices with ECG Functionality & Components Thereof*, 2022 WL 2981155 (U.S.I.T.C. July 27, 2022) ("*ITC ID*").

Just prior to the oral hearing in the IPRs, the ALJ found that Apple violated Section 337 by importing products practicing the '731 and '941 patents. *Id.* at *134. Relevant to the IPR proceedings, the ALJ concluded that AliveCor "present[ed] evidence that would support the non-obviousness of a single device which uses PPG

and ECG data to monitor health." *Id.* at *64.[4] The ALJ found that AliveCor "offer[ed] persuasive"—indeed "strong"—"evidence of industry praise for, and the commercial success of, the [AliveCor product], and (by presumption) the claims it practices." *Id.* The ALJ also found that "'multiple internal [Apple] presentations' and similar evidence … provide probative evidence of copying." *Id.* at *65 (alteration in original). This evidence included "Apple's own FDA submissions." *Id.* The ALJ concluded that this evidence "weighs against a finding of obviousness" for the '941 patent. *Id.* at *66. The ALJ made the same finding as to claims 16 and 17 of the '499 patent for the same reasons (*id.* at *104), but ruled that Apple did not infringe those claims (*id.* at *91-94). For the '731 patent, the ALJ ruled that claims 1, 12, and 16 are invalid "without regard to secondary considerations of non-obviousness." *Id.* at *86.

On December 22, 2022, the Commission issued its final determination affirming the ALJ's finding that Apple violated Section 337. *In the Matter of Certain Wearable Electronic Devices with ECG Functionality & Components Thereof*, 2023 WL 372372 (U.S.I.T.C. Jan. 20, 2023).[5] In doing so, the Commission

[4] The ALJ's finding that Apple made a *prima facie* showing of obviousness, overcome by this secondary indicia evidence, was based on different references than the ones raised in the IPRs. *Id.* at *66, *86-87, *104-105.

[5] The public version of the Commission's decision, cited herein, issued on January 20, 2023.

determined that the ALJ's "findings as to copying and industry praise … are amply supported by the record evidence" and "that the evidence of 'industry praise' and 'copying' together, even without commercial success, is sufficient to overcome the *prima facie* showing of obviousness" as to the '941 patent. *Id.* at *25. The Commission also determined that the ALJ's "secondary consideration findings as to the '941 patent applies to claims 1, 12, and 16 of the '731 patent as well" and thus were "sufficient to overcome the *prima facie* showing of obviousness" for those claims too. *Id.* at *26. The Commission suspended its remedial orders pending resolution of this appeal. *Id.* at *50-51.[6]

In contrast to the ITC proceeding, Apple did not produce any secondary indicia evidence in the IPR proceedings. And when AliveCor sought Apple's consent to use "non-public documents regarding secondary considerations of non-obviousness" in the IPR proceedings or Apple's availability for a conference with the Board about this issue, Apple declined to consent and further stated that even *asking* the Board to require production of that evidence would violate the protective order governing the ITC proceeding. AliveCor thus had no ability to seek production

[6] Both Apple and AliveCor appealed aspects of the Commission's decision. Those appeals have been consolidated and designated as a companion case to this appeal. *See supra*, at xii.

of this evidence in the IPR proceedings without simultaneously risking violation of the ITC protective order.

SUMMARY OF THE ARGUMENT

I. The Board's determinations of obviousness of claims 3, 5, 6, 19, 21, and 22 of the '731 patent and claims 7-9 and 7-19 of the '499 patent, which all recite machine learning, are erroneous for several independent reasons.

First, the Board's obviousness determination rests on legally irrelevant testimony of Apple's prior art expert, Dr. Chaitman. Apple submitted Dr. Chaitman's testimony with its petitions, but in deposition Dr. Chaitman conceded lack of knowledge of basic machine learning concepts. Due to this admitted lack of skill, Dr. Chaitman's petition testimony is unreliable and irrelevant as a matter of law and thus cannot support a finding of obviousness.

Second, the Board's findings disregard clear teachings of the prior art references and read in teachings where none exist. At the same time, the Board's conclusion of obviousness rests on findings having no relationship to the claims. In the claims of the AliveCor patents, pursuant to the obviousness theory that Apple proposed, detection is performed using PPG data, and confirmation is a separate step performed using ECG data. The dependent claims of both patents apply machine learning to the ***detection*** step and, accordingly, to ***PPG data***. But the Board only found it would have been obvious to use machine learning to ***confirm*** an arrhythmia;

it ***did not find*** that using machine learning with PPG data alone for detection of an arrhythmia would have been obvious based on the cited art —a key distinction as neither prior art reference teaches the use of machine learning with PPG data without ECG data. Thus, the FWDs do not establish *prima facie* obviousness.

Third, for both patents, the Board erred in using hindsight reconstruction to find that Shmueli's "search correlations" are machine learning, or somehow render it obvious. There are no teachings whatsoever in Shmueli supporting this conclusion, and the Board failed to consider teachings in Shmueli that the "search correlations" are used for a different purpose than detecting an arrhythmia, as claimed.

II. The Board erred in concluding that "confirming" the presence of an arrhythmia, found in all independent claims of the '731 and '941 patents, is obvious over Shmueli. Contrary to the Board's determination, Shmueli's teachings regarding searching for correlations between PPG and ECG data do not teach confirming the presence of an arrhythmia, as required by the claims. Shmueli teaches neither direct nor indirect confirmation of an arrhythmia. It does not teach analyzing the ECG data for any purpose, including to detect an arrhythmia—a necessary predicate for there to be any confirmation of an arrhythmia. Nor are its search correlations a teaching of indirect arrhythmia detection. Instead, Shmueli clearly teaches—a teaching

ignored by the Board—that the correlations are merely used to align the PPG and ECG signals in time.

Admissions of Apple's expert, Dr. Chaitman, reinforces that Shmueli teaches using ECG to *modify* PPG detection parameters, not to *confirm* anything. Dr. Chaitman admitted that in Shmueli, the ***only*** detection is detection using PPG data. Dr. Chaitman further admitted that Shmueli's "search correlations" are used to modify detection parameters used by the PPG sensor—again, not the ECG sensor—for arrhythmia detection.

III. At the very least, remand is warranted because Apple did not comply with its ongoing, self-executing, and self-enforcing obligation to produce evidence relating to secondary considerations of non-obviousness. Apple, as petitioner, had an ongoing obligation pursuant to 37 C.F.R. § 42.51(b)(1)(iii) to produce evidence inconsistent with any of its arguments, *e.g.*, inconsistent with its position that the claims of AliveCor's patents are invalid as obvious. This obligation clearly covers secondary considerations evidence. Here, Apple cannot contest that there is a bevy of secondary considerations evidence that the ITC found to be so relevant to the obviousness determination that it outweighed *prima facie* obviousness. And Apple cannot contest that it produced no secondary considerations evidence in the IPR proceedings. The Board therefore evaluated obviousness without highly relevant secondary considerations evidence, withheld by Apple, leading to decisions based

on an incomplete record. If this Court does not reverse the FWDs, it should remand for proceedings in which Apple produces all relevant secondary considerations evidence so that the Board can evaluate obviousness on the same complete record as the ITC.

STANDARD OF REVIEW

This Court reviews the Board's claim constructions based on intrinsic evidence *de novo* and any underlying factual findings concerning extrinsic evidence for substantial evidence. *SIPCO, LLC v. Emerson Elec. Co.*, 980 F.3d 865, 870 (Fed. Cir. 2020); *see Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 331 (2015) ("[W]hen the district court reviews only evidence intrinsic to the patent (the patent claims and specifications, along with the patent's prosecution history), the judge's determination will amount solely to a determination of law, and the Court of Appeals will review that construction *de novo*."). This Court likewise reviews "de novo the [Board's] ultimate determination of obviousness and compliance with legal standards, and ... review[s] underlying factual findings for substantial evidence." *Pride Mobility Prods. Corp. v. Permobil, Inc.*, 818 F.3d 1307, 1314 (Fed. Cir. 2016). "Substantial evidence is something less than the weight of the evidence but more than a mere scintilla of evidence." *In re NuVasive, Inc.*, 842 F.3d 1376, 1379-80 (Fed. Cir. 2016) (citation omitted). This Court reviews the admission of expert testimony, including whether an expert can credibly address the relevant technology,

for abuse of discretion. *See, e.g.*, *Kyocera Senco Indus. Tools Inc. v. Int'l Trade Comm'n*, 22 F.4th 1369, 1376 (Fed. Cir. 2022).

ARGUMENT

A patent's claims are obvious only if "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." Pre-AIA 35 U.S.C. § 103(a).

When, as here, a claim of obviousness depends on combining multiple references, a patent challenger must "identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). That is, the patent challenger must prove "that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so." *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1361 (Fed. Cir. 2007) (citation omitted). Finally, the combination of prior art must disclose all the limitations of relevant claims. *Velander v. Garner*, 348 F.3d 1359, 1363 (Fed. Cir. 2003).

A finding of "obviousness cannot be sustained with mere conclusory statements; instead there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006). In performing this analysis, factfinders must be aware of "the distortion caused by hindsight bias and must be cautious of arguments reliant on ex post reasoning." *KSR*, 550 U.S. at 421 (citing *Graham v. John Deere Co.*, 383 U.S. 1, 36 (1966)).

Additionally, if available, "secondary considerations" like "commercial success, long felt but unsolved needs, failure of others, etc," *Graham*, 383 U.S. at 17, must be considered before an obviousness conclusion can be reached. *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1328 (Fed. Cir. 2016). These considerations are important because they might shed "light to the circumstances surrounding the origin of the subject matter sought to be patented." *Graham*, 383 U.S. at 17-18.

Under these standards, the Board's decisions should be reversed, or at the very least vacated.

I. THE PRIOR ART DOES NOT RENDER OBVIOUS THE "MACHINE LEARNING" CLAIMS ('499 AND '731 PATENTS)

A. The Board's Decisions Rest On Legally Irrelevant And Unreliable Opinion Testimony

The Board legally erred or otherwise abused its discretion in relying on the testimony of Apple's expert Dr. Chaitman to invalidate the machine learning claims

in the '731 and '499 patents. Dr. Chaitman is admittedly not an expert in machine learning, and thus his testimony was irrelevant and unreliable as a matter of law. *See, e.g.*, *Kyocera*, 22 F.4th at 1376-77 ("To offer expert testimony from the perspective of a skilled artisan in a patent case—like for claim construction, validity, or infringement—a witness must at least have ordinary skill in the art. ***Without that skill, the witness' opinions are neither relevant nor reliable***") (emphasis added); *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1362 (Fed. Cir. 2008) ("Admitting testimony from a person … with no skill in the pertinent art[] serves only to cause mischief and confuse the factfinder."); *cf. Acoustic Tech., Inc. v. Itron Networked Sol'ns, Inc.*, 949 F.3d 1366, 1375 (Fed. Cir. 2020) ("[C]onclusory expert testimony and attorney argument cannot constitute substantial evidence …."); *TQ Delta, LLC v. Cisco Sys., Inc.*, 942 F.3d 1352, 1362 (Fed Cir. 2019) ("Untethered to any supporting evidence, much less any contemporaneous evidence, [an expert's] *ipse dixit* declaration" does not support obviousness, and "fails to resist the temptation to read into the prior art the teachings of the invention in issue.") (quotation omitted). Because there is no other evidence, let alone substantial evidence, to support the Board's determination of obviousness for the machine learning claims, its decisions should be reversed.

Apple's machine learning arguments for both the '731 and '499 patents rest on the testimony of its expert Dr. Chaitman. And the Board, by adopting Apple's

arguments in full, based its findings on the same evidence. Appx1377 (citing Appx3527-3530 (¶¶ 258-65)); Appx1378 (citing Appx3529-3530 (¶¶ 262-65)); *see* Appx1000 (in '731 patent petition, citing Dr. Chaitman for proposition that "a POSITA would have been motivated to employ a machine learning algorithm to detect arrhythmia based on its many advantages"); Appx346 (same for '499 patent). Similarly, Dr. Chaitman's opinion testimony was the only support for the conclusion that the proposed combinations render the claims obvious. *See, e.g.*, Appx1003 (citing Dr. Chaitman and the prior art for the proposition that '731 claim 3 would have been obvious); Appx349 (same for '499 claim 7). Accordingly, without Dr. Chaitman's testimony, there is no evidence whatsoever supporting the obviousness of the machine learning claims.

And yet Dr. Chaitman is admittedly ***not an expert*** in machine learning. While Dr. Chaitman described in his report different kinds of machine learning algorithms drawn from the specification of the '731 patent, including "support vector machines" and "neural networks" to be "machine learning algorithms" (Appx3408-3409 (¶ 27)), he readily conceded a ***complete lack of experience*** with any of these types of algorithms (Appx8018 (109:5-8) ("I don't know exactly what each of these terms [means], the exact translation of that term, what the definition is, without doing further study on it."); *see* Appx8017 (108:18-20); Appx8017 (108:12-14); Appx8018 (109:12-16)). He further conceded he "couldn't tell" what the various

types of machine learning he claimed were "known" for detecting arrhythmias even are—a necessary predicate for determining whether it would have been obvious to use it. *See* Appx8017 (108:6-11); Appx8018 (109:3-19). His testimony is therefore unreliable and irrelevant with respect to machine learning and cannot establish the obviousness of those claims. *See, e.g.*, *Kyocera*, 22 F.4th at 1376-77; *Sundance*, 550 F.3d at 1362.

Further illustrating the unreliability of Dr. Chaitman's testimony, AliveCor presented unrebutted evidence, in the form of deposition admissions from Apple's ITC expert Collin Stultz, M.D., Ph.D., that practicing cardiologists (and the healthcare community more generally) are skeptical of machine learning and would be hesitant to use it. Appx8287-8288 (211:9-212:8) (When asked why "healthcare professionals [are] wary of using machine learning applications," Dr. Stultz answered "deep learning methods tend to be very obtuse, difficult to explain, it's an impediment to their adoption in the clinical community and their use for patients."). And while the Board dismissed Dr. Stultz's testimony as relating only to "deep learning" (*see* Appx109 n.23), it is indisputable that (a) Dr. Stultz provided this industry skepticism testimony in response to a question about machine learning; and (b) deep learning is a kind of machine learning. Appx8287-8288 (211:9-212:8). Apple offered no evidence rebutting this testimony, which included expert testimony from AliveCor's expert Dr. Efimov that "the nature of machine learning [algorithms]

presents an impediment to their adoption in the clinical community and their use in patients." Appx7787 (¶ 85); Appx7847 (¶ 85). Apple offered no rebuttal evidence to Dr. Efimov from any expert, including Dr. Chaitman or Dr. Stultz, neither of whom submitted a declaration after institution of the IPR proceedings. The industry skepticism of machine learning in the clinical cardiology context (Dr. Chaitman is a practicing cardiologist) is thus *unrebutted*.[7] Accordingly, Dr. Stultz's deposition admission and Dr. Efimov's unrebutted testimony contradicts the obviousness of using machine learning. An expert with even a *de minimis* background in machine learning would have been familiar with this skepticism; Dr. Chaitman, however, lacks even that baseline knowledge, and the Board legally erred in finding obviousness based on his unreliable testimony. *See, e.g.*, *Kyocera*, 22 F.4th at 1376-77; *Sundance*, 550 F.3d at 1362.

After Dr. Chaitman admitted that he was not a machine learning expert, Apple pivoted in reply to its ITC expert, Dr. Stultz. Apple did not submit a declaration from Dr. Stultz in the IPR proceedings; it merely submitted Dr. Stultz's testimony from the co-pending ITC investigation. But Dr. Stultz's ITC testimony cannot cure the errors in the Board's decisions because it had nothing to do with any of the issues in the IPRs. Indeed, the Board did not even rely on Dr. Stultz's testimony for

[7] Apple did not submit any new testimony, from Dr. Chaitman or otherwise, responding to the testimony of AliveCor's expert.

obviousness—the only issue in the IPR proceedings.[8] Instead, the Board cited Dr. Stultz's ITC testimony in passing to note that the Board was "hard-pressed to find the addition of claim language reciting a generic machine learning element distinguishes" the claims "over the cited art." Appx110. However, the concept of "generic functional language," raised only in the ITC, ***is irrelevant to obviousness***. Instead, "generic functional language" relates to the Section 101 inquiry, which is the context in which Dr. Stultz offered his opinions in the ITC. Appx5909 (1083:18-21) (testifying he "analyze[d] certain dependent claims of the '731 patent regarding patent eligibility"); Appx5911 (1085:1-5) (testifying the claimed machine learning is "a generic functional term"). That testimony is thus irrelevant here, as it does not relate to the prior art at issue, motivation to combine, or even obviousness generally. *See NuVasive*, 842 F.3d at 1384 (vacating Board for crediting expert testimony on an unrelated topic).

B. Substantial Evidence Does Not Support The Obviousness Of Machine Learning As Claimed In The AliveCor Patents

If this Court determines that the Board's obviousness conclusion is based on unreliable and irrelevant expert testimony, it need not consider the other errors in the

[8] Nor could it have properly done so. Apple stipulated that it would "not seek resolution in the district court or the ITC of any ground of invalidity that utilizes" any of the prior art forming the part of any ground in any of the three IPR proceedings. Appx4828-4829; Appx4830-4831; Appx4832-4833. Dr. Stultz therefore necessarily could not have offered any opinion testimony regarding the prior art at issue in the IPRs.

Board's analysis. However, if the Court addresses these additional issues, the Board's decisions should still be reversed because they erroneously rely on disclosures in the Li 2012, Hu 1997, and Shmueli references that have nothing to do with the requirements of the claims.

As explained above (*see supra*, at p. 11-13), the claims of the '499 and '731 patents unequivocally require using machine learning to improve arrhythmia ***detection*** based on ***PPG*** data. But the disclosures and references on which Apple relies, if they disclose machine learning at all, apply those techniques to datasets other than PPG.[9] It is simply not enough to find, as the Board did, that machine learning existed, that it has been used in the context of cardiological applications, or even that it has been used for arrhythmia detection.

1. Li 2012 Does Not Render Obvious The Machine Learning Claims ('731 Patent)

The Board's obviousness determination with respect to machine learning based on Li 2012 should be reversed for several reasons.

[9] Li 2012 teaches applying machine learning to a dataset including PPG data but, as discussed in greater detail below, instead teaches using a rule-based heuristic algorithm instead of machine learning when only PPG data is considered. Appx109 n.23.

(a) Despite Acknowledging They Are Separate Claim Requirements, The Board Conflated Detection And Confirmation

The Board's obviousness determination is legally erroneous because the Board failed to address the claim requirement that machine learning is used for ***detection*** (*see* Appx238 ("[T]he processing device is configured to input the PPG data into a machine learning algorithm trained to ***detect*** arrhythmias.") (emphasis added)), and, as a consequence, failed to find that all elements of the claims are taught by the prior art. *See* pre-AIA 35 U.S.C. § 103(a) (requiring a finding the "the subject matter as a whole" is obvious); *see also CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (noting that examiner properly found no obviousness where "the examiner concluded that no combination of the prior art, even if supported by a motivation to combine, would disclose all the limitations of the claims").

In its petition, Apple proposed two alternative theories for obviousness—one tethered to the claims' machine learning detection requirements, another focused on using machine learning for confirmation. Appx1002-1003. Throughout the FWD, the Board conflated these two theories, ultimately adopting the second, "confirmation," alternative. *See* Appx111 ("[W]e agree with Petitioner that after an ECG is measured, it would have been obvious to ***confirm*** arrhythmia detection using a machine learning algorithm based on the PPG data, motion sensor data, and/or

ECG data.") (emphasis added). The claims, however, are unequivocally directed to ***detection***, as the Board found. Appx85. Accordingly, the Board's determination that it would have been obvious to use machine learning for ***confirmation*** is legally erroneous, because it does not support a finding of *prima facie* obviousness of the claims. And in nevertheless finding obviousness, the Board improperly read the machine learning for "detection" requirement out of the claims. *See, e.g.*, *Callicrate v. Wadsworth Mfg., Inc.*, 427 F.3d 1361, 1369 (Fed. Cir. 2005) (holding that it is improper to read out limitation clearly required by claim language and specification); *Unique Concepts, Inc. v. Brown*, 939 F.2d 1558, 1562 (Fed. Cir. 1991) ("All the limitations of a claim must be considered meaningful.").

Regardless of which of Apple's proposed alternatives reads the Board adopted, the Board's obviousness determination also fails because neither read is supported by substantial evidence. For the first alternative (improving *detection* using machine learning based on PPG data) the Board's conclusion fails for the reasons explained above: Li 2012's PPG-only embodiment ***does not use machine learning***. Appx108 n.22. And the second alternative (improving ***confirmation*** using machine learning based on ECG data) has no tie to the requirements of the claims of the '731 patent. Those claims are not directed to using machine learning for improving ***confirmation***, but using machine learning to improve ***detection***. *See* Appx238-239 ('731 patent, claims 3, 19) ("input[ting] the PPG data into a machine

learning algorithm trained to detect arrhythmias"). As the Board concluded, detecting via PPG and confirming via ECG are "discrete requirements" of the claims. Appx85. Thus, under either of Apple's two inconsistent alternative reads, the Board's obviousness determination lacks substantial evidence on this record.

(b) Li 2012 Teaches Using Machine Learning Only With A Large Multi-Source Dataset, And Teaches Using Other Techniques When PPG Alone Is Analyzed

Li 2012's teachings do not apply to the '731 machine learning claims and even in combination with Shmueli and/or Osorio would not render the claims obvious. Contrary to the Board's determination, a POSITA reading Li 2012 would have recognized its teaching to use rule-based, heuristic algorithms on PPG data, and that Li 2012 has no teaching that would lead a POSITA to conclude that using machine learning for arrhythmia detection would have been obvious. *See, e.g.*, *Institut Pasteur & Universite Pierre Et Marie Curie v. Focarino*, 738 F.3d 1337, 1345 (Fed. Cir. 2013) (reversing *inter partes* reexamination rejection upheld by Board because Board lacked substantial evidence to conclude that the prior art disclosed a particular claim limitation).[10]

[10] The ITC rejected Apple's similar argument that the AMON prior art at issue there renders obvious the machine learning claims of the '731 patent in part because the "learning algorithm referenced by Apple corresponds to the ECG sensor and its ability to recognize QRS widths, RR distances, and QT intervals," "not the PPG sensor." *ITC ID*, 2022 WL 2981155, at *81.

Li 2012 teaches using machine learning on a dataset with ***multiple*** data sources, including ECG, ABP, and PPG. Appx3874. Each source in this dataset is critical—as Li 2012 recognizes, if even one of these sources is removed, the algorithm's efficiency plummets. Appx3878-3879 (Tables 6-7 (showing that removing one data source—ABP—resulted in a sizable drop, from 30% to 20% in false alarm suppression)). Accordingly, a POSITA reviewing Li 2012 would have been motivated to train any machine learning algorithm on as many data sources as possible, given the known reduction in algorithm efficiency as those data sources are removed.

At the same time, a POSITA would have been aware of Li 2012's PPG-only embodiment for arrhythmia detection. Yet, as the Board itself recognized, Li 2012's PPG-only embodiment teaches a "rule-based, heuristic algorithm," ***not*** machine learning. Appx108 n.22. That finding is particularly relevant here because while the claims of the '731 patent do not state, for example, that ECG data is not to be used for arrhythmia detection, that limitation is evident by the claims' recitation that ECG data is used for another purpose—confirmation.

Nevertheless, the Board disregarded Li 2012's clear teaching to use rule-based heuristics (*i.e.*, not machine learning) on PPG data and implicitly determined that it would have been obvious to use machine learning instead. *See* Appx109 (rejecting AliveCor's argument that POSITA would not have applied machine learning to PPG

data in Li 2012). Here, the Board relied on Li 2012's teachings to "keep the number of free parameters which we need to learn as low as possible" and that its system "could easily be adapted to other alarms in the ICU." Appx109. But these disclosures are not supported by Dr. Chaitman's declaration—he does not mention these aspects of Li 2012. Instead, Apple highlighted these portions of Li 2012 in its reply without any expert support. Appx1377. Apple's interpretation of these disclosures is simply unsworn attorney argument, which cannot be the basis for a finding of obviousness. *See Gemtron Corp. v. Saint-Gobain Corp.*, 572 F.3d 1371, 1380 (Fed. Cir. 2009) ("[U]nsworn attorney argument … is not evidence and cannot rebut … other admitted evidence ….").

(c) The Proposed Combination Changes Li 2012's Principle Of Operation

The Board's obviousness determination should also be reversed because it failed to consider that plucking Li 2012's multi-dataset machine learning out of the ICU context, reducing the number of variables to Li 2012's algorithm to exclude ECG (as claimed in the '731 patent) directly contrary to its teachings, would fundamentally alter that reference's mode of operation. *See, e.g.*, *Plas-Pak Indus. v. Sulzer Mixpac AG*, 600 F. App'x 755, 758 (Fed. Cir. 2015) ("[C]hange in a reference's 'principle of operation' is unlikely to motivate a person of ordinary skill to pursue a combination with that reference.") (citing *In re Mouttet*, 686 F.3d 1322,

1332 (Fed. Cir. 2012); *In re Ratti*, 270 F.2d 810, 813 (C.C.P.A. 1959)).[11] As AliveCor explained below, Li 2012's system becomes inoperable for its intended purpose if ECG data is removed. Appx1334. Li 2012 specifically teaches that removing ECG from its ICU-collected set of heart data would have exponentially reduced the effectiveness of its system, rendering it inoperable for its intended purpose. Appx3878-3879 (Tables 6-7 (removing one data source reduced false alarm suppression (the goal of Li 2012) from 30% to 20%)). But the record is clear that at the time of the invention, unlike PPG, ECG measurement techniques use the "***gold standard tool – 12 lead ECG***, or Holter monitors and similar wearable or implantable devices." Appx91 (emphasis added). For this reason too, Li 2012 does not support the Board's obviousness determination.

2. Hu 1997 Does Not Render Obvious The Machine Learning Claims ('499 Patent)

For the '499 patent, Apple relied on an entirely different reference for machine learning—Hu 1997. As the Board found, Hu 1997 ***does not disclose PPG data at all***. Appx46 ("Hu 1997 exemplifies the detection of arrhythmia ***using ECG data***."

[11] Indeed, Apple's obviousness theory required applying Li 2012's dataset to PPG only: "Thus, in the Shmueli-Osorio-Li-2012 combination, Shmueli's PPG sensor is used to determine heart rate information, and Osorio's motion sensor is used to determine the user's activity level. Then, the combined device determines current HRV based on the heart rate information (from the PPG data) and detects arrhythmia using a machine learning algorithm based on the PPG data, heart rate, HRV, motion sensor data, and activity level." Appx1002 (citation omitted; emphasis omitted).

(emphasis added)). Instead, Hu 1997 teaches using machine learning with ***ECG*** data. Appx4801 (describing using "a 'mixture-of-experts' (MOE) approach to develop a customized electrocardiogram (ECG) beat classifier in an effort to further improve the performance of ECG processing and to offer individualized healthcare").

As an initial matter, as discussed above (*supra* p. 19), despite the parties' agreement that the "heart rate sensor" used for arrhythmia detection recited in the independent claims of the '499 patent refers to a PPG sensor (Appx306 ("The '499 patent teaches sensing a heart rate with a PPG sensor.")), the Board erroneously construed the machine learning dependent claims of the '499 patent as not being drawn to PPG data. Appx50-51. There is no dispute that at least claims 7 and 17 expressly recite "further comprising ***determining***," calling back to the independent claims' preamble recitation of "determining a presence of an arrhythmia." Appx206-207 (emphasis added). The independent claim then recites several steps, beginning with "sensing a heart rate" and concluding with "alerting said first user to sense an [ECG]." Appx206. These steps together comprise the arrhythmia determination, working together to detect an "irregularity in … heart rate variability," *i.e.*, arrhythmia detection. Appx206. And it is only when this arrhythmia is detected—after its "presence" is "determined"—that a user is "alerted" to take an ECG in order to confirm that detection. The claims of the '499 patent,

however, do not require an ECG measurement be taken. Appx206-207. This Court should correct that error on *de novo* review. *See, e.g.*, *Teva Pharms.*, 574 U.S. at 331.

Moreover, despite the consensus that Hu 1997 lacks any teaching of PPG and the substantial material differences between machine learning for ECG data and machine learning for PPG data, the Board erroneously adopted Apple's arguments that "the source of the heart rate parameters (*e.g.*, ECG or SpO_2/PPG) would not have deterred a POSA from applying machine learning to them, given the advantages of the approach in enhancing performance and detection accuracy." Appx46. This is classic hindsight, and neither Apple nor its expert explained why a POSITA would have been motivated to use machine learning ***with PPG*** as the claims require. *Ecolochem, Inc. v. S. Cal. Edison Co.*, 227 F.3d 1361, 1371 (Fed. Cir. 2000) ("We 'cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.'") (quoting *In re Fine*, 837 F.2d 1071, 1075 (Fed. Cir. 1988)). There is no evidence in the record indicating that a POSITA would have selected machine learning from Hu 1997 and applied it to PPG data as claimed.[12]

[12] Apple led the Board into a common mistake in the obviousness analysis, substituting "could have made" for "would have made." *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015) ("[O]bviousness concerns whether a skilled artisan not only could have made but would have been motivated to make the

Instead, Apple proposed and the Board adopted a vague rationale for its combination—"enhancing performance and detection accuracy" (Appx46)—which is insufficient as a matter of law to provide motivation to combine. *See Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1373-74 (Fed. Cir. 2008) (holding district court was correct when it ruled that a "generalized motivation to develop a method is not the kind of motivation required by the patent laws"); *In re Beasley*, 117 F. App'x 739, 744 (Fed. Cir. 2004) ("[C]onclusory statements of generalized advantages and convenient assumptions about skilled artisans" are "inadequate to support a finding of motivation, which is a factual question that cannot be resolved on 'subjective belief and unknown authority.'") (quoting *In re Sang Su Lee*, 227 F.3d 1338, 1344 (Fed. Cir. 2002)). And while this vague motivation is derived from the disclosures of Hu 1997, it cannot provide a motivation to combine the prior art to meet the limitations of the claims because it is provided in the context of *ECG* data.

Adopting Apple's and the Board's rationale, moreover, would render every machine learning application obvious in every context. The asserted motivation to combine captures the very purpose of machine learning algorithms: enhancing the

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combinations or modifications of prior art to arrive at the claimed invention."). Apple's reasoning for the combination, taken at face value, merely alleges that a POSITA *could have* applied machine learning to PPG data, just as Hu 1997 teaches applying it to ECG data. This is insufficient to support a finding of obviousness. *See id.*

performance and accuracy of algorithms. Because that vague and conclusory motivation to combine would require agreeing that the benefits of machine learning are sufficient reason to use machine learning with *any* dataset, a finding of obviousness here would render all machine learning obvious *per se*. That cannot be correct. *See, e.g.*, *In re Ochiai*, 71 F.3d 1565, 1571-72 (Fed. Cir. 1995) (noting that there are no "*per se* rules of obviousness" but, instead, it is at all times a "fact-intensive inquiry").

Finally, Hu 1997 is directed to analysis of clinically recorded ECG data, and there is no dispute this type of data is ***superior*** to PPG for arrhythmia detection. Appx4801 ("In a *clinical setting*, such as an *intensive care unit*, it is essential for automated systems to accurately detect and classify [ECG] signals on a real-time basis.") (emphasis added); Appx8138 (62:9-21). Accordingly, like Li 2012, applying Hu 1997's ECG-specific machine learning out of the ICU context, to the inferior PPG measurement tool, would fundamentally alter Hu 1997's mode of operation, rendering motivation to combine unlikely. *See Plas-Pak*, 600 F. App'x at 758. The Board improperly failed to consider this issue too.

3. Shmueli's "Search Correlations" Are Not Machine Learning ('499 And '731 Patents)

For both the '499 and '731 patents, in the grounds where the obviousness combination is based on Li 2012 and Hu 1997, Apple raised in its petitions an alternative argument that Shmueli's "search correlations" are machine learning and

therefore render obvious the machine learning claims. *See* Appx1002 ("A POSITA would have understood that [Shmueli's] disclosure [of search correlations] *refers to machine learning*, which focuses on algorithms capable of learning and/or adapting their structure (e.g., parameters) based on a set of observed data.") (quotation omitted; emphasis added). Beyond adopting Apple's argument, the Board articulated no supporting rationale explaining why a POSITA would have found machine learning obvious over Shmueli's search correlations. Appx106; Appx111. Accordingly, it is impossible to discern whether the Board followed a proper path to a finding of obviousness. *NuVasive*, 842 F.3d at 1382-85 (vacating and remanding Board decision where it was impossible to identify Board's path in determining that a POSITA would have been motivated to combine prior art references); *see Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc.*, 419 U.S. 281, 286 (1974) (agency decision cannot be upheld where "the agency's path may [not] reasonably be discerned"). This is dispositive with respect to machine learning obviousness over Shmueli.

In any event, were the Court to conclude that the Board adopted Apple's relevant arguments in full merely because it "agree[d] with [Apple],"[13] the Board

[13] Apple based its obviousness argument for both the '499 and '731 patents on a single paragraph from its expert's declaration (Appx3529 (¶ 262)) and a background reference on machine learning unrelated to Shmueli that contains no discussion of search correlations like what is taught in Shmueli (Appx4669).

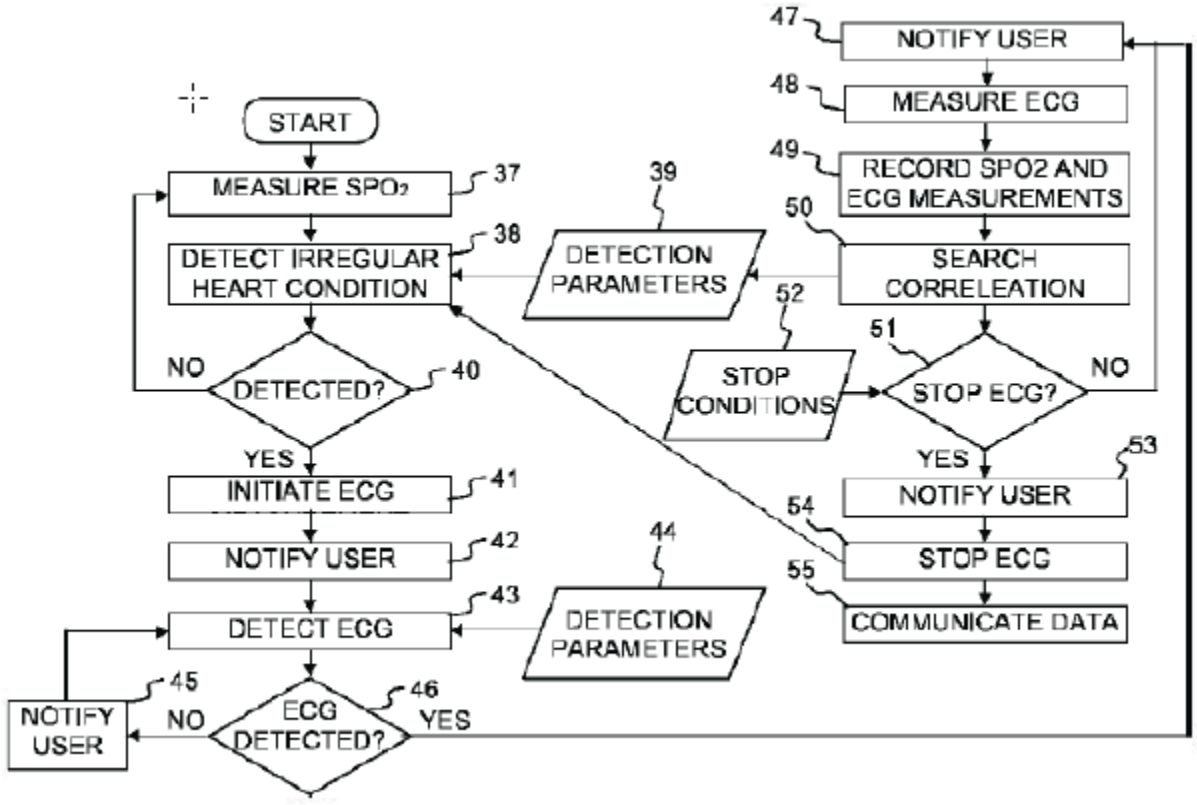
erred in concluding that "[c]onsidering the state of the art as a whole," a POSITA "would have understood that Shmueli disclosed the use of machine learning, or would have found it obvious to employ machine [learning] in carrying out the 'search correlation' function of Figure 7, step 50." Appx111.[14] The Board cited no evidence to support this conclusion, which is unsurprising given the lack of evidence in Apple's briefs, though the reference to the "state of the art" suggests the Board relied on its finding that "those of ordinary skill in the art had … both [an] interest and success in adapting machine learning to various biomedical applications." Appx110. That finding is not supported by substantial evidence for several reasons.

First, that finding rested on the unreliable testimony of Apple's unqualified expert. Appx110 (citing Appx3467-3468 (¶ 117) (testifying that machine learning was the "mainstream technique to detect arrhythmia" as of the critical date); Appx3527 (¶ 259) (testifying regarding "examples of known arrhythmia detection techniques" in 2009)). As discussed above (*see supra* Part I.A), Apple's expert's testimony is unreliable and irrelevant as a matter of law because he is not a skilled artisan with respect to machine learning. *See Kyocera*, 22 F.4th at 1376-77; *Sundance*, 550 F.3d at 1362. That testimony is also impermissibly conclusory. *See,*

[14] The Board did not reach this issue as to the '499 patent, but the same arguments and analysis would apply. *See* Appx51 (declining to address Apple's "alternative argument that Shmueli [alone] teaches or suggests a machine learning algorithm").

e.g., *TQ Delta*, 942 F.3d at 1358; *Acoustic Tech*, 949 F.3d at 1375. Moreover, Dr. Chaitman's lack of skill in machine learning meant he was unaware of industry-wide skepticism regarding the use of machine learning in the cardiology context. Appx8287-8288 (211:9-212:8). This skepticism militates against the obviousness of the machine learning claims. Thus, his testimony about what a POSITA would have understood to constitute machine learning (Appx3527 (¶ 259) does not provide substantial evidence for the Board's decisions.

Second, even if, contrary to all evidence, Shmueli's search correlations could constitute machine learning, Shmueli still cannot render obvious the claims because Shmueli's search correlations are performed on ***ECG*** data, not PPG data, as required by the claims. *See supra* Part I.B.1. As Apple argued, element 50 in Shmueli, which corresponds to the search correlations (the alleged machine learning), is applied to "the ECG signal" only after ***an ECG*** is measured. Appx1001-1002. The Board adopted this argument in finding the claims obvious. Appx111. Element 50's inclusion on the right-hand side of Shmueli's Figure 7, a flow chart showing the operation of the system, indicates that Shmueli's search correlations are applied to ECG data:



Appx68. There is no dispute that the left-hand side of Shmueli's Figure 7 relates to SpO_2 measurements, while the right-hand side relates to ECG measurements, nor did the Board make any contrary findings.

The Board, by adopting Apple's argument that Shmueli renders obvious the machine learning claims, wrongly found that Shmueli's search correlations could be applied to PPG and not ECG data. There is nothing in the record—no evidence and no argument—suggesting how or why it would have been obvious to modify Shmueli's system in this way. At best, this is an impermissible hindsight-based reconstruction of the claims from the prior art. *See, e.g.*, *Ecolochem,* 227 F.3d at 1371; *In re Schweickert*, 676 F. App'x 988, 996 (Fed. Cir. 2017) (reversing

obviousness finding under the substantial evidence standard because a "broadly-stated conclusion"—that "a skilled artisan could combine" two references "and would do so because these references were within the knowledge of a skilled artisan"—"suffers from hindsight bias"). But regardless, the complete lack of evidence supporting single-reference obviousness based on Shmueli is insufficient to survive substantial evidence review. *See In re Giannelli*, 739 F.3d 1375, 1380 (Fed. Cir. 2014) (reversing Board decision where "no explanation why or how a person having ordinary skill in the art would modify the prior art … to arrive at the" challenged claims). Given Shmueli's sparse disclosure, the Board's findings regarding Shmueli are mere conjecture, made in support of its legally erroneous conclusion that machine learning is obvious regardless of what the prior art teaches. *See Ochiai*, 71 F.3d at 1572 (holding that there are no "*per se* rules of obviousness").

II. THE PRIOR ART DOES NOT RENDER OBVIOUS "CONFIRMING THE PRESENCE OF THE ARRHYTHMIA" ('731 AND '941 PATENTS)

The Board's decisions for the '731 and '941 patents should also be reversed as to all invalidated claims because substantial evidence does not support the Board's conclusion that Shmueli teaches "confirming" the presence of the arrhythmia, as required by the independent claims of both patents.[15]

[15] The '731 patent's claims recite a "memory" that "cause[s] the processing device to … *confirm* the presence of the arrhythmia based on the ECG data." Appx238

Adopting Apple's reply arguments, the Board found confirmation in Shmueli in two ways, neither of which is supported by substantial evidence: "*directly* through analysis of ECG data or *indirectly* through updates to detection parameters used for assessment of SpO_2/PPG data." Appx94 (emphasis added). To the extent there is any disclosure in Shmueli of on-device analysis, it is vague and non-specific. There is no teaching or even suggestion to a POSITA that any on-device analysis in Shmueli is a "confirmation" under any construction, including the plain meaning. Nor is there any teaching or suggestion in Shmueli that its use of "search correlations" to modify "detection parameters" is a confirmation of the presence of the arrhythmia. Indeed, it is undisputed that Shmueli only teaches detecting an irregular heart condition (according to Apple, an arrhythmia), ***using PPG data***. Accordingly, the Board's conclusions regarding both "direct" and "indirect" confirmation are not supported by substantial evidence.

First, the Board's conclusion that Shmueli teaches "direct" confirmation is based on the Board's adoption of Apple's argument that Shmueli teaches "analyz[ing] ECG data to detect (and confirm) irregular heart conditions." Appx94.

('731 patent, claim 1) (emphasis added). The '941 patent's claims recite "receiving electric signals of the user from an [ECG] sensor … on the smartwatch to confirm a presence of the arrhythmia." Appx257 ('941 patent, claim 1).

But there is no evidence—certainly nothing in Shmueli—explaining what this alleged analysis even ***is***.

The only disclosure in Shmueli that could amount to analysis of the ECG data is in the context of creating new ***detection*** parameters via search correlations:

> Then, the software program proceeds to element 48 to perform the ECG measurement and to element 49 to record the SpO_2 and the ECG measurements and preferably store them in the memory unit 28. Preferably, the SpO_2 and the ECG signals are correlated and stamped with a time stamp. The SpO_2 measurement, the ECG measurement and their recordation and storage (elements 37, 47 and 49 respectively) are continued and performed in parallel until a stopping condition is met.
>
> Optionally but preferably the software program proceeds to element 50 to search for correlations between the SpO_2 signal and the ECG signal to produce new detection parameters, or modify existing detection parameters, so as to enhance the detection algorithms of the irregular heart conditions. Searching for correlation (element 50) can be executed in real-time (together with elements 37, 47 and 49) or later after the ECG measurement is concluded.

Appx3830. This is not in dispute—there is no other teaching in Shmueli that could possibly qualify as ECG data analysis. Instead, the sole basis for reading confirmation into Shmueli is the testimony of Apple's expert Dr. Chaitman, who simply treats searching for correlations in ECG data and confirmation based on ECG data as the same thing. Appx3462-3464 (¶ 112) ("Thus, a POSITA would have understood that the software at element 50, element 39 and element 38 causes the processing device to confirm the presence of the arrhythmia based on the ECG data, by searching for correlations between the PPG and ECG data, modifying detection

parameters, and confirming the presence of arrhythmia."). This conclusory expert testimony is not a substitute for substantial evidence. *See, e.g.*, *Acoustic Tech.*, 949 F.3d at 1375; *TQ Delta*, 942 F.3d at 1358.

Shmueli's teachings are lacking throughout. Shmueli does not (1) provide any detail whatsoever about what analysis occurs when the PPG/SpO_2 and ECG data are "correlated"; (2) explain what it means to "correlate" PPG/SpO_2 and ECG data other than to apply a "time stamp" to the data; or, most critically, (3) teach that "correlating" involves any detection or confirmation of the presence of the arrhythmia. But without a teaching that "correlation" includes the ability to detect an arrhythmia, there can be no confirmation. Indeed, this critical question is left unanswered throughout both Apple's briefing and the Board's decisions for the '731 and '941 patents: What, if anything, is "confirmed" in Shmueli? Apple provided no answer because there is not a shred of evidence even hinting at what the answer could be. Instead, Shmueli is clear that the correlations are for the purpose of "enhanc[ing] the ***detection*** algorithms of the irregular heart conditions"—***detection*** algorithms performed only by the ***PPG sensor***. Appx3830 (emphasis added); *see* Appx3828 (disclosing "procedure for identifying correlations between SpO_2 measurement and ECG measurement of a particular subject to detect user-specific irregular heart conditions"); Appx3829 ("Using said correlation in said step of detecting an irregular heart condition from said SpO_2 measurement.").

Moreover, Apple's prior art expert Dr. Chaitman—the only Apple expert to testify regarding the prior art cited in Apple's petitions—conceded that in Shmueli the only detection of an irregular heart condition is performed by the PPG sensor. Appx7996-7997 (87:19-88:13). This means that in Shmueli ***only the PPG data is ever analyzed*** to identify the presence of the arrhythmia—the ECG data never is. *See* Appx7996-7997 (87:19-88:13). If the ECG data is never analyzed for the purpose of detecting arrhythmias, then there can be no confirmation. Shmueli therefore necessarily cannot render the confirmation step obvious.

Second, for many of the same reasons, substantial evidence is lacking for the obviousness theory based on the so-called "indirect" confirmation "through updates to detection parameters used for assessment of SpO_2/PPG data." Assuming *arguendo* that the ECG data in Shmueli is analyzed, that does not mean that the ECG data is analyzed to confirm "the presence of the arrhythmia," as claimed. Dr. Chaitman (and by extension Apple in its petitions and the Board in its decisions) assumes—in conclusory fashion—that improving the detection parameters as a result of the search correlations necessarily entails confirmation. Appx3461-3464 (¶¶ 110-12). But as with direct confirmation, Shmueli does not disclose anything to back up Dr. Chaitman's conclusory assumption. Again, this cannot amount to substantial evidence. *See, e.g.*, *Acoustic Tech.*, 949 F.3d at 1375; *TQ Delta*, 942 F.3d at 1358.

Third, Apple and the Board wrongly relied on Shmueli's teaching that one of the "stop conditions" of the ECG measurement is that "the irregular heart condition has stopped." Appx3464 (¶ 113). Again, nothing in Shmueli teaches that this is a confirmation as required by the claims, or even that the ECG data is analyzed to detect an arrhythmia. Instead, once again Apple's argument and by extension the Board's conclusion is based on Dr. Chaitman's conclusory assumption that "a POSITA would have understood" this to "require[] the software program to confirm the presence of arrhythmia using the ECG data." Appx3464 (¶ 113). This too does not amount to substantial evidence. *See, e.g.*, *Acoustic Tech.*, 949 F.3d at 1375; *TQ Delta*, 942 F.3d at 1358.

Finally, the Board ignored the limited disclosures in Shmueli regarding the meaning of "correlation." Shmueli teaches performing minimal analysis on the ECG data for the express purpose of correlating the PPG and ECG data ***in time***. Appx3830 (explaining that the SpO_2 and ECG signals are "correlated and stamped *with a time stamp*") (emphasis added). This interpretation of Shmueli is not limited to AliveCor and its expert. In fact, Dr. Chaitman conceded that the detection parameters in Shmueli are merely meant to improve the PPG/SpO_2 sensor's ability to detect irregular heart conditions. *See* Appx7996-7997 (87:19-88:2) (agreeing that correlations between SpO_2 measurements are searched for "to produce new detection parameters or modify existing detection parameters" for PPG).

The Board erred by failing to consider the "time stamp" disclosure in Shmueli, and by failing to address AliveCor's argument that Shmueli's "correlations" are merely an attempt to align the ECG and PPG signals in time. *See* Appx648; Appx1306; Appx1857. Substantial evidence cannot support this incomplete analysis by the Board, which fails to account for Shmueli's clear teachings regarding the meaning of "correlation" in that reference. *See In re Warsaw Orthopedic, Inc.*, 832 F.3d 1327, 1332 (Fed. Cir. 2016) ("When the PTAB examines the scope and content of prior art … it must consider the prior art 'in its entirety, i.e., as a whole.'") (quoting *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1568 (Fed. Cir. 1987)); *NuVasive*, 842 F.3d at 1379-80 (holding that substantial evidence is "more than a mere scintilla of evidence").

III. APPLE FAILED TO MAKE A REQUIRED PRODUCTION OF SECONDARY CONSIDERATIONS EVIDENCE

At the very least, the Board's decisions should be vacated because Apple failed to comply with its obligation to produce, as part of "routine discovery," all "relevant information that is inconsistent with a position advanced by the party during the proceeding concurrent with the filing of the documents or things that contains the inconsistency." 37 C.F.R. § 42.51(b)(1)(iii). The fact that the "information may be business confidential … does not shield it from routine discovery." *Aker Biomarine AS v. Neptune*, IPR2014-00003, Paper 93 (PTAB Oct. 6, 2014), at 6.

This obligation is "self-executing and self-enforcing." *BlackBerry Corp. v. Wi-Lan USA Inc.*, IPR2013-00126, Paper 15 (PTAB Aug. 19, 2013), at 2. It is also "ongoing." *Aker Biomarine*, Paper 93 at 5. As such, a party may not even serve requests for discovery for this type of information. *BlackBerry Corp.*, Paper 15 at 2. Indeed, the Board has been clear that "[r]outine discovery does not require any action on the part of [the opposing party] as [§ 42.51(b)(1)(iii)] places the burden upon [each party] to come forward and serve information inconsistent with a position advanced." *Nichia Corp. v. Emcore Corp*., IPR2012-00005, Paper 19 (PTAB March 26, 2013), at 2. Moreover, because parties have a "duty of candor and good faith to the" Board, "hiding relevant information within the scope of 37 C.F.R. § 42.51(b)(1)(iii) is improper." *L'Oreal USA, Inc. v. Liqwd, Inc.*, PGR2017-00012, Paper 37 (PTAB Sept. 27, 2017), at 13. The Board takes these disclosure obligations seriously, going so far as to recently impose sanctions on a party for withholding evidence inconsistent with its arguments. *Spectrum Solutions LLC v. Longhorn Vaccines & Diagnostics, LLC*, IPR2021-00847, Paper 107 (PTAB May 3, 2023) at 48-49.

Here, Apple violated this ongoing and self-executing obligation. It is undisputed that, during the pendency of the IPR proceedings, Apple possessed internal documents and ITC testimony supporting secondary considerations of non-obviousness, including evidence of copying. Indeed, the ITC's ALJ specifically

found that "multiple internal [Apple] presentations and similar evidence do provide probative evidence of copying." *ITC ID*, 2022 WL 2981155, at *65 (citing *Apple Inc. v. Samsung Elecs. Co., Ltd.*, 839 F.3d 1034, 1054 (Fed. Cir. 2016)). The ALJ found that this evidence "point[s] circumstantially to copying by Apple," and "like industry praise …, copying weighs against a finding of obviousness." *Id.* at *66. This evidence is thus plainly inconsistent with Apple's position before the Board—entrenched from its initial petitions through every filing with the Board—that AliveCor's patents were obvious. The reason for the inconsistency is straightforward: The "fact that a competitor copied technology suggests it would not have been obvious." *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1336 (Fed. Cir. 2016); *see Columbia Sportswear N. Am., Inc. v. Seirus Innovative Accessories, Inc*., 2017 WL 1217157, *2-3 (D. Or. Apr. 3, 2017) (explaining that under § 42.51(b)(1)(iii) evidence of copying as an indicator of non-obviousness would be contrary to an "assertion of obviousness in [an] IPR proceeding[]").

What's more, the Board itself has recognized that evidence of copying in other proceedings needs to be produced under § 42.51(b)(1)(iii) as routine discovery. In *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, similar to here, the IPR petitioner had produced evidence tending to show objective indicia of non-obviousness, such as copying and long-felt need, in related federal district court litigation concerning the same patents. IPR2017-01586, Paper 20 (PTAB Feb. 28,

2018), at 2-5. The petitioner sought to shield this evidence from the Board. But the Board would not allow it, holding that the documents were inconsistent with the petitioner's position before the Board "related to objective indicia of nonobviousness." *Id.* at 4. The same is true here. Apple argued before the Board that the patents are obvious while simultaneously withholding evidence of copying from that tribunal—evidence that counsels against obviousness and "must be considered in every case," *WBIP, LLC*, 829 F.3d at 1328.

Apple's choice to withhold this evidence from the Board in violation of its ongoing and self-executing discovery obligations is even more egregious because it also ***affirmatively precluded*** AliveCor from even seeking to have these documents introduced before the Board. Specifically, AliveCor contacted Apple attempting to gain its consent to introduce the documents relevant to secondary considerations in the IPR proceedings. Apple responded in an email that "AliveCor's use of these documents in the IPRs" or even "***use of them as the basis for a discovery request in the IPRs***" "would be a violation of the ITC protective order." Apple thus wielded the ITC protective order as both a sword and shield, allowing Apple to re-attack the validity of AliveCor's patents in a different forum while avoiding the evidence that the public record now shows was probative to those same patents' validity in the ITC. There is only one possible reason for this tactic: Pure gamesmanship in seeking to gerrymander the Board record more to Apple's liking. There is simply

no other valid reason to deprive the Board of the full record needed to conduct a fulsome obviousness analysis required by *Graham v. John Deere Co.*, 383 U.S. 1 (1966). *See id.* at 17-18 ("Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented."); *accord WBIP, LLC*, 829 F.3d at 1328.

In addition to the Board's own decisions, courts have similarly noted the inherent unfairness of allowing a party to argue that a patent is obvious in one proceeding yet simultaneously conceal evidence related to that issue in another proceeding. As one court put it, "it is difficult to comprehend how [a party] can move for summary judgment based on obviousness in this Court and simultaneously request that materials related to the same issue [*i.e.*, copying and commercial success] be withheld from parallel proceedings" such as an IPR proceeding before the Board. *Columbia Sportswear*, 2017 WL 1217157, at *3. By gagging AliveCor with the ITC protective order from even seeking to introduce the evidence in the IPR proceedings, Apple created just that type of prejudicial unfairness. And because of Apple's position, AliveCor had no recourse in the Board to seek admission of the evidence and instead had to rely on Apple to comply with its ongoing and self-executing obligation under § 42.51(b)(1)(iii).

Apple instead ignored its obligation, leaving the Board to issue its decisions on an incomplete record. Thus, should the Court not accept AliveCor's arguments supporting reversal, at a minimum, the Court should still remand these IPR cases to the Board. That way, the Board can consider the evidence of secondary considerations that Apple withheld and can complete the obviousness analysis that it is required to perform under *Graham* and this Court's precedent.

CONCLUSION

This Court should reverse, or alternatively vacate, the Board's FWDs ruling that claims 1-20 of the '499 patent, 1-30 of the '731 patent, and 1-23 of the '941 patent are invalid as obvious.

Dated: May 26, 2023

Respectfully submitted,

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ADDENDUM

IPR2021-00970 - Final Written Decision Appx1

IPR2021-00971 - Final Written Decision Appx56

IPR2021-00972 - Final Written Decision Appx116

IPR2021-00970 - Ex. 1001 - U.S. Patent No. 9,572,499 ..... Appx170

IPR2021-00971 - Ex. 1001 - U.S. Patent No. 10,595,731 ..... Appx208

IPR2021-00972 - Ex. 1001 - U.S. Patent No. 10,638,941 ..... Appx240

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571-272-7822

Paper 43
Entered: December 6, 2022

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE, INC.,
Petitioner,

v.

ALIVECOR, INC.,
Patent Owner.

IPR2021-00970
Patent 9,572,499 B2

Before ROBERT A. POLLOCK, ERIC C. JESCHKE, and DAVID COTTA, *Administrative Patent Judges*.

POLLOCK, *Administrative Patent Judge*.

JUDGMENT

Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

Denying In-Part and Dismissing In-Part as Moot
Patent Owner's Motion to Exclude Evidence
37 C.F.R. § 42.64

I. INTRODUCTION

A. Background

Apple, Inc. ("Petitioner") filed a Petition for an *inter partes* review of claims 1–20 of U.S. Patent No. 9,572,499 B2 ("the '499 patent," Ex. 1001). Paper 2 ("Pet."). AliveCor, Inc. ("Patent Owner") timely filed a Preliminary Response. Paper 6. ("Prelim. Resp."). Petitioner further filed an authorized Reply to the Preliminary Response (Paper 7); Patent Owner filed a responsive Sur-reply (Paper 8). Taking into account the arguments and evidence presented, we determined the information presented in the Petition established that there was a reasonable likelihood that Petitioner would prevail in demonstrating unpatentability of at least one challenged claim of the '499 patent, and we instituted this *inter partes* review as to all challenged claims. Paper 10 ("DI").

After institution, Patent Owner filed a Patent Owner Response (Paper 28, "PO Resp."); Petitioner filed a Reply to the Patent Owner Response (Paper 30, "Reply"); Patent Owner filed a (corrected) Sur-reply (Paper 36, "Sur-reply").

Patent Owner also filed a motion to exclude (Paper 35, "Mot."); Petitioner opposed the motion (Paper 37); and Patent Owner filed a reply in support of its motion (Paper 39).

An oral hearing was held on September 14, 2022, and a transcript of the hearing is included in the record. Paper 42 ("Tr.").

We have jurisdiction under 35 U.S.C. § 6. This decision is a Final Written Decision under 35 U.S.C. § 318(a) as to the patentability of claims 1–20 of the '449 patent. For the reasons discussed below, we hold that

Petitioner has demonstrated by a preponderance of the evidence that claims 1–20 are unpatentable.

B. Real Parties-in-Interest

Petitioner identifies itself, Apple Inc., as the real party-in-interest. Pet. 84. Patent Owner, identifies itself, AliveCor, Inc., as the real party-in-interest. Paper 15, 2.

C. Related Matters

According to Patent Owner:

> U.S. Patent No. 9,572,499 has been asserted by Patent Owner against Petitioner in *AliveCor, Inc. v. Apple, Inc.*, Case No. 6:20-cv-01112-ADA, filed in the United States District Court for the Western District of Texas, and in Investigation No. 337-TA-1266 before the International Trade Commission, *In the Matter of Certain Wearable Electronic Devices with ECG Functionality and Components Thereof*. Apple also filed IPR petitions against the other patents asserted in those actions: PR2021-00971 (USP 10,595,731) and IPR2021-00972 (USP 10,638,941).

Paper 15, 2; *see* Pet. 84. We further note that US Patent No. 10,595,731 ("the '731 patent"), at issue in IPR2021-00971, is related by a chain of continuation applications to Application No. 14/730,122, which issued as the '499 patent challenged here. *See* U.S. Patent No. 10,595,731, code (63); Ex. 1001, code (21); Prelim. Resp. 3–4. As such, the '731 and '499 patents share substantially the same specification.

D. Priority Date of the '499 Patent

The '499 patent claims priority to, *inter alia*, a series of provisional applications filed between December 12, 2013, and June 19, 2014. Ex. 1001, code (60); *see* Pet. 2; Prelim. Resp. 3–4. Petitioner contends, and Patent Owner does not presently contest, that the claims of the '499 patent are not

entitled the benefit of the earliest of those applications such that the critical date is December 12, 2014, the filing date of application No. 14/569,513. Pet. 2–3. Because Patent Owner does not contest this assertion or the prior art status of any asserted reference, we need not determine whether the challenged claims are entitled to the benefit of the earliest-filed provisional application. *See generally* Prelim. Resp. 4, 31–43; PO Resp.

E. Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability (Pet. 1):

Ground	Claims Challenged	35 U.S.C §[1]	Reference(s)/Basis
1	1–6, 10–16, 20	§ 103	Shmueli,[2] Osorio[3]
2	7–9, 17–19	§ 103	Shmueli, Osorio, Hu 1997[4]

In support of its patentability challenge, Petitioner relies on, *inter alia*, the Declaration of Dr. Bernard R. Chaitman, M.D. Ex. 1003. Patent Owner similarly relies on the Declarations of Dr. Igor Efimov, Ph.D. Ex. 2001; Ex. 2016.

[1] The Leahy-Smith America Invents Act ("AIA") included revisions to 35 U.S.C. § 103 that became effective on March 16, 2013. Because we determine the priority date of the challenged claims is no earlier than the '449 patent's filing date of March 14, 2014 (*see infra* I.D), we apply the AIA versions of the statutory bases for unpatentability.

[2] WO2012/140559, publ. Oct. 18, 2012. Ex. 1004.

[3] U.S. 2014/0275840, publ. Sept. 18, 2014. Ex. 1005.

[4] Hu et al., 44(9) "*A Patient-Adaptable ECG Beat Classifier Using a Mixture of Experts Approach*," IEE Transactions on Biomed. Engineering 891–900 (1997). Ex. 1049.

F. The ’499 Patent and Relevant Background

The ’499 patent relates to medical devices, systems, and methods for detecting cardiac conditions, including cardiac arrhythmias. Ex. 1001, 1:20–24, 2:8–16. In general:

> In response to the continuous measurement and recordation of the heart rate of the user, parameters such as heart rate (HR), heart rate variability (R-R variability or HRV), and heart rate turbulence (HRT) may be determined. These parameters and further parameters may be analyzed to detect and/or predict one or more of atrial fibrillation, tachycardia, bradycardia, bigeminy, trigeminy, or other cardiac conditions.

Id. at 2:48–55; *see id.* at 18:44–54 (Table 2, listing atrial fibrillation, sinus and supraventricular tachycardias, bradycardia, bigeminy, and trigemini among the types of arrhythmias).

According to Dr. Chaitman, “HRV analysis is an important tool in cardiology to help diagnose various types of arrhythmia.” Ex. 1003 ¶ 35. “HRV is defined as the variation of RR intervals with respect to time and reflects beat-to-beat heart rate (HR) variability,” and “can be accurately determined based on either ECG [electrocardiogram] data or PPG [photoplethysmography] data.” *Id.* ¶¶ 35–36. “An R-R interval represents a time elapsed between successive R-waves of a QRS complex[5] of the ECG that occur between successive heart beats.” *Id.* ¶ 29. “If the RR intervals over a time period are close to each other in value, then ventricular rhythm is

[5] “[E]lectrical activity of the heart based on depolarization and repolarization of the atria and ventricles . . . typically show[s] up as five distinct waves on [an] ECG readout – P-wave, Q-wave, R-wave, S-wave, and T-wave.” Ex. 1003 ¶ 29. “A QRS complex is a combination of the Q, R, and S waves occurring in succession and represents the electrical impulse of a heartbeat as it spreads through the ventricles during ventricular depolarization.” *Id.*

understood to be 'regular.' In contrast, if there are significant variations in the RR intervals over a time period, then the ventricular rhythm is understood to be 'irregular.'" *Id.* ¶ 37 (citations omitted).

The Specification explains that during cardiac arrhythmia, "the electrical activity of the heart is irregular or is faster (tachycardia) or slower (bradycardia) than normal," and in some forms, "can cause cardiac arrest and even sudden cardiac death." Ex. 1001, 1:31–35. The '449 patent identifies atrial fibrillation as the most common form of cardiac arrhythmia—which occurs when electrical conduction through the atria of the heart is irregular, fast, and disorganized, leading to irregular activation of ventricles. *Id.* at 1:35–40; *see* Ex. 2001 ¶ 39. Although atrial fibrillation, may cause no symptoms, it is associated with palpitations, shortness of breath, fainting, chest pain, congestive heart failure, as well as atrial clot formation, which can lead to clot migration and stroke. Ex. 1001, 1:31–45. "Atrial fibrillation is typically diagnosed by taking an electrocardiogram (ECG) of a subject, which shows a characteristic atrial fibrillation waveform." *Id.* at 1:43–45.

The Specification discloses body-worn devices for detecting the occurrence of arrhythmias using a combination of ECG and PPG electrodes. *See, e.g.*, *id.* at 24:58–25:16, Fig. 14. PPG, or photoplethysmography, uses an optical sensor to detect the fluctuation of blood flow, and can provide a measure of heart rate. *See id.* at 25:13–16. According to the Specification, fluctuations in heart rate not explained by changing activity levels may be interpreted as an advisory condition for recording an ECG, or electrocardiogram, which is a typical method for diagnosing episodes of arrhythmia. *Id.* at 1:43–45, 1:51–56, 24:58–25:33.

The collected data may also be analyzed using machine learning algorithms to, for example, determine appropriate trigger thresholds, detect and predict health conditions, or provide a heart health score. *See, e.g.*, *id.* at 3:8–19, 3:50–4:7, 8:28–31, 8:65–9:1, 9:8–11, 12:44–54. "The machine learning based algorithm(s) may allow software application(s) to identify patterns and/or features of the R-R interval data and/or the raw heart rate signals or data to predict and/or detect atrial fibrillation or other arrhythmias." *Id.* at 8:65–9:1. In particular,

> [a]ny number of machine learning algorithms or methods may be trained to identify atrial fibrillation or other conditions such as arrhythmias. These may include the use of decision tree learning such as with a random forest, association rule learning, artificial neural network, inductive logic programming, support vector machines, clustering, Bayesian networks, reinforcement learning, representation learning similarity and metric learning, sparse dictionary learning, or the like.

Id. at 9:58–67.

Figure 14, reproduced below, shows one embodiment of a body-worn device. *Id.* at 6:11–13.

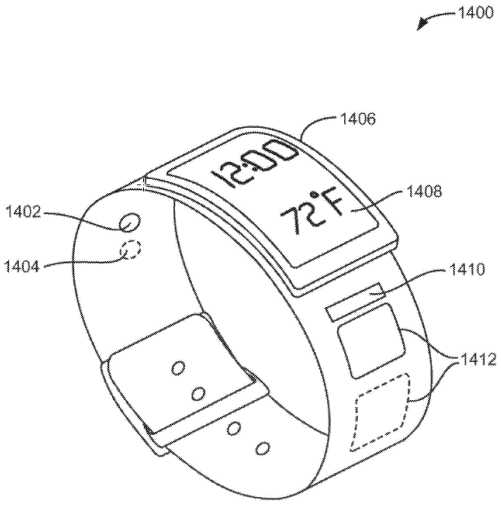


Figure 14, shows "smart watch 1400 which includes at least one heart rate monitor 1402 and at least one activity monitor 1404," such as an

accelerometer. *Id.* at 24:58–60, 25:5–22. Analysis of signals from these monitors can be used to "determine if heart rate and activity measurements represent an advisory condition for recording an ECG," and trigger signals for recording an ECG if an advisory condition is detected. *Id.* at 24:63–25:4. The collected data may also be analyzed using machine learning algorithms to provide a heart health score. *See, e.g.*, *id.* at 3:34–4:14, 8:28–31, 8:65–9:1, 12:34–54.

Figure 10, illustrated below shows another embodiment involving a body-worn device." *Id.* at 5:61–63.

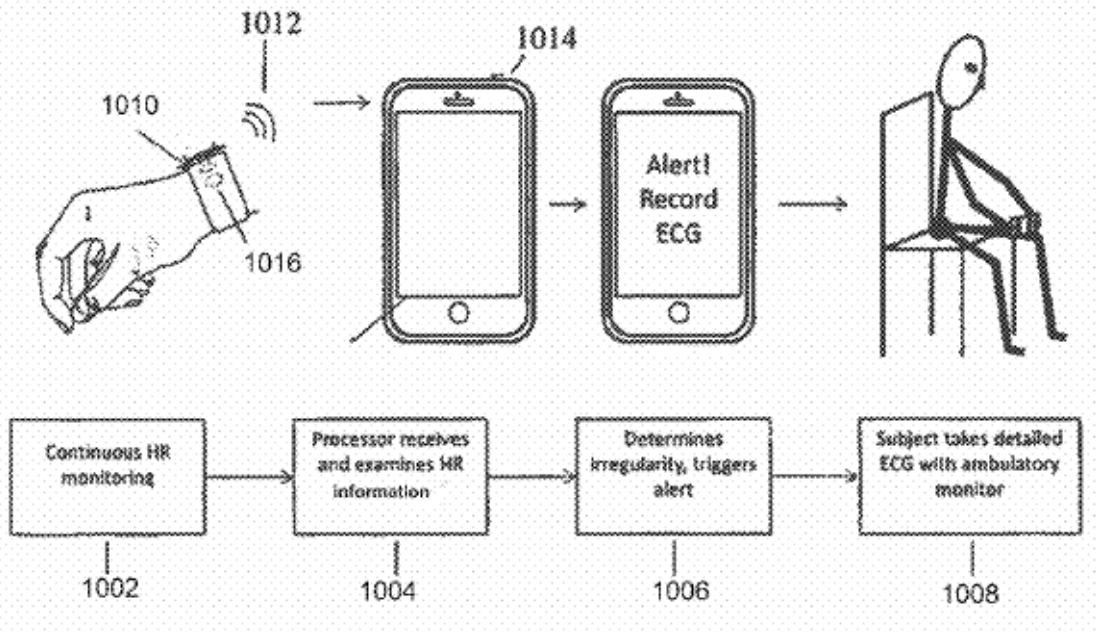


Figure 10 illustrates "a method for monitoring a subject to determine when to record an electrocardiogram (ECG)." *Id.* at 23:12–14. According to the Specification:

> In FIG. **10,** a subject is wearing a continuous heart rate monitor (configured as a watch **1010,** including electrodes **1016),** shown in step **1002.** The heart rate monitor transmits (wirelessly **1012)** heart rate information that is received by the smartphone **1018,** as shown in step **1004.** The smartphone includes a processor

> that may analyze the heart rate information **1004,** and when an irregularity is determined, may indicate **1006** to the subject that an ECG should be recorded.

Id. at 23:14–23. In some embodiments, the ECG device is "present in a smart watch band or a smart phone." *Id.* at 25:28–29. "The ECG, heart rate, and rhythm information can be displayed on the computer or smartphone, stored locally for later retrieval, and/or transmitted in real-time to a web server." *Id.* at 25:40–44.

G. Challenged Claims

Petitioner challenges claims 1–20, of which claims 1 and 11 are independent. Claims 1 and 11 recite:

> 1. A method of determining a presence of an arrhythmia of a first user, said method comprising
>
> sensing a heart rate of said first user with a heart rate sensor coupled to said first user;
>
> transmitting said heart rate of said first user to a mobile computing device, wherein said mobile computing device is configured to sense an electrocardiogram;
>
> determining, using said mobile computing device, a heart rate variability of said first user based on said heart rate of said first user;
>
> sensing an activity level of said first user with a motion sensor;
>
> comparing, using said mobile computing device, said heart rate variability of said first user to said activity level of said first user; and
>
> alerting said first user to sense an electrocardiogram of said first user, using said mobile computing device, in response to an irregularity in said heart rate variability of said first user.

> 11. A system for determining the presence of an arrhythmia of a first user, comprising
>
> a heart rate sensor coupled to said first user;
>
> a mobile computing device comprising a processor, wherein said mobile computing device is coupled to said heart rate sensor, and wherein said mobile computing device is configured to sense an electrocardiogram of said first user; and
>
> a motion sensor
>
> non-transitory computer readable medium encoded with a computer program including instructions executable by said processor to cause said processor to receive a heart rate of said first user from said heart rate sensor, sense an activity level of said first user from said motion sensor, determine a heart rate variability of said first user based on said heart rate of said first user, compare an activity level of said first user to said heart rate variability of said first user, and alert said first user to record an electrocardiogram using said mobile computing device.

The dependent claims recite, for example, that the mobile computing device comprises a smartphone (claims 5 and 15) or a smartwatch (claims 6 and 16); that the presence of an arrhythmia is determined using a machine learning algorithm (claims 7 and 17); and the use of biometric data such as temperature, blood pressure, or inertial data of the first user (claims 3–4, 13–14).

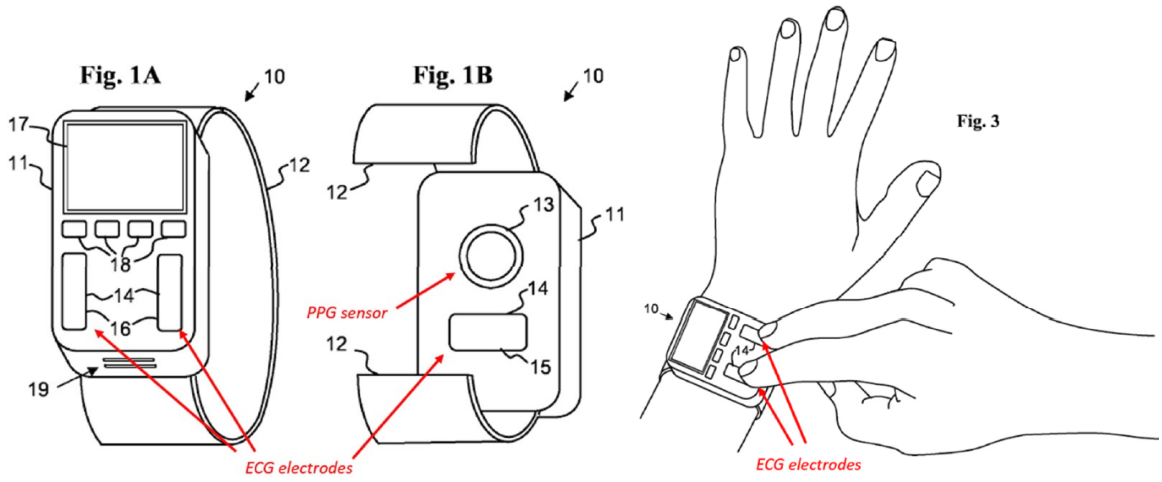
H. Overview of the Asserted References

1) Shmueli (Exhibit 1004)

Shmueli, titled "Pulse Oximetry Measurement Triggering ECG Measurement," addresses "solutions . . . for monitoring infrequent events of

irregular ECG." Ex. 1004, code (54), 2.[6] According to Shmueli, "[t]he present invention preferably performs measurements of intermittent irregular heart-related events without requiring the fixed wiring of the ECG device to the patient." *Id.* at 8.

Shmueli discloses body-worn cardiac monitoring devices "equipped with two types of sensing devices: an oximetry (SpO_2) measuring unit and an ECG measuring unit." *Id.*[7] Shmueli's Figures 1A, 1B, and 4, reproduced below, exemplify one embodiment (annotations by Petitioner in red):



Pet. 9–10. Figures 1A, 1B, and 3 show three views of a wrist-mount heart monitoring device having three ECG electrodes 14 and a PPG sensor 13. Ex. 1004, 6, 9–10. Figure 1A shows two of the ECG electrodes, 14/16, on the face of the device. *Id.* at 9. Figure 1B shows a third ECG electrode,

[6] Throughout this opinion, we cite to the native pagination. For clarity with respect to citations to Shmueli, we understand the native pagination to be the numbers at the top of the page.

[7] As used by Shmueli "the terms 'oxygen saturation in the blood', 'blood oxygen saturation', 'pulse oximeter', oximetry, SpO_2, and photoplethysmography have the same meaning and may be used interchangeably, except for those places where a difference between such terms is described." *Id.* at 7; *see* Tr. 6:22–7:12, 73:18–21, 95:7–11.

14/15, along with PPG sensor 13, of the back of the device. *Id.* Figure 3 shows the device as worn on a patient's wrist, with PPG sensor 13 and ECG electrode 14/15 in contact with the patient's left wrist and ECG electrodes 14/16 in contact with two fingers of the patient's right hand. *Id.* Petitioner annotates each of Figures 1A, 1B, and 3 with arrows identifying the ECG electrodes. Petitioner has also annotated Figure 1B with an arrow identifying PPG sensor 13. In connection with these devices, Shmueli discloses

> a method for triggering measurement of electrocardiogram (ECG) signal of a subject, the method including the steps of: continuously measuring SpO2 at least one of a wrist and a finger of the subject, detecting an irregular heart condition from the SpO2 measurement, notifying the subject to perform an ECG measurement, and initiating ECG measurement at least partially at the wrist.

Id. at 2; *see* Abstract.

Shmueli explains that "[d]eriving heart beat rate from oximetry, as well as other artifacts of the heart activity and blood flow, is . . . known in the art," as are various body-worn oximetry devices. *Id.* at 8. Shmueli further explains that the use of oximetry in combination with ECG measurements is also known in the art. *Id.* Shmueli states, for example, that "US patent No. 7,598,878 (Goldreich) describes a wrist mounted device equipped with an ECG measuring device and a SpO_2 measuring device." *Id.* However, Shmueli, notes "Goldreich does not teach interrelated measurements of ECG and SpO_2" and, thus, does not "enable a patient to perform ECG measurement as soon as an irregular heart activity develops and without requiring the ECG to be constantly wired to the patient." *Id.* According to Shmueli:

> The present invention resolves this problem by providing a combined oximetry and electrocardiogram measuring system

and a method in which the oximetry measurement is performed continuously and/or repeatedly, and the ECG measurement is triggered upon detection of an intermittent irregular heart-related events without requiring the fixed wiring of the ECG device to the patient.

Id. Consistent with this disclosure, Shmueli claims:

1. A method for triggering measurement of electrocardiogram (ECG) signal of a subject, the method comprising the steps of:

continuously measuring SpO2 at least one of a wrist and a finger of said subject;

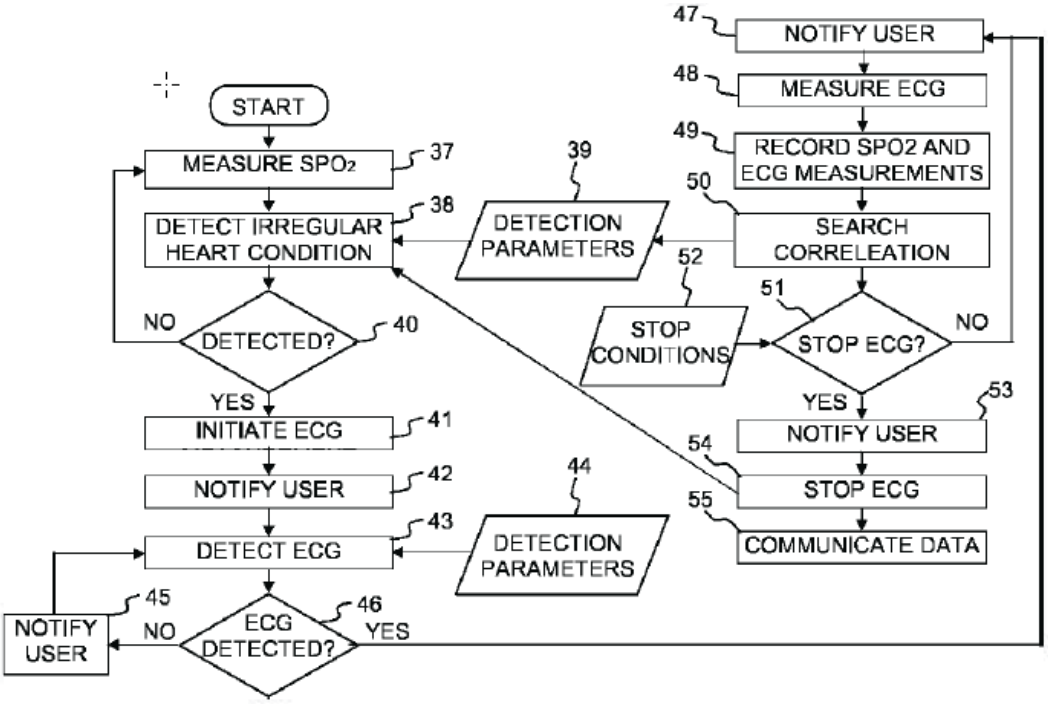
detecting an irregular heart condition from said SpO2 measurement;

notifying said subject to perform an ECG measurement; and

initiating ECG measurement at least partially at said wrist.

Id. at 16.

Shmueli Figure 7 is reproduced below:



"Fig. 7 is a simplified flow chart of a software program preferably executed by the processor of the wrist-mounted heart monitoring device." *Id.* at 7; *see also id.* at 12–13 (further describing the steps of the software program illustrated in Figure 7).

2) Osorio (Exhibit 1005)

Osorio, titled "Pathological State Detection Using Dynamically Determined Body Data Variability Range Values," "relates to medical device systems and methods capable of detecting a pathological body state of a patient, which may include epileptic seizures, and responding to the same." Ex. 1005, code (54), ¶ 2. Although broadly referencing "a pathological body state," Osorio repeatedly exemplifies such conditions in terms of detecting epileptic events. *See*, *e.g.*, *id.* ¶ 37 (referencing values that may "be indicative of a certain pathological state (e.g., epileptic seizure)"), ¶ 46 ("In one embodiment, the pathological state is an epileptic event, e.g., an epileptic seizure."), ¶ 56 ("HRV range may be taken as an indication of an occurrence of a pathological state, e.g., an epileptic seizure"), ¶ 66 ("The dynamic relationship between non-pathological HRVs and activity levels may be exploited to detect pathological states such as epileptic seizures").

Consistent with the broad disclosure and narrow exemplification in the body of its specification, Osorio's claim 1 is directed to "[a] method for detecting a pathological body state of a patient," whereas claim 7 limits the pathological state to an epileptic event. *Id.* at claim 1, claim 7; *also compare id.* at claim 14, *with* claim 17 (similarly limiting a pathological state to an epileptic event).

According to Osorio, the disclosed methods, systems, and related devices, detect a pathological state of a patient by determining when a body

data variability value, or "BDV," is outside of a "value range," and where the threshold levels of that range vary in response to the patient's physical activity (measured by, e.g., an accelerometer) or mental/emotional state. *See, e.g.*, *id.* at Abstract, ¶¶ 3–8, 28, 33, 35. In this respect, Osorio states that "false negative and false positive detections of pathological events may be reduced by dynamically determining pathological or non-pathological ranges for particular body indices based on activity type and level or other variables (e.g., environmental conditions)." *Id.* ¶ 36.

Osorio's Figure 1 is reproduced below.

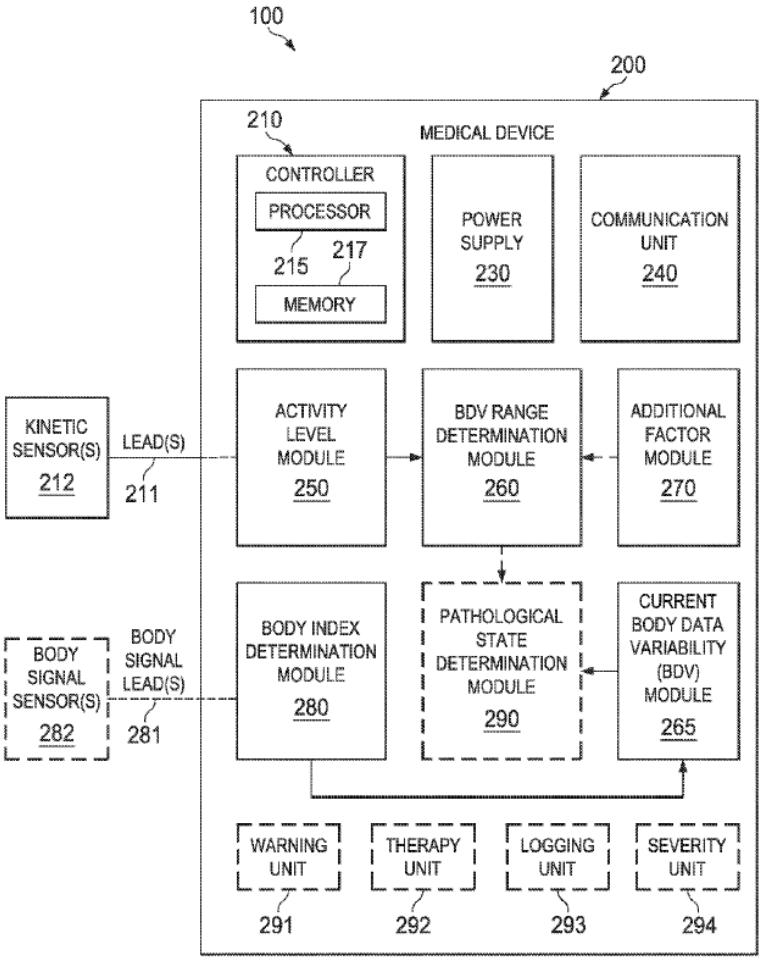


FIG. 1

Figure 1 shows a schematic representation of medical device system 100, including kinetic sensor(s) 212 and body signal sensor(s) 282 connected to medical device 200 by leads 211 and 281, respectively. *Id.* ¶ 33. "[A]ctivity sensor(s) 212 may each be configured to collect at least one signal from a patient relating to an activity level of the patient," and include, for example, an accelerometer, an inclinometer, a gyroscope, or an ergometer. *Id.* Figure 1 also shows a current body data variability (BDV) module 265, which may "may comprise an O_2 saturation variability (O2SV) module 330 configured to determine O2SV from O_2 saturation data," and "an HRV module 310 configured to determine HRV from heart rate data." *Id.* ¶¶ 10, 13, 53, Fig. 2C. Osorio discloses that "medical device system 100 may be fully or partially implanted, or alternatively may be fully external." *Id.* ¶ 33.

Figure 8, reproduced below, shows one embodiment of Osorio's monitoring method.

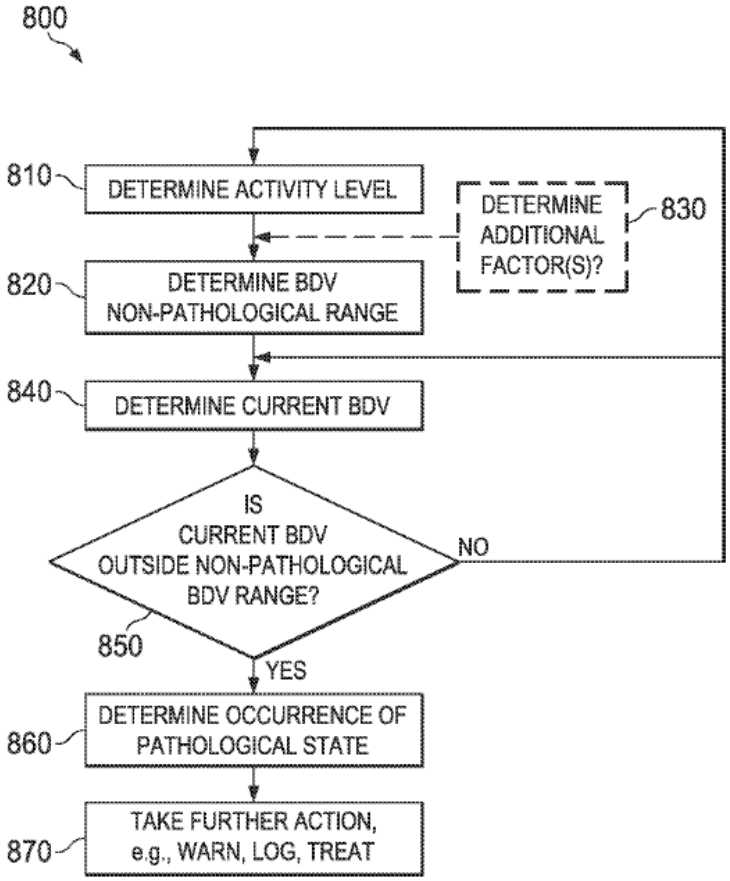


FIG. 8

Figure 8 shows that an activity level is determined at 810, and a non-pathological BDV range is determined at 820 based on the activity level. *Id.* ¶ 77. A current BDV is determined at 840 and compared to the non-pathological BDV range at 850. *Id.* ¶ 78. If the current BDV is outside the non-pathological range, then a pathological state is determined at 860 and a further action, such as warning, treating, or logging the occurrence and/or severity of the pathological state, is taken at 870. *Id.*

According to Osorio, body indices that may be the subject of BDV monitoring include:

> heart rhythm variability, a heart rate variability (HRV), a respiratory rate variability (RRV), a blood pressure variability (BPV), a respiratory rhythm variability, respiratory sinus arrhythmia, end tidal CO2 concentration variability, power variability at a certain neurological index frequency band (e.g., beta), an EKG morphology variability, a heart rate pattern variability, an electrodermal variability (e.g., a skin resistivity variability or a skin conductivity variability), a pupillary diameter variability, a blood oxygen saturation variability, a kinetic activity variability, a cognitive activity variability, arterial pH variability, venous pH variability, arterial-venous pH difference variability, a lactic acid concentration variability, a cortisol level variability, or a catecholamine level variability.

Id. ¶ 43; *see also id.* ¶ 42 (similar) ¶¶ 45–46 (monitoring heart rate for episodes of tachycardia and bradycardia). "In one embodiment, the severity [of a pathological state] may be measured by a magnitude and/or duration of a pathological state such as a seizure, a type of autonomic change associated with the pathological state (e.g., changes in heart rate, breathing rate, brain electrical activity, the emergence of one or more cardiac arrhythmias, etc.)." *Id.* ¶ 71.

With respect to HRV, in particular, Osorio teaches: "By monitoring the patient's activity level, HR, and HRV, it is possible to determine when the patient's HRV falls outside the non-pathological ranges as the patient's activity levels change over time." *Id.* ¶ 66. Osorio's Figure 4A, reproduced below, shows heart rate variability as a function of activity level. *See id.* ¶ 58.

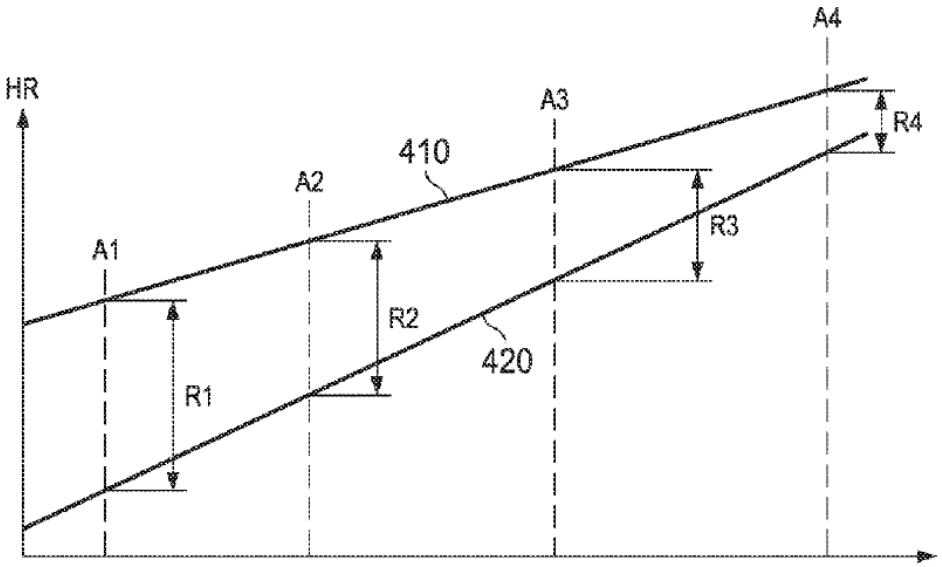


FIG. 4A

Figure 4A plots a patient's heart rate (HR) on the Y-axis and a patient's activity level on the X-axis. *Id.* Markers A1 though A4 represent increasing activity from a sleep state (A1) through vigorous activity (A4). *Id.* Boundary lines 410 and 420, respectively, represent the upper and lower limits of non-pathological heart rate, and include representative ranges R1 through R4. *Id.* at Fig. 4A. According to Osorio,

> the upper and lower bounds of the non-ictal[8] HR region increase as activity level increases (e.g., from a sleep state to a resting, awake state) and reach their highest values for strenuous exertion. In addition, the width of the non-pathological HR ranges narrows as activity levels and heart rates increase, which is consistent with the known reduction in HRV at high levels of exertion. When the patient is in a non-pathological state (e.g., when an epileptic patient is not having a seizure), for a particular activity level the patient's HRV should

[8] "Ictal" refers to the active, middle stage of a seizure and corresponds with intense electrical brain activity. *See* https://epilepsyfoundation.org.au/understanding-epilepsy/seizures/seizure-phases/.

> fall within a non-pathological HRV range associated with that activity level.

Id. ¶ 58.

Osorio further presents Figure 11 as "depict[ing] pathological and non-pathological BDV (e.g., HRV) value ranges." *Id.* ¶¶ 23, 91. In this illustration, Osorio shows that HRV values falling below 0.5 bpm and above 4 bpm are always pathological when activity level is low (e.g., resting or walking), whereas intermediate HRV values (0.5–4 bpm) may be pathological when considered in light of the patient's activity level. *Id*. Osorio further notes that the boundaries between normal and pathological may be adjusted based on an individual's physiology. "For example, in an epilepsy patient also suffering from tachycardia, and having base resting heart rate of 100-110 bpm, a decline in heart rate to 70 bpm may be indicative of a seizure slowing down the heart rate, even though a heart rate of 70 bpm is generally 'normal' across a typical population." *Id.* ¶ 45.

3) Hu 1997 (Ex. 1049)

Hu 1997 discloses the use of "a 'mixture-of-experts' (MOE) approach to develop a customized electrocardiogram (ECG) beat classifier in an effort to further improve the performance of ECG processing and to offer individualized health care." Ex. 1049, Abstract. Hu's "approach is based on three popular artificial neural network (ANN)-related algorithms, namely, the self organizing maps (SOM), learning vector quantization (LVQ) algorithms, along with the mixture-of-experts (MOE) method." *Id.* at 892. According to Hu 1997, "Software packages of both SOM and LVQ are available in the public domain, and the application of these packages to the ECG beat classification problem is straight forward." *Id.* at 893 (internal citation omitted).

Hu 1997 reports that, "[t]ested with MIT/BIH arrhythmia database, we observe significant performance enhancement using this approach." *Id.* at Abstract. Hu 1997 further states that use of the MOE method will result in "significant performance enhancement at low cost," and "can be easily adapted to other automated patient monitoring algorithms and eventually support decentralized remote patient-monitoring systems." *Id.* at 895, 899.

II. ANALYSIS

A. Legal Standards

"In an IPR, the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Technology, Inc.*, 815 F.3d 1356, 1363 (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify "with particularity . . . the evidence that supports the grounds for the challenge to each claim")). This burden of persuasion never shifts to Patent Owner. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (discussing the burden of proof in *inter partes* review).

In *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), the Supreme Court reaffirmed the framework for determining obviousness set forth in *Graham v. John Deere Co.*, 383 U.S. 1 (1966). The *KSR* Court summarized the four factual inquiries set forth in *Graham* (383 U.S. at 17–18) that are applied in determining whether a claim is unpatentable as obvious under 35 U.S.C. § 103 as follows: (1) determining the scope and content of the prior art; (2) ascertaining the differences between the prior art and the claims at issue; (3) resolving the level of ordinary skill in the art; and

(4) considering objective evidence indicating obviousness or non-obviousness, if present. *KSR*, 550 U.S. at 406.

"[W]hen a patent 'simply arranges old elements with each performing the same function it had been known to perform' and yields no more than one would expect from such an arrangement, the combination is obvious." *Id.* at 417 (quoting *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 282 (1976)). But in analyzing the obviousness of a combination of prior art elements, it can also be important to identify a reason that would have prompted one of skill in the art "to combine . . . known elements in the fashion claimed by the patent at issue." *Id.* at 418. A precise teaching directed to the specific subject matter of a challenged claim is not necessary to establish obviousness. *Id.* Rather, "any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *Id.* at 420. Accordingly, a party that petitions the Board for a determination of unpatentability based on obviousness must show that "a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so." *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1381 (Fed. Cir. 2016) (quotations and citations omitted). Under the proper inquiry, "obviousness cannot be avoided simply by a showing of some degree of unpredictability in the art so long as there was a reasonable probability of success." *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1364 (Fed. Cir. 2007).

B. Level of Ordinary Skill in the Art

In determining the level of skill in the art, we consider the type of problems encountered in the art, the prior art solutions to those problems, the rapidity with which innovations are made, the sophistication of the technology, and the educational level of active workers in the field. *See Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986); *see also Orthopedic Equip. Co. v. United States*, 702 F.2d 1005, 1011 (Fed. Cir. 1983).

Petitioner asserts that a person of ordinary skill in the art would have been someone with

> at least a combination of Bachelor's Degree (or a similar Master's Degree, or higher degree) in an academic area emphasizing health science, or a related field, and two or more years of work experience with cardiac monitoring technologies (e.g., as a cardiologist).

Pet. 8. Petitioner further contends that "[a]dditional education or industry experience may compensate for a deficit in one of the other aspects of the requirements stated above." *Id.*

In its Preliminary Response, Patent Owner took the position that one of ordinary skill in the art would have had "specialized engineering skills" including "a degree in biomedical or electrical engineering (or an equivalent), and/or extensive experience working with tools for detecting cardiac conditions." Prelim. Resp. 9–10 (citing Ex. 2001 ¶ 52). Although Patent Owner does not expressly define the person of ordinary skill in the art post-institution, it appears to argue that such a person would have an engineering degree or comparable experience. *See* PO Resp. 38 (arguing that "a cardiologist who is not an engineer lacks the necessary knowledge to develop a smartwatch with PPG or ECG sensors"); Sur-reply 23–24

(similar); *but see* Tr. 39:20–40:12 (Petitioner arguing that Patent Owner waived its opportunity to propose a definition).

In our Institution Decision, we noted that

> the research and development of medical devices is often the work of a multidisciplinary team, and courts and tribunals have frequently identified the hypothetical person of ordinary skill as a composite or team of individuals with complementary backgrounds and skills. *See, e.g.*, *AstraZeneca Pharm. LP v. Anchen Pharm., Inc.*, 2012 WL 1065458, at *19, *22 (D.N.J. Mar. 29, 2012), *aff'd*, 498 F. App'x 999 (Fed. Cir. 2013) (collecting cases); *Apotex Inc. v. Novartis AG*, IPR2017-00854, Paper 109 at 10–11 (PTAB July 11, 2018) (collecting cases).

DI 27–28. We further determined such a team in the context of the '499 patent might include specialists in electrical engineering, mechanical engineering, biomedical engineering, computer science, and cardiology. *Id.* at 28. With respect to the last of these, we noted that because the '499 patent "relates to methods and systems for managing health and disease such as cardiac diseases including arrhythmia and atrial fibrillation," it appeared reasonable that this hypothetical multidisciplinary team would include a cardiologist. *See id.*; *see also* Tr. 39:5–19 (Petitioner arguing that prior art Exhibits 1021, 1033, 1036, 1076–1078, 2024, and 2029 evidence "teams of people, medical doctors, cardiologists working together with engineers); Ex. 1001, 1:29–33.

Patent Owner argues that we should reject our originally proposed definition in light of, for example, Petitioner's proposed definition before the ITC, which required an engineering background and "at least two years of relevant work experience designing wearable devices and/or sensors for measuring physiological signals." PO Resp. 29 (citing Ex. 2004, 6) (emphasis removed). As noted at oral argument, however, Patent Owner

truncates the full extent of Petitioner's ITC definition, which further states that "a hypothetical person of ordinary skill in the art could also be a person with a medical degree (MD or DO) and with at least two years of work experience using biomedical sensors and/or analyzing their data (in the context of industry, in biomedical academic research, or in practice treating patients)". Ex. 2004, 6; Tr. 40:13–41:10. Patent Owner's assertion that our originally proposed definition, would "classify all cardiologists as POSITAs," is well taken. Accordingly, we apply the following modified definition, which is consistent with Petitioner's representation before the ITC. For the purpose of this proceeding, a person of ordinary skill in the art may be a member of an interdisciplinary team including persons with backgrounds in electrical engineering, mechanical engineering, biomedical engineering, computer science, and/or cardiology, and having at least two years of relevant work experience designing, using, or analyzing data from, cardiac monitoring devices.

The parties' dispute regarding the definition of one of ordinary skill in the art relates to Dr. Chaitman's alleged lack of "specialized engineering skills," and the bases for Dr. Efimov's opinions on the meaning of "medical technology at issue in this proceeding, such as 'irregular heart condition' and 'pathological state.'" *See, e.g.*, PO Resp. 28–31; Reply 27–28. Neither party has sought to exclude expert testimony in this proceeding, and the arguments bear on the amount of weight we should accord the opinions of either expert. *See, e.g.*, Tr. 49:22–52:21.

As discussed in our Institution Decision, Dr. Chaitman is a well-respected cardiologist with "extensive experience working with tools for detecting cardiac conditions," who would qualify as one of ordinary skill in

the art even under Patent Owner's then-proposed definition. *See* DI 26–28. Despite Patent Owner's subsequent position that the ordinarily skilled artisan should have an engineering degree and "design experience" in developing wearable cardiac sensors, the arguments and evidence adduced at trial do not alter our initial determination. *See, e.g.*, PO Resp. 37–41; Reply 27–28; Sur-reply 22–24; *see generally* Tr. 40:25–46:19, 55:2–56:13. Rather, we agree with Petitioner's argument in support of Dr. Chaitman's qualifications, that this proceeding involves "piecing together known technologies and . . . the analysis of cardiac data" including PPG data, ECG data and activity level. Tr. 38:4–18. Thus, one of ordinary skill in the art with an understanding of cardiac monitoring technology "would understand how these types of data work, how they interplay and how the data could be processed on these devices." *Id.*

Dr. Efimov has extensive experience in the design of cardiac monitoring and related technologies, but Petitioner asserts that he "is unable to offer credible testimony on the meaning of [relevant] medical terminology," because he is not a doctor. Reply 28; Sur-reply 23–24 (arguing that "Dr. Efimov is a recognized expert in the field of clinical cardiac electrophysiology"). Considering the totality of Dr. Efimov's background, including extensive work on the physiology, diagnostics, and therapy of cardiac arrhythmias, we do not adopt Petitioner's position. *See*, *e.g.*, Ex. 2001 ¶¶ 2–15.

We also note that neither of the parties' experts possesses advanced skills in computer science, or more specifically, machine learning. *See generally* Tr. 43:21–46:17. In this respect, we find that although programming skills may be relevant to the implementation of certain of the

challenged claims, they are not prerequisites for qualifying a person of ordinary skill in the art for this proceeding. *See id.* at 38:4–18.

In light of the above, we determine that Dr. Chaitman and Dr. Efimov are both qualified to testify as to the understanding of a person of ordinary skill in the art, we, nevertheless, consider the weight of both parties' experts on a particular topic in light of the strengths and weaknesses of their respective background.

C. Claim Construction

We interpret a claim "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b)." 37 C.F.R. § 42.100(b). Under this standard, we construe the claim "in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." *Id.* "[W]e need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy.'" *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Ltd.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

Patent Owner notes that the ITC applied the plain and ordinary meaning to the terms "arrhythmia," "alert," and "heart rate monitor." PO Resp. 32 (citing Ex. 2010, 12–13). We understand "arrhythmia" as used in the context of the '499 patent refers to "a cardiac condition in which the electrical activity of the heart is irregular or is faster (tachycardia) or slower (bradycardia) than normal." *Id.* at 31–36 (quoting Ex. 1001, 1:31–33). This term does not appear to be in dispute. *See* Tr. 21:18–22:3 ("[Board"]: . . . Patent Owner raised the issue of claim construction for the term arrhythmia.

Is there any dispute there? [Petitioner's counsel]: Honestly, Your Honor, we considered that -- put a lot of energy into considering it. We don't believe so."); *see also id.* at 53:24–54:2 ("[Board]: . . . Your claim construction of arrhythmia is merely a matter of precision and clarification rather than a contested point; is that correct? [Patent Owner's counsel]: I believe that's largely correct.").

With the above understanding, we apply the plain and ordinary meaning to all claim terms.

D. Ground 1: Obviousness over Shmueli and Osorio

As Ground 1, Petitioner challenges claims 1–6, 10–16, and 20 as obvious over Shmueli in combination with Osorio. Pet. 8–68. Petitioner provides an element-by-element comparison of the asserted art to the challenged claims. *Id.* at 17–68.

According to Petitioner, "Shmueli's wrist-mounted heart monitoring device detects an irregular heart condition (arrhythmia) based on PPG and ECG measurements" but "does not expressly account for a user's activity level." *Id.* at 17. As a marker for activity level, Petitioner points to Osorio as teaching to "determin[e] HRV from HR and using HRV to detect the pathological event." *Id.* at 17–18 (citing Ex. 1003 ¶ 66). Petitioner asserts that, "it was well-known that HRV can be accurately derived from heart rate sensed using PPG or ECG data," and one of ordinary skill in the art "would have found it obvious that Shmueli's method derives HRV based on this heart rate information because HRV is a common physiological parameter derived from heart rate measurements to detect irregular heart conditions."

Id. at 37 (citing Ex. 1003 ¶ 105; Ex. 1012,[9] Abstract, 95–96; Ex. 1013,[10] Abstract; Ex. 1014,[11] Abstract; Ex. 1015,[12] Abstract).

Relying on the testimony of Dr. Chaitman, Petitioner argues that one of ordinary skill in the art would have found it obvious to improve Shmueli's method by considering activity level as taught by Osorio. *See id.* at 17 (citing, *e.g.*, Ex. 1003 ¶ 65). Petitioner points to Osorio as evidencing benefits of using activity level to detect an irregular heart condition (e.g., improved accuracy, reliability, and reduced false detection). *Id.* (citing Ex. 1005 ¶¶ 29, 36). Petitioner thus contends that one of ordinary skill in the art "would have been motivated to incorporate Osorio's activity sensor and activity level analysis techniques into Shmueli's heart monitoring device . . . to improve the accuracy of detecting a pathological event (e.g., arrhythmia.)" *Id.* at 17–18 (citing Ex. 1005 ¶ 29; Ex. 1003 ¶¶ 65–66); *see also* Ex. 1003 ¶ 76 (Dr. Chaitman's testimony that one of ordinary skill in the art would have understood that modifying Shmueli's device to use Osorio's HRV analysis would have improved the detection of certain arrhythmias, particularly atrial fibrillation). Petitioner similarly asserts that

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[9] Tsipouras et al., "*Automatic arrhythmia detection based on time and time—frequency analysis of heart rate variability*," 74 Computer Methods and Programs in Biomedicine 95–108 (2004). Ex. 1012.

[10] Lu et al., "*Can photoplethysmography variability serve as an alternative approach to obtain heart rate variability information?*" J. Clin. Monit. Comput. (2007). Ex. 1013.

[11] Selvaraj et al., "*Assessment of heart rate variability derived from finger-tip photoplethysmography as compared to electrocardiography*," 32(6) J. Med. Eng. & Technol. 479–484 (2008). Ex. 1014.

[12] Lu et al., "*A comparison of photoplethysmography and ECG recording to analyse heart rate variability in healthy subjects*," 33(8) J. Med. Eng. Technol. 634–41 (2009). Ex. 1015.

one of ordinary skill in the art "would have been motivated to incorporate Osorio's HRV analysis because it is less affected by noise" and, thus, "improve[] the pathological event detection capabilities compared to Shmueli's unmodified heart monitoring device." Pet. 22–23, 24 (citing Ex. 1003 ¶ ¶ 73, 76; Ex. 1039, 52[13]). Petitioner further argues that one of ordinary skill in the art could have combined the teachings of Shmueli and Osorio with a reasonable expectation of success. *Id.* at 21–22, 25, 50, 70.

Patent Owner argues that Ground 1 fails because Petitioner has not shown that 1) either Shmueli or Osorio teaches or suggests arrhythmia detection, or 2) that one of ordinary skill would have been motivated to combine the teachings of Shmueli and Osorio with a reasonable expectation of success. PO Resp. 51–62. We discuss these additional arguments below.

1) Arrhythmia Detection by Shmueli

Independent claims 1 and 11, respectively, are drawn to methods and systems for "determining the presence of an arrhythmia." According to Petitioner, although Shmueli does not explicitly use the term arrhythmia, one of ordinary skill in the art reading Shmueli would have found it obvious that the text "Detect Irregular Heart Condition," in element 38 of Shmueli's Figure 7, refers to detecting the presence of arrhythmia based on PPG data. *See* Pet. 8–13, 28–29; Ex. 1003 ¶¶ 49–51, 82–86.

For the purpose of instituting trial, we determined that "one of ordinary skill in the art would have understood Shmueli's use of 'irregular heart condition' as referring to—or at a minimum, encompassing—

[13] Asl and Setarehdan, "*Support vector machine-Based arrhythmia classification using reduced features of heart rate variability signal*," 44(1) Artif. Intell. Med. 51–64 (2008). Ex. 1039.

arrhythmia, and, thus, disclosing the detection of arrhythmia." DI 44. As discussed below, the arguments and evidence adduced at trial confirm our initial understanding.

Patent Owner argues that Ground 1 fails because Shmueli's reference to irregular heart conditions refers instead to "conditions traditionally detected using SpO_2 monitoring, such as heart attacks or acute heart failure." PO Resp. 52 (citing Ex. 2016 ¶ 63); *see* Sur-reply 9–14 (more narrowly focusing on heart attack detection). Patent Owner raises three arguments supporting its contention that "while an arrhythmia might be an irregular heart condition in the abstract, it cannot be an 'irregular heart condition' as that phrase is used in Shmueli." PO Resp. 53.

Patent Owner argues, first, that "Shmueli could be referring to practically any heart condition that includes an irregular heart condition . . . including: heart attack, angina pectoris, cardiomyopathy, congenital heart disease, . . . coronary heart disease, and heart-valve defect." *Id.* at 54 (citing Ex. 1047, Ex. 1023; Ex. 2016 ¶ 69).

Secondly, Patent Owner argues that one of ordinary skill in the art would not understand Shmueli to refer to arrhythmias because "pulse oximetry was a well-known diagnostic tool for conditions affecting blood oxygen levels including cardiac conditions such as heart attacks" but "PPG was a 'sub-optimal' tool for measuring arrhythmias." *Id.* at 54–55 (citing Ex. 2018, 62:9–21; Ex. 2017, 53:13–54:4, 54:13–55:12; Ex. 2016 ¶¶ 65–66; Ex. 2025).

Third, Patent Owner points to Shmueli's disclosure that "instead of, or in addition to, the oximetry (SpO_2) measuring unit the heart monitoring device may include a unit for measuring CO2 content in the blood." *Id.* at 55

(citing Ex. 1004, 9); Sur-reply 13–14. According to Patent Owner, because CO_2 levels are "not used for arrhythmia detection but can be used to detect heart attacks or acute heart failure," Shmueli's disclosure of using CO_2 measurements supports a conclusion that Shmueli is not directed at arrhythmia detection. PO Resp. 55 (citing Ex. 2016 ¶ 67) (emphasis omitted).

Patent Owner's arguments are unavailing for substantially the reasons set forth at pages 3–11 of Petitioner's Reply and as discussed below. We note, first, that Shmueli discloses that "the terms 'oxygen saturation in the blood', 'blood oxygen saturation', 'pulse oximeter', oximetry, SpO_2, and photoplethysmography have the same meaning and may be used interchangeably." Ex. 1004, 8. Collectively, these terms encompass two distinct functions—measurement of pulse and measurement of blood oxygen content. As discussed below, both of these functions may be performed by a single device (a pulse oximeter).

In general terms, SpO_2 refers to the oxygen content of blood and PPG (photoplethysmography) measures pulse. *See* Ex. 1069, 81:8–13; Ex. 2001 ¶¶ 40–41. According to Dr. Efimov, a SpO_2 sensor detects changes in the color of blood (indicative of degree of oxygenation) using infra-red and red light emitting diodes; PPG (photoplethysmography) on the other hand, measures changes in reflected light as blood vessels pulsate with every heartbeat. Ex. 1069, 79:17–83:20; Ex. 2016 ¶ 13; *see also* Ex. 2001 ¶ 40; Ex. 1003 ¶¶ 31–32. Unlike an SpO_2 sensor, PPG does not necessarily require that the light source is in the infra-red and red portion of the spectrum. Ex. 1069, 79:20–80:24, 83:15–16. But by combining the necessary sensors and using infra-red/red light emitting diodes, their features can be combined

in a single device able to perform pulse oximetry, which measures both pulse rate and oxygen levels. *See id.* at 83:4–85:2. "[T]his combination is an oximeter." *Id.*

Patent Owner, supported by the testimony of Dr. Efimov, focuses on Shmueli's reference to SpO_2, for example, in element 37 of Shmueli's figure 7. Taken strictly at face value, the instruction of element 37 to "Measure SPO_2" refers to the measurement of blood oxygen content, which, Patent Owner argues, may be used for monitoring signs of heart attack, but not arrhythmias. *See* PO Resp. 54–55; Tr. 62:1–10, 70:18–71:1, 73:18–74:6. But as Petitioner points out, Shmueli is not focused solely on monitoring blood oxygen content. *See, e.g.*, Reply 4–8; Ex. 1004, Title. We note in particular, that in describing the operation of Figure 7, Shmueli teaches that "the software program starts in element 37 by measuring SpO_2." Ex. 1004, 12:9–10. Although Shmueli states that element 37 measures "oxygen saturation in the blood," it further states that the measurement is preferably executed using oximetry—which, as noted above, can measure pulse rate in addition to blood oxygen content. *See id.* at 12:10–13; *see also id.* at 8:11–13 ("Deriving heart beat rate from oximetry, as well as other artifacts of the heart activity and blood flow, is . . . known in the art"). Consistent with its title highlighting the use of "Pulse Oximetry Measurement," Shmueli states:

> The software program proceeds to element 38 to derive from the SpO_2 measurement physiological parameters such as pulse rate, pulse amplitude, pulse shape, rate of blood flow, etc. Then, the software program scans the derived physiological parameters to detect various irregularities of the heart condition. The element of measuring SpO_2 (e.g. oxygen saturation in the blood).

Id. at 12:14–17, code (54) ("Pulse Oximetry Measurement Triggering ECG Measurement"); *see* Ex. 1069, 84:18–25.

Dr. Efimov tacitly admits that the above passage discloses that the "Measure SpO_2" command of Shmueli's element 37 measures pulse rate, amplitude and shape, thus, indicating the PPG functionality. Ex. 1069, 119:20–120:13. This type of heart rate data can be used to detect arrythmia. *See id.* at 84:4–25, 120:6–13, 121:2–122:6; Ex. 2017, 90:5–12; Ex. 1003 ¶¶ 31–34, 50–51; Ex. 1061, 16:54–58[14] ("The signal that is collected from the SpO2 sensor may also optionally be used for producing other heart related information . . . . such as heart rate, [pulse wave transit time], irregularity of heart rate etc."

Accepting that the embodiment of Shmueli's Figure 7 was *capable* of detecting arrythmia using SpO_2/PPG data, we adopt Dr. Chaitman's reasoning that one of ordinary skill would have understood Shmueli's "irregular heart condition" to refer to—or at a minimum, render obvious—arrhythmia, "one of the most obvious (if not the most obvious) types of "irregular heart condition[s]," as opposed to, for example, heart attack.[15] *See* Ex, 1003 ¶¶ 48–52, 83–84; *see also* Pet. 28–29; Reply 8; Ex. 2016 ¶ 3; Tr. 15:9–12, 73:6–74:6.

Patent Owner also argues that, whereas ECG is the "gold standard" for arrythmia detection, "PPG was a 'sub-optimal' tool for measuring arrhythmias." *See* PO Resp. 20, 38, 54–55; Ex. 2001 ¶ 41 (Dr. Efimov's

[14] Goldreich, US 7,598,878 B2, issued Oct. 6, 2009. Ex. 11061.

[15] Although Patent Owner argues that Shmueli's use of "irregular heart condition" potentially encompasses many conditions, we note that some of these (e.g., heart-valve defects, and congenital heart defects) are chronic conditions, and thus, not pertinent to Shmueli's detection of episodic events. Rather than attempt to parse the relevance of each, we focus on heart attack, as does Patent Owner. *See* Sur-reply 9–14; Tr. 64:1–10, 73:18–74:6.

statement that "PPG monitoring is reliable in measurements of oxygen saturation and average heart rate, but historically has been found to be less reliable in detecting arrhythmias, especially atrial arrhythmias. Compared to the traditional ECG data, heart rate estimation is more challenging based on the PPG-signal."); Ex. 2016 ¶ 16 (similar).[16] But this is precisely the point of Shmueli, which combines the ease of use of the PPG sensor with a less convenient, but confirmatory, ECG. Thus, Shmueli instructs a user to take an ECG when a problem is identified by SpO_2/PPG so that the ECG can confirm whether or not the SpO_2/PPG detection was accurate. *See* Ex. 1003 ¶¶ 52, 84, 124–125, Ex. 1004, Abstract, 3:15–20, 9:21–29, 12:22–31, 14:16–29, 15:1–3, Fig. 7. As Shmueli explains, this provides the benefit of "enabl[ing] a patient to perform ECG measurement as soon as an irregular heart activity develops and without requiring the ECG to be constantly wired to the patient," as with the more cumbersome implanted, tethered, or Holter devices. Ex. 1004, 2–3, 8; *see* Ex. 1003 ¶¶ 30, 52; Ex. 2016 ¶ 7 ("Clinically, AFib is diagnosed by cardiologists using gold standard tool – 12 lead ECG, or Holter monitors and similar wearable or implantable devices.").

We also do not find persuasive Patent Owner's argument regarding Shmueli's disclosure that "instead of, or in addition to, the oximetry (SpO_2) measuring unit the heart monitoring device may include a unit for measuring CO2 content in the blood." *See* PO Resp. 55 (citing Ex. 1004, 9). Shmueli is relevant "for all that it teaches," and its brief reference to alternative

[16] Supporting its position that the use of PPG to detect arrhythmia was known, Petitioner further points to Amano (U.S. Pat. No. 6,095,984) as disclosing a wrist-worn device that uses pulse oximetry to detect arrhythmia. *See* Pet. 11, Reply 11–13 (citing Ex. 1010); Ex. 1003 ¶ 27 (same); *see also* Ex. 1003 ¶ 161 (further discussing arrhythmia detection using PPG). Patent Owner does not address this contention on the merits. *See* Sur-reply 2, 13.

embodiments does not change our understanding of either Figure 7 or Shmueli as a whole. *See In re Mouttet*, 686 F.3d 1322, 1331 (Fed. Cir. 2012).

In light of the above, and all the evidence adduced at trial, we agree with Petitioner that one of ordinary skill in the art would have understood Shmueli to teach or disclose methods and systems for "determining the presence of an arrhythmia," as required by the challenged claims.

2) Arrhythmia Detection by Osorio

Osorio discloses medical device systems and methods for detecting a pathological state of a patient by determining when a body data variability value, or "BDV," is outside of a "value range," and where the threshold levels of that range vary in response to the patient's physical activity level (measured by, e.g., an accelerometer), sleep/wake state, or other mental/emotional condition. *See* Ex. 1005, Abstract, ¶¶ 3–8, 28, 33, 35, 48, Fig. 4. Osorio states that "false negative and false positive detections of pathological events may be reduced by dynamically determining pathological or non-pathological ranges for particular body indices based on activity type and level or other variables (e.g., environmental conditions)." *Id.* ¶ 36. Osorio discloses that among the body indices subject to BDV monitoring are "heart rhythm variability," "heart rate variability (HRV)," "changes in heart rate," including "tachycardia and bradycardia," and "the emergence of one or more cardiac arrhythmias." *Id.* ¶¶ 42, 43, 45, 46, 71; Ex. 1069, 61:13–16; Ex. 1003 ¶ 54.

Patent Owner argues that we should discount Osorio's express teachings to monitor heart rate for episodes of tachycardia, bradycardia, or other cardiac arrhythmias because the underlying "pathological state" at issue in Osorio is epilepsy, rather than arrhythmia. *See* PO Resp. 57–60; Sur-

reply 14–16; Tr. 56:16–57:23 (Patent Owner's counsel arguing that any change in heartbeat mentioned in Osorio are "in the context of a neurological condition"). Patent Owner's arguments are unavailing for a number of reasons.

First, to the extent Petitioner relies on Osorio for arrhythmia detection, it also relies on Shmueli for this element. *See* Pet. 29 ("Osorio *also* discloses using heart rate data to determine arrhythmia") (emphasis added). Because we determine that Shmueli discloses or renders obvious arrhythmia detection, it is not necessary that we also find that disclosure in Osorio. *See* Section II.D.1, above.

Second, for essentially the reasons set forth in Petitioner's Reply, we do not read Osorio's "pathological state" as limited to neurological conditions. *See* Reply 14–16. We do not dispute that Osorio largely focuses on a particular neurological condition—epilepsy—as an exemplary pathological state. As noted by Petitioner, however, Osorio, consistently employs "permissive language to indicate that its teaching for epileptic seizures are merely exemplary," and its five-paragraph introduction to the invention does not once mention epilepsy. *Id.* at 14–15 (citing Ex. 1005 ¶¶ 2, 27–31, 33, 37, 45–46, 71); *see also* Ex. 1005 ¶¶ 56, 57. Illustrative of Osorio's broad usage of pathological state, the reference discloses that "[a]n occurrence of *any pathological state* that may be associated with a body signal outside a non-pathological BDV range provided by analysis of the patient's activity level may be determined by the pathological state occurrence module." Ex. 1005 ¶ 44 (emphasis added).

We also agree with Petitioner that one of ordinary skill reading Osorio, including its claims, would also understand that its teachings are not

limited to epilepsy. *See* Reply 15–16. In particular, Osorio's claim 1 is directed to "[a] method for detecting a pathological body state of a patient," whereas claim 7 limits the pathological state to an epileptic event. The same relationship is seen with claims 14 and 17 (limiting a pathological state of claim 14 to an epileptic event). Patent Owner's argument that the broader "pathological body state" recited in claims 1 and 14 should be limited to neurological states, is not consistent with our reading of Osorio's specification. To the contrary, our understanding of Osorio is consistent with Dr. Efimov's admission that one of ordinary skill in the art would, in general, understand pathological state to include arrhythmia. Ex. 1069, 50:17–22.[17]

Third, even were we to read Osorio as narrowly drawn to the detection of epilepsy as Patent Owner urges, the reference, nonetheless, contains repeated teachings to monitor heart rate and heart rate variability for signs of arrhythmia. *See* Ex. 1005 ¶¶ 42, 43, 45, 46, 71; Ex. 1069, 58:9–59:3 (Dr. Efimov's agreement that Osorio discloses determining the severity of a neurologic condition based, at least in part, on the identification of cardiac arrhythmia). It is undisputed that a cardiac arrhythmia is a type of pathological condition. Ex. 1003 ¶¶ 49, 53; Ex. 2016 ¶ 70; Ex. 1069, 50:17–51:10. Patent Owner provides no persuasive explanation of why we should ignore Osorio's express teachings relating to the detection of cardiac arrhythmias, merely because Osorio also implicates them in detecting the pathological condition of epilepsy.

[17] We also note Dr. Efimov's testimony at deposition that Osorio and its claims were *focused* on a neurological pathological state—and his repeated refusal to squarely address whether they were *limited* to a neurological pathological state. *See id.* at 65:14–70:7; Reply 15.

3) Reasons to Combine Shmueli and Osorio

Relying on the testimony of Dr. Chaitman, Petitioner argues that "it was well-known that activity level is related to HR and HRV and a POSITA would have found it obvious to improve Shmueli's method by considering activity level." Pet. 17 (citing, *e.g.*, Ex. 1003 ¶ 65). Petitioner further points to Osorio as evidencing benefits of using activity level to detect an irregular heart condition (e.g., improved accuracy, reliability, and reduced false detection). *Id.* (citing Ex. 1005 ¶¶ 29, 36). Accordingly, Petitioner contends, one of ordinary skill in the art "would have been motivated to incorporate Osorio's activity sensor and activity level analysis techniques into Shmueli's heart monitoring device . . . to improve the accuracy of detecting a pathological event (e.g., arrhythmia,) which would have "improved user satisfaction since the user would have been less bothered by false detections." *Id.* at 17–18, 28 (citing Ex. 1005 ¶ 29; Ex. 1003 ¶¶ 66, 81).

Petitioner similarly asserts that one of ordinary skill in the art "would have been motivated to incorporate Osorio's HRV analysis because it is less affected by noise" and, thus, "improve[] the pathological event detection capabilities compared to Shmueli's unmodified heart monitoring device." *Id.* at 22–23, 25 (citing Ex. 1003 ¶¶ 73, 76; Ex. 1039, 52). Supporting Petitioner's position, Dr. Chaitman testifies that one of ordinary skill in the art would have understood that modifying Shmueli's device to use Osorio's HRV analysis would have improved the detection of certain arrhythmias, particularly atrial fibrillation. *See* Ex. 1003 ¶¶ 57, 65–72, 76. Petitioner further argues that one of ordinary skill in the art would have found it obvious to combine the teachings of Shmueli and Osorio with a reasonable expectation of success. Pet. 21–22, 25–26.

Patent Owner argues that one of ordinary skill in the art would not have been motivated to combine Shmueli with Osorio because the two references are directed to different problems: Shmueli to detecting heart conditions, and Osorio to detecting epileptic seizures. PO Resp. 60–62; Sur-reply 16–17. As such, Patent Owner argues that combining the two references would improperly change the basic principles under which the prior art was designed to operate, or render the prior art inoperable for its intended purpose. *See* PO Resp. 61; Sur-reply 16–17 (citing, e.g., *Adidas AG v. Nike Inc.*, 963 F.3d 1355, 1359 (Fed. Cir. 2020) and *Nichia Corp v. Everlight Ams., Inc.*, 855 F.3d 1328, 1340 (Fed. Cir. 2017)). Patent Owner further argues that, absent a finding that Osorio discloses detecting arrhythmias, "there can be no finding of obviousness, because with no arrhythmia detection there is no argument that a POSITA would have been motivated to combine Shmueli and Osorio." PO Resp. 62 (citing *Nichia*, 855 F.3d at 1340).

Patent Owner's arguments are unavailing for the reasons set forth on pages 16–18 of Petitioner's Reply, which we adopt in full. In short, Osorio relates to medical device systems and methods capable of detecting a pathological body state of a patient. Ex. 1005 ¶ 2. As discussed above, we do not read Osorio as limiting "pathological state" to epilepsy or other neurological condition. To the contrary, one of ordinary skill in the art would have understood Osorio's teachings applicable to "any pathological state," including arrythmia. *See, e.g.*, *id.* ¶ 44. As such, the references are not directed to different problems as Patent Owner urges.

Further, even if one of ordinary skill in the art were to read Osorio as limited to the detection neurological events such as epilepsy, Osorio contains

express teachings to monitor heart rate and heart rate variability for signs of arrhythmia. *See* Ex. 1005 ¶¶ 42, 43, 45, 46, 71; Ex. 1069, 58:23–59:3, 61:13–62:7. Whether Osorio's detection of arrhythmias is viewed as a stand-alone goal, or as data for use in monitoring for epileptic seizures, does not materially affect the analysis. "Because Shmueli already renders arrhythmia detection obvious and Osorio motivates use of activity tracking to improve detection of any heart-related pathological conditions," including arrhythmias, it is irrelevant whether Osorio's ultimate goal is the detection of neurological events. Reply 17 (citing Pet. 44–46; Ex. 1004, 13:9–17, Fig. 7).

With respect to Patent Owner's reliance on *Adidas*, it is well established that a finding of obviousness does not require that all features of a secondary reference are "bodily incorporated into the structure of the primary reference." *In re Keller*, 642 F.2d 413, 425 (CCPA 1981). Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. *Id*. "[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill." *KSR*, 550 U.S. at 417. In the present case, we do not understand Petitioner to argue for the wholesale incorporation of Osorio into Shmueli's device. Rather, Petitioner more narrowly argues that one of ordinary skill in the art would find it obvious to incorporate limited elements of Osorio into Shmueli's device: "using activity level monitoring to improve the accuracy of detecting a pathological event (e.g., arrhythmia), and (ii) determining HRV from HR and using HRV to detect the pathological event (e.g.,

arrhythmia),” because, for example, “HRV analysis is more robust . . . and is less affected by noise.” Pet. 17–18, 22–25; *see generally* Ex. 1003 ¶¶ 65–81. Thus, even were Osorio ultimately limited to the detection of neurological events, we find unavailing Patent Owner’s suggestion that these targeted improvements would render Shmueli’s device inoperable for its intended purpose.

In view of the above, and all the argument and evidence adduced at trial, Petitioner has established sufficiently that one of ordinary skill in the art would have been motivated to combine Shmueli and Osorio with a reasonable expectation of success in arriving at the claimed invention.

4) Conclusion as to Ground 1

For the reasons set forth above, we find that the combination of Shmueli and Osorio discloses or renders obvious the arrhythmia detection recited in the challenged claims, and that one of ordinary skill in the art would have been motivated to combine the cited references with a reasonable expectation of success of arriving at the claimed invention. Patent Owner does not specifically challenge any other element under Ground 1. Having reviewed the argument and evidence of record, we find that Petitioner has shown by a preponderance of the evidence that claims 1–6, 10–16, and 20 are unpatentable as obvious in view of Shmueli and Osorio.

E. Ground 2: Obviousness over Shmueli, Osorio, and Hu 1997

As Ground 2, Petitioner challenges dependent claims 7–9 and 17–19 as obvious over Shmueli, Osorio, and further in view of Hu. Pet. 68–77. Petitioner provides an element-by-element comparison of the asserted art to the challenged claims. *Id.*

Illustrative of the claims challenged under Ground 2, claim 7 recites "determining a presence of said arrhythmia using a machine learning algorithm." Petitioner defines machine learning as "algorithms capable of learning and/or adapting their structure (e.g., parameters) based on a set of observed data." Pet. 70 (citing Ex. 1003 ¶ 198; Ex. 1042, 538[18]). According to Petitioner, "[t]he machine learning claims add a generic 'machine learning algorithm,' but provide no details about what that machine learning algorithm is or how it works," and thus, recite "nothing more than generic functional language that adds no inventive concept." Reply 18 (citing, e.g., Ex. 1001, 5:6–10, 9:54–67; Ex. 1069, 169:10–170:14; Ex. 1072, 1084:18–1086:6; 1086:1–6, 1081:11–16; Ex. 1081, 74–76; Ex. 1082, 34:1–35:17).

Petitioner contends that, "by the Critical Date, machine learning algorithms were a well-known and popular technique to detect arrhythmia based on heart rate data." Pet. 68–69 (citing Ex. 1003 ¶ 193; Ex. 1040, 1928;[19] Ex. 1041, 74;[20] *see* Reply 19, 24–25 (citing, e.g., Ex. 1003 ¶¶ 192–199); Ex. 1003 ¶ 26–27 (further citing Ex. 1012, Abstract, 106). Tr. 28:14–35:22; Ex. 1006, Abstract; Ex. 1039, Abstract, 47; *see generally* Ex. 1042 (review of machine learning in biomedical applications). Petitioner further

[18] Sajda, "*Machine learning for detection and diagnosis of disease*," 8 Ann. Rev. Biomed. Eng. 537-65 (2006). Ex. 1042.

[19] Yaghouby and Ayatollahi, "*An arrhythmia classification method based on selected features of heart rate variability signal and support vector machine-based classifier*," Dössel O., Schlegel W.C. (eds.) World Congress on Medical Physics and Biomedical Engineering, September 7–12, 2009, Munich, Germany, 25/4 IFMBE Proc. Ex. 1040.

[20] Dallali, et al., "*Integration of HRV, WT and neural networks for ECG arrhythmias classification*. 6 ARPN J. Eng'g. Applied Sci. 74-82 (2011). Ex. 1041.

contends that one of ordinary skill in the art would have been motivated to combine Shmueli and Osorio with a machine learning algorithm given the advantages of machine learning such as its "superior performance where inputs are complex," and to "increase the accuracy of [arrhythmia] detection." Pet. 69 (citing Ex. 1003 ¶¶ 192–201; Ex. 1042, Abstract; Ex. 1006,[21] Abstract; Ex. 1049, Abstract, 898); Reply 19–20. In addition to its reliance on the general knowledge in the art, Petitioner contends that Hu 1997 and/or Shmueli satisfy the machine learning elements of claims 7–9 and 17–19. *See* Pet. 71–72; Reply 18–27.

With respect to Hu 1997, Petitioner contends that one of ordinary skill in the art "would have been motivated to select Hu-1997's mixture of experts approach because training the machine learning algorithm with both general population data and user-specific data greatly enhances performance and detection accuracy." Pet. 71 (citing Ex. 1049, Abstract, 898–899; Ex. 1003 ¶¶ 60–63). Petitioner presents several scenarios detailing how one of ordinary skill would have combined Hu 1997's machine learning approach to work with Shmueli's PPG sensor and Osorio's motion sensor. *Id.* at 71–72; Ex. 1003 ¶¶200–204. In one such formulation, Petitioner asserts that "in the Shmueli-Osorio-Hu-1997 combination, Shmueli's PPG sensor is used to determine heart rate information, and Osorio's motion sensor is used to determine the user's activity level. Then, the combined device determines current HRV based on the heart rate information (from the PPG data) and detects arrhythmia using a machine learning algorithm

[21] Li Q, Clifford GD, "*Signal quality and data fusion for false alarm reduction in the intensive care unit*," 45(6) J Electrocardiol. 596-603 (2012). ("Li-2012") Ex. 1006.

based on the PPG data, heart rate, HRV, motion sensor data and activity level" Pet. 71 (citing Ex. 1003 ¶ 200) (emphasis removed). Alternatively, "upon detection of the arrhythmia, the combined device notifies the user to take an ECG measurement and confirms the arrhythmia using a machine learning algorithm based on the PPG data, heart rate, HRV, motion sensor data, activity level and the ECG data." *Id.* (citing Ex. 1004, 12:6–30, Fig. 7; Ex. 1003 ¶ 201) (emphasis removed).

In addition to its arguments made with respect to Ground 1, Patent Owner contends that Ground 2 fails because neither Hu 1997 nor Shmueli render obvious determining the presence of an arrhythmia using machine learning. *See* PO Resp. 62–69; Sur-reply 17–22. Arguing that Petitioner's evidence only shows machine learning in contexts *other* than arrhythmia detection, Patent Owner asserts that "mere knowledge of a technique is not a motivation to modify and existing solution to use that technique." Sur-reply 18 (citing Reply 18; *Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1068 (Fed. Cir. 2018)) (emphasis removed). We address Patent Owner's arguments below.

1) Hu 1997

As discussed above, Petitioner offers two ways in which the cited art renders machine learning obvious: 1) by applying Hu's machine learning to data including PPG data but not ECG data, and 2) by applying Hu's machine learning to data including ECG data. We address each in turn.

a. Petitioner's PPG Data Machine Learning Theory

With respect to the application of Hu 1997's machine learning technique to PPG data, Patent Owner asserts that Hu 1997 analyzes ECG data but "***does not disclose machine learning based on PPG data or,***

indeed, PPG at all." PO Resp. 64–65; *see* Tr. 34:19–23. Patent Owner similarly asserts that, "because Hu 1997 only teaches beat classification techniques for ECG data, any disclosure of machine learning in Hu 1997 is not relevant to the claims." PO Resp. 65. Disclosure, however, is not the standard for obviousness under §103, which "requires a suggestion of all limitations in a claim," (*CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003)) and "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

For the reasons set forth at pages 18–25 of the Reply, which we adopt, we agree with Petitioner that one of ordinary skill in the art would have found it obvious to apply Hu 1997's machine learning approach to Shmueli's PPG data. In short, although Hu 1997 exemplifies the detection of arrhythmia using ECG data, we agree with Petitioner that, "the source of the heart rate parameters (e.g., ECG or SpO_2/PPG) would not have deterred a POSA from applying machine learning to them," given the advantages of the approach in enhancing performance and detection accuracy. *See, e.g.*, Reply. 23; Ex. 1049, 899 (machine learning approach provides "significant performance enhancement at low cost"). Accordingly, we agree with Petitioner that one of ordinary skill in the art "would have been motivated to select Hu-1997's mixture of experts approach because training the machine learning algorithm with both general population data and user-specific data greatly enhances performance and detection accuracy." Pet. 71 (citing Ex. 1049, 898–899, Abstract; Ex. 1003 ¶¶ 60–63).

We also agree with Petitioner that one of ordinary skill in the art would have been able to apply Hu 1997's machine learning to the Shmueli-Osorio combination with a reasonable expectation of success. *See* Pet. 70, 75; Reply 24–25. As discussed at the beginning of this Section, machine learning was a topic of interest in many biomedical applications (*see, e.g.*, Ex. 1042), and the record contains credible evidence that "machine learning algorithms were a well-known and popular technique to detect arrhythmia based on heart rate data." *See supra,* (citing e.g., Pet. 68–69; Reply 19, 24–25; Ex. 1003 ¶¶ 26–27, 192–199). Representative of these, Asl "presents an effective cardiac arrhythmia classification algorithm" based on HRV data and employing the support vector machine (SVM) classifier— "a machine-learning technique which has established itself as a powerful tool in many classification problems." Ex. 1039, Abstract, 57. We further note that, Li 2012 discloses a machine learning algorithm using ECG and PPG data for distinguishing arrhythmias from false alarms. Li 2012

> present[s] a novel framework for [false alarm] reduction using a machine learning approach to combine up to 114 signal quality and physiological features extracted from the electrocardiogram, photoplethysmograph, and optionally the arterial blood pressure waveform. A machine learning algorithm was trained and evaluated on a database of 4107 expert-labeled life-threatening arrhythmias, from 182 separate ICU visits.

Ex. 1006, Abstract; *see* Ex. 1003 ¶ 194, 199.

Consistent with the general state of the art, Hu 1997 discloses that its machine learning approach was based on software packages "available in the public domain." Ex. 1049, 893. According to Hu 1997, "the application of these packages to the ECG beat classification problem is straight forward," and the disclosed techniques "can be easily adapted to other automated

patient monitoring algorithms and eventually support decentralized remote patient-monitoring systems." *Id.* at 893, 899. Further with respect to whether Hu 1997's software can be adapted to analyze PPG data, Patent Owner does not contest Petitioner's assertions that "machine learning approaches were known to offer superior performance when the ***inputs are complex***; and known to provide automatic and objective analysis for ***multimodal biomedical data***" and, more specifically, that "[u]sing machine learning to search for 'correlations' between SpO2/PPG and ECG signals was also well known." Reply 26–27 (citing Pet. 69; Ex. 1003 ¶ 194; Ex. 1042, Abstract; Ex. 1080, 4, Abstract; Ex. 1085, Abstract). Moreover, as noted above, Li 2012 expressly includes PPG data in a machine learning approach for improved arrhythmia detection.

In contrast to the above, Patent Owner presents no credible argument or evidence as to why one of ordinary skill in the art would not been motivated to combine the teachings of Hu 1997 with those of Shmueli and Osorio, or would not have had a reasonable expectation of success in adapting Hu 1997's machine learning approach to the detection of arrhythmia using PPG data. *See, e.g.*, PO Resp. 65 (Patent Owner's argument that "Hu 1997 is not relevant to the claims"). Invoking industry skepticism, Patent Owner argues that the published studies "considering [the use of] machine learning in the cardiology space . . . do[] not demonstrate that machine learning was in actual use," and suggests that that clinicians and patients may have difficulty trusting "black box" machine learning applications. PO Resp. 65–66 (citing Ex. 2016 ¶ 85; Ex. 2018, 211:9–22, 212:4–8; Ex. 2026, 47); Tr. 84:1–9 (Patent Owner's counsel asserting that

"AliveCor was the first company ever to receive FDA approval for using machine-learning for cardiological applications").

But beyond the unsupported testimony of its counsel and expert, Patent Owner presents no evidence supporting that machine learning was not in actual use, nor linking this asserted lack of actual use with skepticism as opposed to some other factor. In addition, Petitioner reasonably explains that Patent Owner's "'black box' comment applies to deep learning, not to all machine learning." *See* Reply 19–20; Ex. 1082, 211:10–217:8. Weighed against the teachings of the prior art, we agree with Petitioner that Patent Owner's "alleged skepticism is dwarfed by the overwhelming evidence of the benefits and operability of machine learning." *See* Reply 19.

b. Petitioner's ECG Data Machine Learning Theory

Patent Owner also argues that "in Petitioner's proposed combination, arrhythmia is detected using a PPG measurement, and not ECG, and because Hu 1997 only teaches beat classification techniques for ECG data, any disclosure of machine learning in Hu 1997 is not relevant to the claims". PO Resp. 65. According to Patent Owner, Petitioners proposal to apply machine learning to PPG data "controls and anything else would be an improper change in position." Sur-reply 20. We do not find Patent Owner's argument availing.

Petitioner's application of Hu 1997 to ECG data does not fundamentally change the thrust of Ground 2, which asserts unpatentability based on the teachings of Shmueli, Osorio, and Hu 1997. Indeed, the Petition expressly contemplates including ECG data in the information considered by the machine learning algorithm. Pet. 70 (asserting that "after an ECG was measured as part of Shmueli's method, it would have been

obvious for the combined device to confirm arrhythmia using a machine learning algorithm based on the PPG data (and the heart rate and HRV derived therefrom), motion sensor data (and the activity level derived therefrom), ***and ECG data***") (emphasis added). Nor are we precluded from drawing our own inferences from the arguments and evidence presented at trial. *See Rovalma, S.A. v. Bohler-Edelstahl GmbH & Co. KG*, 856 F.3d 1019, 1027 (Fed. Cir. 2017) (the Board is not precluded "from relying on arguments made by a party and doing its job, as adjudicator, of drawing its own inferences and conclusions from those arguments . . . subject, of course, to the provision of adequate notice and opportunity to be heard"). Petitioner has persuasively explained why a person of ordinary skill in the art would have been motivated to extend Hu 1997's teachings on using machine learning to analyze ECG data to using machine learning to further analyze PPG for the detection of arrhythmia.

Pointing to independent claim 1, Patent Owner also argues that the challenged claims require that machine learning occur at the initial "determining" step and, thus, the claimed method *must* analyze PPG data. PO Resp. 63–64; Sur-reply 20. We do not find this argument availing. Claim 1, for example, concludes with the step of "alerting said first user to sense an electrocardiogram of said first user, using said mobile computing device, in response to an irregularity in said heart rate variability of said first user." Claim 7 provides that the method of claim 1 "further compris[es] determining a presence of said arrhythmia using a machine learning algorithm." Nothing in claim 7 affirmatively links this additional step to the "determining" element of claim 1, as Patent Owner urges. *See* PO Resp. 63–64; Sur-reply 20. To the contrary, we read claim 7 as encompassing the

application of machine learning to ECG data collected in response to the last step of claim 1, which does not require the analysis of PPG data.

Accordingly, we agree with Petitioner that the claims challenged under Ground 2 do not limit how machine learning is used to determine the presence of the arrhythmia. *See* Reply 20–21. As such, we agree with Petitioner that Hu 1997 satisfies the machine learning element of the claims challenged under Ground 2. Petitioner has established—and Patent Owner does not dispute—that Hu 1997 teaches determining a presence of arrhythmias using machine learning on ECG data. *See id.* at 21 (citing Pet. 68; PO Resp. 62–69; Ex. 1049, 891–892); Sur-reply 20–21; Ex. 2016 ¶ 82; Section II.H.3, above. Our reasoning with respect to motivation and reasonable expectation of success in the above section applies equally here, with the caveat that, under this approach, one of ordinary skill in the art need not modify Hu 1997's machine learning protocol to analyze PPG data.

2) Conclusion as to Ground 2

For the reasons set forth above, we find that Hu 1997 discloses or renders obvious the "machine learning" element of claims 7–9 and 17–19. As such, we need not address Petitioner's alternative argument that Shmueli as teaches or suggests a machine learning algorithm that "confirms the arrhythmia using a machine learning algorithm based on the PPG data, heart rate, HRV, motion sensor data, activity level, and/or the ECG data." *See* Pet. 71–72 (emphasis omitted); *see* PO Resp. 63; *Boston Sci. Scimed, Inc. v. Cook Grp. Inc.*, Nos. 2019-1594, -1604, -1605, 2020 WL 2071962, at *4 (Fed. Cir. Apr. 30, 2020) (non-precedential) (recognizing that the "Board need not address issues that are not necessary to the resolution of the proceeding").

Also, for the reasons set forth above, we find that the combination of Shmueli, Osorio, and Hu 1997 discloses or renders obvious all elements of claims 7–9 and 17–19, and that one of ordinary skill in the art would have been motivated to combine the cited references with a reasonable expectation of success. Having reviewed the argument and evidence of record, we find that Petitioner has shown by a preponderance of the evidence that claims 7–9 and 17–19 are unpatentable as obvious in view of Shmueli, Osorio, and Hu 1997.

III. PATENT OWNER'S MOTION TO EXCLUDE

Patent Owner moved to exclude Petitioner's Exhibits 1060–1068 and 1072–1085. *See* Mot. 1. Patent Owner withdrew its motion at oral argument with respect to Exhibits 1072, 1073, 1075, and 1082. Tr. 78:19–79:16, 99:18–23. Of the remaining exhibits, we cite herein only to Exhibit 1061.

Patent Owner challenges Exhibit 1061 as "new evidence . . . not properly raised in Reply." Mot. 1. Patent Owner's argument is unavailing. Petitioner properly employed it in the Reply in responding to Patent Owner's argument that one of ordinary skill in the art would not understand Shmueli's recitation of "irregular activity" to indicate arrhythmia. *See* Reply 8–9; Sur-reply 3; *see also* Pet. vi (listing Ex. 1061); *Anacor Pharm., Inc. v. Iancu*, 889 F.3d 1372, 1380–81 (Fed. Cir. 2018) (stating that a "petitioner in an inter partes review proceeding may introduce new evidence after the petition stage if the evidence is a legitimate reply to evidence introduced by the patent owner"). We, therefore, deny the motion with respect to Exhibit 1061.

Because we do not specifically rely on any other challenged exhibit, we dismiss that portion of Patent Owner's motion as moot.

IV. CONCLUSION

Petitioner has shown, by a preponderance of the evidence, that claims 1–20 are unpatentable under § 103 as obvious in view of Shmueli and Osorio, with or without Hu 1997 as summarized below:[22]

Claims	35 U.S.C. §	References	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1–6, 10–16, 20	103	Shmueli, Osorio	1–6, 10–16, 20	
7–9, 17–19	103	Shmueli, Osorio, Hu 1997	7–9, 17–19	
Overall Outcome			1–20	

V. ORDER

ORDERED, that claims 1–20 of the '499 patent are held to be unpatentable;

FURTHER ORDERED that Patent Owner's Motion to Exclude Evidence is denied with respect to Exhibit 1061, and otherwise dismissed as moot;

[22] Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this Decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding. See* 84 Fed. Reg. 16654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. § 42.8(a)(3), (b)(2).

FURTHER ORDERED that because this is a Final Written Decision, parties to this proceeding seeking judicial review of our decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

IPR2021-00970
Patent 9,572,499 B2

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Paper 42
Entered: December 6, 2022

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE, INC.,
Petitioner,

v.

ALIVECOR, INC.,
Patent Owner.

IPR2021-00971
Patent 10,595,731 B2

Before ROBERT A. POLLOCK, ERIC C. JESCHKE, and DAVID COTTA, *Administrative Patent Judges*.

POLLOCK, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

Denying In-Part and Dismissing In-Part as Moot
Patent Owner's Motion to Exclude Evidence
37 C.F.R. § 42.64

I. INTRODUCTION

A. Background

Apple, Inc. ("Petitioner") filed a Petition for an *inter partes* review of claims 1–30 of U.S. Patent No. 10,595,731 B2 (Ex. 1001, "the '731 patent"). Paper 2 ("Pet."). AliveCor, Inc. ("Patent Owner") timely filed a Preliminary Response. Paper 6 ("Prelim. Resp."). Petitioner further filed an authorized Reply to the Preliminary Response (Paper 7); Patent Owner filed a responsive Sur-reply (Paper 8). Taking into account the arguments and evidence presented, we determined the information presented in the Petition established that there was a reasonable likelihood that Petitioner would prevail in demonstrating unpatentability of at least one challenged claim of the '731 patent, and we instituted this *inter partes* review as to all challenged claims. Paper 10 ("DI").

After institution, Patent Owner filed a Patent Owner Response (Paper 26, "PO Resp."); Petitioner filed a Reply to the Patent Owner Response (Paper 29, "Reply"); Patent Owner filed a (corrected) Sur-reply (Paper 36, "PO Sur-reply").

Patent Owner also filed a motion to exclude (Paper 34, "Mot."); Petitioner opposed the motion (Paper 36, "Opp. Mot."); and Patent Owner filed a reply in support of its motion (Paper 38, "Reply Mot.").

An oral hearing was held on September 14, 2022, and a transcript of the hearing is included in the record. Paper 41 ("Tr.").

We have jurisdiction under 35 U.S.C. § 6. This decision is a Final Written Decision under 35 U.S.C. § 318(a) as to the patentability of claims 1–30 of the '731 patent. For the reasons discussed below, we hold that

Petitioner has demonstrated by a preponderance of the evidence that claims 1–30 are unpatentable.

B. Real Parties-in-Interest

Petitioner identifies itself, Apple Inc., as the real party-in-interest. Pet. 88. Patent Owner, identifies itself, AliveCor, Inc., as the real party-in-interest. Paper 6, 2.

C. Related Matters

According to Patent Owner:

> U.S. Patent No. 10,595,731 has been asserted by Patent Owner against Petitioner in *AliveCor, Inc. v. Apple, Inc.*, Case No. 6:20-cv-01112-ADA, filed in the United States District Court for the Western District of Texas, and in Investigation No. 337-TA-1266 before the International Trade Commission, *In the Matter of Certain Wearable Electronic Devices with ECG Functionality and Components Thereof*. Apple also filed IPR petitions against the other patents asserted in those actions: IPR2021-00970 (USP 9,572,499) and IPR2021-00972 (USP 10,638,941).

Paper 6, 2; *see* Pet. 88. We further note that the ’731 patent at issue here is related by a chain of continuation applications to Application No. 14/730,122, which issued as U.S. Patent No. 9,572,499 (“the ’499 patent”), challenged in IPR2021-00970. *See* Ex. 1001, code (63). As such, the ’731 and ’499 patents share substantially the same specification.

D. Priority Date of the ’731 Patent

The ’731 patent claims priority to, *inter alia*, a series of provisional applications filed between December 12, 2013, and June 19, 2014. Ex. 1001, code (60); *see* Prelim. Resp. 4; Pet. 2 & nn. 1–3. Petitioner contends that the claims of the ’731 patent are not entitled the benefit of the earliest of those applications such that the critical date is March 14, 2014, the filing date of

provisional application No. 61/953,616. Pet. 2–3. Because Patent Owner does not contest this assertion, or the prior art status of any asserted reference, we need not determine whether the challenged claims are entitled to the benefit of the earliest filed provisional application. *See generally* Prelim. Resp. 4; PO Resp. 17, 19.

E. Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability (Pet. 1):

Ground	Claims Challenged	35 U.S.C §[1]	Reference(s)/Basis
1	1, 7, 12, 13, 16, 17, 23–26, 30	§ 103	Shmueli[2]
2	1, 2, 4, 7, 12–14, 16–18, 20, 23–26, 30	§ 103	Shmueli, Osorio[3]
3	3, 5, 6, 19, 21, 22	§ 103	Shmueli, Osorio, Li 2012[4]
4	8–11, 27–29	§ 103	Shmueli, Osorio, Kleiger[5]
5	15	§ 103	Shmueli, Osorio, Chan[6]

[1] The Leahy-Smith America Invents Act ("AIA") included revisions to 35 U.S.C. § 103 that became effective on March 16, 2013. Because we determine the priority date of the challenged claims is no earlier than the '731 patent's filing date of March 14, 2014 (*see infra*), we apply the AIA versions of the statutory bases for unpatentability.

[2] WO2012/140559, publ. Oct. 18, 2012. Ex. 1004.

[3] U.S. 2014/0275840, publ. Sept. 18, 2014. Ex. 1005.

[4] Li Q, Clifford GD, "*Signal quality and data fusion for false alarm reduction in the intensive care unit*," 45(6) J Electrocardiol. 596-603 (2012). ("Li" or "Li-2012") Ex. 1006.

[5] Kleiger RE, Stein PK, "*Bigger JT Jr. Heart rate variability: measurement and clinical utility*." 10(1) Ann Noninvasive Electrocardiol. 88–101 (2005). ("Kleiger") Ex. 1033.

[6] U.S. Pat. No. 7,894,888, issued Feb. 22, 2011. Ex. 1048.

In support of its patentability challenge, Petitioner relies on, *inter alia*, the Declaration of Dr. Bernard R. Chaitman, M.D. Ex. 1003. Patent Owner similarly relies on the Declarations of Dr. Igor Efimov, Ph.D. Ex. 2001; Ex. 2016.

F. The '731 Patent and Relevant Background

The '731 patent relates to medical devices, systems, and methods for detecting cardiac conditions, including cardiac arrhythmias. Ex. 1001, 1:29–33, 2:17–25. In general:

> In response to the continuous measurement and recordation of the heart rate of the user, parameters such as heart rate (HR), heart rate variability (R-R variability or HRV), and heart rate turbulence (HRT) may be determined. These parameters and further parameters may be analyzed to detect and/or predict one or more of atrial fibrillation, tachycardia, bradycardia, bigeminy, trigeminy, or other cardiac conditions.

Id. at 2:57–64; *see id.* at 18:52–63 (Table 2, listing atrial fibrillation, sinus and supraventricular tachycardias, bradycardia, bigeminy, and trigemini among the types of arrhythmias).

According to Dr. Chaitman, "HRV analysis is an important tool in cardiology to help diagnose various types of arrhythmia." Ex. 1003 ¶ 35. "HRV is defined as the variation of RR intervals with respect to time and reflects beat-to-beat heart rate (HR) variability," and "can be accurately determined based on either ECG [electrocardiogram] data or PPG [photoplethysmography] data." *Id.* ¶¶ 35–36. "An R-R interval represents a time elapsed between successive R-waves of a QRS complex[7] of the ECG

[7] "[E]lectrical activity of the heart based on depolarization and repolarization of the atria and ventricles . . . typically show[s] up as five distinct waves on [an] ECG readout – P-wave, Q-wave, R-wave, S-wave, and T-wave." Ex. 1003 ¶ 29. "A QRS complex is a combination of the Q, R, and S waves

that occur between successive heart beats." *Id.* ¶ 29. "If the RR intervals over a time period are close to each other in value, then ventricular rhythm is understood to be 'regular.' In contrast, if there are significant variations in the RR intervals over a time period, then the ventricular rhythm is understood to be 'irregular.'" *Id.* ¶ 37 (citations omitted).

The Specification explains that during cardiac arrhythmia, "the electrical activity of the heart is irregular or is faster (tachycardia) or slower (bradycardia) than normal," and in some forms, "can cause cardiac arrest and even sudden cardiac death." Ex. 1001, 1:40–44. The '731 patent identifies atrial fibrillation as the most common form of cardiac arrhythmia—which occurs when electrical conduction through the atria of the heart is irregular, fast, and disorganized, leading to irregular activation of ventricles. *Id.* at 1:44–49. Although atrial fibrillation may cause no symptoms, it is associated with palpitations, shortness of breath, fainting, chest pain, congestive heart failure, as well as atrial clot formation, which can lead to clot migration and stroke. *Id.* at 1:44–51. "Atrial fibrillation is typically diagnosed by taking an electrocardiogram (ECG) of a subject, which shows a characteristic atrial fibrillation waveform." *Id.* at 1:52–54.

The Specification discloses body-worn devices for detecting the occurrence of arrhythmias using a combination of ECG and PPG electrodes. *See*, *e.g.*, claim 1. PPG, or photoplethysmography, uses an optical sensor to detect the fluctuation of blood flow, and can provide a measure of heart rate. *Id.* at 25:21–24. According to the Specification, fluctuations in heart rate not explained by changing activity levels may be interpreted as an advisory

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occurring in succession and represents the electrical impulse of a heartbeat as it spreads through the ventricles during ventricular depolarization." *Id.*

condition for recording an ECG, or electrocardiogram, which is a typical method for diagnosing episodes of arrhythmia. *Id.* at 1:52–54, 1:60–65, 25:1–35.

The collected data may also be analyzed using machine learning algorithms to, for example, determine appropriate trigger thresholds, detect and predict health conditions, or provide a heart health score. *See, e.g.*, *id.* at 3:43–4:16, 8:38–41, 9:8–11, 12:44–64. "The machine learning based algorithm(s) may allow software application(s) to identify patterns and/or features of the R-R interval data and/or the raw heart rate signals or data to predict and/or detect atrial fibrillation or other arrhythmias." *Id.* at 9:8–11. In particular,

> [a]ny number of machine learning algorithms or methods may be trained to identify atrial fibrillation or other conditions such as arrhythmias. These may include the use of decision tree learning such as with a random forest, association rule learning, artificial neural network, inductive logic programming, support vector machines, clustering, Bayesian networks, reinforcement learning, representation learning similarity and metric learning, sparse dictionary learning, or the like.

Id. at 9:66–10:9.

Figure 14, reproduced below, shows one embodiment of a body-worn device. *Id.* at 6:21–23.

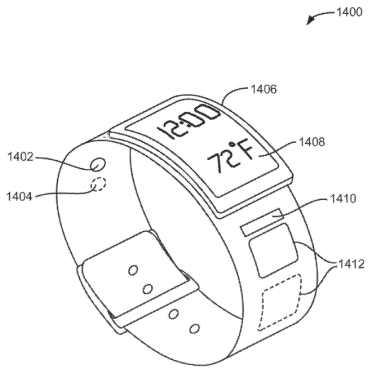


Figure 14, shows "smart watch 1400 which includes at least one heart rate monitor 1402 and at least one activity monitor 1404," such as an accelerometer. *Id.* at 24:66–25:1, 25:13–30. Analysis of signals from these monitors can be used to "determine if heart rate and activity measurements represent an advisory condition for recording an ECG," and trigger signals for recording an ECG if an advisory condition is detected. *Id.* at 25:1–12.

Figure 10, illustrated below, shows another embodiment involving a body-worn device. *Id.* at 6:3–5.

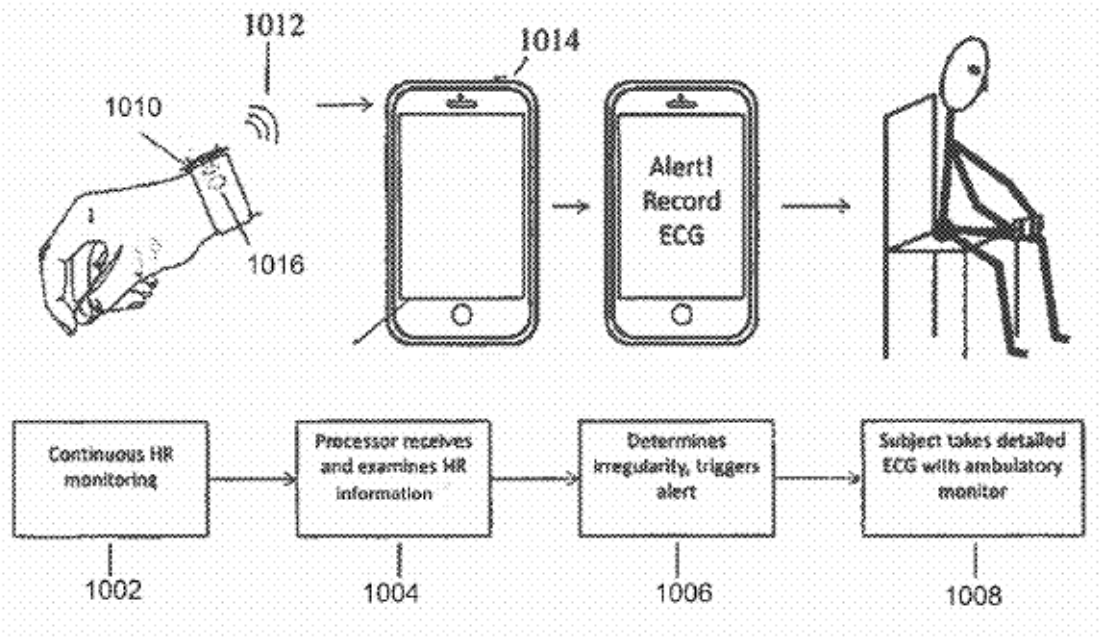


Figure 10 illustrates "a method for monitoring a subject to determine when to record an electrocardiogram (ECG)." *Id.* at 23:20–22. According to the Specification:

> In FIG. **10,** a subject is wearing a continuous heart rate monitor (configured as a watch **1010,** including electrodes **1016),** shown in step **1002.** The heart rate monitor transmits (wirelessly **1012)** heart rate information that is received by the smartphone **1018,** as shown in step **1004.** The smartphone includes a processor that may analyze the heart rate information **1004,** and when an irregularity is determined, may indicate **1006** to the subject that an ECG should be recorded.

Id. at 23:22–30. In some embodiments, the ECG device is "present in a smart watch band or a smart phone." *Id.* at 25:36–37. "The ECG, heart rate, and rhythm information can be displayed on the computer or smartphone, stored locally for later retrieval, and/or transmitted in real-time to a web server." *Id.* at 25:48–50.

G. Challenged Claims

Petitioner challenges claims 1–30, of which claims 1, 17, and 25 are independent. Of these, claim 1 recites:

> 1. A smart watch to detect the presence of an arrhythmia of a user, comprising:
>
> a processing device;
>
> a photoplethysmography ("PPG") sensor operatively coupled to the processing device;
>
> an ECG sensor, comprising two or more ECG electrodes, the ECG sensor operatively coupled to the processing device;
>
> a display operatively coupled to the processing device; and
>
> a memory, operatively coupled to the processing device, the memory having instructions stored thereon that, when executed by the processing device, cause the processing device to:
>
> receive PPG data from the PPG sensor;
>
> detect, based on the PPG data, the presence of an arrhythmia;
>
> receive ECG data from the ECG sensor; and
>
> confirm the presence of the arrhythmia based on the ECG data.

Independent claims 17 and 25 recite similar limitations but are respectively drawn to "[a] method to detect the presence of an arrhythmia of a user on a smart watch," and "non-transitory computer-readable storage medium including instructions."

Among the dependent claims, claims 2, 14, and 18 relate to the use of motion sensor (inertial) data; claims 4 and 20 relate to "determin[ing] heartrate variability ('HRV') data from the PPG data, and detect[ing], based on the HRV data, the presence of the arrhythmia"; claims 3, 5, 6, 19, 21, and 22 recite "a machine learning algorithm trained to detect arrhythmias"; and claim 15 recites a device "configured to display an ECG rhythm strip for the ECG data."

H. Overview of the Asserted References

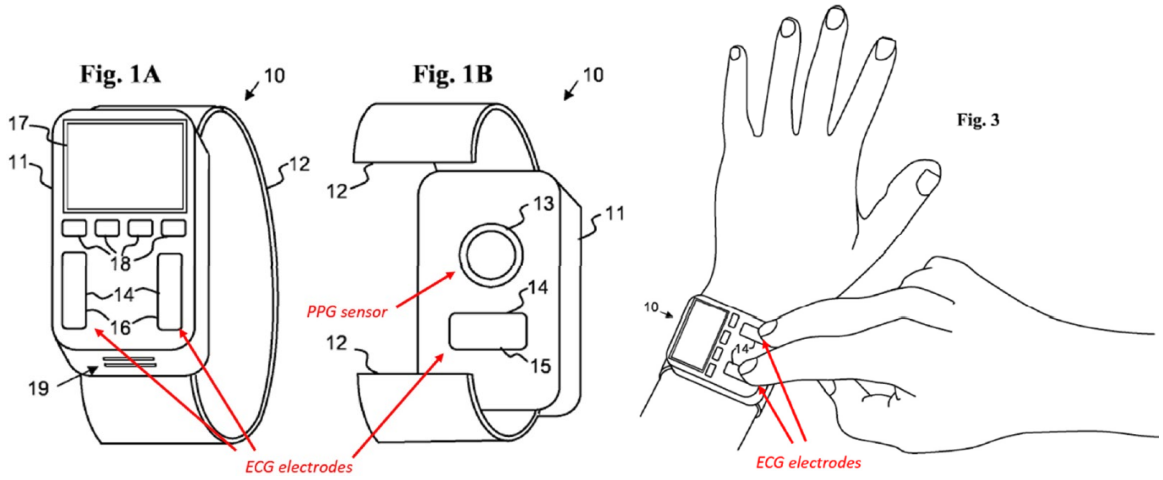
1) Shmueli (Exhibit 1004)

Shmueli, titled "Pulse Oximetry Measurement Triggering ECG Measurement," addresses "solutions . . . for monitoring infrequent events of irregular ECG." Ex. 1004, 2.[8] According to Shmueli, "[t]he present invention preferably performs measurements of intermittent irregular heart-related events without requiring the fixed wiring of the ECG device to the patient." *Id.* at 8.

Shmueli discloses body-worn cardiac monitoring devices "equipped with two types of sensing devices: an oximetry (SpO_2) measuring unit and an ECG measuring unit." *Id.*[9] Shmueli's Figures 1A, 1B, and 4, reproduced below, exemplify one embodiment (annotations by Petitioner in red):

[8] Throughout this opinion, we cite to the native pagination. For clarity with respect to citations to Shmueli, we understand the native pagination to be the numbers at the top of the page.

[9] As used by Shmueli "the terms 'oxygen saturation in the blood', 'blood oxygen saturation', 'pulse oximeter', oximetry, SpO_2, and photoplethysmography have the same meaning and may be used interchangeably, except for those places where a difference between such terms is described." *Id.* at 7; *see* Tr. 6:22–7:12, 73:18–21, 95:7–11.



Pet. 12. Figures 1A, 1B, and 3 show three views of a wrist-mount heart monitoring device having three ECG electrodes 14 and a PPG sensor 13. Ex. 1004, 6, 9–10. Figure 1A shows two of the ECG electrodes, 14/16, on the face of the device. *Id.* at 9. Figure 1B shows a third ECG electrode, 14/15, along with PPG sensor 13, of the back of the device. *Id.* Figure 3 shows the device as worn on a patient's wrist, with PPG sensor 13 and ECG electrode 14/15 in contact with the patient's left wrist and ECG electrodes 14/16 in contact with two fingers of the patient's right hand. *Id.* Petitioner annotates each of Figures 1A, 1B, and 3 with arrows identifying the ECG electrodes. Petitioner has also annotated Figure 1B with an arrow identifying PPG sensor 13. In connection with these devices, Shmueli discloses

> a method for triggering measurement of electrocardiogram (ECG) signal of a subject, the method including the steps of: continuously measuring SpO2 at least one of a wrist and a finger of the subject, detecting an irregular heart condition from the SpO2 measurement, notifying the subject to perform an ECG measurement, and initiating ECG measurement at least partially at the wrist.

Id. at 2; *see* Abstract.

Shmueli explains that "[d]eriving heart beat rate from oximetry, as well as other artifacts of the heart activity and blood flow, is . . . known in

the art," as are various body-worn oximetry devices. *Id.* at 8. Shmueli further explains that the use of oximetry in combination with ECG measurements is also known in the art. *Id.* Shmueli states, for example, that "US patent No. 7,598,878 (Goldreich) describes a wrist mounted device equipped with an ECG measuring device and a SpO_2 measuring device." *Id.* However, Shmueli, notes "Goldreich does not teach interrelated measurements of ECG and SpO_2" and, thus, does not "enable a patient to perform ECG measurement as soon as an irregular heart activity develops and without requiring the ECG to be constantly wired to the patient." *Id.* According to Shmueli:

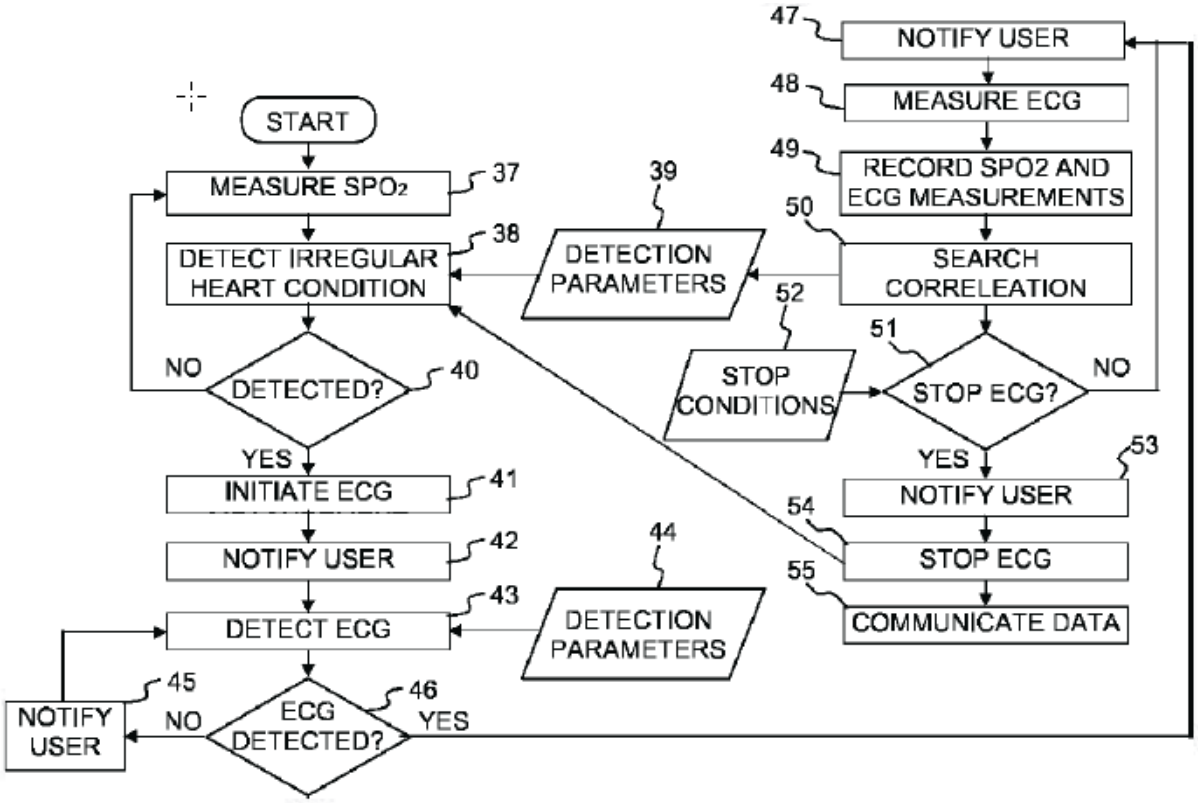
> The present invention resolves this problem by providing a combined oximetry and electrocardiogram measuring system and a method in which the oximetry measurement is performed continuously and/or repeatedly, and the ECG measurement is triggered upon detection of an intermittent irregular heart-related events without requiring the fixed wiring of the ECG device to the patient.

Id. Consistent with this disclosure, Shmueli claims:

> 1. A method for triggering measurement of electrocardiogram (ECG) signal of a subject, the method comprising the steps of:
>
> continuously measuring SpO2 at least one of a wrist and a finger of said subject;
>
> detecting an irregular heart condition from said SpO2 measurement;
>
> notifying said subject to perform an ECG measurement; and
>
> initiating ECG measurement at least partially at said wrist.

Id. at 16.

Shmueli Figure 7 is reproduced below:



"Fig. 7 is a simplified flow chart of a software program preferably executed by the processor of the wrist-mounted heart monitoring device." *Id.* at 7; *see also id.* at 12–13 (further describing the steps of the software program illustrated in Figure 7).

2) Osorio (Exhibit 1005)

Osorio, titled "Pathological State Detection Using Dynamically Determined Body Data Variability Range Values," "relates to medical device systems and methods capable of detecting a pathological body state of a patient, which may include epileptic seizures, and responding to the same." Ex. 1005 ¶ 2. Although broadly referencing "a pathological body state," Osorio repeatedly exemplifies such conditions in terms of detecting epileptic events. *See*, *e.g.*, *id.* ¶ 37 (referencing values that may "be indicative of a certain pathological state (e.g., epileptic seizure)"), ¶ 46 ("In

one embodiment, the pathological state is an epileptic event, e.g., an epileptic seizure."), ¶ 56 ("HRV range may be taken as an indication of an occurrence of a pathological state, e.g., an epileptic seizure"), ¶ 66 ("The dynamic relationship between non-pathological HRVs and activity levels may be exploited to detect pathological states such as epileptic seizures").

Consistent with the broad disclosure and narrow exemplification in the body of its specification, Osorio's claim 1 is directed to "[a] method for detecting a pathological body state of a patient," whereas claim 7 limits the pathological state to an epileptic event. *Id.* at claim 1, claim 7; *also compare id.* at claim 14, *with* claim 17 (similarly limiting a pathological state to an epileptic event).

According to Osorio, the disclosed methods, systems, and related devices, detect a pathological state of a patient by determining when a body data variability value, or "BDV," is outside of a "value range," and where the threshold levels of that range vary in response to the patient's physical activity (measured by, e.g., an accelerometer) or mental/emotional state. *See, e.g.*, *id.* at code (57), ¶¶ 3–8, 28, 33, 35. In this respect, Osorio states that "false negative and false positive detections of pathological events may be reduced by dynamically determining pathological or non-pathological ranges for particular body indices based on activity type and level or other variables (e.g., environmental conditions)." *Id.* ¶ 36.

Osorio's Figure 1 is reproduced below.

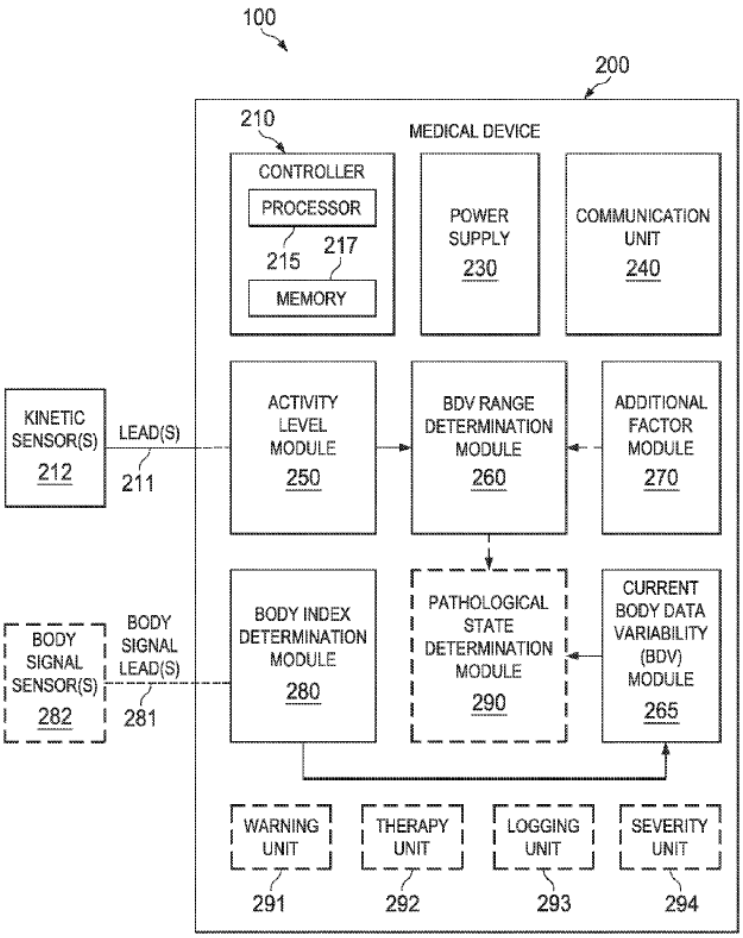


FIG. 1

Figure 1 shows a schematic representation of medical device system 100, including kinetic sensor(s) 212 and body signal sensor(s) 282 connected to medical device 200 by leads 211 and 281, respectively. *Id.* ¶ 33. "[A]ctivity sensor(s) 212 may each be configured to collect at least one signal from a patient relating to an activity level of the patient," and include, for example, an accelerometer, an inclinometer, a gyroscope, or an ergometer. *Id.* Figure 1 also shows a current body data variability (BDV) module 265, which may "may comprise an O_2 saturation variability (O2SV) module 330 configured to determine O2SV from O_2 saturation data," and

"an HRV module 310 configured to determine HRV from heart rate data." *Id.* ¶¶ 10, 13, 53, Fig. 2C. Osorio discloses that "medical device system 100 may be fully or partially implanted, or alternatively may be fully external." *Id.* ¶ 33.

Figure 8, reproduced below, shows one embodiment of Osorio's monitoring method.

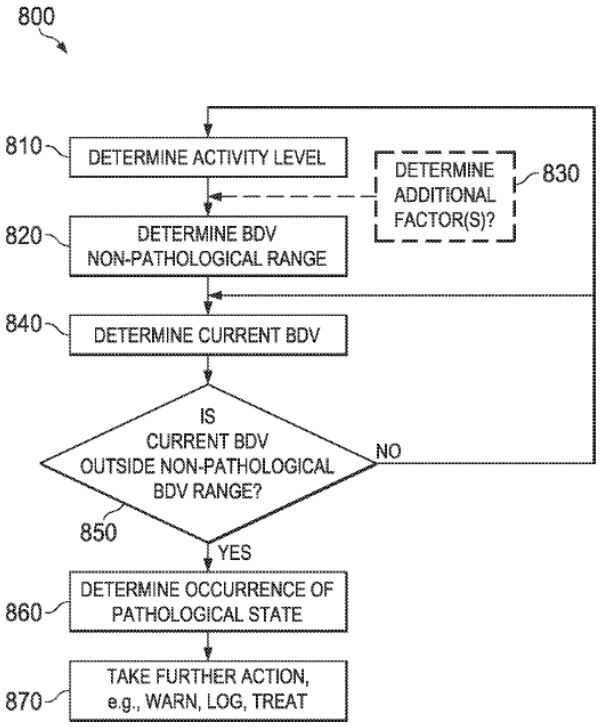


FIG. 8

Figure 8 shows that an activity level is determined at 810, and a non-pathological BDV range is determined at 820 based on the activity level. *Id.* ¶ 77. A current BDV is determined at 840 and compared to the non-pathological BDV range at 850. *Id.* ¶ 78. If the current BDV is outside the non-pathological range, then a pathological state is determined at 860 and a further action, such as warning, treating, or logging the occurrence and/or severity of the pathological state, is taken at 870. *Id.*

According to Osorio, body indices that may be the subject of BDV monitoring include:

> heart rhythm variability, a heart rate variability (HRV), a respiratory rate variability (RRV), a blood pressure variability (BPV), a respiratory rhythm variability, respiratory sinus arrhythmia, end tidal CO2 concentration variability, power variability at a certain neurological index frequency band (e.g., beta), an EKG morphology variability, a heart rate pattern variability, an electrodermal variability (e.g., a skin resistivity variability or a skin conductivity variability), a pupillary diameter variability, a blood oxygen saturation variability, a kinetic activity variability, a cognitive activity variability, arterial pH variability, venous pH variability, arterial-venous pH difference variability, a lactic acid concentration variability, a cortisol level variability, or a catecholamine level variability.

Id. ¶ 43; *see also id.* ¶ 42 (similar) ¶¶ 45–46 (monitoring heart rate for episodes of tachycardia and bradycardia). "In one embodiment, the severity [of a pathological state] may be measured by a magnitude and/or duration of a pathological state such as a seizure, a type of autonomic change associated with the pathological state (e.g., changes in heart rate, breathing rate, brain electrical activity, the emergence of one or more cardiac arrhythmias, etc.)." *Id.* ¶ 71.

With respect to HRV, in particular, Osorio teaches: "By monitoring the patient's activity level, HR, and HRV, it is possible to determine when the patient's HRV falls outside the non-pathological ranges as the patient's activity levels change over time." *Id.* ¶ 66. Osorio's Figure 4A, reproduced below, shows heart rate variability as a function of activity level. *See id.* ¶ 58.

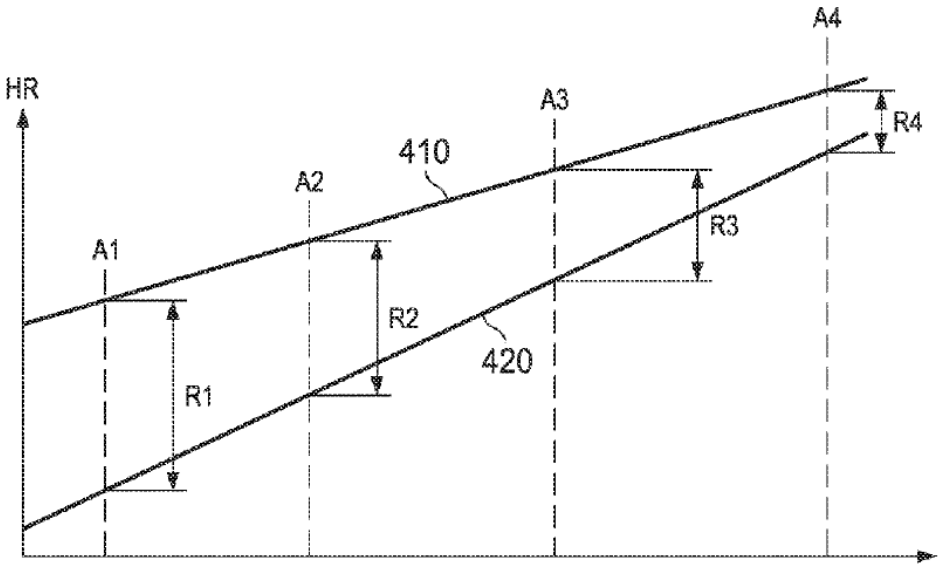


FIG. 4A

Figure 4A plots a patient's heart rate (HR) on the Y-axis and a patient's activity level on the X-axis. *Id.* Markers A1 though A4 represent increasing activity from a sleep state (A1) through vigorous activity (A4). *Id.* Boundary lines 410 and 420, respectively, represent the upper and lower limits of non-pathological heart rate, and include representative ranges R1 through R4. *Id.* at Fig. 4A. According to Osorio,

> the upper and lower bounds of the non-ictal[10] HR region increase as activity level increases (e.g., from a sleep state to a resting, awake state) and reach their highest values for strenuous exertion. In addition, the width of the non-pathological HR ranges narrows as activity levels and heart rates increase, which is consistent with the known reduction in HRV at high levels of exertion. When the patient is in a non-pathological state (e.g., when an epileptic patient is not having a seizure), for a particular activity level the patient's HRV should

[10] "Ictal" refers to the active, middle stage of a seizure and corresponds with intense electrical brain activity. *See* https://epilepsyfoundation.org.au/understanding-epilepsy/seizures/seizure-phases/.

> fall within a non-pathological HRV range associated with that activity level.

Id. ¶ 58.

Osorio further presents Figure 11 as "depict[ing] pathological and non-pathological BDV (e.g., HRV) value ranges." *Id.* ¶¶ 23, 91. In this illustration, Osorio shows that HRV values falling below 0.5 bpm and above 4 bpm are always pathological when activity level is low (e.g., resting or walking), whereas intermediate HRV values (0.5–4 bpm) may be pathological when considered in light of the patient's activity level. *Id*. Osorio further notes that the boundaries between normal and pathological may be adjusted based on an individual's physiology. "For example, in an epilepsy patient also suffering from tachycardia, and having base resting heart rate of 100-110 bpm, a decline in heart rate to 70 bpm may be indicative of a seizure slowing down the heart rate, even though a heart rate of 70 bpm is generally 'normal' across a typical population." *Id.* ¶ 45.

3) Kleiger (Exhibit 1033)

Kleiger is a review article regarding the measurement and clinical utility of heart rate variability (HRV). Ex. 1033, Title. Kleiger discloses various methods for quantifying HRV including time domain, spectral or frequency domain, geometric, and nonlinear methods. *Id.* at 88. According to Kleiger:

> The greatest variation of heart rate occurs with circadian changes, particularly the difference between night and day heart rate, mediated by complex and poorly understood neurohormonal rhythms. Exercise and emotion also have profound effects on heart rate. Fluctuations in heart rate reflect autonomic modulation and have prognostic significance in pathological states.

Id. (internal citation numbers omitted).

> Long-term, usually 24-hour recordings, can be used to assess autonomic nervous responses during normal daily activities in health, disease, and in response to therapeutic interventions, e.g., exercise or drugs. RR interval variability is useful for assessing risk of cardiovascular death or arrhythmic events, especially when combined with other tests, e.g., left ventricular ejection fraction or ventricular arrhythmias.

Id. at Abstract.

4) Li 2012 (Exhibit 1006)

Li 2012 investigates algorithms for reducing cardiac monitor false alarms ("FA") in an intensive care setting. Ex. 1006, 1. Li 2012 explains that a lack of integration between different sensors results in frequent false alarms in intensive care units. *Id.* at Abstract. To reduce these false alarms, Li 2012

> present[s] a novel framework for FA reduction using a machine learning approach to combine up to 114 signal quality and physiological features extracted from the electrocardiogram, photoplethysmograph, and optionally the arterial blood pressure waveform. A machine learning algorithm was trained and evaluated on a database of 4107 expert-labeled life-threatening arrhythmias, from 182 separate ICU visits.

Id. According to Li 2012, the resulting algorithm reduced false alarms with without substantial suppression of true alarms. *Id.* at Abstract, 7, Table 6. For example, "[f]or the ventricular tachycardia alarms, the best FA [false alarm] suppression performance was 30.5% with a TA [true alarm] suppression rate below 1%." *Id.* at Abstract.

5) Chan (Exhibit 1048)

Chan discloses:

> A wristwatch worn by a user for measuring a three-lead ECG [that] includes three electrodes placed separately on the front, either side, and back or strap thereof. The wristwatch further

> includes an electrode panel having the electrode on the front or either side of the watch, sensing elements, pressure, infrared or impedance detectors, and circuits. The electrode panel is capable of sensing the contact or press of fingers to trigger the ECG measuring. While the electrode in the back-side of the watch contacts the hand wearing the watch, the electrode and electrode panel on the front or either side of the watch are pressed by fingers from the other hand, and the electrode in the strap contacts the abdomen or left leg simultaneously. Thus, a three-lead ECG can be measured. ECG data can be transmitted to a personal or hospital computer by wireless networks or flash memory.

Ex. 1048, Abstract.

Chan's Figures 1A and 1B, reproduced below, show an embodiment of the disclosed three-lead ECG wristwatch.

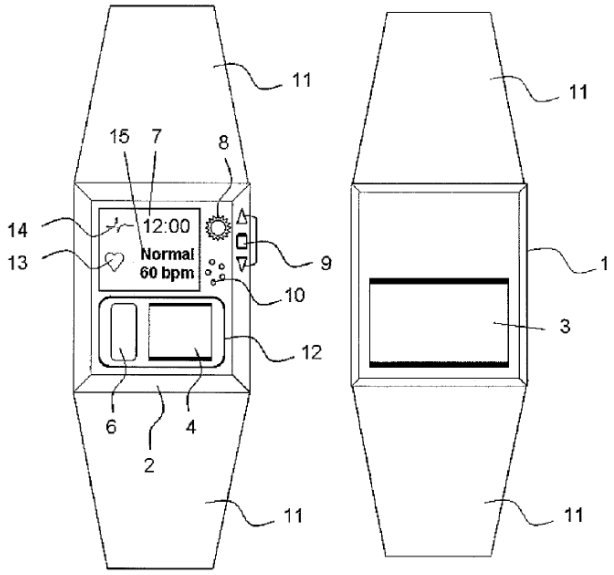


FIG.1A FIG.1B

Figures 1A and 1B, respectively, show the front and rear of a three-lead ECG wristwatch. *Id.* at 2:21–22. Figure 1A shows ECG electrode 4, sensing element 6 (which can detect "pressure, impedance or infrared for recognizing the contact or press made by fingers to initiate an ECG

measurement"), and display 7, which may be an LCD. *Id.* at 2:44–56. Display 7 can display text (e.g., time, heart rate, and, condition (normal vs arrhythmia) as well as "graph/animation, for an event reminding 13 and ECG waveforms 14." *Id*. at 2:56–59; *see also id.* at 4:56–59 (stating, with reference to Figure 7, that "display 57 can show users time, heart rate, waveforms and any other information 61, such as activity level and temperature, if needed").

Chan Figure 2 is reproduced below.

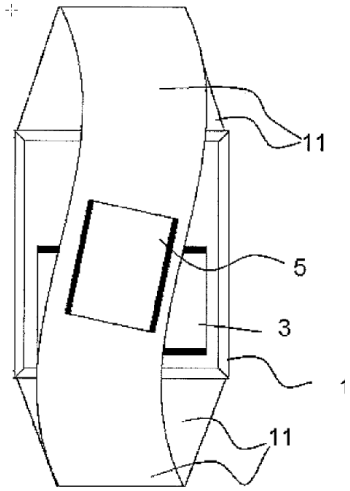


Figure 2 shows an embodiment of the three-lead ECG watch having a third lead 5 on the strap 11. *Id.* at 2:24–25, 3:1–4.

Chan Figure 3B is reproduced below.

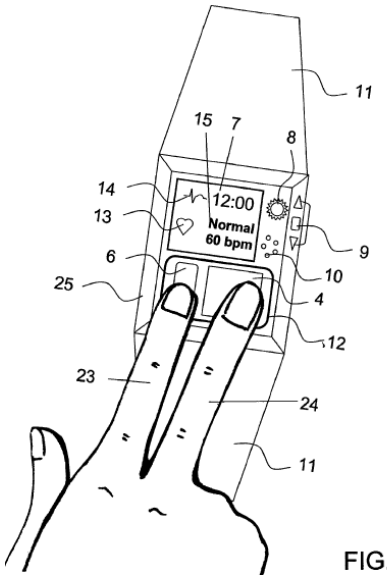


FIG.3B

Figure 3B "demonstrate[s] how to place the wristwatch to make electrodes be contacted by both hands." *Id.* at 2:26–28, 3:5–22.

II. ANALYSIS

A. Legal Standards

"In an IPR, the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Technology, Inc.*, 815 F.3d 1356, 1363 (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify "with particularity . . . the evidence that supports the grounds for the challenge to each claim")). This burden of persuasion never shifts to Patent Owner. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (discussing the burden of proof in *inter partes* review).

In *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), the Supreme Court reaffirmed the framework for determining obviousness set

forth in *Graham v. John Deere Co.*, 383 U.S. 1 (1966). The *KSR* Court summarized the four factual inquiries set forth in *Graham* (383 U.S. at 17–18) that are applied in determining whether a claim is unpatentable as obvious under 35 U.S.C. § 103 as follows: (1) determining the scope and content of the prior art; (2) ascertaining the differences between the prior art and the claims at issue; (3) resolving the level of ordinary skill in the art; and (4) considering objective evidence indicating obviousness or non-obviousness, if present. *KSR*, 550 U.S. at 406.

"[W]hen a patent 'simply arranges old elements with each performing the same function it had been known to perform' and yields no more than one would expect from such an arrangement, the combination is obvious." *Id.* at 417 (quoting *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 282 (1976)). But in analyzing the obviousness of a combination of prior art elements, it can also be important to identify a reason that would have prompted one of skill in the art "to combine . . . known elements in the fashion claimed by the patent at issue." *Id.* at 418. A precise teaching directed to the specific subject matter of a challenged claim is not necessary to establish obviousness. *Id.* Rather, "any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *Id.* at 420. Accordingly, a party that petitions the Board for a determination of unpatentability based on obviousness must show that "a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so." *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1381 (Fed. Cir. 2016) (quotations and citations omitted). Under

the proper inquiry, "obviousness cannot be avoided simply by a showing of some degree of unpredictability in the art so long as there was a reasonable probability of success." *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1364 (Fed. Cir. 2007).

B. Level of Ordinary Skill in the Art

In determining the level of skill in the art, we consider the type of problems encountered in the art, the prior art solutions to those problems, the rapidity with which innovations are made, the sophistication of the technology, and the educational level of active workers in the field. *See Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986); *see also Orthopedic Equip. Co. v. United States*, 702 F.2d 1005, 1011 (Fed. Cir. 1983).

Petitioner asserts that a person of ordinary skill in the art would have been someone with

> at least a combination of Bachelor's Degree (or a similar Master's Degree, or higher degree) in an academic area emphasizing health science, or a related field, and two or more years of work experience with cardiac monitoring technologies (e.g., as a cardiologist).

Pet. 7–8. Petitioner further contends that "[a]dditional education or industry experience may compensate for a deficit in one of the other aspects of the requirements stated above." *Id.* at 8.

In its Preliminary Response, Patent Owner took the position that one of ordinary skill in the art would have had "specialized engineering skills" including "a degree in biomedical or electrical engineering (or an equivalent), and/or extensive experience working with tools for detecting cardiac conditions." Prelim. Resp. 9 (citing Ex. 2001 ¶ 52). Although Patent Owner does not expressly define the person of ordinary skill in the art post-

institution, it appears to argue that such a person would have an engineering degree or comparable experience. *See* PO Resp. 28 (arguing that "a cardiologist who is not an engineer lacks the necessary knowledge to develop a smartwatch with PPG or ECG sensors"); Sur-reply 24–25 (similar); *but see,* Tr. 39:20–40:12 (Petitioner arguing that Patent Owner waived its opportunity to propose a definition).

> In our Institution Decision, we noted that
>
> > the research and development of medical devices is often the work of a multidisciplinary team, and courts and tribunals have frequently identified the hypothetical person of ordinary skill as a composite or team of individuals with complementary backgrounds and skills. *See, e.g.*, *AstraZeneca Pharm. LP v. Anchen Pharm., Inc.*, 2012 WL 1065458, at *19, *22 (D.N.J. Mar. 29, 2012), *aff'd*, 498 F. App'x 999 (Fed. Cir. 2013) (collecting cases); *Apotex Inc. v. Novartis AG*, IPR2017-00854, Paper 109 at 10–11 (PTAB July 11, 2018) (collecting cases).

DI 27–28. We further determined such a team in the context of the '731 patent might include specialists in electrical engineering, mechanical engineering, biomedical engineering, computer science, and cardiology. *Id.* at 28. With respect to the last of these, we noted that because the '731 patent "relates to methods and systems for managing health and disease such as cardiac diseases including arrhythmia and atrial fibrillation," it appeared reasonable that this hypothetical multidisciplinary team would include a cardiologist. *See id.* & n.10 (noting that the Kleiger reference is authored by a Ph.D. and two M.D.s); Ex. 1001, 1:29–33; *see also* Tr. 39:5–19 (Petitioner arguing that prior art Exhibits 1021, 1033, 1036, 1076–1078, 2024, and 2029 evidence "teams of people, medical doctors, cardiologists working together with engineers).

Patent Owner argues that we should reject our originally proposed definition in light of, for example, Petitioner's proposed definition before the ITC, which required an engineering background and "at least two years of relevant work experience designing wearable devices and/or sensors for measuring physiological signals." PO Resp. 29 (citing Ex. 2004, 6). As noted at oral argument, however, Patent Owner truncates the full extent of Petitioner's ITC definition, which further states that "a hypothetical person of ordinary skill in the art could also be a person with a medical degree (MD or DO) and with at least two years of work experience using biomedical sensors and/or analyzing their data (in the context of industry, in biomedical academic research, or in practice treating patients)". Ex. 2004, 6; Tr. 40:13–41:10.

Patent Owner's assertion that our originally proposed definition, would "classify all cardiologists as POSITAs," is well taken. Accordingly, we apply the following modified definition, which is consistent with Petitioner's representation before the ITC. For the purpose of this proceeding, a person of ordinary skill in the art may be a member of an interdisciplinary team including persons with backgrounds in electrical engineering, mechanical engineering, biomedical engineering, computer science, and/or cardiology, and having at least two years of relevant work experience designing, using, or analyzing data from, cardiac monitoring devices.

The parties' dispute regarding the definition of one of ordinary skill in the art relates to Dr. Chaitman's alleged lack of "specialized engineering skills," and the bases for Dr. Efimov's opinions on the meaning of "medical technology at issue in this proceeding, such as 'irregular heart condition' and

'pathological state.'" *See e.g.*, PO Resp. 28–31; Reply 27–28. Neither party has sought to exclude expert testimony in this proceeding, and the arguments bear on the amount of weight we should accord the opinions of either expert. *See e.g.*, Tr. 49:22–52:21.

As discussed in our Institution Decision, Dr. Chaitman is a well-respected cardiologist with "extensive experience working with tools for detecting cardiac conditions," who would qualify as one of ordinary skill in the art even under Patent Owner's then-proposed definition. *See* DI 26–28. Despite Patent Owner's subsequent position that the ordinarily skilled artisan should have an engineering degree and "design experience" in developing wearable cardiac sensors, the arguments and evidence adduced at trial do not alter our initial determination. *See, e.g.*, PO Resp. 28; Reply 27–38; Sur-reply 25; *see generally* Tr. 40:25–46:19, 55:2–56:13. Rather, we agree with Petitioner's argument in support of Dr. Chaitman's qualifications, that this proceeding involves "piecing together known technologies and . . . the analysis of cardiac data" including PPG data, ECG data and activity level. Tr. 38:4–18. Thus, one of ordinary skill in the art with an understanding of cardiac monitoring technology "would understand how these types of data work, how they interplay and how the data could be processed on these devices." *Id.*

Dr. Efimov has extensive experience in the design of cardiac monitoring and related technologies, but Petitioner asserts that he "is unable to offer credible testimony on the meaning of [relevant] medical terminology," because he is not a doctor. Reply 28; Sur-reply 25 (arguing that "Dr. Efimov is a recognized expert in the field of clinical cardiac electrophysiology"). Considering the totality of Dr. Efimov's background,

including extensive work on the physiology, diagnostics, and therapy of cardiac arrhythmias, we do not adopt Petitioner's position. *See*, *e.g.*, Ex. 2001 ¶¶ 2–15.

We also note that neither of the parties' experts possesses advanced skills in computer science, or more specifically, machine learning. *See generally* Tr. 43:21–46:17. In this respect, we find that although programming skills may be relevant to the implementation of certain of the challenged claims, they are not prerequisites for qualifying a person of ordinary skill in the art for this proceeding. *See id.* at 38:4–18.

In light of the above, we determine that Dr. Chaitman and Dr. Efimov are both qualified to testify as to the understanding of a person of ordinary skill in the art, we, nevertheless, consider the weight of both parties' experts on a particular topic in light of the strengths and weaknesses of their respective background.

C. Claim Construction

We interpret a claim "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b)." 37 C.F.R. § 42.100(b). Under this standard, we construe the claim "in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." *Id.* "[W]e need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy.'" *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Ltd.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

Patent Owner notes that the ITC applied the plain and ordinary meaning to the terms "arrhythmia" and "confirm" or "confirming." PO Resp. 21 (citing Ex. 2010, 12–13). We understand "arrhythmia" as used in the context of the '731 patent refers to "a cardiac condition in which the electrical activity of the heart is irregular or is faster (tachychardia) or slower (bradycardia) than normal." *See id.* at 24–25 (quoting Ex. 1001, 1:40–42). This term does not appear to be in dispute. *See* Tr. 21:18-22:3 ("[Board"]: . . . Patent Owner raised the issue of claim construction for the term arrhythmia. Is there any dispute there? [Petitioner's counsel]: Honestly, Your Honor, we considered that -- put a lot 23 of energy into considering it. We don't believe so."); *see also,* Tr. 53:24-54:2 ("[Board]: . . . Your claim construction of arrhythmia is merely a matter of precision and clarification rather than a contested point; is that correct? [Patent Owner's counsel]: I believe that's largely correct.").

Patent Owner also asserts, and we agree, that "confirm" and "confirming" are discrete requirements from "detect" in claims 3, 5, 6, 19, 21, and 22. See *id.* at 25. Accepting these clarifications, we apply the plain and ordinary meaning to all claim terms.

D. Ground 1: Obviousness over Shmueli

As Ground 1, Petitioner challenges claims 1, 7, 12, 13, 16, 17, 23–26, and 30 as obvious over Shmueli. Pet. 8–39. Petitioner contends that Shmueli discloses or renders obvious each element of claims 1, 7, 12, 13, 16, 17, 23–26, and 30, and sets forth an element-by-element comparison of the asserted art to the challenged claims. Pet. 13–39. Patent Owner contends that Ground 1 fails because Petitioner has not shown that Shmueli teaches or suggests either 1) arrhythmia detection, or 2) the use of ECG data to confirm

the initial detection of an irregular heart condition using PPG data. PO. Resp. 42–47, 51–57; Sur-reply 6–16. We address the contested limitations below.

1) Arrhythmia Detection by Shmueli

Claim 1 requires a processing device to receive PPG data from a PPG sensor and "detect, based on the PPG data, the presence of an arrhythmia."[11] According to Petitioner, although Shmueli does not explicitly use the term arrhythmia, one of ordinary skill in the art reading Shmueli would have found it obvious that the text "Detect Irregular Heart Condition," in element 38 of Shmueli's Figure 7, refers to detecting the presence of arrhythmia based on PPG data. *See* Pet. 22–24; Ex. 1003 ¶¶ 47–51.

For the purpose of instituting trial, we determined that "one of ordinary skill in the art would have understood Shmueli's use of 'irregular heart condition' as referring to—or at a minimum, encompassing—arrhythmia, and, thus, disclosing the detection of arrhythmia." DI 33–34. As discussed below, the arguments and evidence adduced at trial confirm our initial understanding.

Patent Owner argues that Ground 1 fails because Shmueli's reference to irregular heart conditions refers instead to "conditions traditionally detected using SpO_2 monitoring, such as heart attacks or acute heart failure." PO Resp. 42; *see* Ex. 2016 ¶ 73; Sur-reply 9–14 (more narrowly focusing on heart attack detection). Patent Owner raises three arguments supporting its contention that "while an arrhythmia might be an irregular heart condition in the abstract, it cannot be an 'irregular heart condition' as that phrase is used

[11] Although we focus on claim 1 for simplicity, independent claims 17 and 25 recite equivalent language.

in Shmueli." PO Resp. 43. Patent Owner argues, first, that "Shmueli could be referring to practically any heart condition that includes an irregular heart condition . . . including: heart attack, angina pectoris, cardiomyopathy, congenital heart disease, . . . coronary heart disease, and heart-valve defect." *Id.* at 44–45 (citing Ex. 1047, 1023; Ex. 2016 ¶ 69). Secondly, Patent Owner argues that one of ordinary skill in the art would not understand Shmueli to refer to arrhythmias because "pulse oximetry was a well-known diagnostic tool for conditions affecting blood oxygen levels including cardiac conditions such as heart attacks" but "PPG was a 'sub-optimal' tool for measuring arrhythmias." *Id.* at 45–46 (citing Ex. 2018, 62:9–21; Ex. 2017, 53:13–54:4, 54:13–55:12; Ex. 2016 ¶¶ 70–71; Ex. 2025). Third, Patent Owner points to Shmueli's disclosure that "instead of, or in addition to, the oximetry (SpO_2) measuring unit the heart monitoring device may include a unit for measuring CO2 content in the blood." PO Resp. 46 (citing Ex. 1004, 9); Sur-reply 13–14. According to Patent Owner, because CO_2 levels are "not used for arrhythmia detection but can be used to detect heart attacks or acute heart failure," Shmueli's disclosure of using CO_2 measurements supports a conclusion that Shmueli is not directed at arrhythmia detection. PO Resp. 46 (citing Ex. 2016 ¶ 72). Patent Owner's arguments are unavailing for substantially the reasons set forth at pages 3–11 of Petitioner's Reply and as discussed below.

We note, first, that Shmeli discloses that "the terms 'oxygen saturation in the blood', 'blood oxygen saturation', 'pulse oximeter', oximetry, SpO_2, and photoplethysmography have the same meaning and may be used interchangeably." Ex. 1004, 8. Collectively, these terms encompass two distinct functions—measurement of pulse and measurement of blood oxygen

content. As discussed below, both of these functions may be performed by a single device (a pulse oximeter).

In general terms, SpO_2 refers to the oxygen content of blood and PPG (photoplethysmography) measures pulse. *See* Ex. 1069, 81:8–13; Ex. 2001 ¶¶ 40–41. According to Dr. Efimov, a SpO_2 sensor detects changes in the color of blood (indicative of degree of oxygenation) using infra-red and red light emitting diodes; PPG (photoplethysmography) on the other hand, measures changes in reflected light as blood vessels pulsate with every heartbeat. Ex. 1069 79:17–83:20; Ex. 2016 ¶ 13; *see also* Ex. 2001 ¶ 40; Ex. 1003 ¶ 31. Unlike an SpO_2 sensor, PPG does not necessarily require that the light source is in the infra-red and red portion of the spectrum. Ex. 1069, 79:20–80:24, 83:15–16. But by combining the necessary sensors and using infra-red/red light emitting diodes, their features can be combined in a single device able to perform pulse oximetry, which measures both pulse rate and oxygen levels. *See id.* at 83:4–85:2. "[T]his combination is an oximeter." *Id.*

Patent Owner, supported by the testimony of Dr. Efimov, focuses on Shmueli's reference to SpO_2, for example, in element 37 of Shmueli's Figure 7. Taken strictly at face value, the instruction of element 37 to "Measure SPO_2" refers to the measurement of blood oxygen content, which, Patent Owner argues, may be used for monitoring signs of heart attack, but not arrhythmias. *See* PO Resp. 45; Tr. 62:1–10, 70:18–71:1, 73:18–74:6. But as Petitioner points out, Shmueli is not focused solely on monitoring blood oxygen content. *See, e.g.*, Reply 4–6; Ex. 1004, Title. We note in particular, that in describing the operation of Figure 7, Shmueli teaches that "the software program starts in element 37 by measuring SpO_2." Ex. 1004, 12:9–10. Although Shmueli states that element 37 measures "oxygen saturation in

the blood," it further states that the measurement is preferably executed using oximetry—which, as noted above, can measure pulse rate in addition to blood oxygen content. *See id.* at 12:10–13; *see also id.* at 8:11–13 ("Deriving heart beat rate from oximetry, as well as other artifacts of the heart activity and blood flow, is . . . known in the art"). Consistent with its title highlighting the use of "Pulse Oximetry Measurement," Shmueli states:

> The software program proceeds to element 38 to derive from the SpO_2 measurement physiological parameters such as pulse rate, pulse amplitude, pulse shape, rate of blood flow, etc. Then, the software program scans the derived physiological parameters to detect various irregularities of the heart condition. The element of measuring SpO_2 (e.g. oxygen saturation in the blood).

Id. at 12:14–17, code (54) ("Pulse Oximetry Measurement Triggering ECG Measurement"); *see* Ex. 1069, 84:18–25.

Dr. Efimov tacitly admits that the above passage discloses that the "Measure SpO_2" command of Shmueli's element 37 measures pulse rate, amplitude and shape, thus, indicating the PPG functionality. Ex. 1069, 119:20–120:13. This type of heart rate data can be used to detect arrythmia. *See,* Ex. 1069, 84:4–25, 120:6–13, 121:2–122:6; Ex. 2017, 90:5–12; Ex. 1003 ¶¶ 26–27, 50; Ex. 1061, 16:54–58[12] ("The signal that is collected from the SpO2 sensor may also optionally be used for producing other heart related information . . . . such as heart rate, [pulse wave transit time], irregularity of heart rate etc.").

Accepting that the embodiment of Shmueli's Figure 7 was *capable* of detecting arrythmia using SpO_2/PPG data, we adopt Dr. Chaitman's reasoning that one of ordinary skill would have understood Shmueli's

[12] Goldreich, US 7,598,878 B2, issued Oct. 6, 2009.

"irregular heart condition" to refer to—or at a minimum, render obvious—arrhythmia, "one of the most obvious (if not the most obvious) types of "irregular heart condition[s]," as opposed to, for example, heart attack.[13] *See* Ex, 1003 ¶¶ 47–51, 72–73; *see also* Pet. 13; Reply 8; Ex. 2016 ¶ 3; Tr. 15:9–12, 73:6–74:6.

Patent Owner also argues that, whereas ECG is the "gold standard" for arrythmia detection, "PPG was a 'sub-optimal' tool for measuring arrhythmias." *See* PO Resp. 11, 20, 27–28, 33, 46 (citations omitted); Ex. 2001 ¶ 41 (Dr. Efimov's statement that "PPG monitoring is reliable in measurements of oxygen saturation and average heart rate, but historically has been found to be less reliable in detecting arrhythmias, especially atrial arrhythmias."); Ex. 2016 ¶ 16 (same). [14] But this is precisely the point of Shmueli, which combines the ease of use of the PPG sensor with a less convenient, but confirmatory, ECG. As stated by Petitioner, "Shmueli instructs a user to take an ECG when a problem is identified by SpO2/PPG so that the ECG can confirm whether or not the SpO2/PPG detection was accurate." Reply 2 (citing Pet. 12, 26–28; Ex. 1003 ¶¶ 51, 109–113; Ex. 1004, Abstract, 3:15–20, 9:21–29, 12:22–31, 14:16–29, 15:1–3, Fig. 7).

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[13] Although Patent Owner argues that Shmueli's use of "irregular heart condition" potentially encompasses many conditions, we note that some of these (e.g., heart-valve defects, and congenital heart defects) are chronic conditions, and thus, not pertinent to Shmueli's detection of episodic events. Rather than attempt to parse the relevance of each, we focus on heart attack, as does Patent Owner. *See* Sur-Reply 9–14; Tr. 64:1–10, 73:18–74:6.

[14] Supporting its position that it was known to detect arrhythmia using PPG, Petitioner further points to Amano's disclosure of a wrist-worn device that uses pulse oximetry to detect arrhythmia. *See* Pet. 10, 24, Reply 10–11 (citing Ex. 1020, US Pat. No. 6,095,984); Ex. 1003 ¶ 27 (same). Patent Owner does not address this contention on the merits. *See* Sur-reply 2, 13.

This provides the benefit of "enabl[ing] a patient to perform ECG measurement as soon as an irregular heart activity develops and without requiring the ECG to be constantly wired to the patient," as with the more cumbersome implanted, tethered, or Holter devices. Ex. 1004, 2–3, 8; Ex. 1003 ¶¶ 29, 51, 104; Ex. 2016 ¶ 7 ("Clinically, AFib is diagnosed by cardiologists using gold standard tool – 12 lead ECG, or Holter monitors and similar wearable or implantable devices.").

We also do not find persuasive Patent Owner's argument regarding Shmueli's disclosure that "instead of, or in addition to, the oximetry (SpO_2) measuring unit the heart monitoring device may include a unit for measuring CO2 content in the blood." *See* PO Resp. 46 (citing Ex. 1004, 9). Shmueli is relevant "for all that it teaches," and its brief reference to alternative embodiments does not change our understanding of either Figure 7 or Shmueli as a whole. *See In re Mouttet*, 686 F.3d 1322, 1331 (Fed. Cir. 2012).

In light of the above, and all the evidence adduced at trial, we agree with Petitioner that one of ordinary skill in the art would have understood Shmueli to teach or suggest a processing device to receive PPG data from a PPG sensor and "detect, based on the PPG data, the presence of an arrhythmia," as recited in independent claim 1.

2) Confirmation Using ECG Data

Claim 1 requires a processing device to receive ECG data from the ECG sensor and "confirm the presence of the arrhythmia based on the ECG data." Independent claims 17 and 25 recite similar language. As noted above, we find that Shmueli teaches or suggests detecting an irregular heart condition (arrhythmia) based on PPG data. Patent Owner argues that Ground 1 fails because Shmueli does not render obvious using ECG data to confirm

that initial detection. PO Resp. 51–57. We do not find Patent Owner's arguments availing for the reasons set forth in the Petition, the Reply, and as discussed below.

With reference to Shmueli's Figure 7 (which was reproduced and discussed *supra* § I.H.1), Petitioner presents several lines of evidence supporting its contention that Shmueli renders the confirmation step obvious. Pet. 26–29; Reply 13–17. Petitioner argues, for example, "ECG is undisputedly the gold standard for detecting heart conditions, which makes it obvious that Shmueli's ECG measurements are used to confirm irregular heart conditions detected by its SpO_2/PPG measurements." Reply 13. Focusing on the flow chart of Shmueli's Figure 7, Petitioner argues that that one of ordinary skill in the art

> would have found it obvious that the software at element 38 causes the processing device to detect, based on the PPG data, the presence of arrhythmia. APPLE-1003, ¶112. Thus, a POSITA would have understood that the software at element 50, element 39, and element 38 causes the processing device to confirm the presence of the arrhythmia based on the ECG data, by searching for correlations between the PPG and ECG data, modifying detection parameters, and confirming the presence of arrhythmia. APPLE-1003, ¶112. It is beneficial to confirm the presence of arrhythmia because it allows the user to make informed decisions regarding whether to seek further medical help. *Id*.

Pet. 27.

> Further with respect to Figure 7, Petitioner argues that,
>
> after the software confirms the detected arrhythmia at element 50, element 39, and element 38 by searching for correlations between the PPG and ECG data, the software proceeds to element 51 to determine a set of stop conditions (element 52), such as whether "***the irregular heart condition has stopped.***" APPLE-1004, 13:22-29. Shmueli discloses that, when the

> software program detects that "***the irregular heart condition has stopped***" (element 51), the software program notifies the user that the ECG measurement has stopped (element 53) and stops the ECG measurement (element 54). APPLE-1004, 13:22-29. A POSITA would have understood that determining whether "the irregular heart condition has stopped" also requires the software program to confirm the presence of arrhythmia using the ECG data. APPLE-1003, ¶113.

Pet. 28.

Patent Owner, however, contends that "the mere fact of taking an ECG following a PPG does not disclose 'confirming.'" PO Resp. 52 (citing Ex. 2016 ¶ 82). Rather, Patent Owner contends, Shmueli uses SpO_2 as the primary detection mechanism and merely *notifies* the user that an ECG measurement is required. *Id.* (citing Ex. 1004, 11–14). Addressing Petitioner's reliance on "Search Correlation" element 50, "Detection Parameters" element 39, and "Detect Irregular Heart Condition" element 38, Patent Owner argues that Shmueli does not explain what the correlations are. PO Resp. 53–54 (citing Ex. 1004, 13; Ex. 2016 ¶ 84). We do not find these arguments persuasive.

Despite the limited detail regarding its algorithm, the referenced passage in Shmueli explains that "the software program proceeds to element 50 to search for correlations between the SpO_2 signal and the ECG signal to produce new detection parameters, or modify existing detection parameters, so as to enhance the detection algorithms of the irregular heart conditions." Ex. 1004, 13. Shmueli further discloses that "[s]earching for correlation (element 50) can be executed in real-time (together with elements 37, 47 and 49) or later after the ECG measurement is concluded." *Id.* Considering the relationship between elements 38, 39, and 50, and Shmueli's disclosure that the process may be conducted "in real-time" for the purpose of "enhanc[ing]

detection algorithms of the irregular heart conditions," we agree with Petitioner that Figure 7 of Shmueli shows that the "ECG analysis (element 50) leads to new detection parameters (element 39) used for more accurate detection of the irregular heart condition (element 38) with SpO_2/PPG data." *See* Reply 14–15; Ex. 1004, Fig. 7, 14:16–21. In this respect we agree with Petitioner's assessment that the "Challenged Claims only require confirming presence of arrhythmia 'based on' ECG data, and thus, are broad enough to encompass confirming the presence of arrhythmia based on new parameters generated from analyzing the ECG data." Reply 16. As such, we agree with Petitioner that Shmueli teaches or suggests "analyz[ing] ECG data to detect (and confirm) irregular heart conditions." *Id.* at 15.

In sum, we agree with Petitioner's characterization of how Shmueli confirms the presence of an irregular heart condition, such as arrhythmia:

> Shmueli works as follows: (1) continuously measuring SpO2/PPG data; (2) measuring ECG data upon detecting an irregular heart condition; and (3) correlating SpO2/PPG and ECG data to confirm presence of the irregular heart condition (directly through analysis of ECG data or indirectly through updates to detection parameters used for assessment of SpO2/PPG data).

Reply 16 (citing Pet. 12, 26–28; Ex. 1004, 12:22–15:3, Fig. 7).

We also note Shmueli's teaching that "[t]he SpO_2 measurement, the ECG measurement and their recordation and storage (elements 37, 47 and 49 respectively) are continued and performed in parallel until a stopping condition is met." Ex. 1004, 13. Conditions for stopping the ECG measurement include a determination that "[t]he irregular heart condition has stopped," at which point "the software program preferably notifies the user that the ECG measurement has stopped." *Id.* In sum, we agree with Petitioner that one of ordinary skill in the art would have understood that

determining whether "[t]he irregular heart condition has stopped," and notifying the user requires, as a predicate, that the software program confirm the presence of arrhythmia using the ECG data. Pet. 28 (emphasis omitted); Ex. 1003 ¶¶ 109–113.

Patent Owner also argues that Shmueli's "ECG data is merely measured and stored" and that any "ECG analysis is performed off the device, after the data is sent to a remote server." PO Resp. 55–56 (citing e.g., Ex. 1004, 14; Ex. 2016 ¶ 87). We do not find these arguments availing. To the contrary, Shmueli states that "the wrist-mounted heart monitoring device preferably transmits to the remote server the collected data, such as the recorded ECG measurement," whereupon the "remote server preferably *further analyzes*" collected ECG data. *See* Ex. 1004, 14 (emphasis added). Shmueli's disclosure that ECG data may be transmitted to a remote server for *further* analysis presupposes that the data is first analyzed prior to transmission in this embodiment. In addition, Shmueli describes the embodiment represented in Figure 7 as "a simplified flow chart of a software program *preferably executed by the processor of the wrist-mounted heart monitoring device*." Ex. 1004, 7:6–7 (emphasis added). As such, the confirmation step embodied in elements 38, 39, and 50 preferably occurs locally. *See* Reply 17. Shmueli's teaching that, in a subsequent step, "[a]fter concluding the ECG measurement (element 54) the software program preferably proceeds to element 55 to communicate with a remote server," also indicates that the steps of confirming the presence of arrhythmia and stopping the ECG measurement may occur locally, and prior to communication with any remote server. *See* Ex. 1004, 14.

Patent Owner further argues that the ECG data is not involved in the confirming step because Shmueli's sole stop condition for the ECG measurement occurs when the SpO_2 sensor no longer detects an irregular heart condition. *See* PO Resp. 56–57. We agree with Petitioner, however, that

> In Shmueli, when an irregular heart condition is detected and ECG measurement is initiated, the SpO2 measurement "***preferably*** continues," suggesting that the SpO2 measurement may stop in some embodiments. APPLE- 1004, 13:19-22. In these embodiments where SpO2 measurement has stopped, ECG is the only measurement that can be used to perform the operations described by Shmueli, including determining whether "the irregular heart condition has stopped." APPLE-1004, 14:22-29.

Reply 16–17; *see also* Tr. 19:21–21:2 (highlighting the relationship between element 54 ("Stop ECG") and element 38 ("Detect Irregular Heart Condition" using SPO_2/PPG). Considering the argument and evidence of record, we agree with Petitioner that, with respect to the stop condition, "Shmueli renders obvious 'confirmation' of the irregular heart condition based on ECG data" based its disclosure of "embodiments where the SpO2 measurement does not continue." *Id.* at 17.

3) Conclusion as to Ground 1

For the reasons set forth above, we find that Shmueli discloses or renders obvious the arrhythmia detection and confirmation elements of independent claims 1, 17, and 25. Patent Owner does not challenge any other element under Ground 1. Having reviewed the argument and evidence of record, we find that Petitioner has shown by a preponderance of the evidence that claims 1, 7, 12, 13, 16, 17, 23–26, 30 are unpatentable as obvious in view of Shmueli.

E. Ground 2: Obviousness over Shmueli and Osorio

As Ground 2, Petitioner challenges claims 1, 2, 4, 7, 12–14, 16–18, 20, 23–26, and 30 as obvious over Shmueli in combination with Osorio. Pet. 39–67. Of these, claims 2, 4, 14, 18, and 20 recite a "motion sensor" (claims 2 and 4), "motion sensor data" (claims 18 and 20) or "inertial data of the user" (claim 14). Petitioner provides an element-by-element comparison of the asserted art to the challenged claims. *Id.* at 43–67. In short, Petitioner argues that "Shmueli's wrist-mounted heart monitoring device detects an irregular heart condition (arrhythmia) based on PPG and ECG measurements" but "does not expressly account for a user's activity level." Pet. 43. As a marker for activity level, Petitioner points to Osorio as teaching to "determin[e] HRV from HR and using HRV to detect the pathological event." *Id.* at 43–44 (citing Ex. 1003 ¶ 152).

Patent Owner argues that Ground 2 fails for the reasons discussed with respect to Ground 1, which we find unavailing. *See* PO Resp. 42–47, 51–57; section II.D., above.

Patent Owner further contends that Ground 2 fails because Petitioner has not shown that 1) either Shmueli (discussed above) or Osorio teaches or suggests arrhythmia detection or 2) that one of ordinary skill would have been motivated to combine the teachings of Shmueli and Osorio. PO Resp. 47–51, 57–60. We discuss these additional arguments below.

1) Arrhythmia Detection by Osorio

Osorio discloses medical device systems and methods for detecting a pathological state of a patient by determining when a body data variability value, or "BDV," is outside of a "value range," and where the threshold levels of that range vary in response to the patient's physical activity level

(measured by, e.g., an accelerometer), sleep/wake state, or other mental/emotional condition. *See* Ex. 1005, Abstract, ¶¶ 3–8, 28, 33, 35, 48, Fig. 4. Osorio states that "false negative and false positive detections of pathological events may be reduced by dynamically determining pathological or non-pathological ranges for particular body indices based on activity type and level or other variables (e.g., environmental conditions)." *Id.* ¶ 36. Osorio discloses that among the body indices subject to BDV monitoring are "heart rhythm variability," "heart rate variability (HRV)," "changes in heart rate," including "tachycardia and bradycardia," and "the emergence of one or more cardiac arrhythmias." *Id*. ¶¶ 42, 43, 45, 46, 71; Ex. 1069, 61:13–16; Ex. 1003 ¶ 54.

Patent Owner argues that we should discount Osorio's express teachings to monitor heart rate for episodes of tachycardia, bradycardia, or other cardiac arrhythmias because the underlying "pathological state" at issue in Osorio is epilepsy, rather than arrhythmia. *See* PO Resp. 47–51; Sur-reply 14–16; Tr. 56:16–57:23 (Patent Owner's counsel arguing that any change in heartbeat mentioned in Osorio are "in the context of a neurological condition"). Patent Owner's arguments are unavailing for a number of reasons.

First, to the extent Ground 2 relies on Osorio for arrhythmia detection, *per se*, it is invariably in combination with Shmueli. *See, e.g.*, Pet. 54–55 ("Osorio *also* discloses using heart rate data to determine arrhythmia") (emphasis added), 56 (same). Because we determine that Shmueli discloses or renders obvious arrhythmia detection, it is not necessary that we also find that disclosure in Osorio. *See* Section II.D, above.

Second, for essentially the reasons set forth in Petitioner's Reply, we do not read Osorio's "pathological state" as limited to neurological conditions. *See* Reply 11–13. We do not dispute that Osorio largely focuses on a particular neurological condition—epilepsy—as an exemplary pathological state. As noted by Petitioner, however, Osorio, consistently employs "permissive language to indicate that its teaching for epileptic seizures are merely exemplary," and its five-paragraph introduction to the invention does not once mention epilepsy. Reply 11–12 (citing Ex. 1005 ¶¶ 2, 27–31, 37, 46); *see also* Ex. 1005 ¶¶ 56, 57. Illustrative of Osorio's broad usage of pathological state, the reference discloses that "[a]n occurrence of *any pathological state* that may be associated with a body signal outside a non-pathological BDV range provided by analysis of the patient's activity level may be determined by the pathological state occurrence module." Ex. 1005 ¶ 44 (emphasis added).

We also agree with Petitioner that one of ordinary skill reading Osorio, including its claims, would also understand that its teachings are not limited to epilepsy. *See* Reply 12–13. In particular, Osorio's claim 1 is directed to "[a] method for detecting a pathological body state of a patient," whereas claim 7 limits the pathological state to an epileptic event. The same relationship is seen with claims 14 and 17 (limiting a pathological state of claim 14 to an epileptic event). Patent Owner's argument that the broader "pathological body state" recited in claims 1 and 14 should be limited to neurological states, is not consistent with our reading of Osorio's specification. To the contrary, our understanding of Osorio is consistent with Dr. Efimov's admission that one of ordinary skill in the art would, in

general, understand pathological state to include arrhythmia. Ex. 1069, 50:17–22.[15]

Third, even were we to read Osorio as narrowly drawn to the detection of epilepsy as Patent Owner urges, the reference, nonetheless, contains repeated teachings to monitor heart rate and heart rate variability for signs of arrhythmia. *See* Ex. 1005 ¶¶ 42, 43, 45, 46, 71; Ex. 1069, 59:23–60:3 (Dr. Efimov's agreement that Osorio discloses determining the severity of a neurologic condition based, at least in part, on the identification of cardiac arrhythmia). It is undisputed that a cardiac arrhythmia is a type of pathological condition. Ex. 1003 ¶ 55; Ex. 2016 ¶ 75; Ex. 1069, 58:9–59:3. Patent Owner provides no persuasive explanation of why we should ignore Osorio's express teachings relating to the detection of cardiac arrhythmias, merely because Osorio also implicates them in detecting the pathological condition of epilepsy.

2) Reasons to Combine Shmueli and Osorio

Relying on the testimony of Dr. Chaitman, Petitioner argues that "it was well-known that activity level is related to HR and HRV and a POSITA would have found it obvious to improve Shmueli's method by considering activity level." Pet. 43 (citing, *e.g.*, Ex. 1003 ¶ 151). Petitioner further points to Osorio as evidencing benefits of using activity level to detect an irregular heart condition (e.g., improved accuracy, reliability, and reduced false detection). *Id.* (citing Ex. 1005 ¶¶ 29, 36). Accordingly, Petitioner contends, one of ordinary skill in the art "would have been motivated to incorporate

[15] We also note Dr. Efimov's testimony at deposition that Osorio and its claims were *focused* on a neurological pathological state—and his repeated refusal to squarely address whether they were *limited* to a neurological pathological state. *See id.* at 65:14–70:7.

Osorio's activity sensor and activity level analysis techniques into Shmueli's heart monitoring device . . . to improve the accuracy of detecting a pathological event (e.g., arrhythmia)," which would have "improved user satisfaction since the user would have been less bothered by false detections." *Id.* at 43–44, 54 (citing Ex. 1005 ¶ 29; Ex. 1003 ¶¶ 151–152, 167).

Petitioner similarly asserts that one of ordinary skill in the art "would have been motivated to incorporate Osorio's HRV analysis because it is less affected by noise" and, thus, "improve[] the pathological event detection capabilities compared to Shmueli's unmodified heart monitoring device." *Id.* at 48–50 (citing Ex. 1003 ¶¶ 159, 162; Ex. 1039, 52[16]). Supporting Petitioner's position, Dr. Chaitman testifies that one of ordinary skill in the art would have understood that modifying Shmueli's device to use Osorio's HRV analysis would have improved the detection of certain arrhythmias, particularly atrial fibrillation. *See* Ex. 1003 ¶ 162. Petitioner further argues that one of ordinary skill in the art could have combined the teachings of Shmueli and Osorio with a reasonable expectation of success. Pet. 45–48.

Patent Owner argues that one of ordinary skill in the art would not have been motivated to combine Shmueli with Osorio because the two references are directed to different problems: Shmueli to detecting heart conditions, and Osorio to detecting epileptic seizures. PO Resp. 57–58; Sur-reply 16–17. As such, Patent Owner argues that combining the two references would improperly change the basic principles under which the prior art was designed to operate, or render the prior art inoperable for its

[16] Asl and Setarehdan, "*Support vector machine-based arrhythmia classification using reduced features of heart rate variability signal*," 44(1) Artif. Intell. Med. 51–64 (2008). Ex. 1039.

intended purpose. *See* PO Resp. 59; Sur-reply 16–17 (citing, e.g., *Adidas AG v. Nike Inc.*, 963 F.3d 1355, 1359 (Fed. Cir. 2020) and *Nichia Corp v. Everlight Ams., Inc.,* 855 F.3d 1328, 1340 (Fed. Cir. 2017)). Patent Owner further argues that, absent a finding that Osorio discloses detecting arrhythmias, "there can be no finding of obviousness, because with no arrhythmia detection there is no argument that a POSITA would have been motivated to combine Shmueli and Osorio." PO Resp. 59–60 (citation omitted).

Patent Owner's arguments are unavailing for the reasons set forth on pages 17–18 of Petitioner's Reply, which we adopt in full. In short, Osorio relates to medical device systems and methods capable of detecting a pathological body state of a patient. Ex. 1005 ¶ 2. As discussed above, we do not read Osorio as limiting "pathological state" to epilepsy or other neurological condition. To the contrary, one of ordinary skill in the art would have understood Osorio's teachings applicable to "any pathological state," including arrythmia. *See e.g., id.* at 44. As such, the references are not directed to different problems as Patent Owner urges.

Further, even if one of ordinary skill in the art were to read Osorio as limited to the detection neurological events such as epilepsy, Osorio contains express teachings to monitor heart rate and heart rate variability for signs of arrhythmia. *See* Ex. 1005 ¶¶ 42, 43, 45, 46, 71; Ex. 1069, 58:23–59:3; 61:13–62:7. Whether Osorio's detection of arrhythmias is viewed as a stand-alone goal, or as data for use in monitoring for epileptic seizures, does not materially affect the analysis. "Because Shmueli already renders arrhythmia detection obvious and Osorio motivates use of activity tracking to improve detection of any heart-related pathological conditions," including

arrhythmias, it is irrelevant whether Osorio's ultimate goal is the detection of neurological events. Reply 18 (citing Pet. 23–24; Ex. 1004, 13:9–17, Fig. 7).

With respect to Patent Owner's reliance on *Adidas*, it is well established that a finding of obviousness does not require that all features of a secondary reference are "bodily incorporated into the structure of the primary reference." *In re Keller*, 642 F.2d 413, 425 (CCPA 1981). Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. *Id*. "[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill." *KSR*, 550 U.S. at 417. In the present case, we do not understand Petitioner to argue for the wholesale incorporation of Osorio into Shmueli's device. Rather, Petitioner more narrowly argues that one of ordinary skill in the art would find it obvious to incorporate two elements of Osorio into Shmueli's device: "using activity level monitoring to improve the accuracy of detecting a pathological event (e.g., arrhythmia), and (ii) determining HRV from HR and using HRV to detect the pathological event (e.g., arrhythmia)," because, for example, "HRV analysis is more robust . . . and is less affected by noise." Pet. 30, 43–44, 48–49; *see generally* Ex. 1003 ¶¶ 151–167. Thus, even were Osorio ultimately limited to the detection of neurological events, Patent Owner's suggestion that these targeted improvements would render Shmueli's device inoperable for its intended purpose is unavailing.

In view of the above, and all the argument and evidence adduced at trial, Petitioner has established sufficiently that one of ordinary skill in the

art would have been motivated to combine Shmueli and Osorio with a reasonable expectation of success.

3) Conclusion as to Ground 2

For the reasons set forth above, we find that the combination of Shmueli and Osorio discloses or renders obvious the arrhythmia detection recited in independent claims 1, 17, and 25, and that one of ordinary skill in the art would have been motivated to combine the cited references with a reasonable expectation of success in arriving at the challenged claims. Patent Owner does not specifically challenge any other element under Ground 2. Having reviewed the argument and evidence of record, we find that Petitioner has shown by a preponderance of the evidence that claims 1, 2, 4, 7, 12–14, 16–18, 20, 23–26, and 30 are unpatentable as obvious in view of Shmueli and Osorio.

F. Ground 3: Obviousness over Shmueli, Osorio, and Li

As Ground 3, Petitioner challenges claims 3, 5, 6, 19, 21, and 22 as obvious over Shmueli, Osorio, and Li. Pet. 1, 67–73. Petitioner provides an element-by-element comparison of the asserted art to the challenged claims. *Id.* at 70–73.

Claims 3, 5, 6, 19, 21, and 22 recite inputting PPG or HRV data into a "machine learning algorithm trained to detect arrhythmias." Petitioner points to the '731 patent's high-level discussion of machine learning and disclosure that "[a]ny number of machine learning algorithms or methods may be trained to identify atrial fibrillation or other conditions such as arrhythmias." Pet. 67 (citing Ex. 1001, 9:55–10:11). Consistent with that high level of abstraction, Petitioner contends that "machine learning . . . focuses on algorithms capable of learning and/or adapting their structure (e.g.,

parameters) based on a set of observed data," and that such "algorithms were a well-known and popular technique to detect arrhythmia based on heart rate data." *Id.* at 67, 69 (citing Ex. 1003 ¶ 259; Ex. 1040, 1928;[17] Ex. 1041, 74;[18] Ex. 1042, 538;[19] Ex. 1003 ¶ 262); Tr. 28:14–35:22; *see also* Ex. 1042 (review of machine learning in biomedical applications).

Illustrative of the use of machine learning, Petitioner relies on Li as disclosing

> a machine learning algorithm to detect arrhythmia based on PPG and ECG data. APPLE-1006, Abstract. Li-2012 utilized a machine learning algorithm to combine up to 114 features extracted from PPG and ECG data. *Id.* Li-2012 demonstrates that its machine learning algorithm can reduce false alarm by more than 30% (29.84% on training, 30.46% on test data) with a true alarm suppression rate below 1%. APPLE-1006, p.7 and Table 6.

Pet. 67. Petitioner further argues that to detect arrhythmia, one of ordinary skill in the art would have been motivated to combine Shmueli and Osorio with machine learning given its many advantages including to "increase detection accuracy by reducing false alarms," as taught by Li. *Id.* at 67–68 (citing Ex. 1003 ¶¶ 258–265; Ex. 1042; Ex. 1006, Abstract); *see id.* at 70–72; Tr. 62:10–15; Reply 20.

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[17] Yaghouby and Ayatollahi, "*An arrhythmia classification method based on selected features of heart rate variability signal and support vector machine-based classifier*," Dössel O., Schlegel W.C. (eds) World Congress on Medical Physics and Biomedical Engineering, September 7–12, 2009, Munich, Germany, 25/4 IFMBE Proc.

[18] Dallali, et al., "*Integration of HRV, WT and neural networks for ECG arrhythmias classification*. 6 ARPN J. Eng'g. Applied Sci. 74-82 (2011).

[19] Sajda, "*Machine learning for detection and diagnosis of disease*," 8 Ann. Rev. Biomed. Eng. 537-65 (2006). Ex. 1042.

In addition to its reliance on Li, Petitioner argues that one of ordinary skill in the art would also have recognized Shmueli to disclose the use of machine language in the context of the software program diagramed in Shmueli's Figure 7. *Id.* at 68–69. In particular, Petitioner points to Shmueli's teaching that "after an ECG was measured, "the software program proceeds to element 50 to search for correlations between the SpO2 signal and the ECG signal ***to produce new detection parameters, or modify existing detection parameters, so as to enhance the detection algorithms of the irregular heart conditions***." *Id.* (citing Ex. 1004, 13:16–19). Petitioner presents evidence that the ordinarily skilled artisan would have understood that this disclosure refers to the use of machine learning, and would have had a reasonable expectation of success in using a machine learning to detect arrhythmia. *Id.* at 69 (citing Ex. 1042, 538; Ex. 1003 ¶ 262–263; Ex. 1006, 7, Tab. 6; Ex. 1012, Abstract; [20] Ex. 1038, Abstract;[21] Ex. 1039, Abstract).

Patent Owner argues that one of ordinary skill in the art would not have been motivated to combine Li 2012 with Shmueli and Osorio with a reasonable expectation of success. PO Resp. 60–65; Sur-reply 19–23.

Patent Owner first contends that Ground 3 fails because "while Li 2012 does describe machine learning, it does not describe using machine learning to detect arrhythmias," "makes no mention of arrythmias, and gives no disclosure on how machine learning could be applied to detecting

[20] Tsipouras et al., "*Automatic arrhythmia detection based on time and time—frequency analysis of heart rate variability*," 74 Computer Methods and Programs in Biomedicine 95–108 (2004).
[21] Tavassoli et al., Classification of cardiac arrhythmia with respect to ECG and HRV signal by genetic programming,) 3(1) Can. J. Art. Intel. Machine Learning Pattern Recognition 1–13 (2012).

arrythmias." PO Resp. 4, 60; *see* Sur-reply 21–22. Rather, Patent Owner argues, Li 2012 "takes in data in data from multiple sources, with over 100 variables, and weights those variables to its algorithm to reduce the [false alarm] rate of arrhythmias." *Id.* at 61. As such, Patent Owner argues, Li 2012 does not teach arrhythmia detection but "using machine learning to ***avoid*** incorrect arrhythmia detection," which is "the opposite of what the claims require." *Id.* at 62 (citing Ex. 2016 ¶ 98).

Patent Owner's arguments are unavailing for the reasons detailed in pages 21–23 of Petitioner's Reply. *See also* Tr. 32:20–33:12. In short, we agree with Petitioner that in disclosing the use of machine learning to minimize false positives, Li 2012 necessarily detects true positives. "[F]alse positive reduction is simply a means of improving the accuracy of true positive detection" because "labeling the alarms as true (arrhythmia detected) and false requires distinguishing arrhythmia from non-arrhythmia." Reply 21 (citing Ex. 1006, 2, 4, 6, Tables 4–7; Pet. 67). In practice, Li 2012's system "only detects an arrhythmia when the machine learning algorithms accept it as a true arrhythmia." *Id*. at 22 (citing Ex. 1006, 2–4, 7–8).

Patent Owner further argues that the Li 2012 machine learning framework is based on "'114 variables . . . [that] were extracted from ***ECG, ABP [arterial blood pressure], PPG, and SpO2*** signals." Ex. 1006, 4. Pointing to Petitioner's statement that the combination of Li 2012, Shmueli, and Osorio, would result in a device that "would 'detect[] arrhythmia using a machine learning algorithm based on the PPG data, heart rate, HRV, motion sensor data, and activity level," Patent Owner argues Petitioner's combination "would disregard at least ECG and ABP data." PO Resp. 63–64

(citing Pet. 68, 69; Ex. 2017, 129:11–13). Patent Owner contends that, "Li 2012 provides no disclosure of any machine learning utilizing only one (PPG) of four signals (PPG, ECG, ABP, SpO2) and Petitioner provides no explanation how the Li 2012 machine learning algorithm could be adapted to work exclusively with PPG data." PO Resp. 63–64 (citing Ex. 2016, ¶ 100).

Patent Owner explains that "Li 2012 understood that certain measurements are not always available, such as the ABP measurement." PO Resp. 64 (citing Ex. 1006, 7). Patent Owner argues that a comparison of Tables 6 and 7 of Li 2012 show the results using all measurements, and results excluding ABP data, respectively. *Id.* According to Patent Owner, "[w]hen ABP is excluded, FA suppression decreases from a maximum of 30.46% to a maximum of 20.75%—a 50% reduction." *Id.*, (citing Ex. 1006, Table 6, 7, Ex. 2017, 127:3–128:9). Patent Owner reasons that

> because Petitioner's proposed Shmueli-Osorio-Li 2012 combination would require Li 2012 to operate using only a small fraction of its ECG, PPG, ABP, and SpO2 dataset, in the face of Li 2012's disclosure that removing even one set of variables—from the ABP sensor—causes a significant reduction in Li 2012's effectiveness, Petitioner's proposed combination renders Li 2012 inoperable for its intended purpose.

PO Resp. 64–65 (citing, e.g., Ex. 2016 ¶¶ 101–102).

Patent Owner's arguments are unavailing for essentially reasons detailed in pages 23–25 of Petitioner's Reply.[22] As an initial matter, we look

[22] Petitioner does not persuade us, however, that Li 2012's citation to Li and Clifford involves a machine learning, rather than rule-based, heuristic algorithm. *See* Reply 23 (citing Ex. 1006, 3, reference 14); Ex. 2017, 109:20–24; Tr. 82:21–83:9, 85:23–86:7. Although Li and Clifford is titled "Dynamic time warping and machine learning for signal quality assessment of pulsatile signals," Li 2012 describes its teaching as "using . . . Dynamic

to the plain language of claims 3, 5, 6, 19, 21, and 22, which require the input of at least PPG or HRV data into a machine learning algorithm. Claim 5, for example, recites a processing device . . . configured to input the HRV data into a machine learning algorithm trained to detect arrhythmias." None of the claims challenged under Ground 3 preclude ECG data (or any other data used in Li 2012) from also being input into the algorithm.

With respect to Patent Owner's argument that one of ordinary skill in the art reading Li 2012 would not expect that machine learning could have been adapted to detect arrhythmia using only PPG data, we note Li 2012's teaching that to "keep the number of free parameters which we need to learn as low as possible." Ex. 1003, 4. We also note Li 2012's disclosure that its teachings "could easily be adapted to other alarms in the ICU and have a much wider impact to the general monitoring environment." *Id.* at 8. We do not find persuasive Patent Owner's counsel's argument that Li 2012's "machine-learning algorithm is completely inapplicable to the patents at hand i[n] that it's about an in-clinic setting where you're hooked up to all kinds of devices." *See* Tr. 104:1–10. To the contrary, we find that one of ordinary skill in the art would immediately recognize the applicability of Li 2012's teachings to the development of a body-worn sensor such as disclosed in Shmueli.[23]

Time Warping (DTW), multiple-template matching, and a heuristic fusion algorithm," and as including a function to "heuristically to classify each beat." *Cf.* Ex. 1006, 3 and reference 14.

[23] Patent Owner also argues that clinicians and patients may have difficulty trusting "black box" machine learning applications. PO Resp. 65. To the extent this concern has any applicability here, Petitioner reasonably explains that Patent Owner's "'black box' comment applies to deep learning, not to all machine learning." *See* Reply 20; Ex. 1082, 211:10–217:8.

Our findings are informed by the general state of art. The record supports a finding that those of ordinary skill in the art had a both interest and success in adapting machine learning to various biomedical applications. *See* PO Resp. 65; s*ee e.g.*, Ex. 1042 (reviewing machine learning models and applications in the biomedical sciences); Ex. 1002 ¶¶ 117, 259. Asl for example, "presents an effective cardiac arrhythmia classification algorithm" based on HRV data and employing the support vector machine (SVM) classifier— "a machine-learning technique which has established itself as a powerful tool in many classification problems." Ex. 1039, Abstract, 47.

We also note the testimony of Dr. Stultz, Petitioner's expert before the ITC, that a machine learning algorithm without specifics is nothing more than generic, functional language. *See* Reply 19 (citing, e.g., Ex. 1072, 1086:1–6, 1081:11–16; Ex, 1081, 74–76; Ex. 1082, 34:1–35:17; 113–115). As Petitioner points out, although claims 3, 5, 6, 19, 21, and 22 recite "a machine learning algorithm," the '731 patent "provide[s] no details about what that machine learning algorithm is or how it works." Reply 18–19 (citing Ex. 1001, 5:15–19, 9:63-10:9). Despite this lack of guidance, the Specification teaches that "[a]ny number of machine learning algorithms or methods may be trained to identify atrial fibrillation or other conditions such as arrhythmias." Ex. 1001, 9:67–10:3. Moreover, the record indicates that the types of learning generically listed in the '731 patent were all known in the art. Reply 19 (citing Ex. 1069, 169:10–170:14; Ex. 1072, 1084:18–1086:6); *see, e.g.*, Ex. 1001, 10:3–9). We are hard-pressed to find the addition of claim language reciting a generic machine learning algorithm element distinguishes claims 3, 5, 6, 19, 21, and 22 over the cited art.

Considering all the art and argument of record, and the level of ordinary skill in the art, we agree with Petitioner that "after an ECG is measured, it would have been obvious to confirm arrhythmia detection using a machine learning algorithm based on the PPG data, motion sensor data, and/or ECG data." *See* Reply 25 (citing Pet., 68–70; Ex. 1003 ¶¶ 262–265).

Patent Owner also opposes Petitioner's alternative argument, that one of ordinary skill in the art would have understood element 50 of Shmueli's Figure 7, as referring to the use of machine learning. PO Resp. 65–67. Sur-reply 24. In particular, Patent Owner argues that the "detection parameters" referenced in connection with element 50 do not evidence machine learning, but exemplify "a rule-based algorithm," which is the antithesis of machine learning. PO Resp. 65–67 (citing Ex. 2016 ¶¶ 104–105; Ex. 2017, 109:20–24); Sur-reply 24 (citing Ex. 2016 ¶¶ 86–90).

Considering the state of the art as a whole (discussed above), we agree with Petitioner that one of ordinary skill in the art would have understood that Shmueli disclosed the use of machine learning, or would have found it obvious to employ machine language in carrying out the "search correlation" function of Figure 7, step 50.

G. Grounds 4–5: Obviousness over Shmueli and Osorio further in view of Kleiger, or Chan

As Ground 4, Petitioner challenges claims 8–11 and 27–29 as obvious over Shmueli, Osorio and Kleiger; as Ground 5, Petitioner challenges claim 15 as obvious over Shmueli and Chan, with or without Osorio. Pet. 1, 73–81. Petitioner provides an element-by-element comparison of the asserted art to the challenged claims. *Id.* Patent Owner presents no arguments with respect to Grounds 4 and 5 that have not been discussed above. *See* PO Resp. 29–60 (consolidating arguments). Having reviewed the argument and evidence of

record, we find that Petitioner has shown by a preponderance of the evidence that claims 8–11 and 27–29 are unpatentable as obvious over Shmueli, Osorio and Kleiger, and that claim 15 is unpatentable as obvious in view of Shmueli, Osorio and Chan.

III. PATENT OWNER'S MOTION TO EXCLUDE

Patent Owner moved to exclude Petitioner's Exhibits 1060–1068 and 1072–1085. *See* Mot. 1. Patent Owner withdrew its motion at oral argument with respect to Exhibits 1072, 1073, 1075, and 1082. Tr. 78:19–79:16, 99:18–23. Of the remaining exhibits, we cite herein only to Exhibit 1061.

Patent Owner challenges Exhibit 1061 as "new evidence . . . not properly raised in Reply." Mot. 1. Patent Owner's argument is unavailing. Petitioner properly employed it in the Reply in responding to Patent Owner's argument that one of ordinary skill in the art would not understand Shmueli's recitation of "irregular activity" to indicate arrhythmia. *See* Reply 8–9; Sur-reply 3; *see also* Pet. vi (listing Ex. 1061); *Anacor Pharm., Inc. v. Iancu*, 889 F.3d 1372, 1380–81 (Fed. Cir. 2018) (stating that a "petitioner in an inter partes review proceeding may introduce new evidence after the petition stage if the evidence is a legitimate reply to evidence introduced by the patent owner"). We, therefore, deny the motion with respect to Exhibit 1061.

Because we do not specifically rely on any other challenged exhibit, we dismiss that portion of Patent Owner's motion as moot.

IV. CONCLUSION

Petitioner has shown, by a preponderance of the evidence, that claims 1–30 are unpatentable under § 103 as obvious in view of Shmueli alone or in combinations with Osorio, Li 2012, Kleiger, and/or Chan as summarized below:[24]

Claims	35 U.S.C. §	Reference(s)	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1, 7, 12, 13, 16, 17, 23–26, 30	103	Shmueli	1, 7, 12, 13, 16, 17, 23–26, 30	
1, 2, 4, 7, 12–14, 16–18, 20, 23–26, 30	103	Shmueli, Osorio	1, 2, 4, 7, 12–14, 16–18, 20, 23–26, 30	
3, 5, 6, 19, 21, 22	103	Shmueli, Osorio, Li 2012	3, 5, 6, 19, 21, 22	
8–11, 27–29	103	Shmueli, Osorio, Kleiger	8–11, 27–29	
15	103	Shmueli, Osorio, Chan	15	
Overall Outcome			1–30	

[24] Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this Decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding. See* 84 Fed. Reg. 16654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. § 42.8(a)(3), (b)(2).

V. ORDER

ORDERED, that claims 1–30 of the '731 patent are held to be unpatentable;

FURTHER ORDERED that Patent Owner's Motion to Exclude Evidence is denied with respect to Exhibit 1061, and otherwise dismissed as moot;

FURTHER ORDERED that because this is a Final Written Decision, parties to this proceeding seeking judicial review of our decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

IPR2021-00971
Patent 10,595,731 B2

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Paper 43
Date: December 6, 2022

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE, INC.,
Petitioner,

v.

ALIVECOR, INC.,
Patent Owner.

IPR2021-00972
Patent 10,638,941 B2

Before ROBERT A. POLLOCK, ERIC C. JESCHKE, and DAVID COTTA, *Administrative Patent Judges*.

COTTA, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

Denying In-Part and Dismissing In-Part as Dismissing Patent Owner's Motion to Exclude Evidence as Moot
37 C.F.R. § 42.64

I. INTRODUCTION

A. Background

Apple, Inc. ("Petitioner") filed a Petition for an *inter partes* review of claims 1–23 of U.S. Patent No. 10,638,941 B2 (Ex. 1001, "the '941 patent"). Paper 2 ("Pet."). AliveCor, Inc. ("Patent Owner") timely filed a Preliminary Response. Paper 6 ("Prelim. Resp."). Petitioner further filed an authorized Reply to the Preliminary Response (Paper 7); Patent Owner filed a responsive Sur-reply (Paper 8). Taking into account the arguments and evidence presented, we determined that the information presented in the Petition established that there was a reasonable likelihood that Petitioner would prevail in demonstrating unpatentability of at least one challenged claim of the '941 patent, and we instituted this *inter partes* review as to all challenged claims. Paper 10 ("DI").

After institution, Patent Owner filed a Patent Owner Response (Paper 27, "PO Resp."); Petitioner filed a Reply to the Patent Owner Response (Paper 29, "Reply"); Patent Owner filed a (corrected) Sur-reply (Paper 35, "PO Sur-reply").

Patent Owner also filed a motion to exclude (Paper 34, "Mot."); Petitioner opposed the motion (Paper 36, "Opp. Mot."); and Patent Owner filed a reply in support of its motion (Paper 38, "Reply Mot.").

An oral hearing was held on September 14, 2022, and a transcript of the hearing is included in the record. Paper 41 ("Tr.").

We have jurisdiction under 35 U.S.C. § 6. This decision is a Final Written Decision under 35 U.S.C. § 318(a) as to the patentability of claims

1–23 of the '941 patent. For the reasons discussed below, we hold that Petitioner has demonstrated by a preponderance of the evidence that claims 1–23 are unpatentable.

B. Real Parties-in-Interest

Petitioner identifies itself, Apple Inc., as the real party-in-interest. Pet. 84. Patent Owner, identifies itself, AliveCor, Inc., as the real party-in-interest. Paper 4, 2.

C. Related Matters

According to Patent Owner:

> U.S. Patent No. 10,638,941 has been asserted by Patent Owner against Petitioner in *AliveCor, Inc. v. Apple, Inc.*, Case No. 6:20-cv-01112-ADA, filed in the United States District Court for the Western District of Texas, and in Investigation No. 337-TA-1266 before the International Trade Commission, *In the Matter of Certain Wearable Electronic Devices with ECG Functionality and Components Thereof*. Apple also filed IPR petitions against the other patents asserted in those actions: IPR2021-00970 (USP 9,572,499) and IPR2021-00971 (USP 10,595,731).

Paper 6, 2; *see* Pet. 84.

D. Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability (Pet. 1):

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1, 5, 7–9, 11, 12, 16, 18–20, 22, 23	103[1]	Shmueli,[2] Osorio[3]
2–4, 6, 13–15, 17	103	Shmueli, Osorio, Lee-2013[4]
10, 21	103	Shmueli, Osorio, Chan[5]

In support of its patentability challenge, Petitioner relies on, *inter alia*, the Declaration of Dr. Bernard R. Chaitman, M.D. Ex. 1003. Patent Owner similarly relies on the Declarations of Dr. Igor Efimov, Ph.D. Exs. 2001 and 2016.

E. Technological Background

Electrocardiography measures "the electrical activity of the heart, which can be indicative of various heart diseases." Ex. 1003 ¶ 28 (Chaitman Decl.). "In conventional clinical practice, [electrocardiography] and telemetry are used at a hospital to diagnose cardiac arrhythmias." *Id.* ¶ 30.

An electrocardiogram ("ECG") represents "electrical activity of the heart based on depolarization and repolarization of the atria and ventricles, which typically show up as five distinct waves on [an] ECG readout –

[1] The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA"), amended 35 U.S.C. §§ 102 and 103. Based on the filing date of the '941 patent, we apply the AIA versions of §§ 102 and 103.
[2] Shmueli et al., WO 2012/140559 A1, published Oct. 18, 2012, (Ex. 1004, "Shmueli").
[3] Osorio, U.S. Patent Publication No. 2014/0275840 A1, published Sept. 18, 2014, (Ex. 1005, "Osorio").
[4] Jinseok Lee et al., *Atrial Fibrillation Detection using a Smart Phone*, 15:1 INT'L. J. OF BIOELECTROMAGNETISM 26–29 (2013) (Ex. 1011, "Lee-2013").
[5] Chan et al., U.S. Patent No. 7,894,888 B2, issued Feb. 22, 2011 (Ex. 1048, "Chan").

P-wave, Q-wave, R-wave, S-wave, and T-wave." *Id.* ¶ 29. "An R-R interval represents a time elapsed between successive R-waves of a QRS complex[6] of the ECG that occur between successive heart beats." *Id.* "If [the] R-R interval durations over a time period are close to one another in value, then ventricular rhythm is understood to be 'regular.' In contrast, if there are significant variations in the R-R interval durations over a time period, then the ventricular rhythm is understood to be 'irregular.'" *Id.* ¶ 29 (internal citations omitted).

"Photoplethysmography (PPG) is a simple noninvasive optical technique" that uses a "light source to illuminate subcutaneous tissue and a photo detector with spectral characteristics matching those of the light source" to "monitor[] beat-to-beat relative blood volume changes in the microvascular bed of peripheral tissues." *Id.* ¶ 31. According to Dr. Chaitman, "the information derived from RR intervals of ECG can also be derived from the pulse period of a PPG reading." *Id.* ¶ 32. PPG is "sometimes . . . referred to as blood oxygen saturation, pulse oximeter, oximetry, and SpO2." *Id.* ¶ 31.

Heart rate variability ("HRV") is defined as "the variation of RR intervals with respect to time and reflects beat-to-beat heart rate (HR) variability." *Id.* ¶ 34. It "can be accurately determined based on either ECG data or PPG data." *Id.* ¶ 35. With respect to the former, this involves measuring RR intervals. *Id.* ¶ 29. According to Dr. Chaitman, "HRV

[6] "A QRS complex is a combination of the Q, R, and S waves occurring in succession and represents the electrical impulse of a heartbeat as it spreads through the ventricles during ventricular depolarization." Ex. 1003 ¶ 29.

analysis is an important tool in cardiology to help diagnose various types of arrhythmia." *Id.* ¶ 34.

F. The '941 Patent

The '941 patent discloses that "[i]rregular heartbeats and arrhythmias are associated with significant morbidity and mortality in patients." Ex. 1001, 1:17–18. According to the '941 patent, "[n]on-invasive cardiac monitoring is useful in diagnosing cardiac arrhythmia." *Id.* at 1:21–22. In furtherance of this use, the '941 patent discloses "systems, devices, and methods for cardiac monitoring," including, for example "portable computing devices such as smartphones, smartwatches, laptops, and tablet computers." *Id.* at 1:26–30.

The '941 patent explains that "certain parameter values may be conveniently sensed continuously such as, for example, heart rate and activity level, and analyzed to predict or determine the presence of an arrhythmia." *Id.* at 1:58–61. For example, the '941 patent describes analyzing heart rate and activity level and identifying discordance between these two parameters to determine the presence or the future onset of an arrhythmia. *Id.* at 1:61–66. If the presence or the future onset of an arrhythmia is identified, an electrocardiogram (ECG) may be initiated. *Id.* at 2:1–3.

Figure 7 of the '941 patent is reproduced below.

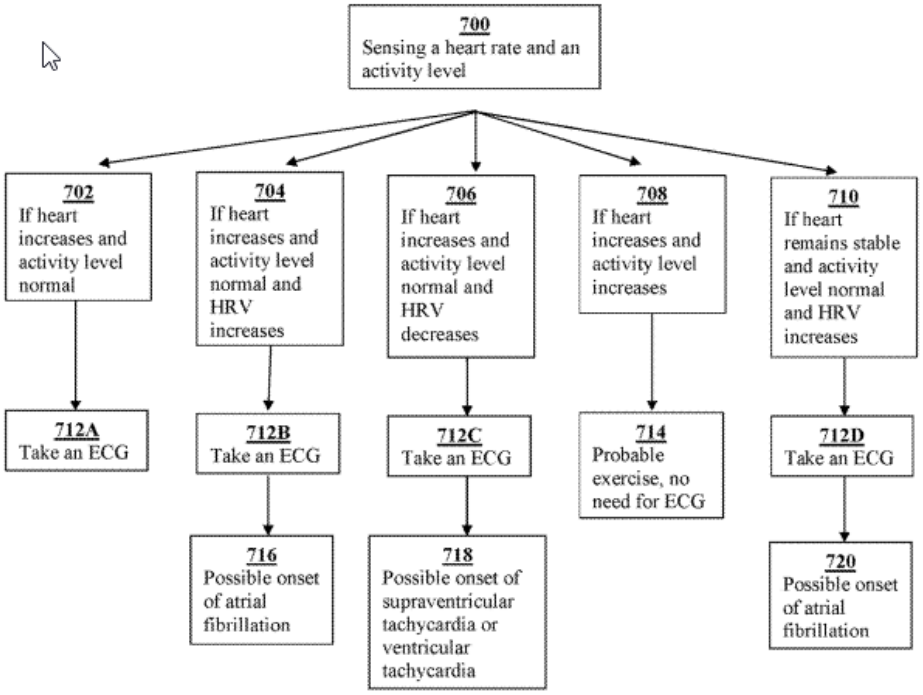


FIG. 7

Figure 7 schematically depicts "an algorithm for discordance monitoring." *Id.* at 3:53–54. The '941 patent explains that a heart rate and an activity level are sensed in step 700. *Id.* at 14:49–51. The '941 patent describes sensing an activity level with a gyroscope or an accelerometer and sensing heart rate using "light based or other commonly used heart rate sensors." *Id.* at 14:51–54. Figure 7 depicts various possible outcomes from the sensing of heart rate and activity level. *Id.* at Fig. 7, elements 702, 704, 706, 708, 710. For example, in step 702, the sensors detect "an increased heart rate . . . together with a normal or resting activity level." *Id.* at 14:59–60. This result is identified as a "discordance [that] may indicate the presence of an arrhythmia." *Id.* at 14:59–66. "As such, an ECG is caused to be sensed in step 712A." *Id.* at 14:66–67. Steps 704, 706, 708, and 710 depict other

potential outcomes from the sensing of heart rate and activity level as well as the actions taken for each potential outcome. *Id.* at 15:22–58.

G. Challenged Claims

The '941 patent includes twenty-three claims. All of those are challenged here. Pet. 1. Claims 1 and 12 are the only independent claims. Claim 1 is illustrative of the claims challenged in this Petition and reads as follows:

> 1. A method of cardiac monitoring, comprising:
> sensing an activity level of a user with a first sensor on a smartwatch worn by the user;
> when the activity level is resting, sensing a heart rate parameter of the user with a second sensor on the smartwatch;
> determining, by a processing device, that a discordance is present between the activity level value and the heart rate parameter;
> based on the presence of the discordance, indicating to the user, using the smartwatch, a possibility of an arrhythmia being present; and
> receiving electric signals of the user from an electrocardiogram sensor ("ECG") on the smartwatch to confirm a presence of the arrhythmia, wherein the ECG sensor comprises a first electrode and a second electrode.

Ex. 1001, 17:2–18.

H. Overview of the Asserted References

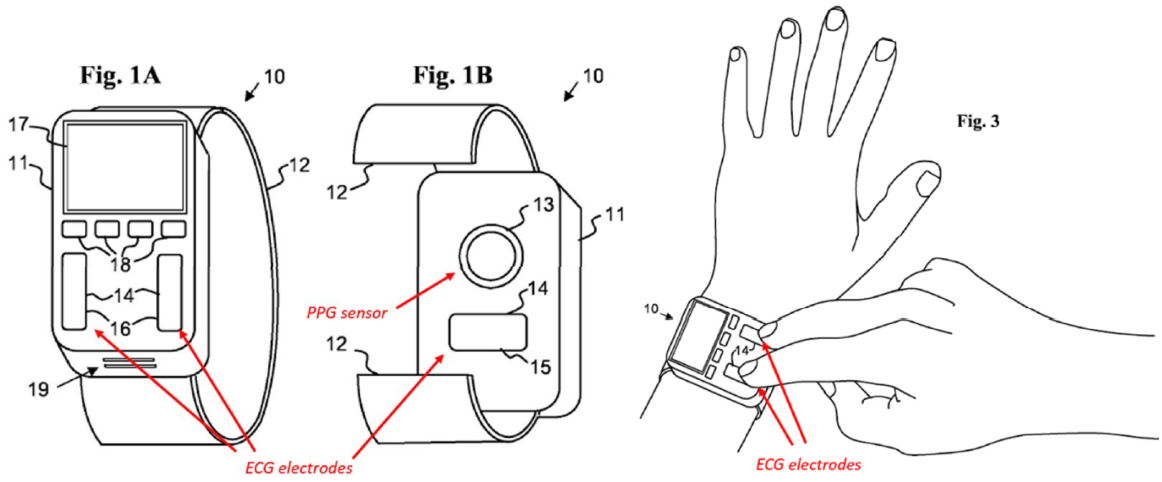
1) Shmueli (Exhibit 1004)

Shmueli, titled "Pulse Oximetry Measurement Triggering ECG Measurement," addresses "solutions . . . for monitoring infrequent events of irregular ECG." Ex. 1004, 2.[7] According to Shmueli, "[t]he present

[7] Throughout this decision, we refer to native pagination wherever it is available. For clarity with respect to citations to Shmueli, we understand the native pagination to be the numbers at the top of the page.

invention preferably performs measurements of intermittent irregular heart-related events without requiring the fixed wiring of the ECG device to the patient." *Id.* at 8.

Shmueli's discloses body-worn cardiac monitoring devices "equipped with two types of sensing devices: an oximetry (SpO_2) measuring unit and an ECG measuring unit." *Id.* at 9.[8] Shmueli's Figures 1A, 1B, and 3, reproduced below, exemplify one embodiment (annotations by Petitioner in red):



Pet. 12. Figures 1A, 1B, and 3 show three views of a wrist-mount heart monitoring device having three ECG electrodes 14 and a PPG sensor 13. Ex. 1004, 6, 9–10. Figure 1A shows two of the ECG electrodes, 14/16, on the face of the device. *Id.* at 9. Figure 1B shows a third ECG electrode, 14/15, along with PPG sensor 13, of the back of the device. *Id.* Figure 3 shows the device as worn on a patient's wrist, with PPG sensor 13 and ECG

[8] As used by Shmueli, "the terms 'oxygen saturation in the blood', 'blood oxygen saturation', 'pulse oximeter', oximetry, SpO_2, and photoplethysmography have the same meaning and may be used interchangeably, except for those places where a difference between such terms is described." *Id.* at 7; *see* Tr. 6:22–7:12, 73:18–21, 95:7–11.

electrode 14/15 in contact with the patient's left wrist and ECG electrodes 14/16 in contact with two fingers of the patient's right hand. *Id.* Petitioner annotates each of Figures 1A, 1B, and 3 with arrows identifying the ECG electrodes. Pet. 12. Petitioner has also annotated Figure 1B with an arrow identifying PPG sensor 13. *Id.* In connection with these devices, Shmueli discloses

> a method for triggering measurement of electrocardiogram (ECG) signal of a subject, the method including the steps of: continuously measuring SpO2 at least one of a wrist and a finger of the subject, detecting an irregular heart condition from the SpO2 measurement, notifying the subject to perform an ECG measurement, and initiating ECG measurement at least partially at the wrist.

Ex. 1004. at 2; *see* Abstract.

Shmueli explains that "[d]eriving heart beat rate from oximetry, as well as other artifacts of the heart activity and blood flow, is . . . known in the art," as are various body-worn oximetry devices. *Id.* at 8. Shmueli further explains that the use of oximetry in combination with ECG measurements is also known in the art. *Id.* Shmueli states, for example, that "US patent No. 7,598,878 (Goldreich) describes a wrist mounted device equipped with an ECG measuring device and a SpO_2 measuring device." *Id.* However, Shmueli, notes "Goldreich does not teach interrelated measurements of ECG and SpO_2" and, thus, does not "enable a patient to perform ECG measurement as soon as an irregular heart activity develops and without requiring the ECG to be constantly wired to the patient." *Id.* According to Shmueli:

> The present invention resolves this problem by providing a combined oximetry and electrocardiogram measuring system and a method in which the oximetry measurement is performed continuously and/or repeatedly, and the ECG measurement is

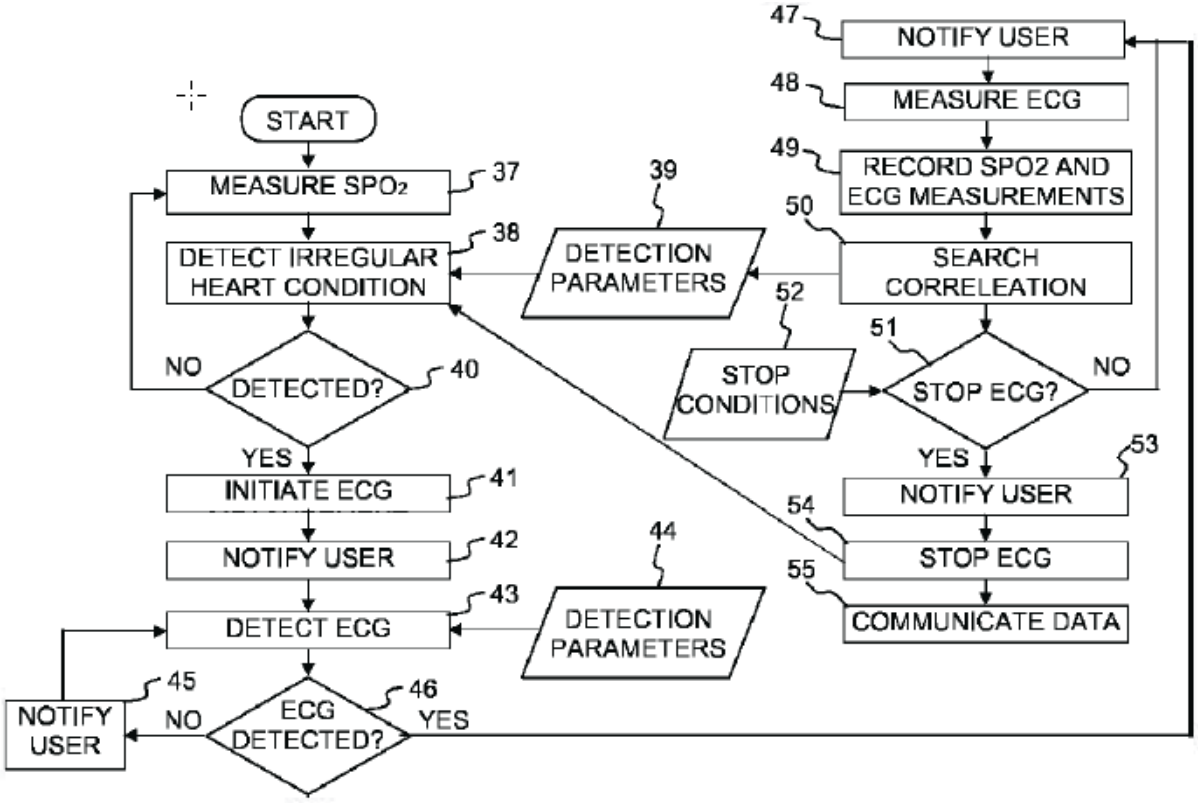
> triggered upon detection of an intermittent irregular heart-related events without requiring the fixed wiring of the ECG device to the patient.

Id. Consistent with this disclosure, Shmueli's claims:

> 1. A method for triggering measurement of electrocardiogram (ECG) signal of a subject, the method comprising the steps of:
>
> continuously measuring SpO_2 at least one of a wrist and a finger of said subject;
>
> detecting an irregular heart condition from said SpO_2 measurement;
>
> notifying said subject to perform an ECG measurement; and
>
> initiating ECG measurement at least partially at said wrist.

Id. at 16.

Shmueli Figure 7 is reproduced below:



"Fig. 7 is a simplified flow chart of a software program preferably executed by the processor of the wrist-mounted heart monitoring device." *Id.* at 7; *see*

also id. at 12–13 (further describing the steps of the software program illustrated in Figure 7).

2) Osorio (Exhibit 1005)

Osorio, titled "Pathological State Detection Using Dynamically Determined Body Data Variability Range Values," "relates to medical device systems and methods capable of detecting a pathological body state of a patient, which may include epileptic seizures, and responding to the same." Ex. 1005 ¶ 2. Although broadly referencing "a pathological body state," Osorio repeatedly exemplifies such conditions in terms of detecting epileptic events. *See*, *e.g.*, *id.* ¶ 37 (referencing values that may "be indicative of a certain pathological state (e.g., epileptic seizure)"), ¶ 46 ("In one embodiment, the pathological state is an epileptic event, e.g., an epileptic seizure."), ¶ 56 ("HRV range may be taken as an indication of an occurrence of a pathological state, e.g., an epileptic seizure"), ¶ 66 ("The dynamic relationship between non-pathological HRVs and activity levels may be exploited to detect pathological states such as epileptic seizures").

Consistent with the broad disclosure and narrow exemplification in the body of its specification, Osorio's claim 1 is directed to "[a] method for detecting a pathological body state of a patient," whereas claim 7 limits the pathological state to an epileptic event. *Id.* at claim 1, claim 7; *also compare id.* at claim 14, *with* claim 17 (similarly limiting a pathological state to an epileptic event).

According to Osorio, the disclosed methods, systems, and related devices, detect a pathological state of a patient by determining when a body data variability value, or "BDV," is outside of a "value range," and where the threshold levels of that range vary in response to the patient's physical

activity (measured by, e.g., an accelerometer) or mental/emotional state. *See, e.g.*, *id.* at code (57), ¶¶ 3–8, 28, 33, 35. In this respect, Osorio states that "false negative and false positive detections of pathological events may be reduced by dynamically determining pathological or non-pathological ranges for particular body indices based on activity type and level or other variables (e.g., environmental conditions)." *Id.* ¶ 36.

Osorio's Figure 1 is reproduced below.

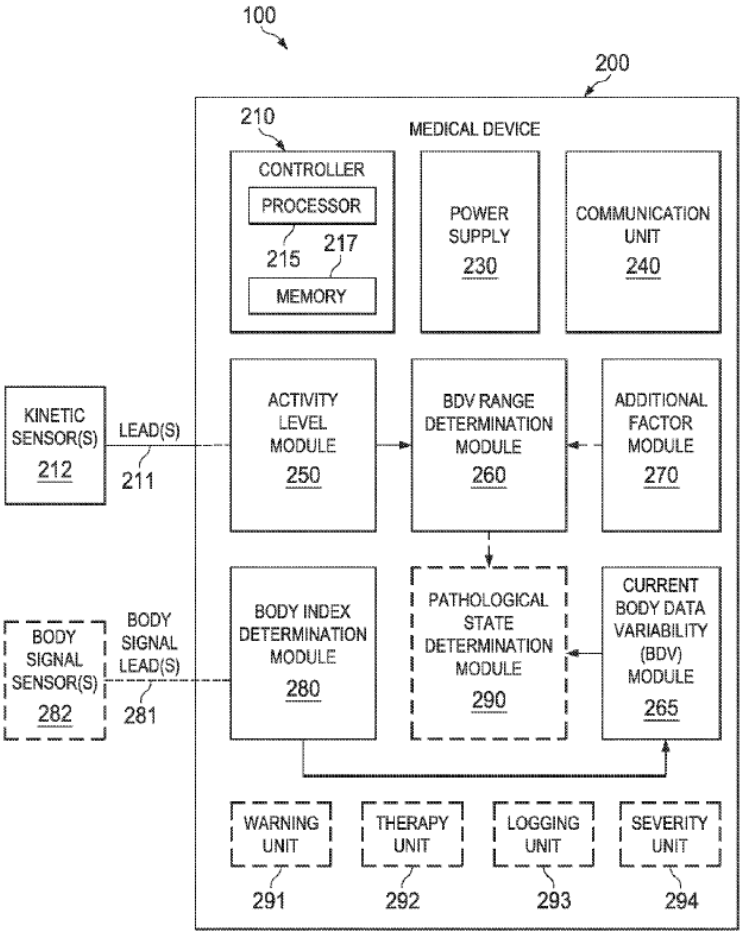


FIG. 1

Figure 1 shows a schematic representation of medical device system 100, including kinetic sensor(s) 212 and body signal sensor(s) 282 connected to medical device 200 by leads 211 and 281, respectively. *Id.* ¶ 33. "[A]ctivity

sensor(s) 212 may each be configured to collect at least one signal from a patient relating to an activity level of the patient," and include, for example, an accelerometer, an inclinometer, a gyroscope, or an ergometer. *Id.* Figure 1 also shows a current body data variability (BDV) module 265, which may "may comprise an O_2 saturation variability (O2SV) module 330 configured to determine O2SV from O_2 saturation data," and "an HRV module 310 configured to determine HRV from heart rate data." *Id.* ¶¶ 10, 53, Fig. 2C. Osorio discloses that "medical device system 100 may be fully or partially implanted, or alternatively may be fully external." *Id.* ¶ 33.

Figure 8, reproduced below, shows one embodiment of Osorio's monitoring method.

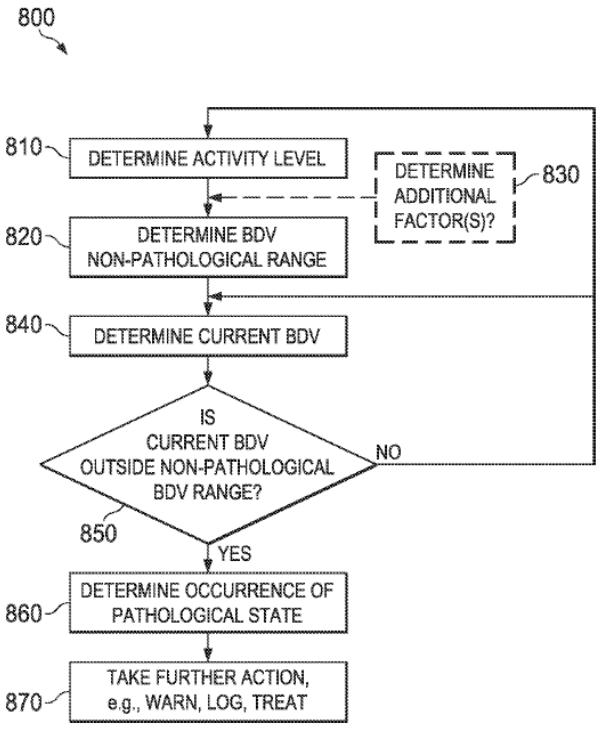


FIG. 8

Figure 8 shows that an activity level is determined at 810, and a non-pathological BDV range is determined at 820 based on the activity level. *Id.* ¶ 77. A current BDV is determined at 840 and compared to the non-

pathological BDV range at 850. *Id.* ¶ 78. If the current BDV is outside the non-pathological range, then a pathological state is determined at 860 and a further action, such as warning, treating, or logging the occurrence and/or severity of the pathological state, is taken at 870. *Id.*

According to Osorio, body indices that may be the subject of BDV monitoring include:

> heart rhythm variability, a heart rate variability (HRV), a respiratory rate variability (RRV), a blood pressure variability (BPV), a respiratory rhythm variability, respiratory sinus arrhythmia, end tidal CO_2 concentration variability, power variability at a certain neurological index frequency band (e.g., beta), an EKG morphology variability, a heart rate pattern variability, an electrodermal variability (e.g., a skin resistivity variability or a skin conductivity variability), a pupillary diameter variability, a blood oxygen saturation variability, a kinetic activity variability, a cognitive activity variability, arterial pH variability, venous pH variability, arterial-venous pH difference variability, a lactic acid concentration variability, a cortisol level variability, or a catecholamine level variability.

Id. ¶ 43; *see also id.* ¶ 42 (similar) ¶¶ 45–46 (monitoring heart rate for episodes of tachycardia and bradycardia). "In one embodiment, the severity [of a pathological state] may be measured by a magnitude and/or duration of a pathological state such as a seizure, a type of autonomic change associated with the pathological state (e.g., changes in heart rate, breathing rate, brain electrical activity, the emergence of one or more cardiac arrhythmias, etc.)." *Id.* ¶ 71.

With respect to HRV, in particular, Osorio teaches: "By monitoring the patient's activity level, HR, and HRV, it is possible to determine when the patient's HRV falls outside the non-pathological ranges as the patient's activity levels change over time." *Id.* ¶ 66. Osorio's Figure 4A, reproduced

below, shows heart rate variability as a function of activity level. *See id.* ¶ 58.

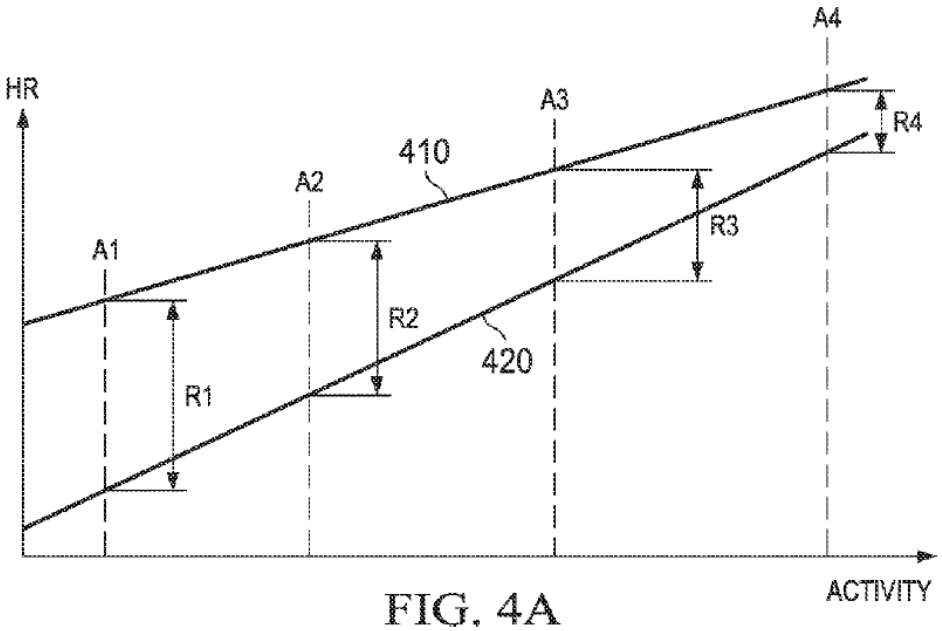


FIG. 4A

Figure 4A plots a patient's heart rate (HR) on the Y-axis and a patient's activity level on the X-axis. *Id.* at Fig. 4A. Markers A1 though A4 represent increasing activity from a sleep state (A1) through vigorous activity (A4). *Id.* Boundary lines 410 and 420, respectively, represent the upper and lower limits of non-pathological heart rate, and include representative ranges R1 through R4. *Id.* According to Osorio,

> the upper and lower bounds of the non-ictal[9] HR region increase as activity level increases (e.g., from a sleep state to a resting, awake state) and reach their highest values for strenuous exertion. In addition, the width of the non-pathological HR ranges narrows as activity levels and heart rates increase, which is consistent with the known reduction in HRV at high levels of exertion. When the patient is in a non-pathological state (e.g., when an epileptic patient is not having a

[9] "Ictal" refers to the active, middle stage of a seizure and corresponds with intense electrical brain activity. *See* https://epilepsyfoundation.org.au/understanding-epilepsy/seizures/seizure-phases/.

> seizure), for a particular activity level the patient's HRV should fall within a non-pathological HRV range associated with that activity level.

Id. ¶ 58.

Osorio further presents Figure 11 as "depict[ing] pathological and non-pathological BDV (e.g., HRV) value ranges." *Id.* ¶¶ 23, 91. In this illustration, Osorio shows that HRV values falling below 0.5 bpm and above 4 bpm are always pathological when activity level is low (e.g., resting or walking), whereas intermediate HRV values (0.5–4 bpm) may be pathological when considered in light of the patient's activity level. *Id*. Osorio further notes that the boundaries between normal and pathological may be adjusted based on an individual's physiology. "For example, in an epilepsy patient also suffering from tachycardia, and having base resting heart rate of 100-110 bpm, a decline in heart rate to 70 bpm may be indicative of a seizure slowing down the heart rate, even though a heart rate of 70 bpm is generally 'normal' across a typical population." *Id.* ¶ 45.

3) Lee-2013 (Exhibit 1011)

Lee-2013, titled "Atrial Fibrillation Detection Using a Smart Phone," discloses a study to assess whether "an iPhone 4s can be used to detect atrial fibrillation (AF) based on its ability to record a pulsatile PPG signal from a fingertip using the built-in camera lens." Ex. 1011, 26.

Lee-2013 teaches that atrial fibrillation is the "most common sustained arrhythmia," with "[o]ver 3 million Americans" diagnosed. *Id.* According to Lee-2013, there is a "pressing need to develop methods for accurate AF detection and monitoring in order to improve patient care and reduce healthcare costs." *Id.* In response to this need, the authors of Lee-2013 developed "a smartphone application to measure pulsatile time series

and then use this data to detect AF real-time." *Id.* Lee-2013's study concluded that "AF can be accurately detected from pulsatile signals in the fingertip using the camera of an iPhone 4s." *Id.* at 29.

4) Chan (Exhibit 1048)

Chan discloses:

> A wristwatch worn by a user for measuring a three-lead ECG [that] includes three electrodes placed separately on the front, either side, and back or strap thereof. The wristwatch further includes an electrode panel having the electrode on the front or either side of the watch, sensing elements, pressure, infrared or impedance detectors, and circuits. The electrode panel is capable of sensing the contact or press of fingers to trigger the ECG measuring. While the electrode in the back-side of the watch contacts the hand wearing the watch, the electrode and electrode panel on the front or either side of the watch are pressed by fingers from the other hand, and the electrode in the strap contacts the abdomen or left leg simultaneously. Thus, a three-lead ECG can be measured. ECG data can be transmitted to a personal or hospital computer by wireless networks or flash memory.

Ex. 1048, Abstract.

Chan's figures 1A and 1B, reproduced below, show an embodiment of the disclosed three-lead ECG wristwatch.

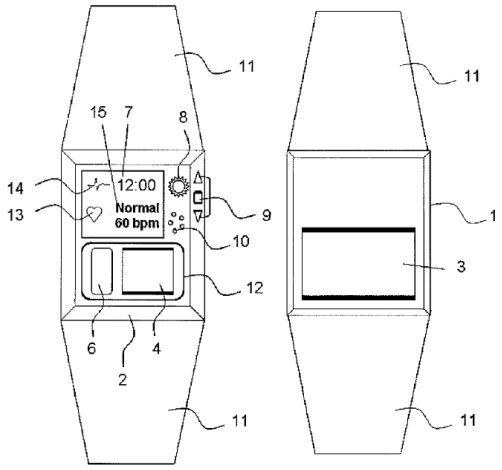


FIG.1A FIG.1B

Figures 1A and 1B, respectively, show the front and back views of a three-lead ECG wristwatch. *Id.* at 2:21–22. Figure 1A shows ECG electrode 4, sensing element 6 (which can detect "pressure, impedance or infrared for recognizing the contact or press made by fingers to initiate an ECG measurement"), and display 7, which may be an LCD. *Id.* at 2:44–56. Display 7 can display text (e.g., time, heart rate, and, condition (normal vs arrhythmia) as well as "graph/animation, for an event reminding 13 and ECG waveforms 14." *Id*. at 2:56–59; *see also id.* at 4:56–59 (stating, with reference to Figure 7, that "display 57 can show users 59 time, heart rate, waveforms and any other information 61, such as activity level and temperature, if needed").

Chan Figure 2 is reproduced below.

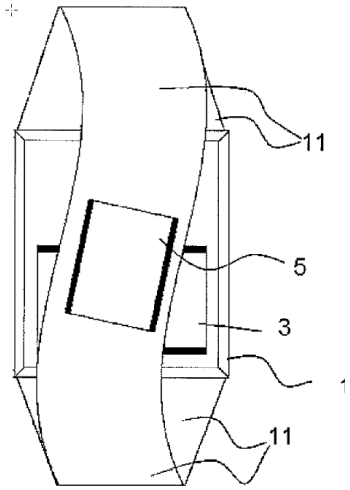


Figure 2 shows an embodiment of the three-lead ECG watch having a third lead 5 on the strap 11. *Id.* at 2:24–25, 3:1–4.

Chan Figure 3B is reproduced below.

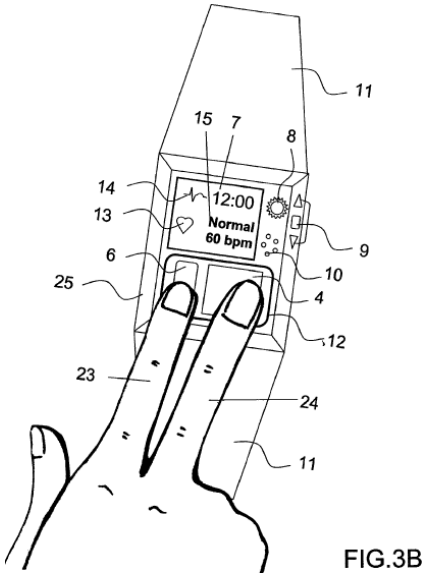


Figure 3B "demonstrate[s] how to place the wristwatch to make electrodes be contacted by both hands." *Id.* at 2:26–28, 3:5–22.

II. ANALYSIS

A. Legal Standards

"In an IPR, the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify "with particularity . . . the evidence that supports the grounds for the challenge to each claim")). This burden of persuasion never shifts to Patent Owner. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (discussing the burden of proof in *inter partes* review).

In *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), the Supreme Court reaffirmed the framework for determining obviousness set forth in *Graham v. John Deere Co.*, 383 U.S. 1 (1966). The *KSR* Court summarized the four factual inquiries set forth in *Graham* (383 U.S. at 17–18) that are applied in determining whether a claim is unpatentable as obvious under 35 U.S.C. § 103 as follows: (1) determining the scope and content of the prior art; (2) ascertaining the differences between the prior art and the claims at issue; (3) resolving the level of ordinary skill in the art; and (4) considering objective evidence indicating obviousness or non-obviousness, if present. *KSR*, 550 U.S. at 406.

"[W]hen a patent 'simply arranges old elements with each performing the same function it had been known to perform' and yields no more than one would expect from such an arrangement, the combination is obvious." *Id.* at 417 (quoting *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 282 (1976)). But in analyzing the obviousness of a combination of prior art elements, it can also be important to identify a reason that would have prompted one of skill

in the art "to combine . . . known elements in the fashion claimed by the patent at issue." *Id.* at 418. A precise teaching directed to the specific subject matter of a challenged claim is not necessary to establish obviousness. *Id.* Rather, "any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *Id.* at 420. Accordingly, a party that petitions the Board for a determination of unpatentability based on obviousness must show that "a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so." *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1381 (Fed. Cir. 2016) (quotations and citations omitted). Under the proper inquiry, "obviousness cannot be avoided simply by a showing of some degree of unpredictability in the art so long as there was a reasonable probability of success." *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1364 (Fed. Cir. 2007).

B. Level of Ordinary Skill in the Art

In determining the level of skill in the art, we consider the type of problems encountered in the art, the prior art solutions to those problems, the rapidity with which innovations are made, the sophistication of the technology, and the educational level of active workers in the field. *See Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986); *see also Orthopedic Equip. Co. v. United States*, 702 F.2d 1005, 1011 (Fed. Cir. 1983).

Petitioner asserts that a person of ordinary skill in the art would have been someone with

> at least a combination of [a] Bachelor's Degree (or a similar Master's Degree, or higher degree) in an academic area emphasizing health science, or a related field, and two or more years of work experience with cardiac monitoring technologies (e.g., as a cardiologist).

Ex. 1003 ¶ 10 (Dr. Chaitman testimony defining the POSA based on his "knowledge and experience in the field and [his] review of the '941 patent and file history") (cited at Pet. 10 n.3). Petitioner further contends that "[a]dditional education or industry experience may compensate for a deficit in one of the other aspects of the requirements stated above." *Id.*

In its Preliminary Response, Patent Owner took the position that one of ordinary skill in the art would have had "specialized engineering skills" including "a degree in biomedical or electrical engineering (or an equivalent), and/or extensive experience working with tools for detecting cardiac conditions." Prelim. Resp. 9 (citing Ex. 2001 ¶¶ 51–53). Although Patent Owner does not expressly define the person of ordinary skill in the art post-institution, it appears to argue that such a person would have an engineering degree or comparable experience. *See* PO Resp. 26 (arguing that "a cardiologist who is not an engineer 'lacks the necessary knowledge to develop a smartwatch with PPG or ECG sensors'"); Sur-reply 21 (similar); *but see* Tr. 39:20–40:12 (arguing that Patent Owner waived its opportunity to propose a definition).

In our Institution Decision, we noted that

> the research and development of medical devices is often the work of a multidisciplinary team, and courts and tribunals have frequently identified the hypothetical person of ordinary skill as a composite or team of individuals with complementary backgrounds and skills. *See, e.g.*, *AstraZeneca Pharm. LP v. Anchen Pharm., Inc.*, 2012 WL 1065458, at *19, *22 (D.N.J. Mar. 29, 2012), *aff'd*, 498 F. App'x 999 (Fed. Cir. 2013)

(collecting cases); *Apotex Inc. v. Novartis AG*, IPR2017-00854, Paper 109 at 10–11 (PTAB July 11, 2018) (collecting cases).

DI 25. We further determined such a team in the context of the '941 patent might include specialists in electrical engineering, mechanical engineering, biomedical engineering, computer science, and cardiology. *Id.* With respect to the last of these, we noted that because the '941 patent "relate[s] to, e.g., 'methods of cardiac monitoring" to "confirm a presence of [an] arrhythmia" it appeared reasonable that this hypothetical multidisciplinary team would include a cardiologist. *Id.* at 26 & n.9 (noting that the Lee-2013 reference is authored by a group comprised of three people Department of Biomedical Engineering at Worcester Polytechnic Institute, and two people from the Department of Medicine at the University of Massachusetts, Worcester); Ex. 1001, 1:30–33; *see also* Tr. 39:5–19 (Petitioner arguing that prior art Exhibits 1021, 1033, 1036, 1076–1078, 2024, and 2029 evidence "teams of people, medical doctors, cardiologists working together with engineers").

Patent Owner argues that we should reject our originally proposed definition in light of, for example, Petitioner's proposed definition before the ITC, which required an engineering background and "at least two years of relevant work experience designing wearable devices and/or sensors for measuring physiological signals." PO Resp. 27 (citing Ex. 2004, 6). As noted at oral argument, however, Patent Owner truncates the full extent of Petitioner's ITC definition, which further states that "a hypothetical person of ordinary skill in the art could also be a person with a medical degree (MD or DO) and with at least two years of work experience using biomedical sensors and/or analyzing their data (in the context of industry, in biomedical academic research, or in practice treating patients)." Ex. 2004, 6; Tr. 40:13–41:10. Patent Owner's assertion that our originally proposed definition,

would "classify all cardiologists as [persons of ordinary skill in the art]," is well taken. PO Resp. 25. Accordingly, we apply the following modified definition, which is consistent with Petitioner's representation before the ITC. For the purpose of this proceeding, a person of ordinary skill in the art may be a member of an interdisciplinary team including persons with backgrounds in electrical engineering, mechanical engineering, biomedical engineering, computer science, and/or cardiology, and having at least two years of relevant work experience designing, using, or analyzing data from, cardiac monitoring devices.

The parties' dispute regarding the definition of one of ordinary skill in the art relates to Dr. Chaitman's alleged lack of "specialized engineering skills," and the bases for Dr. Efimov's opinions on the meaning of "medical technology at-issue in this proceeding, such as 'irregular heart condition' and 'pathological state.'" *See e.g.*, PO Resp. 27–29; Reply 27–28. Neither party has sought to exclude expert testimony in this proceeding, and the arguments bear on the amount of weight we should accord the opinions of either expert. *See e.g.*, Tr. 49:22–52:21.

As discussed in our Institution Decision, Dr. Chaitman is a well-respected cardiologist with "extensive experience working with tools for detecting cardiac conditions," who would qualify as one of ordinary skill in the art even under Patent Owner's then-proposed definition. *See* DI 24–26. Despite Patent Owner's subsequent position that the ordinarily skilled artisan should have an engineering degree and "design experience" in developing wearable cardiac sensors, the arguments and evidence adduced at trial do not alter our initial determination regarding Dr. Chaitman's qualification to testify. DI 24–26 (our initial determination); PO Resp. 25–

29; Reply 27–28; Sur-reply 21–23; *see generally* Tr. 40:25–46:19. In this respect we agree with Petitioner's argument in support of Dr. Chaitman's qualifications, that this proceeding involves "piecing together known technologies and . . . the analysis of cardiac data" including PPG data, ECG data and activity level. Tr. 38:4–18. Thus, one of ordinary skill in the art with an understanding of cardiac monitoring technology "would understand how these types of data work, how they interplay and how the data could be processed on these devices." *Id.*

Dr. Efimov has extensive experience in the design of cardiac monitoring and related technologies, but Petitioner asserts that he "is unable to offer credible testimony on the meaning of [relevant] medical terminology," because he is not a doctor. Reply 28; Sur-reply 22 (arguing that "Dr. Efimov is a recognized expert in the field of clinical cardiac electrophysiology"). Considering the totality of Dr. Efimov's background, including extensive work on the physiology, diagnostics, and therapy of cardiac arrhythmias, we do not adopt Petitioner's position. *See*, *e.g.*, Ex. 2001 ¶¶ 2–15.

In light of the above, we determine that Dr. Chaitman and Dr. Efimov are both qualified to testify as to the understanding of a person of ordinary skill in the art, we, nevertheless, consider the weight of both parties' experts on a particular topic in light of the strengths and weaknesses of their respective background.

C. Claim Construction

We interpret a claim "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b)." 37 C.F.R. § 42.100(b). Under this standard, we construe the claim

"in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." *Id.* "[W]e need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy.'" *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Ltd.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

Petitioner offers a construction for the claim term "discordance," proposing that it should be construed to mean "when a first sensed parameter value would not be expected to coincide with a second sensed parameter value." Pet. 8–10. Patent Owner does not propose a competing construction and, in the ITC Investigation, proposed "[n]o construction required" for the term "discordance." Ex. 2009, 4. Having reviewed the evidence and argument of record, we determine that we do not need to construe the term "discordance" in order to resolve this dispute. *See Vivid Techs.*, 200 F.3d at 803 ("[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.").

Patent Owner identifies the term "arrhythmia" and the phrase "confirm the presence of arrhythmia" as needing construction. PO Resp. 22. For the term "arrhythmia," Patent Owner represents that during the ITC proceeding both parties "agreed" that a person of ordinary skill in the art would understand the term arrhythmia to be "a cardiac condition in which the electrical activity of the heart is irregular or is fast[er] or slower than normal." *Id.* at 23. Patent Owner cites intrinsic and extrinsic evidence supporting this construction and proposes that we adopt it here. *Id.* at

23–24. Petitioner does not address Patent Owner's proposed construction. *See generally* Reply; Tr. 21:18-22:3 ("[Board]: . . . Patent Owner raised the issue of claim construction for the term arrhythmia. Is there any dispute there? [Petitioner's counsel]: Honestly, Your Honor, we considered that -- put a lot of energy into considering it. We don't believe so."); *see also* Tr. 53:24–54:2 ("[Board]: . . . Your claim construction of arrhythmia is merely a matter of precision and clarification rather than a contested point; is that correct? [Patent Owner's counsel]: I believe that's largely correct.").

Patent Owner's proposed construction is consistent with the intrinsic and extrinsic evidence. *See e.g.*, Ex. 1047 (medical dictionary defining arrhythmias as "[a]n abnormal rate or rhythm of the heartbeat" caused by "a disturbance in the electrical impulses within the heart"); Ex. 1001, 4:4 ("Heart function is also measured in terms of regularity of rhythm. . . . When there is an abnormality of rhythm, the condition is typically referred to as an arrhythmia."). Although it is not clear that the term is in dispute, for clarity, we understand the term "arrhythmia" as used in the context of the '941 patent to mean: a cardiac condition in which the electrical activity of the heart is irregular or is faster (tachycardia) or slower (bradycardia) than normal.

As for the phrase "confirming the presence of arrhythmia," Patent Owner contends that this term should be given its plain meaning. PO Resp. 22. Petitioner does not address construction of this phrase (*see generally* Reply), and we do not see any need to construe it here. *See Vivid Techs.*, 200 F.3d at 803.

D. Ground 1: Obviousness over Shmueli

As Ground 1, Petitioner asserts that claims 1, 5, 7–9, 11, 12, 16, 18–20, 22, and 23 are unpatentable as obvious over the combination of Shmueli and Osorio. Pet. 11–65; *see id.* at 31–53 (claim 1), 54–60 (claims depending from claim 1), 60–63 (claim 12), 63–65 (claims depending from claim 12). Petitioner contends that the combination of Shmueli and Osorio discloses or renders obvious each element of claims 1, 5, 7–9, 11, 12, 16, 18–20, 22, and 23, and sets forth an element-by-element comparison of the asserted art to the challenged claims. Pet. 31–65. According to Petitioner, "Shmueli's wrist-mounted heart monitoring device detects an irregular heart condition (arrhythmia) based on PPG and ECG measurements" but "does not expressly account for a user's activity level." Pet. 20. Petitioner contends that it was "well-known that activity level is related to HR and HRV." *Id.* (citing evidence). Petitioner then points to Osorio as evidence of the "benefits (e.g., improved accuracy, reliability, and reduced false detection) of using activity level to detect an irregular heart condition." *Id.* (citing Ex. 1005 ¶¶ 29, 36). Petitioner contends that in view of these benefits, a person of ordinary skill in the art "would have been motivated to incorporate Osorio's activity sensor and activity level analysis techniques into Shmueli's heart monitoring device." *Id.* (citing Ex. 1005 ¶ 29; Ex. 1003 ¶ 69).

Petitioner contends that the person of ordinary skill in the art would have incorporated two specific teachings from Osorio in a modified version of Shmueli's device: "(i) using activity level monitoring to improve the accuracy of detecting a pathological event (e.g., arrhythmia), and (ii) determining HRV from HR and using HRV to detect the pathological event (e.g., arrhythmia)." *Id.*

Patent Owner contends that Ground 1 fails because 1) Petitioner has not shown that either Shmueli or Osorio teaches or suggests arrhythmia detection, 2) Petitioner has not shown that Shmueli renders obvious the use of ECG data to confirm the initial detection of an irregular heart condition using PPG data, and 3) Petitioner has not shown that a person of ordinary skill in the art would have been motivated to combine Shmueli and Osorio. PO. Resp. 39–56; Sur-reply 10–19. We address the contested matters below.

1) Arrhythmia Detection by Shmueli

Claim 1 requires "indicating to the user, . . . a possibility of an arrhythmia being present." Ex. 1001, 17:11–13. Claim 12, the only other independent claim, includes a similar limitation. *Id.* at 18:14–16. Although Shmueli does not explicitly use the term arrhythmia, it does disclose "detecting an irregular heart condition" using both PPG and ECG data. *See e.g.*, Ex. 1004, Abstract. Petitioner cites the testimony of Dr. Chaitman that arrhythmia is "one of the most obvious (if not the most obvious) types of 'irregular heart condition' that can be determined using PPG and ECG data." Ex. 1003 ¶ 55 (citing Ex. 1016, 6081, Ex. 1020, Abstract, 44:29–32, Ex. 1011, Abstract). Thus, according to Petitioner, a person of ordinary skill would have understood and/or found it obvious that the text "Detect Irregular Heart Condition," in element 38 of Shmueli's Figure 7, refers to detecting the presence of arrhythmia based on PPG data. *See* Pet. 14–15; Ex. 1003 ¶ 56–57.

Patent Owner argues that Ground 1 fails because Shmueli's reference to irregular heart conditions refers instead to "conditions traditionally detected using SpO_2 monitoring, such as heart attacks or acute heart failure." PO Resp. 39; *see* Ex. 2016 ¶ 61; Sur-reply 10–14 (more narrowly focusing on heart attack detection). Patent Owner raises three arguments supporting

its contention that "while an arrhythmia might be an irregular heart condition in the abstract, it cannot be an 'irregular heart condition' as that phrase is used in Shmueli." PO Resp. 40. First, Patent Owner argues that "Shmueli could be referring to practically any heart condition that includes an irregular heart condition . . . including: heart attack, angina pectoris, cardiomyopathy, congenital heart disease, . . . coronary heart disease, and heart-valve defect." *Id.* at 41–42 (citing Ex. 1047, 1023); *see also* Ex. 2016 ¶ 62. Second, Patent Owner argues that one of ordinary skill in the art would not understand Shmueli to refer to arrhythmias because "pulse oximetry was a well-known diagnostic tool for conditions affecting blood oxygen levels including cardiac conditions such as heart attacks" but "PPG was a 'sub-optimal' tool for measuring arrhythmias." *Id.* at 43 (citing Ex. 2018, 62:9–21; Ex. 2017, 53:13–54:4, Ex. 2016 ¶ 64; Ex. 2025). Third, Patent Owner points to Shmueli's disclosure that "instead of, or in addition to, the oximetry (SpO_2) measuring unit[,] the heart monitoring device may include a unit for measuring CO_2 content in the blood." PO Resp. 44 (citing Ex. 1004, 9); Sur-reply 13–14. According to Patent Owner, because CO_2 levels are "not used for arrhythmia detection but ***can*** be used to detect heart attacks or acute heart failure," Shmueli's disclosure of using CO_2 measurements "supports the conclusion that Shmueli is not directed at arrhythmia detection." PO Resp. 44 (citing Ex. 2016 ¶ 65). Patent Owner's arguments are unavailing for substantially the reasons set forth at pages 3–15 of Petitioner's Reply and as discussed below.

In general terms, SpO_2 refers to the oxygen content of blood and PPG (photoplethysmography) measures pulse.[10] *See* Ex. 1069, 81:8–13; Ex. 2001 ¶¶ 40–41. According to Dr. Efimov, an SpO_2 sensor detects changes in the color of blood (indicative of degree of oxygenation) using infra-red and red light emitting diodes; PPG (photoplethysmography) on the other hand, measures changes in reflected light as blood vessels pulsate with every heartbeat. Ex. 1069, 79:17–83:20; *see also* Ex. 2001 ¶ 40; Ex. 1003 ¶ 31. Unlike an SpO_2 sensor, PPG can, but does not necessarily require, that the light source is in the infra-red and red portion of the spectrum. Ex. 1069, 79:20–80:24, 83:15–16. But by combining the necessary sensors and using infra-red/red light emitting diodes, their features can be combined in a single device able to perform pulse oximetry, which measures both pulse rate and oxygen levels. *See id.* at 83:4–85:2 ("[T]his combination is an oximeter.").

Patent Owner, supported by the testimony of Dr. Efimov, focuses on Shmueli's reference to SpO_2, for example, in element 37 of Shmueli's figure 7. Taken strictly at face value, the instruction of element 37 to "Measure SPO_2" refers to the measurement of blood oxygen content, which, Patent Owner argues, may be used for monitoring signs of heart attack, but not arrhythmias. *See* PO Resp. 44–45; Tr. 62:1–10, 70:18–71:1, 73:18–74:6. But as Petitioner points out, Shmueli is not focused solely on monitoring blood oxygen content. *See, e.g.*, Reply 4–6; Ex. 1004, Title. We note in particular, that in describing the operation of Figure 7, Shmueli teaches that "the software program starts in element 37 by measuring SpO_2." Ex. 1004,

[10] As noted above, Shmueli discloses that "the terms 'oxygen saturation in the blood', 'blood oxygen saturation', 'pulse oximeter', oximetry, SpO_2, and photoplethysmography have the same meaning and may be used interchangeably." *See* Ex. 1004, 8.

12:9–10. Although Shmueli states that element 37 measures "oxygen saturation in the blood," it further states that the measurement is preferably executed using oximetry—which, as noted above, can measure pulse rate in addition to blood oxygen content. *See id.* at 12:10–13; *see also id.* at 8 ("Deriving heart beat rate from oximetry, as well as other artifacts of the heart activity and blood flow, is . . . known in the art."). Consistent with its title highlighting the use of "Pulse Oximetry Measurement," Shmueli states:

> The software program proceeds to element 38 to derive from the SpO_2 measurement physiological parameters such as pulse rate, pulse amplitude, pulse shape, rate of blood flow, etc. Then, the software program scans the derived physiological parameters to detect various irregularities of the heart condition.

Id. at 12:14–17; *see* Ex. 1069, 84:18–25.

Dr. Efimov tacitly admits that the above passage discloses that the "Measure SpO_2" command of Shmueli's element 37 measures pulse rate, amplitude and shape, thus, indicating the PPG functionality. Ex. 1069, 119:20–120:13. This type of heart rate data can be used to detect arrythmia. *See* Ex. 1069, 84:4–25, 120:6–13, 121:2–122:6; Ex. 2017, 90:5–12; Ex. 1003 ¶¶ 26–27, 31–32, 54, 56; Ex. 1061, 16:54–58[11] ("The signal that is collected from the SpO2 sensor may also optionally be used for producing other heart related information . . . such as heart rate, PWTT [pulse wave transit time], irregularity of heart rate etc.").

Accepting that the embodiment of Shmueli's Figure 7 was capable of detecting arrythmia using SpO_2/PPG data, we adopt Dr. Chaitman's reasoning that one of ordinary skill would have understood Shmueli's "irregular heart condition" to refer to—or at a minimum, render obvious—

[11] Goldreich, US 7,598,878 B2, issued Oct. 6, 2009.

arrhythmia, "one of the most obvious (if not the most obvious) types of 'irregular heart condition[s],'" as opposed to, for example, heart attack.[12] *See* Ex, 1003 ¶¶ 49–57; *see also* Pet. 13–15; Reply 3–9; Ex. 2016 ¶ 3; Tr. 15:9–12, 73:6–74:6.

Patent Owner also argues that, whereas ECG is the "gold standard" for arrythmia detection, "PPG was a 'sub-optimal' tool for measuring arrhythmias." *See* PO Resp. 25, 43; *see also id.* at 9–10, 25–26, 31; Ex. 2001 ¶ 41 (Dr. Efimov's statement that "PPG monitoring is reliable in measurements of oxygen saturation and average heart rate, but historically has been found to be less reliable in detecting arrhythmias, especially atrial arrhythmias. Compared to the traditional ECG data, heart rate estimation is more challenging based on the PPG-signal."); Ex. 2016 ¶ 16 (similar). But this is precisely the point of Shmueli, which combines the ease of use of the PPG sensor with a less convenient, but confirmatory, ECG. As stated by Petitioner, "Shmueli instructs a user to take an ECG when a problem is identified by SpO_2/PPG so that the ECG can confirm whether or not the SpO_2/PPG detection was accurate." Reply 2 (citing Pet. 15, 53; Ex. 1003 ¶¶ 57, 121; Ex. 1004, Abstract, 3:15–20, 9:21–29, 12:22–31, 14:16–29, Fig. 7). As Shmueli explains, this provides the benefit of "enabl[ing] a patient to perform ECG measurement as soon as an irregular heart activity develops and without requiring the ECG to be constantly wired to the patient," as with the more cumbersome implanted, tethered, or Holter devices. Ex. 1004, 2–3,

[12] Although Patent Owner argues that Shmueli's use of "irregular heart condition" potentially encompasses many conditions, we note that some of these (e.g., heart-valve defects, and congenital heart defects) are chronic conditions, and thus, not pertinent to Shmueli's detection of episodic events. Rather than attempt to parse the relevance of each, we focus on heart attack, as does Patent Owner. *See* Sur-reply 10–14; Tr. 64:1–10, 73:18–74:6.

8; Ex. 1003 ¶ 57; Ex. 2016 ¶ 7 ("Clinically, AFib is diagnosed by cardiologists using gold standard tool – 12 lead ECG, or Holter monitors and similar wearable or implantable devices.").

We also do not find persuasive Patent Owner's argument regarding Shmueli's disclosure that "instead of, or in addition to, the oximetry (SpO_2) measuring unit[,] the heart monitoring device may include a unit for measuring CO_2 content in the blood." *See* PO Resp. 44 (citing Ex. 1004, 9). Shmueli is relevant "for all that it teaches," and its brief reference to alternative embodiments does not change our understanding of either Figure 7 or Shmueli as a whole. *See In re Mouttet*, 686 F.3d 1322, 1331 (Fed. Cir. 2012).

In light of the above, and all the evidence adduced at trial, we agree with Petitioner that one of ordinary skill in the art would have understood Shmueli to disclose or render obvious a method of cardiac monitoring comprising "indicating to the user, . . . a possibility of an arrhythmia being present," as recited in independent claim 1[13]

2) *Arrhythmia Detection by Osorio*

Osorio discloses medical device systems and methods for detecting a pathological state of a patient by determining when a body data variability value, or "BDV," is outside of a "value range," and where the threshold levels of that range vary in response to the patient's physical activity level (measured by, e.g., an accelerometer), sleep/wake state, or other mental/emotional condition. *See* Ex. 1005, Abstract, ¶¶ 3–8, 28, 33, 35, 48, Fig. 4. Osorio states that "false negative and false positive detections of pathological events may be reduced by dynamically determining

[13] As noted above, independent claim 12 includes similar language.

pathological or non-pathological ranges for particular body indices based on activity type and level or other variables (e.g., environmental conditions)." *Id.* ¶ 36. Osorio discloses that among the body indices subject to BDV monitoring are "heart rhythm variability," "heart rate variability (HRV)," changes in heart rate, including tachycardia and bradycardia, and "the emergence of one or more cardiac arrhythmias." *Id*. ¶¶ 42, 43, 45, 46, 71; Ex. 1069, 61:13–16; Ex. 1003 ¶ 60.

Patent Owner argues that we should discount Osorio's express teachings to monitor heart rate for episodes of tachycardia, bradycardia, or other cardiac arrhythmias because the underlying "pathological state" at issue in Osorio is epilepsy, rather than arrhythmia. *See* PO Resp. 45–48; Sur-reply 14–16; Tr. 56:16–57:23 (Patent Owner's counsel arguing that any changes in heartbeat mentioned in Osorio are "in the context of a neurological condition"). Patent Owner's arguments are unavailing for a number of reasons.

First, to the extent Ground 1 relies on Osorio for arrhythmia detection, *per se*, it is invariably in combination with Shmueli. *See e.g.*, Pet. 20–31. Because we determine that Shmueli discloses or renders obvious arrhythmia detection, it is not necessary that we also find that disclosure in Osorio. *See* Section II.D.1, above.

Second, for essentially the reasons set forth in Petitioner's Reply, we do not read Osorio's "pathological state" as limited to neurological conditions. *See* Reply 15–18. We do not dispute that Osorio largely focuses on a particular neurological condition—epilepsy—as an exemplary pathological state. As noted by Petitioner, however, Osorio, consistently employs "permissive language to indicate that its teaching for epileptic

seizures are merely exemplary," and its five-paragraph introduction to the invention does not once mention epilepsy. Reply 15–16 (citing Ex. 1005 ¶¶ 2, 37, 46); *see also* Ex. 1005 ¶¶ 56, 57. Illustrative of Osorio's broad usage of pathological state, the reference discloses that "[a]n occurrence of *any pathological state* that may be associated with a body signal outside a non-pathological BDV range provided by analysis of the patient's activity level may be determined by the pathological state occurrence module." Ex. 1005 ¶ 44 (emphasis added).

We also agree with Petitioner that one of ordinary skill reading Osorio, including its claims, would also understand that its teachings are not limited to epilepsy. *See* Reply 16–17. In particular, Osorio's claim 1 is directed to "[a] method for detecting a pathological body state of a patient," whereas claim 7 limits the pathological state to an epileptic event. The same relationship is seen with claims 14 and 17 (limiting a pathological state of claim 14 to an epileptic event). Patent Owner's argument that the broader "pathological body state" recited in claims 1 and 14 should be limited to neurological states (Sur-Reply 15), is not consistent with our reading of Osorio's specification. To the contrary, our understanding of Osorio is consistent with Dr. Efimov's admission that one of ordinary skill in the art would, in general, understand pathological state to include arrhythmia. Ex. 1069, 51:17–52:10.

Third, even were we to read Osorio as narrowly drawn to the detection of epilepsy as Patent Owner urges, the reference, nonetheless, contains repeated teachings to monitor heart rate and heart rate variability for signs of arrhythmia. *See* Ex. 1005 ¶¶ 42, 43, 45, 46, 71; Ex. 1069, 58:9–59:3; (Dr. Efimov's agreement that Osorio discloses determining the

severity of a neurologic condition based, at least in part, on the identification of cardiac arrhythmia), 61:13–62:7 (Dr. Efimov's testimony that Osorio uses identification of cardiac arrhythmia to diagnosis a neurological pathological state). It is undisputed that a cardiac arrhythmia is a type of pathological condition. Ex. 1003 ¶ 61; Ex. 1069, 50:17–51:10. Patent Owner provides no persuasive explanation of why we should ignore Osorio's express teachings relating to the detection of cardiac arrhythmias, merely because Osorio also implicates them in detecting the pathological condition of epilepsy.

3) Confirmation Using ECG Data

Claim 1 requires "receiving electric signals of the user from an electrocardiogram sensor ('ECG') on the smartwatch to confirm a presence of the arrhythmia." Ex. 1001, 17:14–16. Independent claim 12 includes similar language. *Id.* at 18:18–19. As noted above, we find that Shmueli teaches or suggests "indicating . . . a possibility of an arrhythmia being present" based on PPG data. *See supra* § II.D.1. Patent Owner argues that "Petitioner relies exclusively on Shmueli for this 'confirm' limitation'" and that Ground 1 fails because Shmueli does not render obvious using ECG data to confirm that initial detection. PO Resp. 48–54. We do not find Patent Owner's arguments availing for the reasons set forth in the Petition, the Reply, and as discussed below.

Petitioner presents several lines of evidence supporting its contention that Shmueli renders the confirmation step obvious. Pet. 51–53; Reply 18–20. Petitioner argues, for example, "ECG is undisputedly the gold standard for detecting heart conditions, which makes it obvious that Shmueli's ECG measurements are used to confirm irregular heart conditions detected by its SpO_2/PPG measurements." Reply 18. Focusing on the flow chart of

Shmueli's Figure 7 (which was reproduced and discussed *supra* § I.H.1), Petitioner argues:

> A [person of ordinary skill in the art] would have understood and/or found obvious that the monitoring technique shown in Shmueli's Figure 7 contemplates using ECG data to confirm the initial detection of an irregular heart condition using PPG data. APPLE-1004, 8:24-29. This is because Shmueli criticizes other heart monitoring devices for "not consider[ing] a requirement to enable a patient to perform ECG measurement as soon as an irregular heart activity develops and without requiring the ECG to be constantly wired to the patient." *Id.*, 8:21-24. A [person of ordinary skill in the art] would have recognized that Shmueli's focus on enabling ECG measurements "as soon as" an irregular heart condition is detected enables ECG data to be used to confirm the detection of the irregular heart condition using PPG data, thereby improving detection accuracy compared to prior art heart monitoring devices. APPLE-1004, 13:16-21; APPLE-1003, ¶57.

Pet. 15; *see also id.* at 53.

Patent Owner, however, contends that "the mere fact of taking an ECG following a PPG does not discloses 'confirming.'" PO Resp. 49 (citing Ex. 2016 ¶ 74). Rather, Patent Owner contends, "***all*** detection of irregular heart conditions in Shmueli is by SpO_2 measurement" and Shmueli merely *notifies* the user that an ECG measurement is required. *Id.* at 49–50 (citing Ex. 1004, 11–14). Patent Owner notes that Petitioner incorrectly annotates Figure 7 to include the language "alerting said first user to sense an electrocardiogram," which language appears in the related '499 patent, but not in the challenged '941 patent. *Id.* at 51. According to Patent Owner, Petitioner has provided "no evidence that Figure 7 of Shmueli teaches 'confirm[ing] the presence of' an arrhythmia" and, "[i]n any case, Shmueli does not disclose 'confirming.'" *Id.* at 51 (citing Ex. 2016 ¶ 75). We do not find these arguments persuasive.

Shmueli sought to address a problem that prior art monitoring devices did not "enable a patient to perform ECG measurement as soon as an irregular heart activity develops and without requiring the ECG to be constantly wired to the patient." Ex. 1004, 8:21–32, 13:16–21. Shmueli addressed this problem by providing "a combined oximetry and electrocardiogram measuring system . . . in which the oximetry measurement is performed continuously and/or repeatedly, and the ECG measurement is triggered upon detection of an intermittent irregular heart-related event." *Id.* at 8:24-30. We do not agree with Patent Owner that Shmueli's improvement over the prior art was only to "provid[e] an ECG that does not have to be 'constantly wired to the patient.'" Pet. 49. Rather, we agree with Dr. Chaitman that Shmueli "improves detection accuracy compared to prior art heart monitoring devices" by "enabling ECG data 'as soon as' an irregular heart condition is detected," which allows "ECG data to be used to confirm the detection of the irregular heart condition using PPG data." Ex. 1003 ¶ 121. We thus credit Dr. Chaitman's testimony that the person of ordinary skill in the art would have found it obvious to use ECG, as taught by Shmueli, to confirm an irregular heart condition, such as an intermittently occurring arrhythmia. *Id.*

In addition, with reference to Figure 7, Shmueli explains that "the software program proceeds to element 50 to search for correlations between the SpO_2 signal and the ECG signal to produce new detection parameters, or modify existing detection parameters, so as to enhance the detection algorithms of the irregular heart conditions." Ex. 1004, 13. Shmueli further discloses that "[s]earching for correlation (element 50) can be executed in real-time (together with elements 37, 47 and 49) or later after the ECG

measurement is concluded." *Id.* Considering the relationship between elements 38, 39, and 50, and Shmueli's disclosures that the process may be conducted "in real-time" and that the process "enhance[s] detection algorithms of the irregular heart conditions," we agree with Petitioner that Figure 7 of Shmueli shows that the "ECG analysis (element 50) leads to new detection parameters (element 39) used for more accurate detection of the irregular heart condition (element 38) with SpO_2/PPG data." *See* Reply 20; Ex. 1004, Fig. 7, 13:16–21. In this respect we agree with Petitioner's assessment that the "Challenged Claims only require 'receiving' ECG data 'to confirm' arrhythmia, and thus, are broad enough to encompass confirmation with SpO_2/PPG data based on new parameters generated from analyzing ECG data." Reply 20–21. As such, we agree with Petitioner that Shmueli teaches or suggests "analyz[ing] ECG data to detect (and confirm) irregular heart conditions." *Id.* at 20.

In sum, we agree with Petitioner's characterization of how Shmueli confirms the presence of an irregular heart condition, such as arrhythmia:

> Shmueli works as follows: (1) continuously measuring SpO_2/PPG data; (2) measuring ECG data upon detecting an irregular heart condition; and (3) correlating SpO_2/PPG and ECG data to confirm presence of the irregular heart condition (directly through analysis of ECG data or indirectly through updates to detection parameters used for assessment of SpO_2/PPG data).

Reply 21 (citing Ex. 1003 ¶¶ 57, 121; Ex. 1004, 12:22–15:3, Fig. 7).

Patent Owner also argues that Shmueli's "ECG data is merely measured and stored" and that any "ECG analysis is performed off the device, after the data is sent to a remote server." PO Resp. 52 (citing e.g., Ex. 1004, 11–14; Ex. 2016 ¶ 78; 2017, 93:1–13). We do not find these arguments persuasive. Shmueli states that "the wrist-mounted heart

monitoring device preferably transmits to the remote server the collected data, such as the recorded ECG measurement," whereupon the "remote server preferably *further analyzes*" collected ECG data. *See* Ex. 1004, 14 (emphasis added). Shmueli's disclosure that ECG data may be transmitted to a remote server for *further* analysis presupposes that the data is first analyzed prior to transmission in this embodiment. In addition, Shmueli describes the embodiment represented in Figure 7 as "a simplified flow chart of a software program *preferably executed by the processor of the wrist-mounted heart monitoring device*." Ex. 1004, 7:6–7 (emphasis added). As such, the confirmation step embodied in elements 38, 39, and 50 preferably occurs locally. *See* Reply 23. Shmueli's teaching that, in a subsequent step, "[a]fter concluding the ECG measurement (element 54) the software program preferably proceeds to element 55 to communicate with a remote server," also indicates that the steps of confirming the presence of arrhythmia and stopping the ECG measurement may occur locally, and prior to communication with any remote server. *See* Ex. 1004, 14.

Patent Owner further argues that the ECG data is not involved in the confirming step because Shmueli's sole stop condition for the ECG measurement occurs when the SpO_2 sensor no longer detects an irregular heart condition. *See* PO Resp. 53. We agree with Petitioner, however, that Shmueli discloses that

> when an irregular heart condition is detected (element 40) and ECG measurement is initiated (element 41), the SpO_2 measurement (element 37) "***preferably*** continues," suggesting that the SpO_2 measurement may stop in some embodiments. APPLE-1004, 13:19-22. In these embodiments where SpO2 measurement has stopped, ECG is the only measurement that can be used to perform the operations described by Shmueli,

> including determining whether "the irregular heart condition has stopped." APPLE-1004, 14:22-29.

Reply 22; *see also* Tr. 19:21–21:2 (highlighting the relationship between element 54 ("Stop ECG") and element 38 ("Detect Irregular Heart Condition" using SPO_2/PPG). Considering the argument and evidence of record, we agree with Petitioner that, with respect to the stop condition, "Shmueli renders obvious 'confirmation' of the irregular heart condition based on ECG data" based its disclosure of "embodiments where the SpO_2 measurement does not continue." *Id.* at 22.

4) Reasons to Combine Shmueli and Osorio

Relying on the testimony of Dr. Chaitman, Petitioner argues that "it was well-known that activity level is related to HR and HRV and a [person of ordinary skill in the art] would have found it obvious to improve Shmueli's method by considering activity level." Pet. 20 (citing, *e.g.*, Ex. 1003 ¶ 69). Petitioner further points to Osorio as evidencing the benefits of using activity level to detect an irregular heart condition (e.g., improved accuracy, reliability, and reduced false detection). *Id.* (citing Ex. 1005 ¶¶ 29, 36). Accordingly, Petitioner contends, one of ordinary skill in the art "would have been motivated to incorporate Osorio's activity sensor and activity level analysis techniques into Shmueli's heart monitoring device." *Id.* (citing Ex. 1003 ¶ 69). Doing so would "improve[] the accuracy of detecting a pathological event (e.g., arrhythmia)" (*id.* (citing Ex. 1003 ¶ 70)), "resulting in improved user satisfaction since the user would have been less bothered by false detections." *Id.* at 31 (citing Ex. 1003 ¶84).

Petitioner similarly asserts that one of ordinary skill in the art "would have been motivated to incorporate Osorio's HRV analysis because processing HRV from R-R intervals of an ECG signal was known to be less

affected by noise compared to processing morphological features of the ECG signal." *Id.* at 25–26. According to Petitioner, a person of ordinary skill would have implemented this modification by incorporating Osorio's software modules into Shmueli's device, thus, "improv[ing] the pathological event detection capabilities compared to Shmueli's unmodified heart monitoring device." *Id.* at 26–28 (citing Ex. 1003 ¶¶ 78–81; Ex. 1005 ¶¶ 43, 53, 55, 56, 65, 66, 80; Ex. 1039, 52[14]). Supporting Petitioner's position, Dr. Chaitman testifies that one of ordinary skill in the art would have understood that modifying Shmueli's device to use Osorio's HRV analysis would have improved the detection of certain arrhythmias, particularly atrial fibrillation. *See* Ex. 1003 ¶ 80. Petitioner further argues that one of ordinary skill in the art would have found it obvious to combine the teachings of Shmueli and Osorio with a reasonable expectation of success. Pet. 24–25.

Patent Owner argues that one of ordinary skill in the art would not have been motivated to combine Shmueli with Osorio because the two references are directed to different problems: Shmueli to detecting heart conditions, and Osorio to detecting epileptic seizures. PO Resp. 54–56; Sur-reply 16–17. As such, Patent Owner argues, combining the two references would improperly change the basic principles under which the prior art was designed to operate or render the prior art inoperable for its intended purpose. *See* PO Resp. 59; Sur-reply 16–17 (citing, e.g., *Adidas AG v. Nike Inc.*, 963 F.3d 1355, 1359 (Fed. Cir. 2020) and *Nichia Corp v. Everlight Ams., Inc.,* 855 F.3d 1328, 1340 (Fed. Cir. 2017)). Patent Owner further

[14] Asl and Setarehdan, "*Support vector machine-based arrhythmia classification using reduced features of heart rate variability signal*," 44(1) Artif. Intell. Med. 51–64 (2008), Ex. 1039.

argues that, absent a finding that Osorio discloses detecting arrhythmias, "there can be no finding of obviousness, because with no arrhythmia detection there is no argument that a [person of ordinary skill in the art] would have been motivated to combine Shmueli and Osorio." PO Resp. 56 (citation omitted).

Patent Owner's arguments are unavailing for the reasons set forth on pages 23–25 of Petitioner's Reply, which we adopt in full. In short, Osorio relates to medical device systems and methods capable of detecting a pathological body state of a patient. Ex. 1005 ¶ 2. As discussed above, we do not read Osorio as limiting "pathological state" to epilepsy or other neurological conditions. To the contrary, one of ordinary skill in the art would have understood Osorio's teachings to be applicable to "any pathological state," including arrythmia. *See e.g.*, *id.* ¶ 44. As such, the references are not directed to different problems as Patent Owner urges.

Further, even if one of ordinary skill in the art were to read Osorio as limited to the detection neurological events such as epilepsy, Osorio contains express teachings to monitor heart rate and heart rate variability for signs of arrhythmia. *See* Ex. 1005 ¶¶ 42, 43, 45, 46, 71; Ex. 1069, 58:23–59:3; 61:13–62–7. Whether Osorio's detection of arrhythmias is viewed as a stand-alone goal, or as data for use in monitoring for epileptic seizures, does not materially affect the analysis. "Because Shmueli already renders arrhythmia detection obvious and Osorio motivates use of activity tracking to improve detection of any heart-related pathological conditions," including arrhythmias, it is irrelevant whether Osorio's ultimate goal is the detection of neurological events. *See* Reply 24.

With respect to Patent Owner's reliance on *Adidas*, it is well established that a finding of obviousness does not require that all features of a secondary reference are "bodily incorporated into the structure of the primary reference." *In re Keller*, 642 F.2d 413, 425 (CCPA 1981). "Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art." *Id*. (citation omitted). "[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill." *KSR*, 550 U.S. at 417. In the present case, we do not understand Petitioner to argue for the wholesale incorporation of Osorio into Shmueli's device. Rather, Petitioner more narrowly argues that one of ordinary skill in the art would find it obvious to incorporate two elements of Osorio into Shmueli's device: "(i) using activity level monitoring to improve the accuracy of detecting a pathological event (e.g., arrhythmia), and (ii) determining HRV from HR and using HRV to detect the pathological event (e.g., arrhythmia)." Pet. 20. Thus, even were Osorio ultimately limited to the detection of neurological events, we find unavailing Patent Owner's suggestion that these targeted improvements would render Shmueli's device inoperable for its intended purpose.

In view of the above, and all the argument and evidence adduced at trial, Petitioner has established sufficiently that one of ordinary skill in the art would have been motivated to combine Shmueli and Osorio with a reasonable expectation of success in arriving at the claimed invention.

5) Conclusion as to Ground 1

For the reasons set forth above, we find that the combination of Shmueli and Osorio discloses or renders obvious the arrhythmia detection

and confirmation recited in the challenged claims. We also find that one of ordinary skill in the art would have been motivated to combine the cited references with a reasonable expectation of success in arriving at the challenged claims. Patent Owner does not specifically challenge any other aspect of Petitioner's showing with respect to Ground 1. Having reviewed the argument and evidence of record, we find that Petitioner has shown by a preponderance of the evidence that claims 1, 5, 7–9, 11, 12, 16, 18–20, 22, and 23 are unpatentable as obvious in view of Shmueli and Osorio.

E. Ground 2: Obviousness over Shmueli, Osorio, and Lee-2013

Petitioner challenges claims 2–4, 6, 13–15, and 17 as obvious over the combination of Shmueli, Osorio, and Lee-2013. Pet. 65–72. Petitioner contends that the combination of Shmueli, Osorio, and Lee-2013 discloses or renders obvious each element of claims 2–4, 6, 13–15, and 17, and sets forth an element-by-element comparison of the asserted art to the challenged claims. Pet. 68–72; *see also id.* at 31–53 (for elements of independent claim 1) and 60–63 (for elements of independent claim 12). Claims 2–4 and 6 depend from claim 1 while claims 13–15 and 17 depend from claim 12. Claims 2–4 and 13–15 additionally recite, *inter alia*, that the arrhythmia is atrial fibrillation. Claim 6 and 17 additionally recite that the arrhythmia is selected from a group comprising three different arrhythmias, one of which is AF.

According to Petitioner, "Shmueli and Osorio each describe[] techniques for generally detecting arrhythmias, but do not address detection of specific types of arrhythmias, such as AF." Pet. 66. Petitioner contends that "AF detection was well-known by the Critical Date, as demonstrated by Lee-2013." *Id.* Petitioner contends that the person of ordinary skill "would

have been motivated to incorporate Lee-2013's AF detection techniques into the Shmueli-Osorio device . . . since Lee-2013 teaches that '[a]trial fibrillation is the most common sustained arrhythmia'" and "incorporating AF detection into the Shmueli-Osorio device [would] provide[] a new capability for classifying an arrhythmia." *Id.* (citing Ex. 1011, 26; Ex. 1003 ¶ 152). Petitioner asserts that a person of ordinary skill in the art would have had "a reasonable expectation of success in implementing the Shmueli-Osorio-Lee-2013 device since the combination involves using a well-known diagnostic technique (detecting AF) using well-known data (PPG data, which is disclosed in each reference) and well-known statistical techniques for AF assessment (RMSSD, ShE, SampE)." *Id.* at 67–68 (citing Ex. 1003 ¶ 154; Ex. 1011, Abstract; Ex. 1004, 11:16–18).

Patent Owner argues that Lee-2013 teaches to use a smartphone camera to detect PPG and expressly teaches that this is advantageous because it "does not involve a separate ECG sensor and instead employs built-in hardware," making it "cost-effective" and "novel." PO Resp. 56–57 (quoting Ex. 2017, 29). According to Patent Owner, the person of ordinary skill in the art "would not have been motivated to incorporate Lee 2013 into a device including an ECG sensor in the face of a clear disclosure that the benefit of Lee 2013 is derived from not using such a sensor." *Id.* at 57 (citing Ex. 2016 ¶ 86). In addition, Patent Owner argues that Lee-2013 discloses detecting AF using PPG data while the claims require using an ECG to confirm the presence of arrhythmia. Patent Owner asserts that Petitioner "does not even argue that any of the prior art discloses confirming [AF] using ECG data." *Id.*

1) Detecting and Confirming Atrial Fibrillation

The evidence of record supports that there are 8 kinds of arrhythmia, of which atrial fibrillation is the most common. Ex. 1016, 6080 ("There are 8 kinds of arrhythmia according to the Minnesota code that is widely used in the clinical field"); Ex. 1011, 26 (Lee-2013, disclosing that "[a]trial fibrillation is the most common sustained arrhythmia"); Ex. 1069, 23:5–9 (Dr. Efimov's testimony agreeing that "atrial fibrillation is the most common cardiac arrhythmia present"). We agree with, and credit, the testimony of Dr. Chaitman that, "[g]iven the prominence of AF, a [person of ordinary skill in the art] would have recognized that incorporating AF detection into the Shmueli-Osorio device provides a new capability for classifying an arrhythmia as AF" and "been motivated to incorporate Lee-2013's AF detection techniques into the Shmueli-Osorio device." Ex. 1003 ¶ 152. We further agree with Dr. Chaitman that the combined Shmueli-Osorio-Lee-2013 device would provide an improvement over Lee-2013's technique because it provides wrist-mounted detection "without requiring the user to carry a separate mobile device" and because it "improves the accuracy of AF detection provided be Lee-2013 alone since the Shmueli-Osorio-Lee-2013 device uses ECG data to confirm AF detection based on PPG data." *Id.* ¶¶ 152, 153.

We recognize that Lee-2013 touts that its application is "novel and cost effective" because it "does not involve a separate ECG sensor and instead employs built-in hardware." Ex. 1011, 29. But, we do not interpret this disclosure as teaching away from the use of ECG sensors because it does not disparage ECG sensors, particularly where the ECG sensor is part of the built-in hardware, as in Shmueli, rather than a separate device. Ex. 1004, Fig. 4 (Figures 1A, 1B of Shmueli, showing a wrist-mount heart

monitoring device having three ECG electrodes 14 and a PPG sensor 13); *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1364 (Fed. Cir. 2006) ("We will not read into a reference a teaching away from a process where no such language exists."). Nor does this disclosure diminish the motivation to combine Lee-2013 with Shmueli and Osorio because the benefits of the combination (a new capacity in the Shmueli-Osorio device for classifying arrhythmia as AF and improved accuracy of AF detection as compared to Lee-2013 alone) can be obtained without compromising the benefit of Lee-2013 – that it does not "involve a *separate* ECG sensor." Ex. 1011, 29 (emphasis added). Specifically, AF can be detected using the built-in PPG sensor already present in Shmueli. *See* Ex. 1003 ¶ 154 (discussing implementation of the proposed Shmueli-Osorio-Lee-2013 device).

As for Patent Owner's argument that the prior art does not disclose confirming AF using an ECG, we find that the evidence of record supports that such confirmation would have been obvious. Dr. Chaitman testifies that using "ECG data to confirm AF detection based on PPG data" would "improve[] the accuracy of AF detection provided by Lee-2013 alone." Ex. 1003 ¶ 153; *see also* Pet. 67. This testimony is consistent with the evidence that ECG is better at detecting arrhythmia than PPG and, absent persuasive evidence to the contrary, we credit it. *See* PO Resp. 25–26 ("In the clinical setting, there is no dispute that even today, ECG is the gold standard while PPG is a suboptimal replacement"). The evidence of record thus supports 1) that AF is the most common form of arrhythmia, 2) that it was known to use a single device comprising both ECG and PPG sensors to detect a possible arrhythmia (using PPG) and confirm the presence of

arrhythmia (using ECG), and 3) that using ECG data to confirm AF detected using PPG data improves the accuracy of AF detection as compared to a system that uses only PPG data. Accordingly, we agree with Petitioner that it would have been obvious to detect a possible arrhythmia using PPG and confirm the presence of arrhythmia using ECG, wherein the arrhythmia is the most common form of arrhythmia, atrial fibrillation. *KSR*, 550 U.S. at 421 ("A person of ordinary skill is also a person of ordinary creativity, not an automaton.").

2) Conclusion as to Ground 2

For the reasons set forth above, we find that the combination of Shmueli, Osorio, and Lee-2013 discloses or renders obvious the method of claim 1 and the smartwatch of claim 12, wherein the arrythmia is atrial fibrillation. We also find that one of ordinary skill in the art would have been motivated to combine the cited references with a reasonable expectation of arriving at the challenged claims. Patent Owner does not specifically challenge any other aspect of Petitioner's showing with respect to Ground 2, other than arguing that Ground 2 fails for the same reasons it argues that Ground 1 fails. *See* PO Resp. 39–56 (consolidating arguments). For the reasons discussed *supra* § II.D, we are not persuaded by Patent Owner's arguments that Ground 1 fails. Having reviewed the argument and evidence of record, we find that Petitioner has shown by a preponderance of the evidence that claims 2–4, 6, 13–15, and 17 are unpatentable as obvious in view of Shmueli, Osorio, and Lee-2013.

F. Ground 3: Obviousness over Shmueli, Osorio, and Chan

As Ground 3, Petitioner challenges claims 10 and 21 as obvious over Shmueli, Osorio, and Chan. Pet. 72–77. Petitioner provides an element-by-

element comparison of the asserted art to the challenged claims. *Id.* Patent Owner presents no arguments with respect to Ground 3 that have not been discussed above. *See* PO Resp. 39–56 (consolidating arguments). Having reviewed the argument and evidence of record, we find that Petitioner has shown by a preponderance of the evidence that claims 10 and 21 are unpatentable as obvious over Shmueli, Osorio, and Chan.

III. PATENT OWNER'S MOTION TO EXCLUDE

Patent Owner moved to exclude Petitioner's Exhibits 1060–1068, and 1072–1085. Mot. 1. Patent Owner withdrew its motion at oral argument with respect to Exhibits 1072, 1073, 1075, and 1082. Tr. 78:19–79:15–16, 99:18–23. Of the remaining exhibits, we cite herein only to Exhibit 1061.

Patent Owner challenges Exhibit 1061 as "new evidence . . . not properly raised in Reply." Mot. 1; Sur-reply 3. Patent Owner's argument is unavailing. Petitioner properly employed it in the Reply in responding to Patent Owner's argument that one of ordinary skill in the art would not understand Shmueli's recitation of "irregular heart condition" to indicate arrhythmia. *See* Reply 10–11; *see also* Pet. vi (listing Ex. 1061); *Anacor Pharm., Inc. v. Iancu*, 889 F.3d 1372, 1380–81 (Fed. Cir. 2018) (stating that a "petitioner in an inter partes review proceeding may introduce new evidence after the petition stage if the evidence is a legitimate reply to evidence introduced by the patent owner"). We, therefore, deny the motion with respect to Exhibit 1061.

Because we do not specifically rely on any other challenged exhibit, we dismiss that portion of Patent Owner's motion as moot.

IV. CONCLUSION

Petitioner has shown, by a preponderance of the evidence, that claims 1–23 are unpatentable under § 103 as obvious in view of combinations of Shmueli, Osorio, Lee-2013, and Chan as summarized below:[15]

Claims	35 U.S.C. §	Reference(s) /Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1, 5, 7–9, 11, 12, 16, 18–20, 22, 23	103	Shmueli, Osorio	1, 5, 7–9, 11, 12, 16, 18–20, 22, 23	
2–4, 6, 13–15, 17	103	Shmueli, Osorio, Lee-2013	2–4, 6, 13–15, 17	
10, 21	103	Shmueli, Osorio, Chan	10, 21	
Overall Outcome			1–23	

[15] Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this Decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding. See* 84 Fed. Reg. 16654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. § 42.8(a)(3), (b)(2).

V. ORDER

ORDERED, that claims 1–23 of the '941 patent are held to be unpatentable;

FURTHER ORDERED that Patent Owner's Motion to Exclude Evidence is dismissed as moot;

FURTHER ORDERED that because this is a Final Written Decision, parties to this proceeding seeking judicial review of our decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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US009572499B2

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

(10) **Patent No.: US 9,572,499 B2**
(45) **Date of Patent: *Feb. 21, 2017**

(54) **METHODS AND SYSTEMS FOR ARRHYTHMIA TRACKING AND SCORING**

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(73) Assignee: **ALIVECOR, INC.**, San Francisco, CA (US)

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

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **14/730,122**

(22) Filed: **Jun. 3, 2015**

(65) **Prior Publication Data**

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(Continued)

(51) **Int. Cl.**
A61B 5/02 (2006.01)
A61B 5/04 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61B 5/02055*** (2013.01); ***A61B 5/0022*** (2013.01); ***A61B 5/0245*** (2013.01);
(Continued)

(58) **Field of Classification Search**
USPC 600/508–509
See application file for complete search history.

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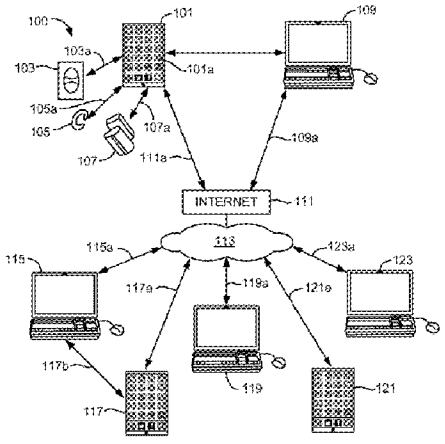
(57) **ABSTRACT**

A dashboard centered around arrhythmia or atrial fibrillation tracking is provided. The dashboard includes a heart or cardiac health score that can be calculated in response to data from the user such as their ECG and other personal information and cardiac health influencing factors. The dashboard also provides to the user recommendations or goals, such as daily goals, for the user to meet and thereby improve their heart or cardiac health score. These goals and recommendations may be set by the user or a medical professional and routinely updated as his or her heart or
(Continued)



cardiac health score improves or otherwise changes. The dashboard is generally displayed from an application provided on a smartphone or tablet computer of the user.

20 Claims, 16 Drawing Sheets

Related U.S. Application Data

(60) Provisional application No. 61/915,113, filed on Dec. 12, 2013, provisional application No. 61/953,616, filed on Mar. 14, 2014, provisional application No. 61/969,019, filed on Mar. 21, 2014, provisional application No. 61/970,551, filed on Mar. 26, 2014, provisional application No. 62/014,516, filed on Jun. 19, 2014.

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A61B 5/024	(2006.01)
A61B 5/0245	(2006.01)
A61B 5/046	(2006.01)
A61B 5/00	(2006.01)
A61B 5/021	(2006.01)
A61B 5/0452	(2006.01)
A61B 5/11	(2006.01)
G06F 19/00	(2011.01)

(52) **U.S. Cl.**

CPC ***A61B 5/02405*** (2013.01); ***A61B 5/02416*** (2013.01); ***A61B 5/046*** (2013.01); ***A61B 5/6898*** (2013.01); ***A61B 5/7264*** (2013.01); ***A61B 5/7275*** (2013.01); ***G06F 19/3418*** (2013.01); *A61B 5/021* (2013.01); *A61B 5/02438* (2013.01); *A61B 5/0452* (2013.01); *A61B 5/1118* (2013.01); *A61B 5/681* (2013.01); *G06F 19/322* (2013.01); *G06F 19/3487* (2013.01)

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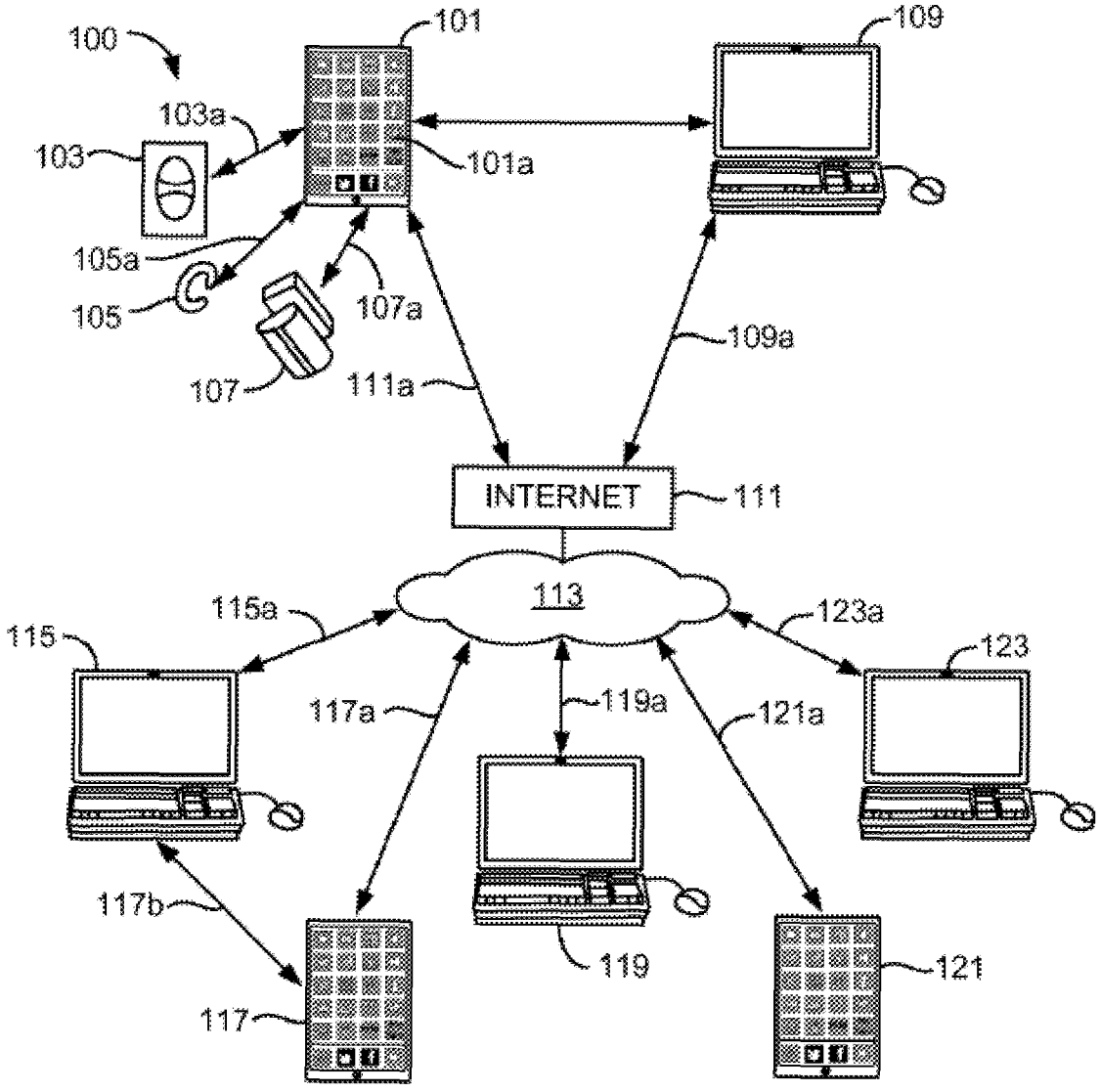
100
101
109
103a
103
101a
105a
105
107a
107
109a
111a
INTERNET
111
113
115a
123a
115
123
117a
119a
121a
117b
119
121
117

FIG. 1

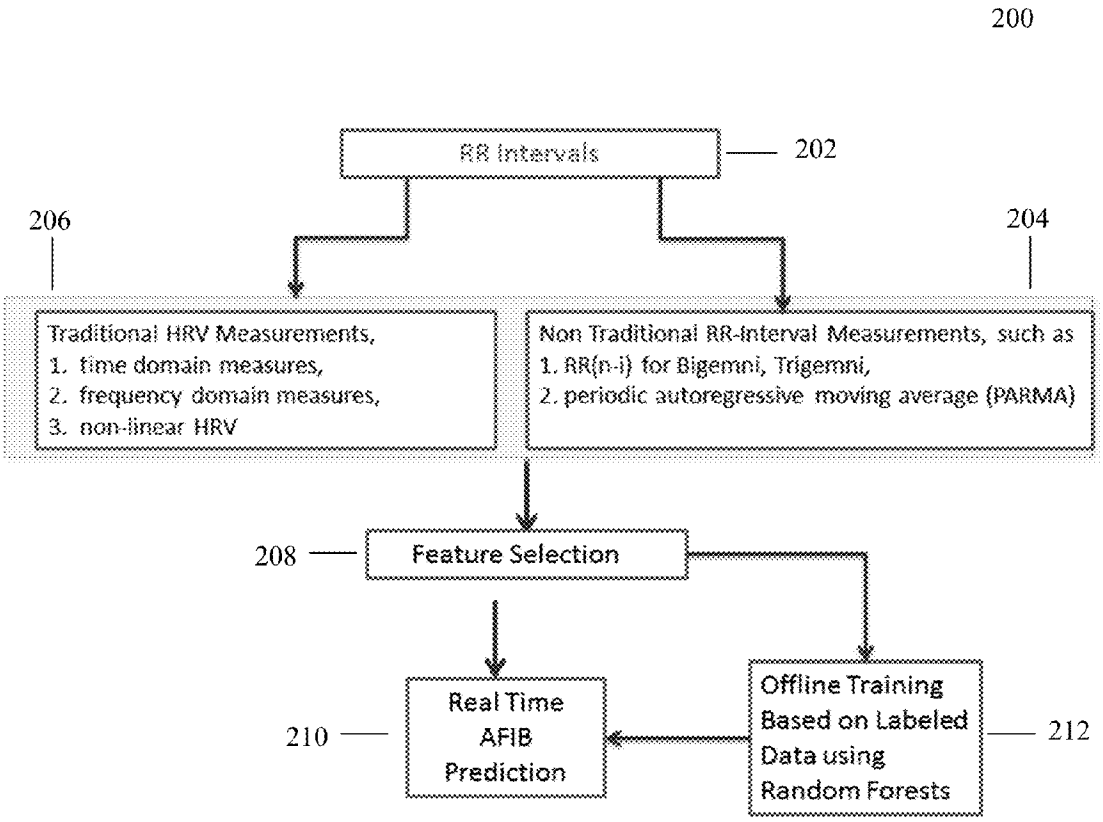
200
RR Intervals
202
206
204
Traditional HRV Measurements,
1. time domain measures,
2. frequency domain measures,
3. non-linear HRV
Non Traditional RR-Interval Measurements, such as
1. RR(n-i) for Bigemni, Trigemni,
2. periodic autoregressive moving average (PARMA)
208
Feature Selection
Real Time
AFIB
Prediction
210
Offline Training
Based on Labeled
Data using
Random Forests
212

FIG. 2

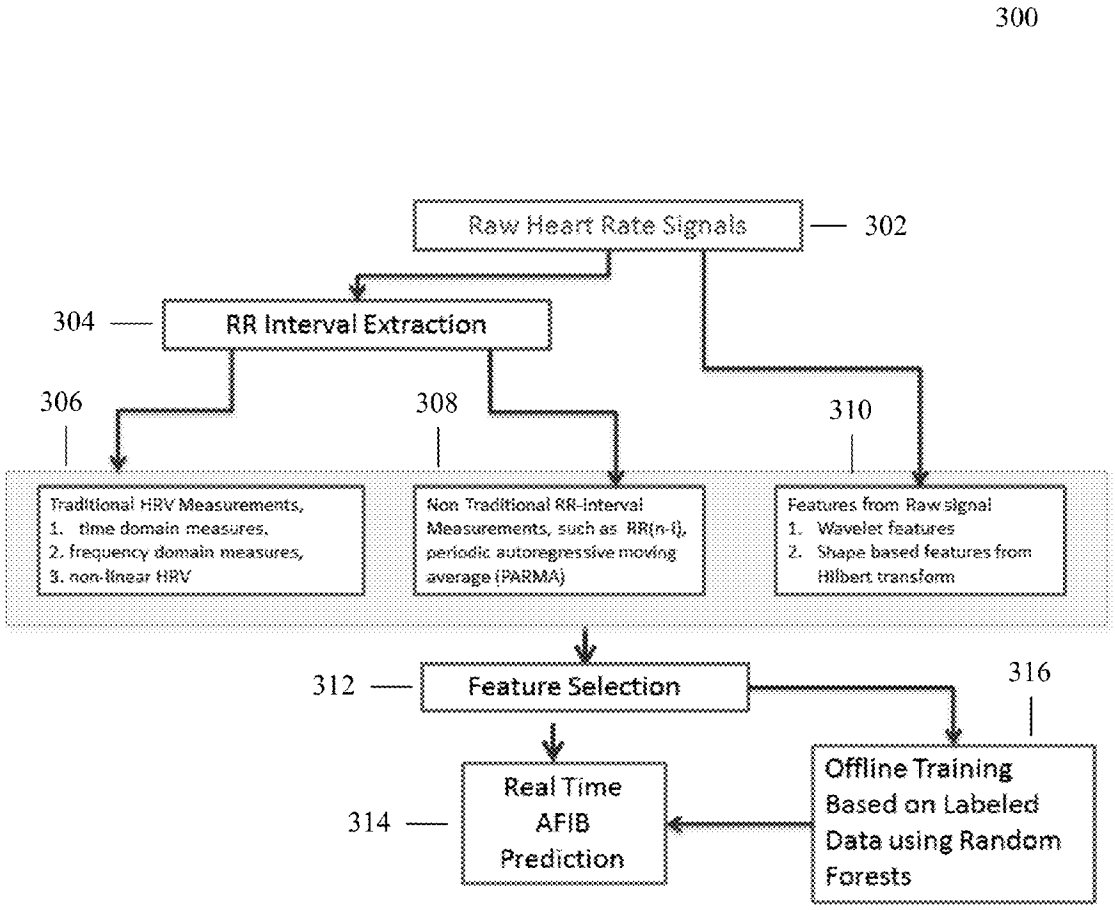
300
Raw Heart Rate Signals
302
304
RR Interval Extraction
306
308
310
Traditional HRV Measurements,
1. time domain measures,
2. frequency domain measures,
3. non-linear HRV
Non Traditional RR-interval Measurements, such as RR(n-i), periodic autoregressive moving average (PARMA)
Features from Raw signal
1. Wavelet features
2. Shape based features from Hilbert transform
312
Feature Selection
316
314
Real Time AFIB Prediction
Offline Training Based on Labeled Data using Random Forests

FIG. 3

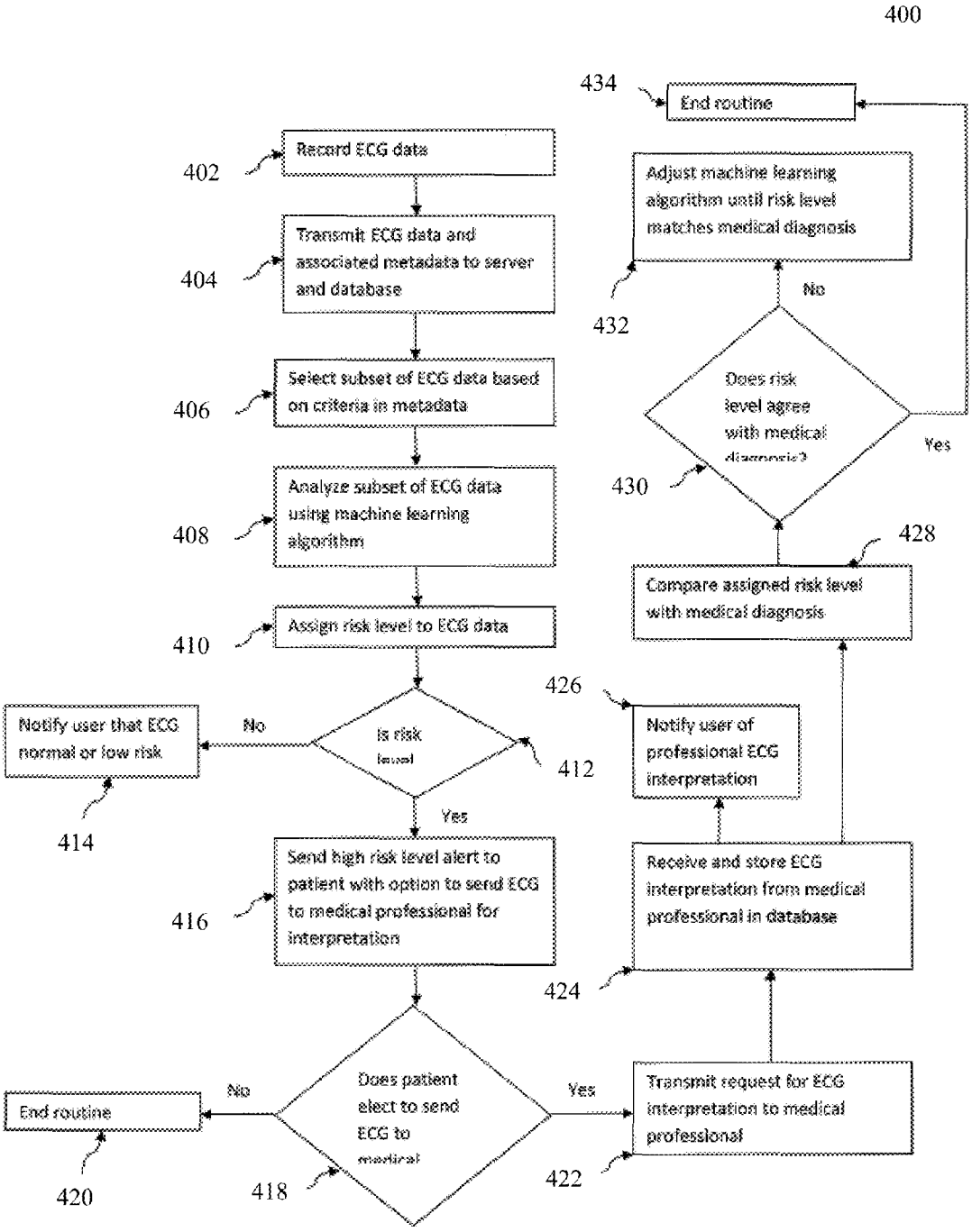
400
434
End routine
Record ECG data
402
Adjust machine learning algorithm until risk level matches medical diagnosis
Transmit ECG data and associated metadata to server and database
404
No
432
Select subset of ECG data based on criteria in metadata
406
Does risk level agree with medical
Yes
Analyze subset of ECG data using machine learning algorithm
408
430
428
Compare assigned risk level with medical diagnosis
Assign risk level to ECG data
410
426
Notify user that ECG normal or low risk
No
Is risk
412
Notify user of professional ECG interpretation
414
Yes
Send high risk level alert to patient with option to send ECG to medical professional for interpretation
416
Receive and store ECG interpretation from medical professional in database
424
Does patient elect to send ECG to
No
Yes
Transmit request for ECG interpretation to medical professional
End routine
420
418
422

FIG. 4

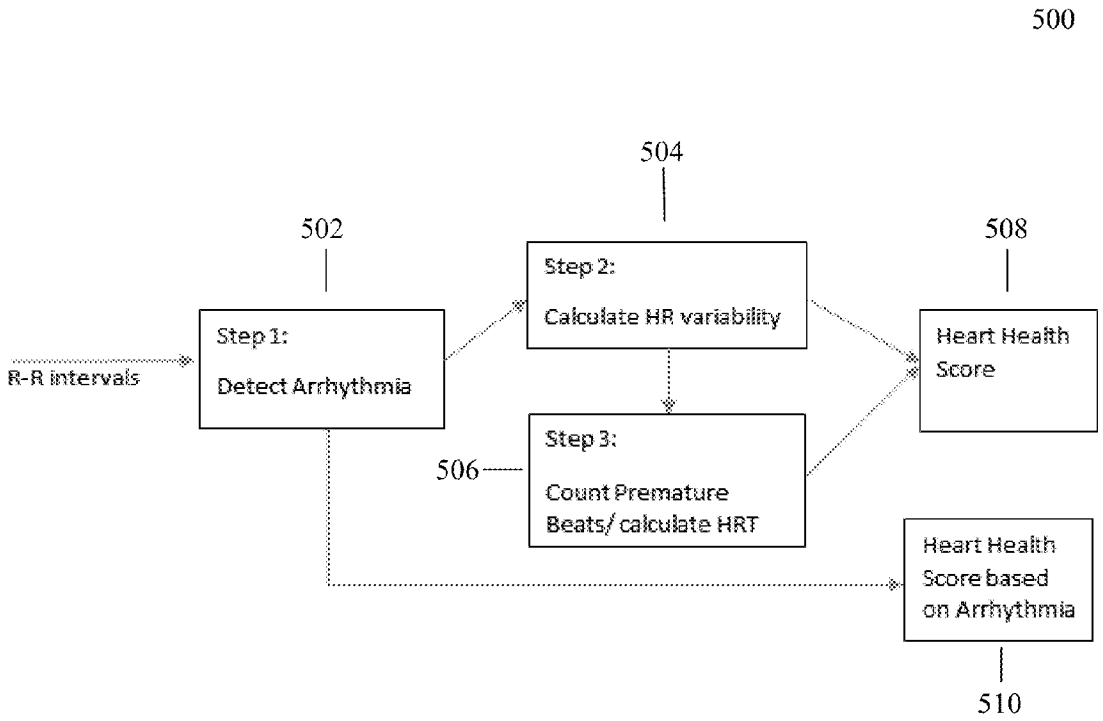
500
504
502
508
Step 2:
Calculate HR variability
Step 1:
Detect Arrhythmia
R-R intervals
Heart Health
Score
506
Step 3:
Count Premature
Beats/ calculate HRT
Heart Health
Score based
on Arrhythmia
510

FIG. 5

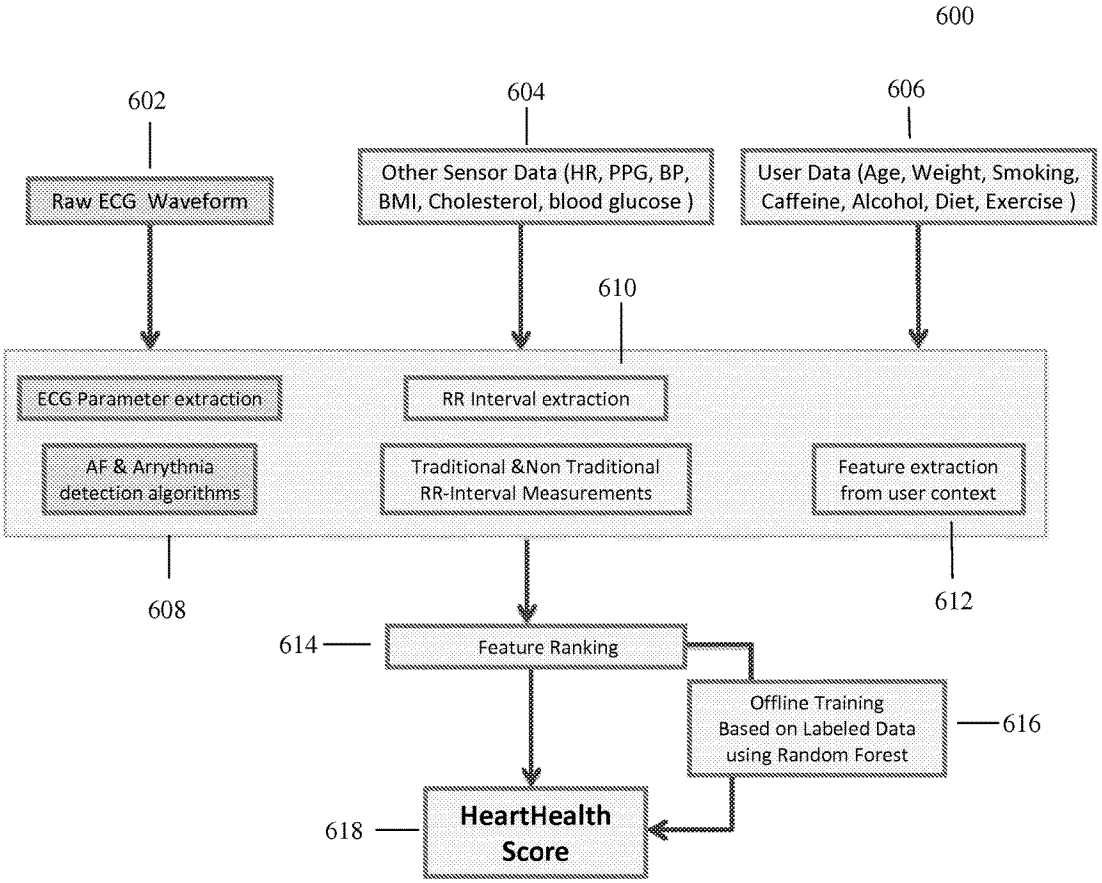
600
602
604
606
Raw ECG Waveform
Other Sensor Data (HR, PPG, BP, BMI, Cholesterol, blood glucose)
User Data (Age, Weight, Smoking, Caffeine, Alcohol, Diet, Exercise)
610
ECG Parameter extraction
RR Interval extraction
AF & Arrythnia detection algorithms
Traditional &Non Traditional RR-Interval Measurements
Feature extraction from user context
608
612
614
Feature Ranking
Offline Training Based on Labeled Data using Random Forest
616
618
HeartHealth Score

FIG. 6

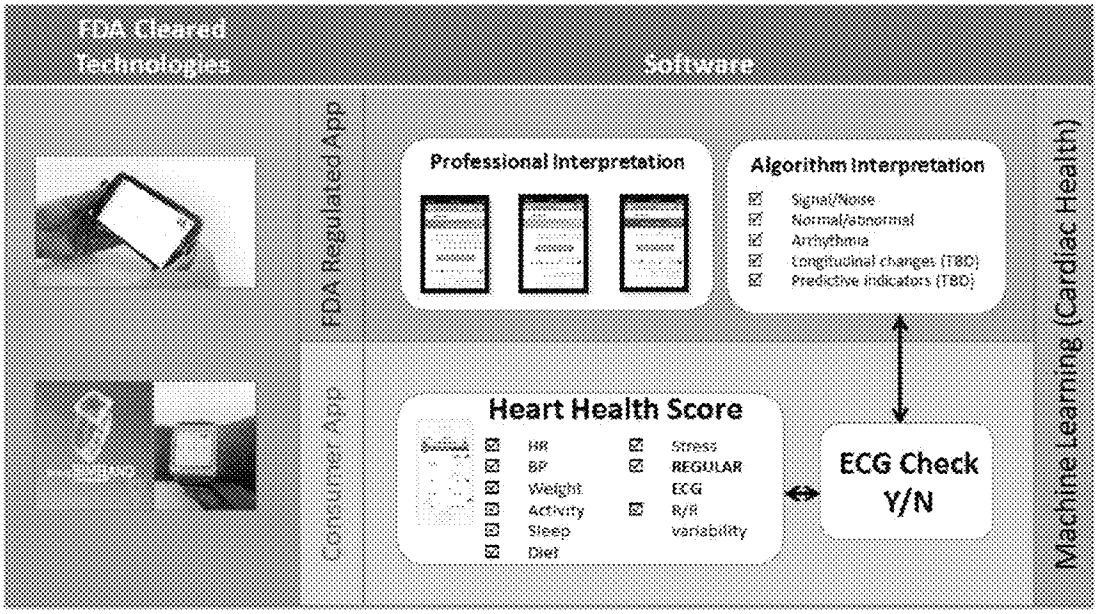
FDA Cleared Technologies
Software
FDA Regulated App
Consumer App
Machine Learning (Cardiac Health)
Professional Interpretation
Algorithm Interpretation
Signal/Noise
Normal/abnormal
Arrhythmia
Longitudinal changes (TBD)
Predictive indicators (TBD)
Heart Health Score
HR
BP
Weight
Activity
Sleep
Diet
Stress
REGULAR ECG
R/R variability
ECG Check Y/N

FIG. 7

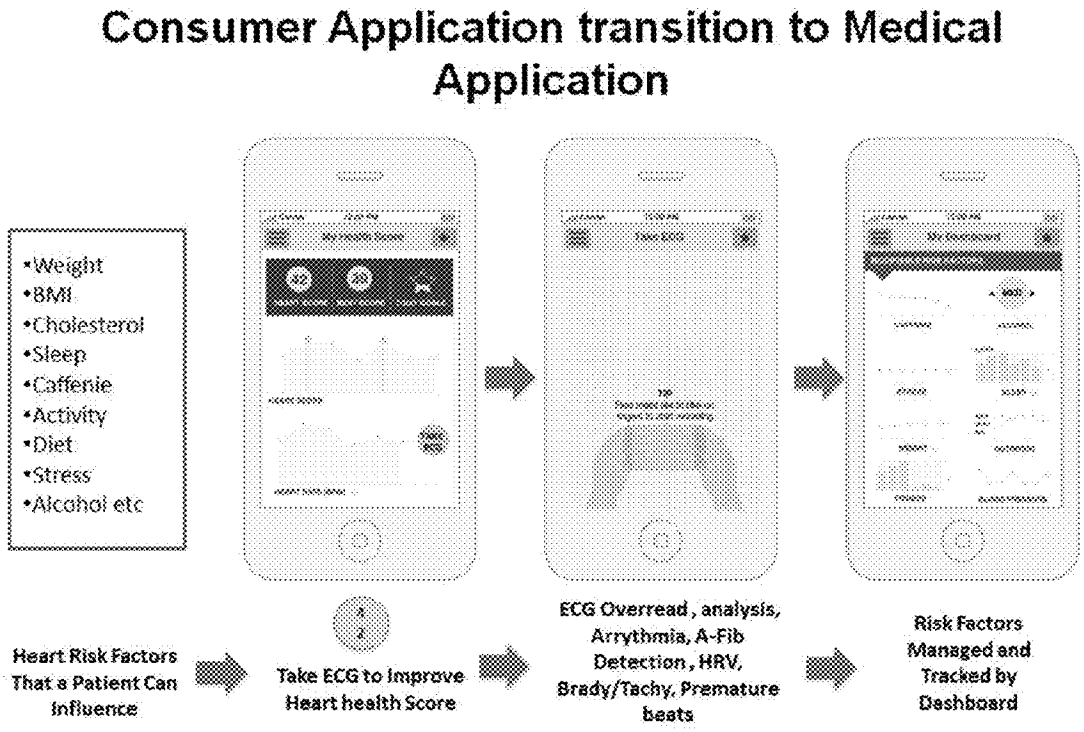
Consumer Application transition to Medical Application
•Weight
•BMI
•Cholesterol
•Sleep
•Caffenie
•Activity
•Diet
•Stress
•Alcohol etc
Heart Risk Factors That a Patient Can Influence
Take ECG to Improve Heart health Score
ECG Overread , analysis, Arrythmia, A-Fib Detection , HRV, Brady/Tachy, Premature beats
Risk Factors Managed and Tracked by Dashboard

FIG. 8

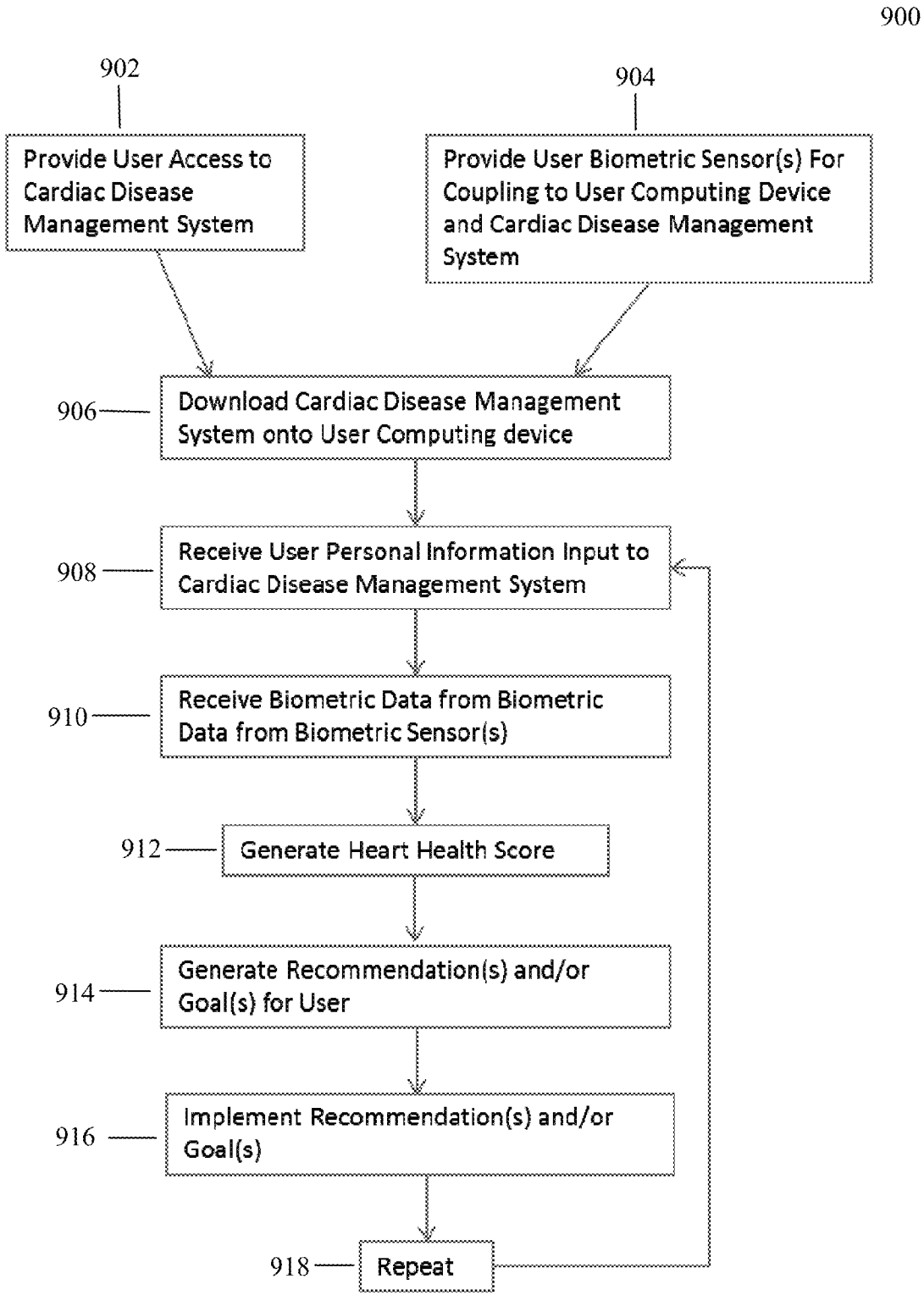
900
902
Provide User Access to Cardiac Disease Management System
904
Provide User Biometric Sensor(s) For Coupling to User Computing Device and Cardiac Disease Management System
906
Download Cardiac Disease Management System onto User Computing device
908
Receive User Personal Information Input to Cardiac Disease Management System
910
Receive Biometric Data from Biometric Data from Biometric Sensor(s)
912
Generate Heart Health Score
914
Generate Recommendation(s) and/or Goal(s) for User
916
Implement Recommendation(s) and/or Goal(s)
918
Repeat

FIG. 9

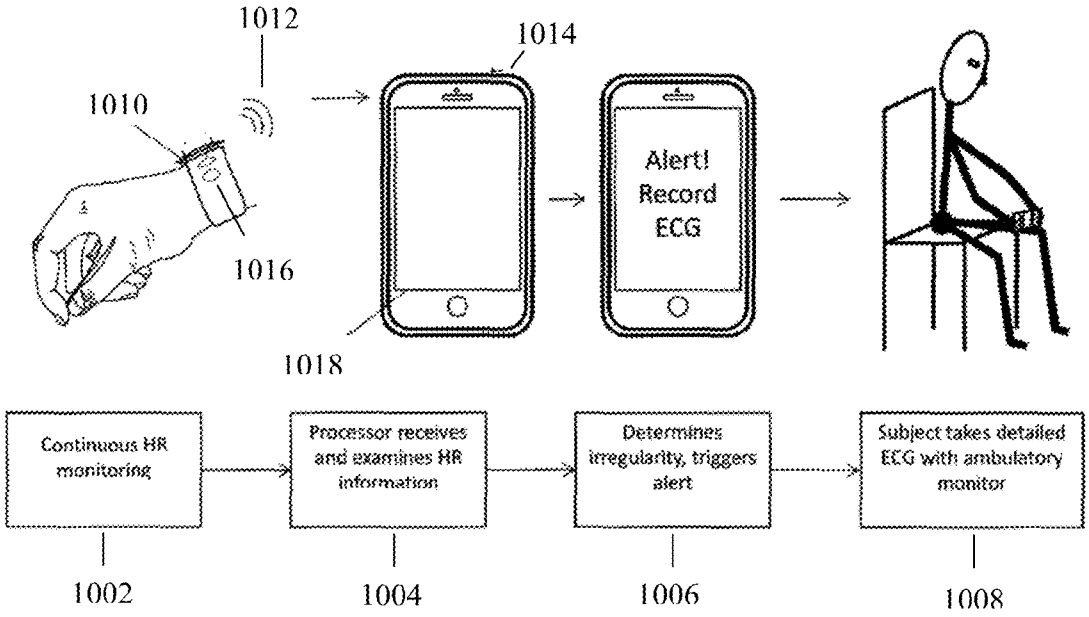
1012
1014
1010
1016
1018
Alert!
Record
ECG
Continuous HR monitoring
Processor receives and examines HR information
Determines irregularity, triggers alert
Subject takes detailed ECG with ambulatory monitor
1002
1004
1006
1008

FIG. 10

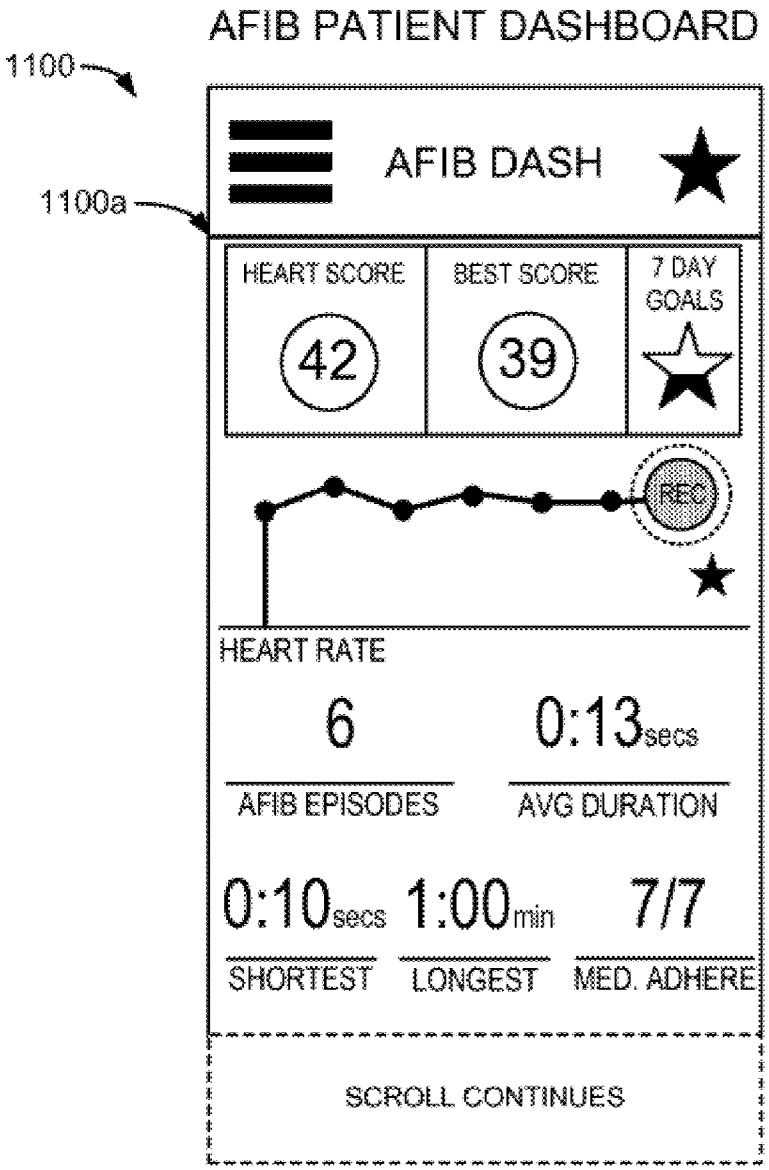
AFIB PATIENT DASHBOARD
1100
1100a
AFIB DASH
HEART SCORE
42
BEST SCORE
39
7 DAY GOALS
REC
HEART RATE
6
AFIB EPISODES
0:13secs
AVG DURATION
0:10secs
SHORTEST
1:00min
LONGEST
7/7
MED. ADHERE
SCROLL CONTINUES

FIG. 11

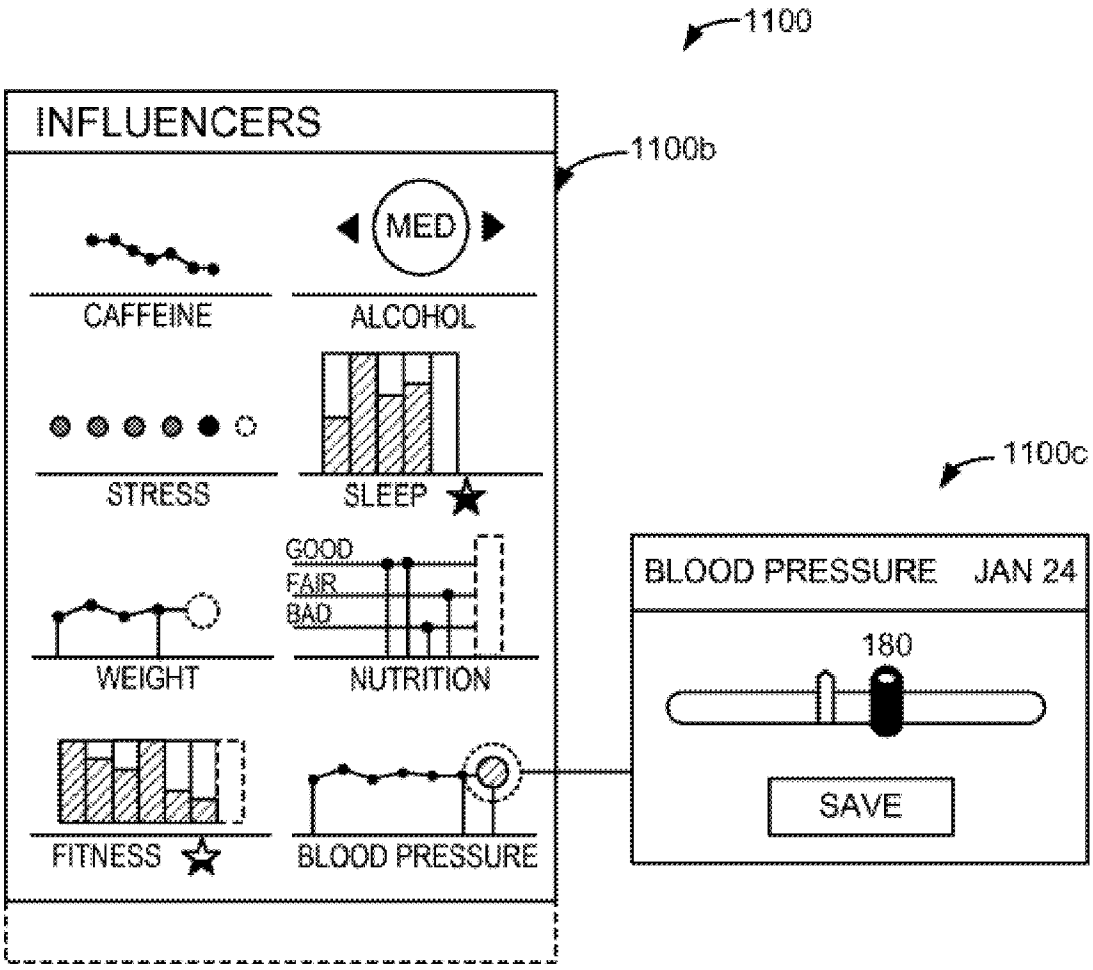
1100
INFLUENCERS
1100b
MED
CAFFEINE
ALCOHOL
STRESS
SLEEP
1100c
GOOD
FAIR
BAD
WEIGHT
NUTRITION
BLOOD PRESSURE JAN 24
180
SAVE
FITNESS
BLOOD PRESSURE

FIG. 11A

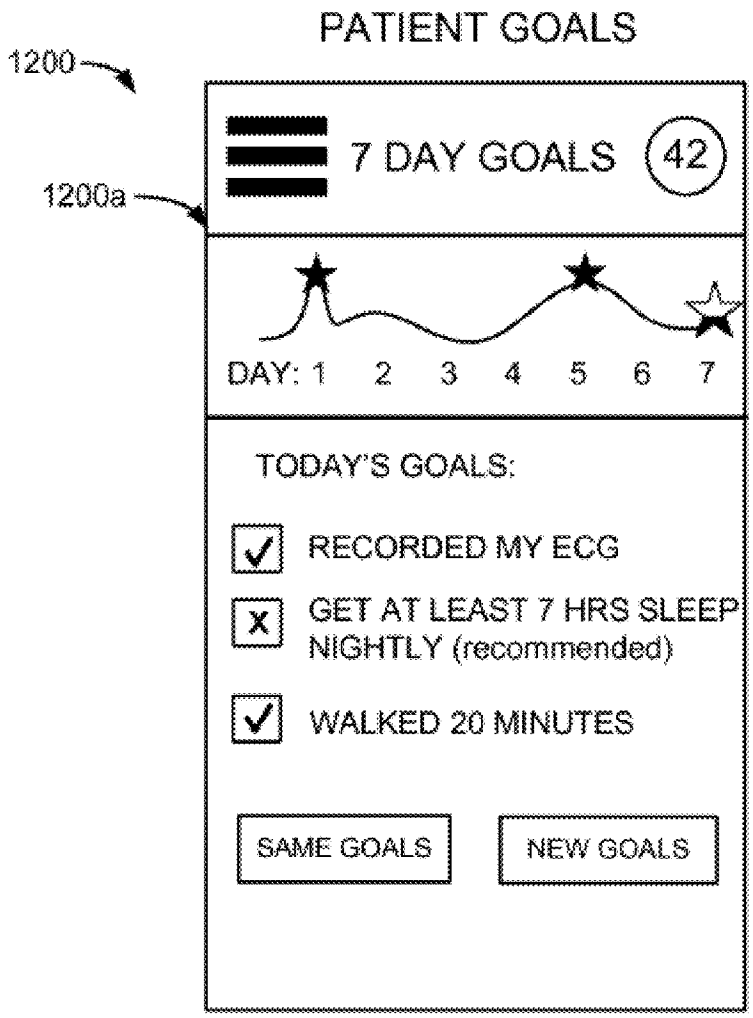
PATIENT GOALS
1200
1200a
7 DAY GOALS
42
DAY: 1 2 3 4 5 6 7
TODAY'S GOALS:
RECORDED MY ECG
GET AT LEAST 7 HRS SLEEP NIGHTLY (recommended)
WALKED 20 MINUTES
SAME GOALS
NEW GOALS

FIG. 12

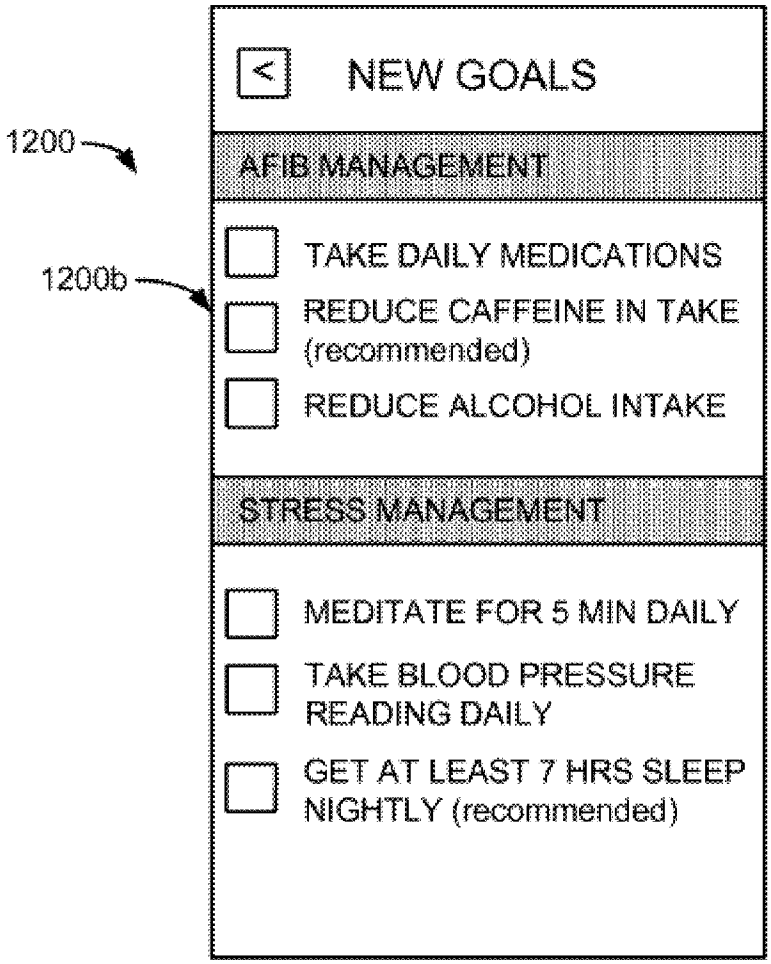
1200
1200b
NEW GOALS
AFIB MANAGEMENT
TAKE DAILY MEDICATIONS
REDUCE CAFFEINE IN TAKE (recommended)
REDUCE ALCOHOL INTAKE
STRESS MANAGEMENT
MEDITATE FOR 5 MIN DAILY
TAKE BLOOD PRESSURE READING DAILY
GET AT LEAST 7 HRS SLEEP NIGHTLY (recommended)

FIG. 12A

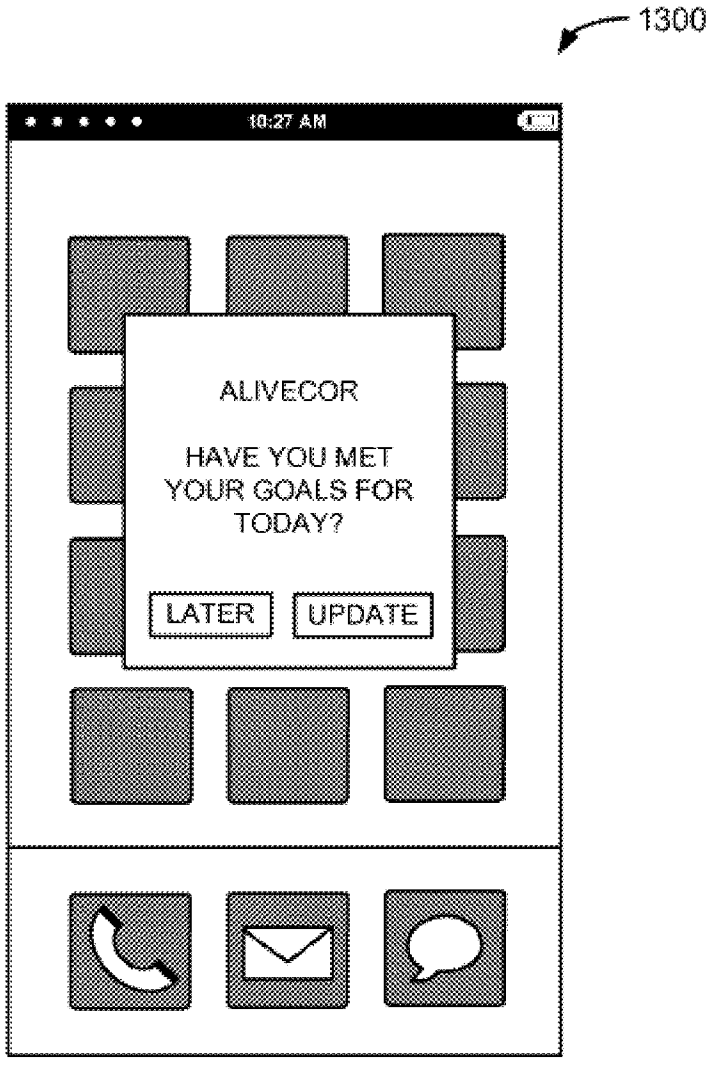
1300
10:27 AM
ALIVECOR
HAVE YOU MET YOUR GOALS FOR TODAY?
LATER
UPDATE

FIG. 13

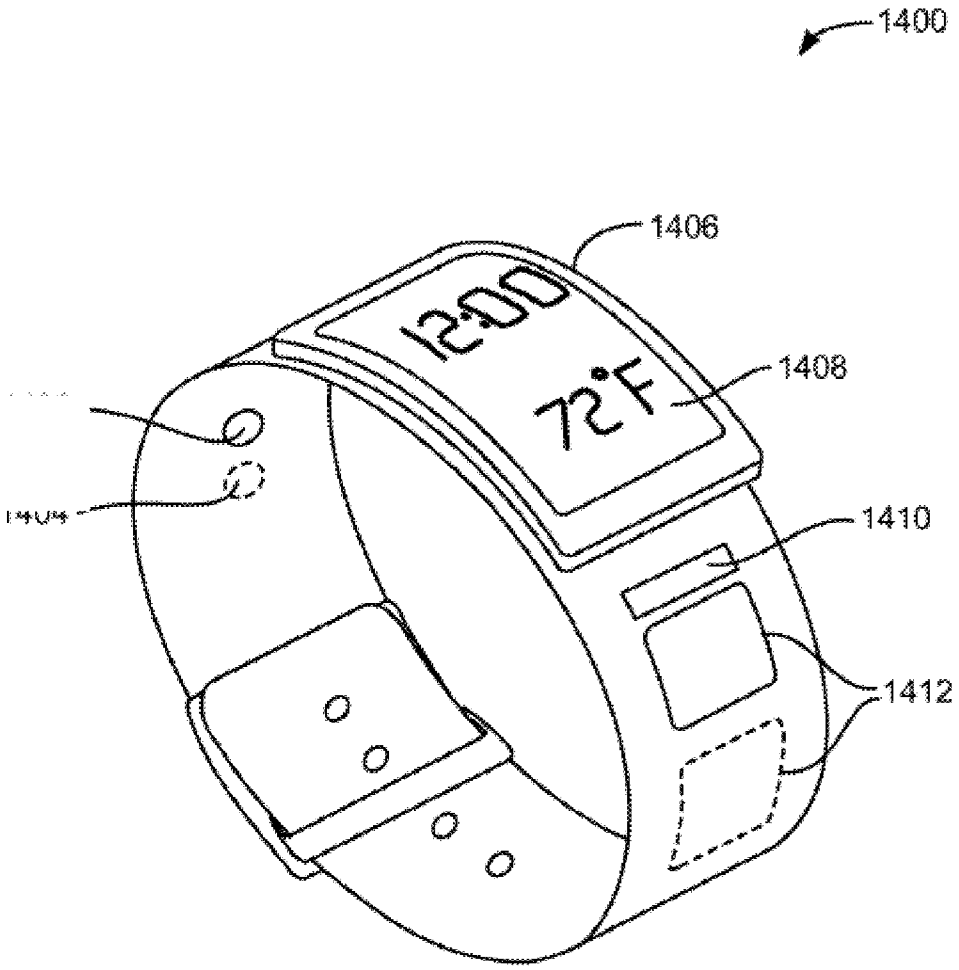

FIG. 14

METHODS AND SYSTEMS FOR ARRHYTHMIA TRACKING AND SCORING

CROSS-REFERENCE

This application is a continuation of U.S. application Ser. No. 14/569,513 filed Dec. 12, 2014, which claims the benefit of U.S. Provisional Application No. 61/915,113, filed Dec. 12, 2013, which application is incorporated herein by reference, U.S. Provisional Application No. 61/953,616 filed Mar. 14, 2014, U.S. Provisional Application No. 61/969,019, filed Mar. 21, 2014, U.S. Provisional Application No. 61/970,551 filed Mar. 26, 2014 which application is incorporated herein by reference, and U.S. Provisional Application No. 62/014,516, filed Jun. 19, 2014, which application is incorporated herein by reference.

BACKGROUND

The present disclosure relates to medical devices, systems, and methods. In particular, the present disclosure relates to methods and systems for managing health and disease such as cardiac diseases including arrhythmia and atrial fibrillation.

Cardiovascular diseases are the leading cause of death in the world. In 2008, 30% of all global death can be attributed to cardiovascular diseases. It is also estimated that by 2030, over 23 million people will die from cardiovascular diseases annually. Cardiovascular diseases are prevalent in the populations of high-income and low-income countries alike.

Arrhythmia is a cardiac condition in which the electrical activity of the heart is irregular or is faster (tachycardia) or slower (bradycardia) than normal. Although many arrhythmias are not life-threatening, some can cause cardiac arrest and even sudden cardiac death. Atrial fibrillation is the most common cardiac arrhythmia. In atrial fibrillation, electrical conduction through the ventricles of heart is irregular and disorganized. While atrial fibrillation may cause no symptoms, it is often associated with palpitations, shortness of breath, fainting, chest, pain or congestive heart failure. Atrial fibrillation is also associated with atrial clot formation, which is associated with clot migration and stroke.

Atrial fibrillation is typically diagnosed by taking an electrocardiogram (ECG) of a subject, which shows a characteristic atrial fibrillation waveform

To treat atrial fibrillation, a patient may take medications to slow heart rate or modify the rhythm of the heart. Patients may also take anticoagulants to prevent atrial clot formation and stroke. Patients may even undergo surgical intervention including cardiac ablation to treat atrial fibrillation.

Often, a patient with arrhythmia or atrial fibrillation is monitored for extended periods of time to manage the disease. For example, a patient may be provided with a Holter monitor or other ambulatory electrocardiography device to continuously monitor a patient's heart rate and rhythm for at least 24 hours.

Current ambulatory electrocardiography devices such as Holter monitors, however, are typically bulky and difficult for subjects to administer without the aid of a medical professional. For example, the use of Holter monitors requires a patient to wear a bulky device on their chest and precisely place a plurality of electrode leads on precise locations on their chest. These requirements can impede the activities of the subject, including their natural movement, bathing, and showering. Once an ECG is generated, the ECG is sent to the patient's physician who may analyze the ECG and provide a diagnosis and other recommendations. Currently, this process often must be performed through hospital administrators and health management organizations and many patients do not receive feedback in an expedient manner.

SUMMARY

Disclosed herein are devices, systems, and methods for managing health and disease such as cardiac diseases, including arrhythmia and atrial fibrillation. In particular, a cardiac disease and/or rhythm management system, according to aspects of the present disclosure, allows a user to conveniently document their electrocardiograms (ECG) and other biometric data and receive recommendation(s) and/or goal(s) generated by the system or by a physician in response to the documented data. The cardiac disease and/or rhythm management system can be loaded onto a local computing device of the user, where biometric data can be conveniently entered onto the system while the user may continue to use the local computing device for other purposes. A local computing device may comprise, for example, a computing device worn on the body (e.g. a head-worn computing device such as a Google Glass, a wrist-worn computing device such as a Samsung Galaxy Gear Smart Watch, etc.), a tablet computer (e.g. an Apple iPad, an Apple iPod, a Google Nexus tablet, a Samsung Galaxy Tab, a Microsoft Surface, etc.), a smartphone (e.g. an Apple iPhone, a Google Nexus phone, a Samsung Galaxy phone, etc.)

A portable computing device or an accessory thereof may be configured to continuously measure one or more physiological signals of a user. The heart rate of the user may be continuously measured. The continuously measurement may be made with a wrist or arm band or a patch in communication with the portable computing device. The portable computing device may have loaded onto (e.g. onto a non-transitory computer readable medium of the computing device) and executing thereon (e.g. by a processor of the computing device) an application for one or more of receiving the continuously measured physiological signal(s), analyzing the physiological signal(s), sending the physiological signal(s) to a remote computer for further analysis and storage, and displaying to the user analysis of the physiological signal(s). The heart rate may be measured by one or more electrodes provided on the computing device or accessory, a motion sensor provided on the computing device or accessory, or by imaging and lighting sources provided on the computing device or accessory. In response to the continuous measurement and recordation of the heart rate of the user, parameters such as heart rate (HR), heart rate variability (R-R variability or HRV), and heart rate turbulence (HRT) may be determined. These parameters and further parameters may be analyzed to detect and/or predict one or more of atrial fibrillation, tachycardia, bradycardia, bigeminy, trigeminy, or other cardiac conditions. A quantitative heart health score may also be generated from the determined parameters. One or more of the heart health score, detected heart conditions, or recommended user action items based on the heart health score may be displayed to the user through a display of the portable computing device.

The biometric data may be uploaded onto a remote server where one or more cardiac technicians or cardiac specialists may analyze the biometric data and provide ECG interpretations, diagnoses, recommendations such as lifestyle recommendations, and/or goals such as lifestyle goals for subject. These interpretations, diagnoses, recommendations,

and/or goals may be provided to the subject through the cardiac disease and/or rhythm management system on their local computing device. The cardiac disease and/or rhythm management system may also include tools for the subject to track their biometric data and the associated interpretations, diagnoses, recommendations, and/or goals from the cardiac technicians or specialists.

An aspect of the present disclosure includes a dashboard centered around arrhythmia or atrial fibrillation tracking. The dashboard includes a heart score that can be calculated in response to data from the user such as their ECG and other personal information such as age, gender, height, weight, body fat, disease risks, etc. The main driver of this heart score will often be the incidence of the user's atrial fibrillation. Other drivers and influencing factors include the aforementioned personal information. The heart score will be frequently related to output from a machine learning algorithm that combines and weights many if not all of influencing factors.

The dashboard will often display and track many if not all of the influencing factors. Some of these influencing factors may be entered directly by the user or may be input by the use of other mobile health monitoring or sensor devices. The user may also use the dashboard as an atrial fibrillation or arrhythmia management tool to set goals to improve their heart score.

The dashboard may also be accessed by the user's physician (e.g. the physician prescribing the system to the user, another regular physician, or other physician) to allow the physician to view the ECG and biometric data of the user, view the influencing factors of the user, and/or provide additional ECG interpretations, diagnoses, recommendations, and/or goals.

Another aspect of the present disclosure provides a method for managing cardiac health. Biometric data of a user may be received. A cardiac health score may be generated in response to the received biometric data. One or more recommendations or goals for improving the generated cardiac health score may be displayed to the user. The biometric data may comprise one or more of an electrocardiogram (ECG), dietary information, stress level, activity level, gender, height, weight, age, body fat percentage, blood pressure, results from imaging scans, blood chemistry values, or genotype data. The recommendations or goals may be updated in response to the user meeting the displayed recommendations or goals. The user may be alerted if one or more recommendations or goals have not been completed by the user, for example if the user has not completed one or more recommendations or goals for the day.

The analysis applied may be through one or more of the generation of a heart health score or the application of one or more machine learning algorithms. The machine learning algorithms may be trained using population data of heart rate. The population data may be collected from a plurality of the heart rate monitoring enabled portable computing devices or accessories provided to a plurality of users. The training population of users may have been previously identified as either having atrial fibrillation or not having atrial fibrillation prior to the generation of data for continuously measured heart rate. The data may be used to train the machine learning algorithm to extract one or more features from any continuously measured heart rate data and identify atrial fibrillation or other conditions therefrom. After the machine learning algorithm has been trained, the machine learning algorithm may recognize atrial fibrillation from the continuously measured heart rate data of a new user who has not yet been identified as having atrial fibrillation or other heart conditions. One or more of training population data or the trained machine learning algorithm may be provided on a central computing device (e.g. be stored on a non-transitory computer readable medium of a server) which is in communication with the local computing devices of the users and the application executed thereon (e.g. through an Internet or an intranet connection.)

A set of instructions for managing cardiac health may be downloaded from the Internet. These set of instructions may be configured to automatically generate the cardiac health score. The cardiac health score may be generated using a machine learning algorithm. The machine learning algorithm may generate the cardiac health score of the user and/or the recommendations and/or goals in response to biometric data from a plurality of users. The set of instructions may be configured to allow a medical professional to access the received biometric data. The cardiac health score and/or the recommendations and/or goals may be generated by the medical professional.

The set of instructions may be stored on a non-transitory computer readable storage medium of one or more of a body-worn computer, a tablet computer, a smartphone, or other computing device. These set of instructions may be capable of being executed by the computing device. When executed, the set of instructions may cause the computing device to perform any of the methods described herein, including the method for managing cardiac health described above.

Another aspect of the present disclosure provides a system for managing cardiac health. The system may comprise a sensor for recording biometric data of a user and a local computing device receiving the biometric data from the sensor. The local computing device may be configured to display a cardiac health score and one or more recommendations or goals for the user to improve the cardiac health score in response to the received biometric data.

The system may further comprise a remote server receiving the biometric data from the local computing device. One or more of the local computing device or the remote server may comprise a machine learning algorithm which generates one or more of the cardiac health score or the one or more recommendations or goals for the user. The remote server may be configured for access by a medical professional. Alternatively or in combination, one or more of the cardiac health score or one or more recommendations or goals may be generated by the medical professional and provided to the local computing device through the remote server.

The sensor may comprise one or more of a hand-held electrocardiogram (ECG) sensor, a wrist-worn activity sensor, a blood pressure monitor, a personal weighing scale, a body fat percentage sensor, a personal thermometer, a pulse oximeter sensor, or any mobile health monitor or sensor. Often, the sensor is configured to be in wireless communication with the local computing device. The local computing device comprises one or more of a personal computer, a laptop computer, a palmtop computer, a tablet computer, a smartphone, a body-worn computer, or the like. The biometric data may comprise one or more of an electrocardiogram (ECG), dietary information, stress level, activity level, gender, height, weight, age, body fat percentage, or blood pressure.

Other physiological signals or parameters such as physical activity, heart sounds, blood pressure, blood oxygenation, blood glucose, temperature, activity, breath composition, weight, hydration levels, an electroencephalograph (EEG), an electromyography (EMG), a mechanomyogram (MMG), an electrooculogram (EOG), etc. may also be

monitored. The user may also input user-related health data such as age, height, weight, body mass index (BMI), diet, sleep levels, rest levels, or stress levels. One or more of these physiological signals and/or parameters may be combined with the heart rate data to detect atrial fibrillation or other conditions. The machine learning algorithm may be configured to identify atrial fibrillation or other conditions in response to heart rate data in combination with one or more of the other physiological signals and/or parameters for instance. Triggers or alerts may be provided to the user in response to the measured physiological signals and/or parameters. Such triggers or alerts may notify the user to take corrective steps to improve their health or monitor other vital signs or physiological parameters. The application loaded onto and executed on the portable computing device may provide a health dash board integrating and displaying heart rate information, heart health parameters determined in response to the heart rate information, other physiological parameters and trends thereof, and recommended user action items or steps to improve health.

INCORPORATION BY REFERENCE

All publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

The novel features of the subject matter disclosed herein are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present disclosure will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the disclosure are utilized, and the accompanying drawings of which:

FIG. **1** shows a system for cardiac disease and rhythm management;

FIG. **2** shows a flow chart of a method **200** for predicting and/or detecting atrial fibrillation from R-R interval measurements;

FIG. **3** shows a flow chart of a method for predicting and/or detecting atrial fibrillation from R-R interval measurements and for predicting and/or detecting atrial fibrillation from raw heart rate signals;

FIG. **4** shows an embodiment of the system and method of the ECG monitoring described herein;

FIG. **5** shows a flow chart of an exemplary method to generate a heart health score in accordance with many embodiments;

FIG. **6** shows an exemplary method of generating a heart score;

FIG. **7** shows a schematic diagram of the executed application described herein;

FIG. **8** shows exemplary screenshots of the executed application;

FIG. **9** shows an exemplary method for cardiac disease and rhythm management;

FIG. **10** shows an exemplary method for monitoring a subject to determine when to record an electrocardiogram (ECG);

FIG. **11** shows an exemplary screenshot of a first aspect of a dashboard application;

FIG. **11**A shows an exemplary screenshot of a second aspect of a dashboard application;

FIG. **12** shows an exemplary screenshot of a first aspect of a goals and recommendations page of the cardiac disease and rhythm management system interface or mobile app;

FIG. **12**A shows an exemplary screenshot of a second aspect of a goals and recommendations page of the cardiac disease and rhythm management system interface or mobile app;

FIG. **13** shows an exemplary screenshot of a user's local computing device notifying the user with a pop-up notice to meet their daily recommendations and goals; and

FIG. **14** shows an embodiment comprising a smart watch which includes at least one heart rate monitor and at least one activity monitor.

DETAILED DESCRIPTION

Devices, systems, and methods for managing health and disease such as cardiac diseases, including arrhythmia and atrial fibrillation, are disclosed. In particular, a cardiac disease and/or rhythm management system, according to aspects of the present disclosure, allows a user to conveniently document their electrocardiograms (ECG) and other biometric data and receive recommendation(s) and/or goal(s) generated by the system or by a physician in response to the documented data.

The term "atrial fibrillation," denoting a type of cardiac arrhythmia, may also be abbreviated in either the figures or description herein as "AFIB."

FIG. **1** shows a system **100** for cardiac disease and rhythm management. The system **100** may be prescribed for use by a user or subject such as being prescribed by the user or subject's regular or other physician or doctor. The system **100** may comprise a local computing device **101** of the user or subject. The local computing device **101** may be loaded with a user interface, dashboard, or other sub-system of the cardiac disease and rhythm management system **100**. For example, the local computing device **101** may be loaded with a mobile software application ("mobile app") **101***a* for interfacing with the system **100**. The local computing device may comprise a computing device worn on the body (e.g. a head-worn computing device such as a Google Glass, a wrist-worn computing device such as a Samsung Galaxy Gear Smart Watch, etc.), a tablet computer (e.g. an Apple iPad, an Apple iPod, a Google Nexus tablet, a Samsung Galaxy Tab, a Microsoft Surface, etc.), a smartphone (e.g. an Apple iPhone, a Google Nexus phone, a Samsung Galaxy phone, etc.).

The local computing device **101** may be coupled to one or more biometric sensors. For example, the local computing device **101** may be coupled to a handheld ECG monitor **103**. The handheld ECG monitor **103** may be in the form of a smartphone case as described in co-owned U.S. patent application Ser. No. 12/796,188 (now U.S. Pat. No. 8,509,882), Ser. Nos. 13/107,738, 13/420,520 (now U.S. Pat. No. 8,301,232), Ser. Nos. 13/752,048, 13/964,490, 13/969,446, 14/015,303, and 14/076,076, the contents of which are incorporated herein by reference.

In some embodiments, the handheld ECG monitor **103** may be a handheld sensor coupled to the local computing device **101** with an intermediate protective case/adapter as described in U.S. Provisional Application No. 61/874,806, filed Sep. 6, 2013, the contents of which are incorporated herein by reference. The handheld ECG monitor **103** may be used by the user to take an ECG measurement which the handheld ECG monitor **103** may send to the local computing device by connection **103***a*. The connection **103***a* may comprise a wired or wireless connection (e.g. a WiFi con-

nection, a Bluetooth connection, a NFC connection, an ultrasound signal transmission connection, etc.). The mobile software application **101***a* may be configured to interface with the one or more biometric sensors including the hand-held ECG monitor **103**.

The local computing device **101** may be coupled to a wrist-worn biometric sensor **105** through a wired or wireless connection **105***a* (e.g. a WiFi connection, a Bluetooth connection, a NFC connection, an ultrasound signal transmission connection, etc.). The wrist-worn biometric sensor **105** may comprise an activity monitor such as those available from Fitbit Inc. of San Francisco, Calif. or a Nike FuelBand available from Nike, Inc. of Oregon. The wrist-worn biometric sensor **105** may also comprise an ECG sensor such as that described in co-owned U.S. Provisional Application No. 61/872,555, the contents of which is incorporated herein by reference.

The local computing device **101** may be coupled to other biometric devices as well such as a personal scale or a blood pressure monitor **107**. The blood pressure monitor **107** may communicate with the local device **101** through a wired or wireless connection **107***a* (e.g. a WiFi connection, a Bluetooth connection, a NFC connection, an ultrasound signal transmission connection, etc.).

The local computing device **101** may directly communicate with a remote server or cloud-based service **113** through the Internet **111** via a wired or wireless connection **111***a* (e.g. a WiFi connection, a cellular network connection, a DSL Internet connection, a cable Internet connection, a fiber optic Internet connection, a T1 Internet connection, a T3 Internet connection, etc.). Alternatively or in combination, the local computing device **101** may first couple with another local computing device **109** of the user, such as a personal computer of the user, which then communicates with the remote server or cloud-based service **113** via a wired or wireless connection **109***a* (e.g. a WiFi connection, a cellular network connection, a DSL Internet connection, a cable Internet connection, a fiber optic Internet connection, a T1 Internet connection, a T3 Internet connection, etc.) The local computing device **109** may comprise software or other interface for managing biometric data collected by the local computing device **101** or the biometric data dashboard loaded on the local computing device **101**.

Other users may access the patient data through the remote server or cloud-based service **113**. These other users may include the user's regular physician, the user's prescribing physician who prescribed the system **100** for use by the user, other cardiac technicians, other cardiac specialists, and system administrators and managers. For example, a first non-subject user may access the remote server or cloud-based service **113** with a personal computer or other computing device **115** through an Internet connection **115***a* (e.g. a WiFi connection, a cellular network connection, a DSL Internet connection, a cable Internet connection, a fiber optic Internet connection, a T1 Internet connection, a T3 Internet connection, etc.). Alternatively or in combination, the first non-subject user may access the remote server or cloud-based service **113** with a local computing device such as a tablet computer or smartphone **117** through an Internet connection **117***a*. The tablet computer or smartphone **117** of the first non-subject user may interface with the personal computer **115** through a wired or wireless connection **117***b* (e.g. a WiFi connection, a Bluetooth connection, a NFC connection, an ultrasound signal transmission connection, etc.). Further, a second non-subject user may access the remote server or cloud-based service **113** with a personal computer or other computing device **119** through an Internet connection **119***a* (e.g. a WiFi connection, a cellular network connection, a DSL Internet connection, a cable Internet connection, a fiber optic Internet connection, a T1 Internet connection, a T3 Internet connection, etc.). Further, a third non-subject user may access the remote server or cloud-based service **113** with a tablet computer or smartphone **121** through an Internet connection **121***a* (e.g. a WiFi connection, a cellular network connection, a DSL Internet connection, a cable Internet connection, a fiber optic Internet connection, a T1 Internet connection, a T3 Internet connection, etc.). Further, a fourth non-subject user may access the remote server or cloud-based service **113** with a personal computer or other computing device **123** through an Internet connection **123***a* (e.g. a WiFi connection, a cellular network connection, a DSL Internet connection, a cable Internet connection, a fiber optic Internet connection, a T1 Internet connection, a T3 Internet connection, etc.). The first non-subject user may comprise an administrator or manager of the system **100**. The second non-subject user may comprise a cardiac technician. The third non-subject user may comprise a regular or prescribing physician of the user or subject. And, the fourth non-subject user may comprise a cardiac specialist who is not the user or subject's regular or prescribing physician. Generally, many if not all of the communication between various devices, computers, servers, and cloud-based services will be secure and HIPAA-compliant.

Aspects of the present disclosure provide systems and methods for detecting and/or predicting atrial fibrillation or other arrhythmias of a user by applying one or more machine learning-based algorithms. A portable computing device (or an accessory usable with the portable computing device) may provide R-R intervals and/or raw heart rate signals as input to an application loaded and executed on the portable computing device. The raw heart rate signals may be provided using an electrocardiogram (ECG) in communication with the portable computing device or accessory such as described in U.S. Ser. No. 13/964,490 filed Aug. 12, 2013, Ser. No. 13/420,520 filed Mar. 14, 2013, Ser. No. 13/108,738 filed May 16, 2011, and Ser. No. 12/796,188 filed Jun. 8, 2010. Alternatively or in combination, the raw heart rate signals may be provided using an on-board heart rate sensor of the portable computing device or by using photoplethysmography implemented by an imaging source and a light source of the portable computing device. Alternatively or in combination, the raw heart rate signals may be from an accessory device worn by the user or attached to the user (e.g. a patch) and which is in communication with the portable computing device. Such wearable accessory devices may include Garmin's Vivofit Fitness Band, Fitbit, Polar Heart Rate Monitors, New Balance's Balance Watch, Basis B1 Band, MIO Alpha, Withings Pulse, LifeCORE Heart Rate Monitor strap, and the like.

R-R intervals may be extracted from the raw heart rate signals. The R-R intervals may be used to calculate heart rate variability (HRV) which may be analyzed in many ways such as using time-domain methods, geometric methods, frequency-domain methods, non-linear methods, long term correlations, or the like as known in the art. Alternatively or in combination, the R-R intervals may be used for non-traditional measurements such as (i) determining the interval between every other or every three R-waves to evaluate for bigeminy or trigeminy or (ii) the generation of a periodic autoregressive moving average (PARMA).

The machine learning based algorithm(s) may allow software application(s) to identify patterns and/or features of the R-R interval data and/or the raw heart rate signals or data to

predict and/or detect atrial fibrillation or other arrhythmias. These extracted and labelled features may be features of HRV as analyzed in the time domain such as SDNN (the standard deviation of NN intervals calculated over a 24 hour period), SDANN (the standard deviation of the average NN intervals calculated over short periods), RMSSD (the square root of the mean of the sum of the squares of the successive differences between adjacent NNs), SDSD (the standard deviation of the successive differences between adjacent NNs), NN50 (the number of pairs of successive NNs that differ by more than 50 ms), pNN50 (the proportion of NN50 divided by total number of NNs), NN20 (the number of pairs of successive NNs that differ by more than 20 ms), pNN20 (the proportion of NN20 divided by the total number of NNs), EBC (estimated breath cycle), NNx (the number of pairs of successive NNs that differ by more than x ms), pNNx (the proportion of NNx divided by the number of NNs), or other features known in the art. Alternatively or in combination, the extracted and labelled features may comprise a nonlinear transform of R-R ratio or R-R ratio statistics with an adaptive weighting factor. Alternatively or in combination, the extracted and labelled features may be features of HRV as analyzed geometrically such as the sample density distribution of NN interval durations, the sample density distribution of differences between adjacent NN intervals, a Lorenz plot of NN or RR intervals, degree of skew of the density distribution, kurtosis of the density distribution, or other features known in the art. Alternatively or in combination, the extracted and labelled features may be features of HRV in the frequency domain such as the power spectral density of different frequency bands including a high frequency band (HF, from 0.15 to 0.4 Hz), low frequency band (LF, from 0.04 to 0.15 Hz), and the very low frequency band (VLF, from 0.0033 to 0.04 Hz), or other frequency domain features as known in the art. Alternatively or in combination, the extracted and labelled features may be non-linear features such as the geometric shapes of a Poincaré plot, the correlation dimension, the nonlinear predictability, the pointwise correlation dimension, the approximate entropy, and other features as known in the art. Other features from the raw heart rate signals and data may also be analyzed. These features include for example a generated autoregressive (AR) model, a ratio of consecutive RR intervals, a normalized ratio of consecutive RR intervals, a standard deviation of every 2, 3, or 4 RR intervals, or a recurrence plot of the raw HR signals, among others.

The features of the analysis and/or measurement may be selected, extracted, and labelled to predict atrial fibrillation or other arrhythmias in real time, e.g. by performing one or more machine learning operation. Such operations can be selected from among an operation of ranking the feature(s), classifying the feature(s), labelling the feature(s), predicting the feature(s), and clustering the feature(s). Alternatively or in combination, the extracted features may be labelled and saved for offline training of a machine learning algorithm or set of machine learning operations. For example, the operations may be selected from any of those above. Any number of machine learning algorithms or methods may be trained to identify atrial fibrillation or other conditions such as arrhythmias. These may include the use of decision tree learning such as with a random forest, association rule learning, artificial neural network, inductive logic programming, support vector machines, clustering, Bayesian networks, reinforcement learning, representation learning, similarity and metric learning, sparse dictionary learning, or the like.

The systems and methods for detecting and/or predicting atrial fibrillation or other conditions such as arrhythmias described herein may be implemented as software provided as a set of instructions on a non-transitory computer readable medium. A processor of a computing device (e.g. a tablet computer, a smartphone, a smart watch, a smart band, a wearable computing device, or the like) may execute this set of instructions to receive the input data and detect and/or predict atrial fibrillation therefrom. The software may be downloaded from an online application distribution platform such as the Apple iTunes or App Store, Google Play, Amazon App Store, and the like. A display of the computing device may notify the user whether atrial fibrillation or other arrhythmias has been detected and/or if further measurements are required (e.g. to perform a more accurate analysis). The software may be loaded on and executed by the portable computing device of the user such as with the processor of the computing device.

The machine learning-based algorithms or operations for predicting and/or detecting atrial fibrillation or other arrhythmias may be provided as a service from a remote server which may interact or communicate with a client program provided on the computing device of the user, e.g. as a mobile app. The interaction or communication may be through an Application Program Interface (API). The API may provide access to machine learning operations for ranking, clustering, classifying, and predicting from the R-R interval and/or raw heart rate data, for example.

The machine learning-based algorithms or operations, provided through a remote server and/or on a local application on a local computing device, may operate on, learn from, and make analytical predictions from R-R interval data or raw heart rate data, e.g. from a population of users. The R-R interval or raw heart rate data may be provided by the local computing device itself or an associated accessory, such as described in U.S. Ser. No. 13/964,490 filed Aug. 12, 2013, Ser. No. 13/420,520 filed Mar. 14, 2013, Ser. No. 13/108,738 filed May 16, 2011, and Ser. No. 12/796,188 filed Jun. 8, 2010. Thus, atrial fibrillation and other arrhythmias or other heart conditions can be in a convenient, user-accessible way.

FIG. **2** shows a flow chart of a method **200** for predicting and/or detecting atrial fibrillation from R-R interval measurements. In a step **202**, an R-R interval of a user is obtained. In a step **204**, the obtained R-R interval is analyzed using one or more traditional heart rate variability measurements such as, for example, time domain measures, frequency domain measures, and non-linear heart rate variability. In a step **206**, the obtained R-R interval is analyzed using one or more non-traditional heart rate variability measurements such as, for example, RR (n-i) for Bigeminy and Trigeminy detection, and the generation of a periodic autoregressive moving average (PARMA). In a step **208**, a feature selection occurs. In a step **210**, a real time prediction or detection of atrial fibrillation, and/or in a step **212**, the heart rate variability measurements may be labelled and saved for offline training of a machine learning algorithm or set of machine learning operations, and then may be subsequently used to make a real time prediction and/or detection of atrial fibrillation.

FIG. **3** shows a flow chart of a method **300** for predicting and/or detecting atrial fibrillation from R-R interval measurements and for predicting and/or detecting atrial fibrillation from raw heart rate signals. In a step **302**, raw heart rate signals are obtained from, for example, an ECG of a user. In a step **304**, R-R intervals are obtained from the obtained raw hearth signals. In a step **306**, the obtained R-R

interval is analyzed using one or more traditional heart rate variability measurements such as, for example, time domain measures, frequency domain measures, and non-linear heart rate variability. In a step **308**, the obtained R-R interval is analyzed using one or more non-traditional heart rate variability measurements such as, for example, RR (n-i) for bigeminy and trigeminy detection, and the generation of a periodic autoregressive moving average (PARMA). In a step **310**, features from the obtained heart rate features are analyzed using one or more of wavelet features and shape based features from a Hilbert transform. In a step **312**, a feature selection occurs. In a step **314**, a real time prediction or detection of atrial fibrillation, and/or in a step **316**, the heart rate variability measurements may be labelled and saved for offline training of a machine learning algorithm or set of machine learning operations, and then may be subsequently used to make a real time prediction and/or detection of atrial fibrillation.

Although the above steps show methods **200** and **300** in accordance with many embodiments, a person of ordinary skill in the art will recognize many variations based on the teaching described herein. The steps may be completed in a different order. Steps may be added or deleted. Some of the steps may comprise sub-steps. Many of the steps may be repeated as often as beneficial to the user or subject.

One or more of the steps of method **200** and **300** may be performed with circuitry, for example, one or more of a processor or a logic circuitry such as a programmable array logic for a field programmable gate array. The circuitry may be programmed to provide one or more of the steps of methods **200** and **300**, and the program may comprise program instructions stored on a non-transitory computer readable medium or memory or programmed steps of the logic circuitry such as the programmable array logic or the field programmable gate array, for example.

Aspects of the present disclosure provide systems and methods for monitoring one or more physiological parameters and providing a trigger message to the user if the one or more physiological parameter meets a pre-determined or learned threshold(s). Two or more of the physiological parameters may be combined to provide a trigger message. That is, a particular trigger message may be provided to the user if two or more pre-determined threshold(s) for the physiological parameter(s) are met.

Table 1 below shows an exemplary table of physiological parameters that may be measured (left column), features of interest to be measured or threshold types to be met (middle column), and exemplary trigger messages (right column).

TABLE 1

Physiological Parameter	Measurements/Threshold	Sample Trigger Messages
Heart Rate	Heart Rate Variability (HRV), Non-linear Transformation of RR Intervals	Measure ECG; See Your Doctor
Heart Sound	Sound Features	Abnormal Heart Sound; Measure ECG; See Your Doctor
Blood Pressure	Upper and Lower Thresholds	High/Low Blood Pressure; Take BP Medication; Exercise; See Your Doctor
Blood Oxygenation	O2 Saturation, O2 Saturation Variability	High Risk of Hypoventilation; High Risk of Sleep Disorder such as Apnea; See Your Doctor
Blood Glucose	Upper and Lower Thresholds	High Risk of Hypoglycemia; See Your Doctor
Temperature	Temperature, Temperature Changes	Fever; Take OTC Fever Medication; See Your Doctor
Physical Activity (accelerometer data)	Gait, Chest Compressions, Speed, Distance	Monitor Senior or Infant Posture, e.g. if senior/infant has fallen
Electrocardiogram (ECG)	ECG Features (E.g. QT, QRS, PR intervals, HRV, etc.	High Risk of Certain Cardiac Diseases; Sleep apnea; See Your Doctor
Breath Content (Breathalyzer data)	Percentage of the Certain Chemicals	High Risk of Certain Dental Disease, Diabetes, etc.; See Your Doctor

The machine learning based algorithms or operations as described herein may be used to determine the appropriate trigger thresholds in response to the raw physiological data input and/or user-input physiological parameters (e.g. age, height, weight, gender, etc.). Features of the raw physiological data input may be selected, extracted, labelled, clustered, and/or analyzed. These processed features may then be analyzed using one or more machine learning operation such as ranking the feature(s), classifying the feature(s), predicting the feature(s), and clustering the feature(s). The various machine learning algorithms described herein may be used to analyze the features to detect and predict health conditions and generate recommendations or user action items to improve the health of the user. For instance, the machine learning algorithms may be trained to identify atrial fibrillation or other conditions in response to the non-heart rate physiological parameter(s) such as age, gender, body mass index (BMI), activity level, diet, and others in combination with the raw heart rate data and HRV that can be extracted therefrom.

The systems and methods for monitoring one or more physiological parameters and providing a trigger message to the user if the one or more physiological parameter meets a pre-determined threshold(s) described herein may be implemented as software provided as a set of instructions on a non-transitory computer readable medium. A processor of a computing device (e.g. a tablet computer, a smartphone, a smart watch, a smart band, a wearable computing device, or the like) may execute this set of instructions to receive the input data and detect and/or predict atrial fibrillation therefrom. The software may be downloaded from an online application distribution platform such as the Apple iTunes or App Store, Google Play, Amazon App Store, and the like.

The software may be loaded on and executed by the portable computing device of the user such as with the processor of the computing device. The software may also provide both the triggering application described herein and the heart rate monitoring and analysis for detecting atrial fibrillation or other heart conditions described herein.

In an embodiment, a method and system for longitudinal monitoring of a patient's or any consumer's (after referred to as "patient") health using various ECG monitoring devices is described herein. The ECG monitoring devices generate ECG signal data which can be stored in a database for further analysis. The ECG data, which can be stored in a database along with other patient information, can be analyzed by a processing device, such as a computer or server, using various algorithms.

Various ECG monitoring or recording devices, hereinafter referred to as ECG monitoring devices, can be used to record the ECG data. For example, the ECG monitoring device can be a handheld, portable, or wearable smartphone based device, as described in U.S. Pat. No. 8,301,232, which is herein incorporated by reference in its entirety for all purposes. A smartphone based device, or a device having wireless or cellular telecommunication capabilities, can transmit the ECG data to a database or server directly through the internet. These types of ECG monitoring devices as well as other ECG monitoring devices include portable devices, wearable recording devices, event recorders, and Holter monitors. Clinical or hospital based ECG recording devices can also be used and integrated into the system. Such devices may be able to transmit stored ECG data through a phone line or wirelessly through the internet or cellular network, or may need to be sent to a data collection center for data collection and processing. The ECG data can be tagged with the type of ECG monitoring device used to record the data by, for example, including it in metadata for indexing and searching purposes.

The ECG monitoring devices can be single lead devices or multiple lead devices, where each lead generally terminates with an electrode. Some embodiments may even be leadless and have electrodes that are integrated with the body or housing of the device, and therefore have a predetermined relationship with each other, such as a fixed spacing apart from each other. The orientation and positioning of the single lead in a single lead device or of each lead of the multiple lead device or of the electrodes of the leadless device can be transmitted with the ECG data. The lead and/or electrode placement may be predetermined and specified to the patient in instructions for using the device. For example, the patient may be instructed to position the leads and/or electrodes with references to one or more anatomical landmarks on the patient's torso. Any deviation from the predetermined lead and/or electrode placement can be notated by the patient or user when transmitting the ECG data. The lead and electrode placement may be imaged using a digital camera, which may be integrated with a smart phone, and transmitted with the ECG data and stored in the database. The lead and electrode placement may be marked on the patient's skin for imaging and for assisting subsequent placement of the leads and electrodes. The electrodes can be attached to the skin using conventional methods which may include adhesives and conducting gels, or the electrodes may simply be pressed into contact with the patient's skin. The lead and electrode placement may be changed after taking one recording or after recording for a predetermined or variable amount of time. The ECG data can be tagged with the numbers of leads and/or electrodes and the lead and/or electrode placement, including whether adhesives and/or conducting gels were used. Again, this information can be including in metadata for indexing and searching purposes.

The ECG signal data can be continuously recorded over a predetermined or variable length of time. Continuous ECG recording devices can record for up to 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, or 14 days. Alternatively or additionally, the ECG data can be recorded on demand by the patient at various discrete times, such as when the patient feels chest pains or experiences other unusual or abnormal feelings. The on demand ECG recorder can have a memory buffer that can record a predetermined amount of ECG data on a rolling basis, and when activated by the patient to record a potential event, a predetermined amount of ECG data can be saved and/or transmitted. The predetermined amount of ECG data can include a predetermined amount of ECG data before activation and a predetermined amount of ECG data after activation such that a window of ECG data is captured that encompasses the potential event. The time period between ECG recordings may be regular or irregular. For example, the time period may be once a day, once a week, once a month, or at some other predetermined interval. The ECG recordings may be taken at the same or different times of days, under similar or different circumstances, as described herein. One or more baseline ECGs can be recorded while the patient is free of symptoms. The baseline ECGs can be periodically recorded and predetermined intervals and/or on-demand. The same ECG recording device or different ECG recording devices may be used to record the various ECG of a particular patient. All this information may be tagged to or associated with the ECG data by, for example, including it in the metadata for indexing and searching purposes.

The ECG data can be time stamped and can be annotated by the patient or health care provider to describe the circumstances during which the ECG was recorded, preceding the ECG recording, and/or following the ECG recording. For example, the system and device can have an user interface for data entry that allows the patient to enter in notes regarding the conditions and circumstances surrounding the ECG recording. This additional data can be also included as metadata for indexing and searching purposes. For example, location, food, drink, medication and/or drug consumption, exercise, rest, sleep, feelings of stress, anxiety, pain or other unusual or abnormal feelings, or any other circumstance that may affect the patient's ECG signal can all be inputted into the device, smart phone, computer or other computing device to be transmitted to the server or database along with the ECG data. The annotated data can also include the patient's identity or unique identifier as well as various patient characteristics including age, sex, race, ethnicity, and relevant medical history. The annotated data can also be time stamped or tagged so that the ECG data can be matched or correlated with the activity or circumstance of interest. This also allows comparison of the ECG before, after and during the activity or circumstance so that the effect on the ECG can be determined.

The ECG data and the associated metadata can be transmitted from the device to a server and database for storage and analysis. The transmission can be real-time, at regular intervals such as hourly, daily, weekly and any interval in between, or can be on demand. The metadata facilitates the searching, organizing, analyzing and retrieving of ECG data. Comparison and analysis of a single patient's ECG data can be performed, and/or comparison of ECG data between patients can be performed. For example, the metadata can be used to identify and select a subset of ECG data where an

activity or circumstance, such as the taking of medication, occurred within a predetermined amount of time to the ECG data. The components of the ECG signal data, such as the P wave, T wave, and QRS complex and the like, the amplitudes of the components, the ratios between the components, the width of the components, and the delay or time separation between the components, can be extracted, compared, analyzed, and stored as ECG features. For example, the P wave and heart rate can be extracted and analyzed to identify atrial fibrillation, where the absence of P waves and/or an irregular heart rate may indicate atrial fibrillation. The extracted ECG features can also be included in the metadata for indexing and searching.

The changes in the ECG signal over time in view of the activities and circumstances can be compared with changes over time and circumstances observed within a database of ECG's. Comparisons may include any comparison of data derived from any other ECG signal or any database of ECG's or any subset of ECG data, or with data derived from any database of ECG's. Changes in any feature of the ECG signal over time may be used for a relative comparison with similar changes in any ECG database or with data derived from an ECG database. The ECG data from the baseline ECG and the ECG data from a potential adverse event can be compared to determine the changes or deviations from baseline values. In addition, both the baseline ECG and the ECG data recorded from the patient can be compared to one or more predetermined template ECGs which can represent a normal healthy condition as well as various diseased conditions, such as myocardial infarction and arrhythmias.

The comparisons and analysis described herein can be used to draw conclusions and insights into the patient's health status, which includes potential health issues that the patient may be experiencing at the time of measurement or at future times. Conclusions and determinations may be predictive of future health conditions or diagnostic of conditions that the patient already has. The conclusions and determinations may also include insights into the effectiveness or risks associated with drugs or medications that the patient may be taking, have taken or may be contemplating taking in the future. In addition, the comparisons and analysis can be used to determine behaviors and activities that may reduce or increase risk of an adverse event. Based on the comparisons and analysis described herein, the ECG data can be classified according to a level of risk of being an adverse event. For example, the ECG data can be classified as normal, low risk, moderate risk, high risk, and/or abnormal. The normal and abnormal designation may require health care professional evaluation, diagnosis, and/or confirmation.

Diagnosis and determination of an abnormality, an adverse event, or a disease state by physicians and other health care professionals can be transmitted to the servers and database to be tagged with and associated with the corresponding ECG data. The diagnosis and determination may be based on analysis of ECG data or may be determined using other tests or examination procedures. Professional diagnosis and determinations can be extracted from the patient's electronic health records, can be entered into the system by the patient, or can be entered into the system by the medical professional. The conclusions and determinations of the system can be compared with actual diagnosis and determinations from medical professions to validate and/or refine the machine learning algorithms used by the system. The time of occurrence and duration of the abnormality, adverse event or disease state can also be included in the database, such that the ECG data corresponding with the occurrence and/or the ECG data preceding and/or following the abnormality, adverse event or disease state can be associated together and analyzed. The length of time preceding or following the abnormality may be predetermined and be up to 1 to 30 days, or greater than 1 to 12 months. Analysis of the time before the abnormality, adverse event or disease state may allow the system to identify patterns or correlations of various ECG features that precede the occurrence of the abnormality, adverse event or disease state, thereby providing advance detection or warning of the abnormality, adverse event or disease state. Analysis of the time following the abnormality, adverse event or disease state can provide information regarding the efficacy of treatments and/or provide the patient or physician information regarding disease progression, such as whether the patient's condition in improving, worsening or staying the same. The diagnosis and determination can also be used for indexing by, for example, including it in the metadata associated with the corresponding ECG data.

As described herein, various parameters may be included in the database along with the ECG data. These may include the patient's age, gender, weight, blood pressure, medications, behaviors, habits, activities, food consumption, drink consumption, drugs, medical history and other factors that may influence a patient's ECG signal. The additional parameters may or may not be used in the comparison of the changes in ECG signal over time and circumstances.

The conclusions, determinations, and/or insights into the patient's health generated by the system may be communicated to the patient directly or via the patient's caregiver (doctor or other healthcare professional). For example, the patient can be sent an email or text message that is automatically generated by the system. The email or text message can be a notification which directs the patient to log onto a secure site to retrieve the full conclusion, determination or insight, or the email or text message can include the conclusion, determination or insight. Alternatively or additionally, the email or text message can be sent to the patient's caregiver. The notification may also be provided via an application on a smartphone, tablet, laptop, desktop or other computing device.

As described herein, the system can identify behaviors, habits, activities, foods, drinks, medications, drugs, and the like which are associated with the patient's abnormal ECG readings. In addition to informing the patient of these associations, the system can provide instructions or recommendations to the patient to avoid these behaviors, habits, activities, foods, drinks, medications, drugs, and the like which are associated with the patient's abnormal ECG readings. Similarly, the system can identify behaviors, habits, activities, foods, drinks, medications, drugs, and the like which are associated with normal or improving ECG readings, and can instruct or recommend that the patient perform these behaviors, habits, and activities and/or consume these foods, drinks, medications, and drugs. The patient may avoid a future healthcare issue, as instructed or recommended by the system, by modifying their behavior, habits or by taking any course of action, including but not limited to taking a medication, drug or adhering to a diet or exercise program, which may be a predetermined course of action recommended by the system independent of any analysis of the ECG data, and/or may also result from insights learned through this system and method as described herein. In addition, the insights of the system may relate to general fitness and or mental wellbeing.

The ECG data and the associated metadata and other related data as described herein can be stored in a central

database, a cloud database, or a combination of the two. The data can be indexed, searched, and/or sorted according to any of the features, parameters, or criteria described herein. The system can analyze the ECG data of a single patient, and it can also analyze the ECG data of a group of patients, which can be selected according to any of the features, parameters or criteria described herein. When analyzing data from a single patient, it may be desirable to reduce and/or correct for the intra-individual variability of the ECG data, so that comparison of one set of ECG data taken at one particular time with another set of ECG data taken at another time reveals differences resulting from changes in health status and not from changes in the type of ECG recording device used, changes in lead and electrode placement, changes in the condition of the skin (i.e. dry, sweaty, conductive gel applied or not applied), and the like. As described above, consistent lead and electrode placement can help reduce variability in the ECG readings. The system can also retrieve the patient's ECG data that were taken under similar circumstances and can analyze this subset of ECG data.

FIG. **4** illustrates an embodiment of the system and method **400** of ECG monitoring described herein. The system can be implemented on a server or computer having a processor for executing the instructions described herein, which can be stored in memory. In step **402**, ECG data can be recorded using any of the devices described herein for one or more patients. In step **404**, the ECG data is transmitted along with associated metadata to a server and database that stores the ECG data. In step **406**, a subset of the ECG data can be selected based on criteria in the metadata, such as user identity, time, device used to record the ECG data, and the like. In step **408**, the subset of ECG data can be analyzed using a machine learning algorithm, which can assign a risk level to the ECG data in step **410**. The system can then determine whether the risk level is high, as shown in step **412**. If the risk level is low, the user can be notified that the ECG is normal or low risk, as shown in step **414**. If the risk level is high, a high risk level alert can be sent to the patient with the option of sending the ECG to the medical professional for interpretation, as shown in step **416**. The system then waits for the user's response to determine whether the patient elects to send the ECG to the medical professional for interpretation, as shown in step **418**. If the patient does not wish to send the ECG to the medical professional for interpretation, the system can end the routine at this point, as shown in **420**. If the patient does elect to send the ECG to the medical professional for interpretation, the request can be transmitted to the medical professional in step **422**. The request to the medical professional can be sent to a workflow auction system as described in U.S. Provisional Application No. 61/800,879, filed Mar. 15, 2013, which is herein incorporated by reference in its entirety for all purposes. Once the medical professional has interpreted the ECG, the system can receive and store the ECG interpretation from the medical professional in the database, as shown in step **424**. The system can then notify the user of the professional ECG interpretation, which can be sent to or accessed by the user, as shown in step **426**. Additionally, the system can compare the assigned risk level with the medical diagnosis in step **428** and can determine whether the risk level determined by the system agrees with the medical diagnosis in step **430**. If the risk level does not agree with the medical diagnosis, the machine learning algorithm can be adjusted until the risk level matches the medical diagnosis, as shown in step **432**. If the risk level does agree with the medical diagnosis, the routine can be ended as shown in step **434**.

Although the above steps show a method **400** in accordance with many embodiments, a person of ordinary skill in the art will recognize many variations based on the teaching described herein. The steps may be completed in a different order. Steps may be added or deleted. Some of the steps may comprise sub-steps. Many of the steps may be repeated as often as beneficial to the user or subject.

One or more of the steps of a method **400** may be performed with circuitry, for example, one or more of a processor or a logic circuitry such as a programmable array logic for a field programmable gate array. The circuitry may be programmed to provide one or more of the steps of a method **400**, and the program may comprise program instructions stored on a non-transitory computer readable medium or memory or programmed steps of the logic circuitry such as the programmable array logic or the field programmable gate array, for example.

Aspects of the present disclosure provide systems and methods for generating a heart health score in response to continuously measured or monitored physiological parameter(s). The score may be given a quantitative value such as be graded from A to F or 0 to 100 for example (e.g. a great score may be an A or 100, a good score may be a B or 75, a moderate score may be a C or 50, a poor score may be a D or 25, and a failing score may be an F or 0.) If an arrhythmia is detected, the score may be below 50 for example. Other scoring ranges such as A to Z, 1 to 5, 1 to 10, 1 to 1000, etc. may also be used. Arrhythmia may be detecting using the machine learning based operations or algorithms described herein.

FIG. **5** shows a flow chart of an exemplary method **500** to generate a heart health score in accordance with many embodiments.

In a step **502**, an arrhythmia is detected. If an arrhythmia is detected (e.g. using the methods and/or algorithms disclosed herein), then the heart health score generated will be below 50. Depending on the severity of the arrhythmia detected, the heart score may be calculated or assigned within the ranges according to the table below in Table 2.

TABLE 2

Arrhythmia	Heart Health score
ATRIAL FIBRILLATION, HR below 100	30-45
ATRIAL FIBRILLATION, HR above 100	15-30
Sinus Tachycardia	20-40
Supraventricular Tachycardia	20-40
Bradycardia	20-40
Bigeminy, Trigeminy	30-50
Short runs of High Heart Rate (VTACH suspect)	10-30

In a step **504** a Heart Rate Variability (HRV) is calculated. HRV can be an indicator of heart health. The value for HRV value for a healthy heart is typically higher than HRV for an unhealthy heart. Also, HRV typically declines with age and may be affected by other factors, like stress, lack of physical activity, etc. HRV may be measured and analyzed using the methods described above. HRV may be calculated in the absence of arrhythmia, which may improve the accuracy of the HRV measurement. HRV may be determined and further analyzed as described above.

In a step **506**, premature beats are counted and Heart Rate Turbulence (HRT) is calculated. Premature beats in the sequence of R-R intervals may be detected. Also, R-R

intervals typically tend to recover at a certain pace after a premature beat. Using these two parameters (prematurity and pace of R-R recovery), HRT parameters may be calculated. There may be known deviations of HRT parameters associated with patients with risk of Congestive Heart Failure (CHF). These deviations, however, may be used to estimate an inverse measure. The number of premature beats per day (or per hour) may also be used as a measure of heart health. A low number of premature beats may indicate better heart health. In summary, the heart health score may be generated by combining at least heart rate variability (HRV), the number of premature beats, and heart rate turbulence (HRT). This combination (in the absence of arrhythmia) may provide an accurate estimate of how healthy the heart of the user is.

In a step **508**, a heart health score is generated, and in a step **510**, a hearth health score is generated based on an arrhythmia. To initially generate the score, a few hours (e.g. 2-5 hours) of measured R-R intervals may be required. A more accurate score may be generated after a week of continuous R-R interval measurements. Longer data sets may be required to detect significant arrhythmias as they may usually be detected within the first 7-8 days of monitoring.

Although the above steps show a method **500** in accordance with many embodiments, a person of ordinary skill in the art will recognize many variations based on the teaching described herein. The steps may be completed in a different order. Steps may be added or deleted. Some of the steps may comprise sub-steps. Many of the steps may be repeated as often as beneficial to the user or subject.

One or more of the steps of a method **500** may be performed with circuitry, for example, one or more of a processor or a logic circuitry such as a programmable array logic for a field programmable gate array. The circuitry may be programmed to provide one or more of the steps of a method **500**, and the program may comprise program instructions stored on a non-transitory computer readable medium or memory or programmed steps of the logic circuitry such as the programmable array logic or the field programmable gate array, for example.

FIG. **6** shows a further method **600** of generating a heart score. In addition to the parameters which may be derived from the heart rate data described above, the heart health score may also be generated in response to further physiological parameters as shown in FIG. **6**.

In a step **602**, a raw ECG waveform is obtained. In a step **608**, ECG parameters are extracted from the raw ECG waveform data and arrhythmia prediction and/or detection algorithms are run to analyze the obtained raw ECG waveform data.

In a step **604**, physiological parameters may be measured using a sensor of the user's local computing device or an accessory thereof. Such measured physiological parameters may include blood pressure, user activity and exercise level, blood oxygenation levels, blood sugar levels, an electrocardiogram, skin hydration or the like of the user. These physiological parameters may be measured over time such as over substantially the same time scale or length as the measurement of heart rate. In a step **610**, an R-R interval is extracted and both traditional and non-traditional heart rate measures are used to analyze the measured heart rate and physiological parameters.

In a step **606**, additional physiological parameters for determining the heart health score may be input by the user. These parameters may include the age, the gender, the weight, the height, the body type, the body mass index (BMI), the personal medical history, the family medical history, the exercise and activity level, the diet, the hydration level, the amount of sleep, the cholesterol level, the alcohol intake level, the caffeine intake level, the smoking status, and the like of the user. For example, the heart health score may be weighted by age and/or gender to provide the user an accurate assessment of his or her heart health in response to the heart rate data. In a step **612**, feature extraction is used to analyze the inputted physiological parameters.

In a step **614** feature ranking and/or feature selection occurs. In a step **618**, a real time prediction or detection of atrial fibrillation, and/or in a step **616**, the heart rate variability measurements may be labelled and saved for offline training of a machine learning algorithm or set of machine learning operations, and then may be subsequently used to make a real time prediction and/or detection of atrial fibrillation. A plurality of heart health scores may be generated by a plurality of users to generate a set of population data. This population data may be used to train the machine learning algorithms described herein such that the trained algorithm may be able to detect and predict atrial fibrillation or other health conditions from user data.

Although the above steps show a method **600** in accordance with many embodiments, a person of ordinary skill in the art will recognize many variations based on the teaching described herein. The steps may be completed in a different order. Steps may be added or deleted. Some of the steps may comprise sub-steps. Many of the steps may be repeated as often as beneficial to the user or subject.

One or more of the steps of a method **600** may be performed with circuitry, for example, one or more of a processor or a logic circuitry such as a programmable array logic for a field programmable gate array. The circuitry may be programmed to provide one or more of the steps of a method **600**, and the program may comprise program instructions stored on a non-transitory computer readable medium or memory or programmed steps of the logic circuitry such as the programmable array logic or the field programmable gate array, for example.

The systems and methods for generating a heart health score in response to continuously measured or monitored physiological parameter(s) may comprise a processor of a computing device and software. A processor of a computing device (e.g. a tablet computer, a smartphone, a smart watch, a smart band, a wearable computing device, or the like) may execute this set of instructions to receive the input data and detect and/or predict atrial fibrillation therefrom. The software may be downloaded from an online application distribution platform such as the Apple iTunes or App Store, Google Play, Amazon App Store, and the like. A display of the computing device may notify the user of the calculated heart health score and/or if further measurements are required (e.g. to perform a more accurate analysis).

FIG. **7** shows a schematic diagram of the executed application described herein. The heart health score may be provided on a software application such as a mobile app downloaded from an application distribution platform and executed on a local computing device of the user as described above. This executed application may instruct the user to take active steps in response to a poor or moderate heart health score. For example, the instructions to the user may be to make a corrective measure such as to modify his or her diet, exercise pattern, sleep pattern, or the like. Alternatively or in combination, the instructions to the user may be to take a further step such as to take an electrocardiogram (e.g. to verify the presence of an arrhythmia), enroll in an electrocardiogram over-read service, or schedule an

appointment with a physician or other medical specialist. If the heart health score is below a desired threshold for good heart health, the executed application may link the user to a second execute application with further application features. Alternatively or in combination, these further features may be unlocked on the first executed application if the heart health score is below the threshold. In at least some cases, a prescription or verification from a medical professional may also be required to unlock the further application features.

FIG. **8** shows screenshots of the executed application. The further features unlocked may include the ability to read electrocardiogram (ECG) data from a sensor coupled to the local computing device and display the electrocardiogram (ECG) in real-time and/or detect and alert for atrial fibrillation based on the electrocardiogram (ECG) in real-time (e.g. as described in U.S. application Ser. Nos. 12/796,188, 13/108,738, 13/420,540, and 13/964,490). As shown in FIG. **8**, these further features may include an electrocardiogram (ECG) over-read service such as that described in U.S. application Ser. No. 14/217,032. The first executed application may comprise a consumer software application and the second executed application may comprise a medical professional or regulated software application or set of features of the first executed application. As described herein and shown in FIG. **8**, the executed application may provide a dash board to track the heart health of the user and show risk factors which may be monitored and tracked by the user. The dash board may be provided with further features such as that described in U.S. Ser. No. 61/915,113 (filed Dec. 12, 2013).

FIG. **9** shows a method **900** for cardiac disease and rhythm management, which may, for example, be implemented with the system **100** described herein. In a step **902**, a user or subject is provided access to a cardiac disease and/or rhythm management system such as system **100**. Step **902** may comprise prescribing the use of the system **100** for the user or subject. In a step **904**, the user or subject is provided one or more biometric sensors. These biometric sensor(s) may couple to a computing device of the user or subject, e.g. a personal desktop computer, a laptop computer, a tablet computer, a smartphone, etc., and associated software loaded thereon.

In a step **906**, the user or subject downloads the cardiac disease and/or rhythm management system software onto their computing device. For example, the system software may comprise a mobile software application ("mobile app") downloaded from the Apple App Store, Google Play, Amazon Appstore, BlackBerry World, Nokia Store, Windows Store, Windows Phone Store, Samsung Apps Store, and the like. The downloaded system software, e.g. mobile app **101***a*, may be configured to interface with the biometric sensors provided to the user or subject in the step **154**.

In a step **908**, personal information input to the cardiac disease management system is received. For example, the user or subject may enter his or her gender, height, weight, diet, disease risk factors, etc. into the mobile app **101***a*. Alternatively or in combination, this personal information may be input on behalf of the user or subject, for example, by a physician of the user or subject.

In a step **910**, biometric data is received from the biometric sensors provided to the user or subject. For example, the system **100** and the mobile app **101***a* may receive ECG data and heart rate from handheld sensor **103**, activity data from wrist-worn activity sensor **105**, blood pressure and heart rate data from mobile blood pressure monitor **107***a*, and other data such as weight and body fat percentage data from a "smart" scale in communication with the local computing device **101**.

In a step **912**, a cardiac health score is generated. The cardiac health score can be generated by considering and weighing one or more influencing factors including the incidence of atrial fibrillation or arrhythmia as detected by the handheld ECG monitor, the heart rate of the user or subject, the activity of the user or subject, hours of sleep and rest of the user or subject, blood pressure of the user or subject, etc. Often, the incidence of atrial fibrillation or arrhythmia will be weighed the most. The cardiac health score may be generated by a physician or a machine learning algorithm provided by the remote server or cloud-based service **113**, for example. A plurality of users and subject may concurrently use the cardiac health and/or rhythm management system **100** and the machine learning algorithm may, for example, consider population data and trends to generate an individual user or subject's cardiac health score.

In a step **914**, one or more recommendations or goals is generated for the user or subject based on or in response to the generated cardiac health score. These recommendation(s) and/or goal(s) may be generated automatically based on or in response to the biometric and personal information of the user or subject. For example, the machine learning algorithm may generate these recommendation(s)/goal(s). Alternatively or in combination, a physician or other medical specialist may generate the recommendation(s) and/or goal(s), for example, based on or in response to the biometric and personal information of the user or subject. The physician or other medical professional may access the patient data through the Internet as described above.

In a step **916**, the patient implements many if not all of the recommendation(s) and/or goal(s) provided to him or her. And in a step **916**, steps **908** to **916** may be repeated such that the user or subject may iteratively improve their cardiac health score and their overall health.

Although the above steps show method **900** of managing cardiac disease and/or rhythm in accordance with many embodiments, a person of ordinary skill in the art will recognize many variations based on the teaching described herein. The steps may be completed in a different order. Steps may be added or deleted. Some of the steps may comprise sub-steps. Many of the steps may be repeated as often as beneficial to the user or subject.

One or more of the steps of the method **900** may be performed with circuitry, for example, one or more of a processor or a logic circuitry such as a programmable array logic for a field programmable gate array. The circuitry may be programmed to provide one or more of the steps of the method **900**, and the program may comprise program instructions stored on a non-transitory computer readable medium or memory or programmed steps of the logic circuitry such as the programmable array logic or the field programmable gate array, for example.

In some embodiments, the heart rate information (or an extracted portion of HR information) may be used to compare to a database of similar information that has been correlated with cardiac events. For example, heart rate information may be compared to a database of HR information extracted for ECG recordings of patients known to be experiencing cardiac problems. Thus, patterns of heart rate information taken from a subject may be compared to patterns of cardiac information in a database. If there is a match (or a match within a reasonable closeness of fit), the patient may be instructed to record an ECG, e.g. using an ambulatory ECG monitor. This may then provide a more

detailed view of the heart. This method may be particularly useful, as it may allow recording and/or transmission and/or analysis of detailed electrical information about the heart at or near the time (or shortly thereafter) when a clinically significant cardiac event is occurring. Thus, the continuous monitoring may allow a subject to be alerted immediately upon an indication of the potential problem (e.g. an increase in HRV suggestive of a cardiac dysfunction). This may allow the coupling of continuous HR monitoring with ECG recording and analysis for disease diagnosis and disease management.

FIG. **10** illustrates one variation of a method for monitoring a subject to determine when to record an electrocardiogram (ECG). In FIG. **10**, a subject is wearing a continuous heart rate monitor (configured as a watch **1010**, including electrodes **1016**), shown in step **1002**. The heart rate monitor transmits (wirelessly **1012**) heart rate information that is received by the smartphone **1018**, as shown in step **1004**. The smartphone includes a processor that may analyze the heart rate information **1004**, and when an irregularity is determined, may indicate **1006** to the subject that an ECG should be recorded. In FIG. **10**, an ambulatory ECG monitor **1014** is attached (as a case having electrodes) to the phone **1018**. The user may apply the ECG monitor as to their body (e.g. chest, between arms, etc.) **1008** to record ECGs that can then be saved and/or transmitted for analysis.

FIGS. **11** and **11**A show screenshots of an atrial fibrillation dashboard **1100** of a user interface for the cardiac disease and/or rhythm management system **100**. FIG. **11** shows a top portion **1100***a* of the atrial fibrillation dashboard **1100** while FIG. **10**A shows a bottom portion **1100***b* of the atrial fibrillation dashboard **1100**.

The top portion **1100***a* of the atrial fibrillation dashboard **1100** as shown in FIG. **10** may display the current cardiac health score of the user or subject, a recent best cardiac health score of the user or subject, and a completion percentage of recommendation(s) and/or goal(s) for the user or subject. The user or subject may tap any one of the cardiac health score displays or the recommendation(s) and/or goal(s) displays to access more detailed information regarding the calculated health score(s) or recommendation(s) and/or goal(s), respectively. The top portion **1100***a* may also show an ECG of the user or subject and a button which may be tapped to record the ECG of the user or subject for the day. As discussed with reference to FIG. **1**, the ECG may be recorded with a handheld sensor **103** in communication with the local computing device **100**. The top portion **1000***a* may also show the number of atrial fibrillation episodes and the average duration of these atrial fibrillation episodes. This number and duration may be generated automatically by software or logic of the mobile app **101***a* based on or in response to the ECG measurements taken by the user or subject. Alternatively or in combination, a physician may access the atrial fibrillation dashboard **1100** of an individual user or subject, evaluate his or her ECGs, and provide the number of atrial fibrillation episodes and their duration to the mobile app **101***a* or other software loaded on the local computing device **101** of the user or subject. The shortest and longest durations of the atrial fibrillation episodes may also be shown by the top portion **1100***a* as well as the user or subject's daily adherence to a medication regime.

The bottom portion **1100***b* of the atrial fibrillation dashboard **1100** as shown in FIG. **10**A may display one or more influencers which influence how the cardiac health score is generated. These influencers may include, for example, caffeine intake, alcohol intake, stress levels, sleep levels, weight, nutrition, fitness and activity levels, and blood pressure. Data for these influencers may be input automatically by one or more biometric sensors coupled to the local computing device **101** and/or the mobile app **101***a*. Alternatively or in combination, the data for these influencers may be input manually by the user or subject by tapping on the respective influencer display. For example, tapping on the blood pressure display area may cause a slider input **1100***c* for blood pressure to pop up. The user or subject may use the slider to enter and save his or her blood pressure for the day. Similar pop-ups or user-selected inputs may be provided for the other influencers. For example, the user or subject may enter his or her daily caffeine or alcohol intake, stress and sleep levels, nutrition levels, or activity and fitness levels (e.g. low/bad, medium/so-so, or high/good based on the user's age, gender, height, weight, etc. as can be indicated by an instruction page of the mobile app **101***a*). The influencer displays may also show the goal progression of the user or subject.

FIGS. **12** and **12**A show screenshots of a goals and recommendations page **1200** of the cardiac disease and rhythm management system interface or mobile app **101***a*. A top portion **1200***a* of the goals and recommendations page **1100** may comprise a listing of 7-day goals for the user or subject. The top portion **1200***a* may further comprise everyday goals for the user or subject which often cannot be removed or changed. The user or subject can check off these goals or recommendations as he or she meets them. The top portion **1200***a* may track goal completion percentage over a 7-day period. The user or subject can set the same goals for the next day and/or set new goals.

A bottom portion **1200***b* of the goals and recommendations page **1200** may comprise a listing of new goals which the user or subject may add. The new goals may be categorized into goals or recommendations for atrial fibrillation management, stress management, and/or other categories. For example, goals for atrial fibrillation management may include taking daily medications, reducing caffeine intake, and reducing alcohol intake. And, goals for stress management may include meditate for 5 minutes daily, take blood pressure reading daily, and getting at least 7 hours of sleep nightly. Using the goals and recommendations page **1200**, the user or subject can set their goals for the week. One or more of these goals may be automatically recommended to the user or subject or be recommended by a physician having access to the dashboard **1100**. For example, goals may be recommended based on last week's progress. The completion of recommended goals can result in the user or subject earning more "points," in effect gamifying health and cardiac rhythm management for the user or subject. Alternatively or in combination, the goals may be set by a physician having access to the dashboard **1100**.

FIG. **13** shows a screenshot of a user's local computing device notifying the user with a pop-up notice **1300** to meet their daily recommendations and goals. By tapping on the pop-up notice, **1300**, the user or subject can be taken to the atrial fibrillation dashboard where the user or subject can update or otherwise manage their cardiac health.

FIG. **14** shows an embodiment comprising a smart watch **1400** which includes at least one heart rate monitor **1402** and at least one activity monitor **1404**. One or more processors are coupled to one or more non-transitory memories of the smart watch and configured to communicate with the heart rate monitor **1402** and the activity monitor **1404**. The one or more processors are further coupled to an output device **1408**. Processor executable code is stored on the one or more memories and when executed by the one or more processors causes the one or more processors to determine if heart rate

and activity measurements represent an advisory condition for recording an ECG, and generate and send notification signals through the output device **1408** when an advisory condition for recording an ECG is determined.

For example, presently available smart watches include motion sensors such as pedometers. Pedometers can be based on an accelerometer or electromechanical mechanism such as a pendulum, magnetic reed proximity switch, and a spring suspended lever arm with metal-on-metal contact. Modern accelerometers are often small micro electro-mechanical systems and are well known by those skilled in the art. Heart rate monitors are readily available with smart phones as well as smart watches. One type uses an optical sensor to detect the fluctuation of blood flow. The signal can be amplified further using, for example, a microcontroller to count the rate of fluctuation, which is actually the heart rate.

An advisory condition for recording an ECG may occur due to, for example, large continuing fluctuations in heart rate. An advisory condition for recording an ECG can also occur when a measured heart rate increases rapidly without a corresponding increase in activity monitored by, for example, an accelerometer. By comparing measured heart rate changes with measured activity changes, the presently disclosed software or "app" minimizes false alarms are minimized. ECG devices are described in U.S. Ser. No. 12/796,188, filed Jun. 8, 2010, now U.S. Pat. No. 8,509,882, hereby expressly incorporated herein by reference in its entirety. The ECG device can be present in a smart watch band or a smart phone. In one embodiment, the ECG device includes an electrode assembly configured to sense heart-related signals upon contact with a user's skin, and to convert the sensed heart-related signals to an ECG electric signal. The ECG device transmits an ultrasonic frequency modulated ECG signal to a computing device such as, for example, a smartphone. Software running on the computing device or smartphone digitizes and processes the audio in real-time, where the frequency modulated ECG signal is demodulated. The ECG can be further processed using algorithms to calculate heart rate and identify arrhythmias. The ECG, heart rate, and rhythm information can be displayed on the computer or smartphone, stored locally for later retrieval, and/or transmitted in real-time to a web server via a 2G/3G/4G, WiFi or other Internet connection. In addition to the display and local processing of the ECG data, the computer or smartphone can transmit, in real-time, the ECG, heart rate and rhythm data via a secure web connection for viewing, storage and further analysis via a web browser interface.

In another embodiment, the converter assembly of an ECG device is integrated with, and electrically connected to the electrode assembly and is configured to convert the electric ECG signal generated by electrode assembly to a frequency modulated ECG ultrasonic signal having a carrier frequency in the range of from about 18 kHz to about 24 kHz. It is sometimes desirable to utilize a carrier frequency in the 20 kHz to 24 kHz range. The ultrasonic range creates both a lower noise and a silent communication between the acquisition electronics and the computing device such as the smartphone, notebook, smart watch and the like.

A kit can include downloadable software such as an "app" for detecting an advisory condition for recording an ECG and an ECG device. The ECG device can be present on a watch band for replacing a specific band on a smart watch. The ECG device can also be provided on a smart phone back plate for replacing an existing removable smartphone back. In another configuration, the ECG device is usable as a smartphone protective case.

Software on the smartphone or smart watch can also combine data and signals from other sensors built into the smartphone or smart watch such as a GPS.

While preferred embodiments of the present disclosure have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the subject matter described herein. It should be understood that various alternatives to the embodiments of the subject matter described herein may be employed in practicing the subject matter described herein. It is intended that the following claims define the scope of the disclosure and that methods and structures within the scope of these claims and their equivalents be covered thereby.

What is claimed is:

1. A method of determining a presence of an arrhythmia of a first user, said method comprising

sensing a heart rate of said first user with a heart rate sensor coupled to said first user;

transmitting said heart rate of said first user to a mobile computing device, wherein said mobile computing device is configured to sense an electrocardiogram;

determining, using said mobile computing device, a heart rate variability of said first user based on said heart rate of said first user;

sensing an activity level of said first user with a motion sensor;

comparing, using said mobile computing device, said heart rate variability of said first user to said activity level of said first user; and

alerting said first user to sense an electrocardiogram of said first user, using said mobile computing device, in response to an irregularity in said heart rate variability of said first user.

2. The method of claim **1**, wherein said heart rate sensor comprises one or more of a patch, a wristband, and an armband.

3. The method of claim **1**, further comprising receiving biometric data of said first user from a biometric data sensor coupled to said first user.

4. The method claim **3**, wherein said biometric data comprises one or more of a temperature of said first user, a blood pressure of said first user, and inertial data of said first user.

5. The method of claim **1**, wherein said mobile computing device comprises a smartphone.

6. The method of claim **1**, wherein said mobile computing device comprises a smartwatch.

7. The method of claim **1**, further comprising determining a presence of said arrhythmia using a machine learning algorithm.

8. The method of claim **7**, wherein said machine learning algorithm stores heart rate and heart rate variability data previously associated with arrhythmias in said first user and determines said presence of said arrhythmia based on said stored heart and heart rate variability data.

9. The method of claim **7**, wherein said machine learning algorithm stores heart rate and heart rate variability data associated with arrhythmias in a second user and determines said presence of said arrhythmia in said first user based on said stored heart and heart rate variability data associated with arrhythmias in said second user.

10. The method of claim 1, wherein an irregularity comprises an increase in said heart rate variability of said first user without a corresponding increase in said activity level of said first user.

11. A system for determining the presence of an arrhythmia of a first user, comprising

a heart rate sensor coupled to said first user;

a mobile computing device comprising a processor, wherein said mobile computing device is coupled to said heart rate sensor, and wherein said mobile computing device is configured to sense an electrocardiogram of said first user; and

a motion sensor

a non-transitory computer readable medium encoded with a computer program including instructions executable by said processor to cause said processor to receive a heart rate of said first user from said heart rate sensor, sense an activity level of said first user from said motion sensor, determine a heart rate variability of said first user based on said heart rate of said first user, compare and activity level of said first user to said heart rate variability of said first user, and alert said first user to record an electrocardiogram using said mobile computing device.

12. The system of claim 11, wherein said heart rate sensor comprises one or more of a patch, a wristband, and an armband.

13. The system of claim 11, wherein said system further comprises a biometric data sensor, and wherein said computer program including instructions executable by said processor further causes said processor to sense biometric data of said first user from said biometric data sensor.

14. The system claim 13, wherein said biometric data comprises one or more of a temperature of said first user, a blood pressure of said first user, and inertial data of said first user.

15. The system of claim 11, wherein said mobile computing device comprises a smartphone.

16. The system of claim 11, wherein said mobile computing device comprises a smartwatch.

17. The system of claim 11, wherein said computer program further causes said processor to determine a presence of said arrhythmia using a machine learning algorithm.

18. The system of claim 17, wherein said machine learning algorithm stores heart rate and heart rate variability data previously associated with arrhythmias in said first user and determines said presence of said arrhythmia based on said stored heart and heart rate variability data.

19. The system of claim 18, wherein said machine learning algorithm stores heart rate and heart rate variability data associated with arrhythmias in a second user and determines said presence of said arrhythmia in said first user based on said stored heart and heart rate variability data associated with arrhythmias in said second user.

20. The system of claim 11, wherein an irregularity comprises an increase in said heart rate variability of said first user without a corresponding increase in said activity level of said first user.

* * * * *

US010595731B2

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

(10) **Patent No.: US 10,595,731 B2**
(45) **Date of Patent: Mar. 24, 2020**

(54) **METHODS AND SYSTEMS FOR ARRHYTHMIA TRACKING AND SCORING**

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

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(22) Filed: **Sep. 30, 2019**

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(51) **Int. Cl.**
A61B 5/024 (2006.01)
A61B 5/0205 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61B 5/02055*** (2013.01); ***A61B 5/0022*** (2013.01); ***A61B 5/0245*** (2013.01); ***A61B 5/02405*** (2013.01); ***A61B 5/02416*** (2013.01); ***A61B 5/046*** (2013.01); ***A61B 5/681*** (2013.01); ***A61B 5/6898*** (2013.01);
(Continued)

(58) **Field of Classification Search**
USPC 600/508–509
See application file for complete search history.

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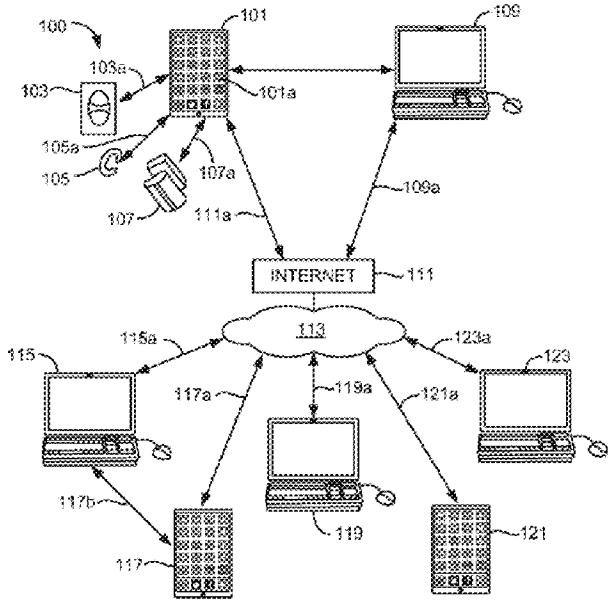
Primary Examiner — Nicole F Lavert
(74) *Attorney, Agent, or Firm* — Womble Bond Dickinson (US) LLP; Daniel E. Ovanezian

(57) **ABSTRACT**

A dashboard centered around arrhythmia or atrial fibrillation tracking is provided. The dashboard includes a heart or cardiac health score that can be calculated in response to data from the user such as their ECG and other personal information and cardiac health influencing factors. The dashboard also provides to the user recommendations or goals, such as daily goals, for the user to meet and thereby improve their heart or cardiac health score. These goals and recommendations may be set by the user or a medical professional and routinely updated as his or her heart or cardiac health score improves or otherwise changes. The dashboard is generally displayed from an application provided on a smartphone or tablet computer of the user.

30 Claims, 16 Drawing Sheets



Related U.S. Application Data

continuation of application No. 15/393,077, filed on Dec. 28, 2016, now Pat. No. 10,159,415, which is a continuation of application No. 14/730,122, filed on Jun. 3, 2015, now Pat. No. 9,572,499, which is a continuation of application No. 14/569,513, filed on Dec. 12, 2014, now Pat. No. 9,420,956.

(60) Provisional application No. 62/014,516, filed on Jun. 19, 2014, provisional application No. 61/970,551, filed on Mar. 26, 2014, provisional application No. 61/969,019, filed on Mar. 21, 2014, provisional application No. 61/953,616, filed on Mar. 14, 2014, provisional application No. 61/915,115, filed on Dec. 12, 2013.

(51) **Int. Cl.**

A61B 5/0245	(2006.01)
A61B 5/046	(2006.01)
A61B 5/00	(2006.01)
G16H 20/40	(2018.01)
G16H 40/67	(2018.01)
G16H 40/63	(2018.01)
G16H 15/00	(2018.01)
G16H 10/60	(2018.01)
A61B 5/021	(2006.01)
A61B 5/0452	(2006.01)
A61B 5/11	(2006.01)
G16H 50/30	(2018.01)

(52) **U.S. Cl.**

CPC ***A61B 5/7264*** (2013.01); ***A61B 5/7275*** (2013.01); ***A61B 5/746*** (2013.01); ***G16H 20/40*** (2018.01); ***G16H 40/67*** (2018.01); *A61B 5/021* (2013.01); *A61B 5/02438* (2013.01); *A61B 5/0452* (2013.01); *A61B 5/1118* (2013.01); *G16H 10/60* (2018.01); *G16H 15/00* (2018.01); *G16H 40/63* (2018.01); *G16H 50/30* (2018.01)

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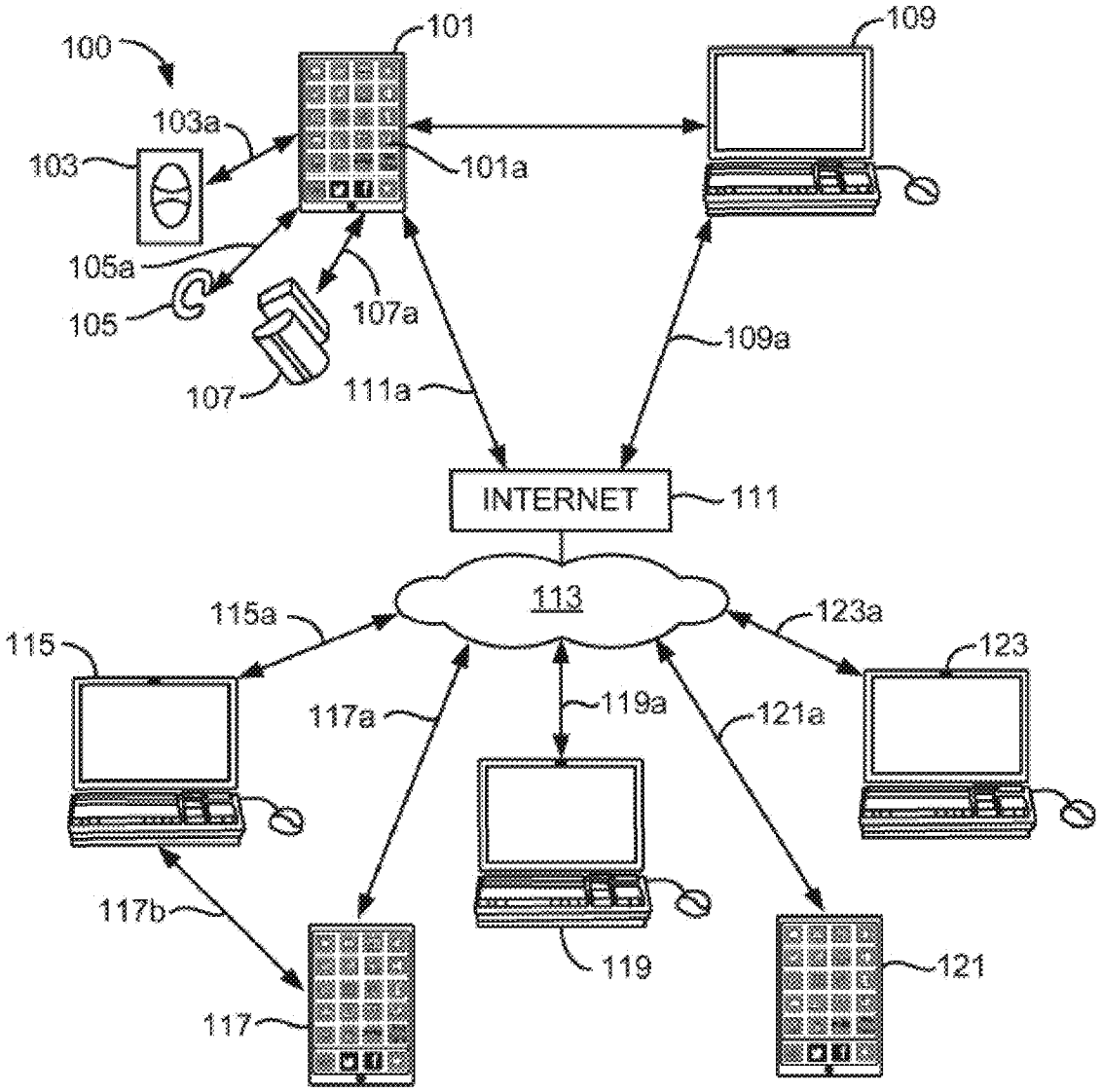
100
101
109
103a
103
101a
105a
105
107a
107
109a
111a
INTERNET
111
113
115a
123a
115
123
117a
119a
121a
117b
119
121
117

FIG. 1

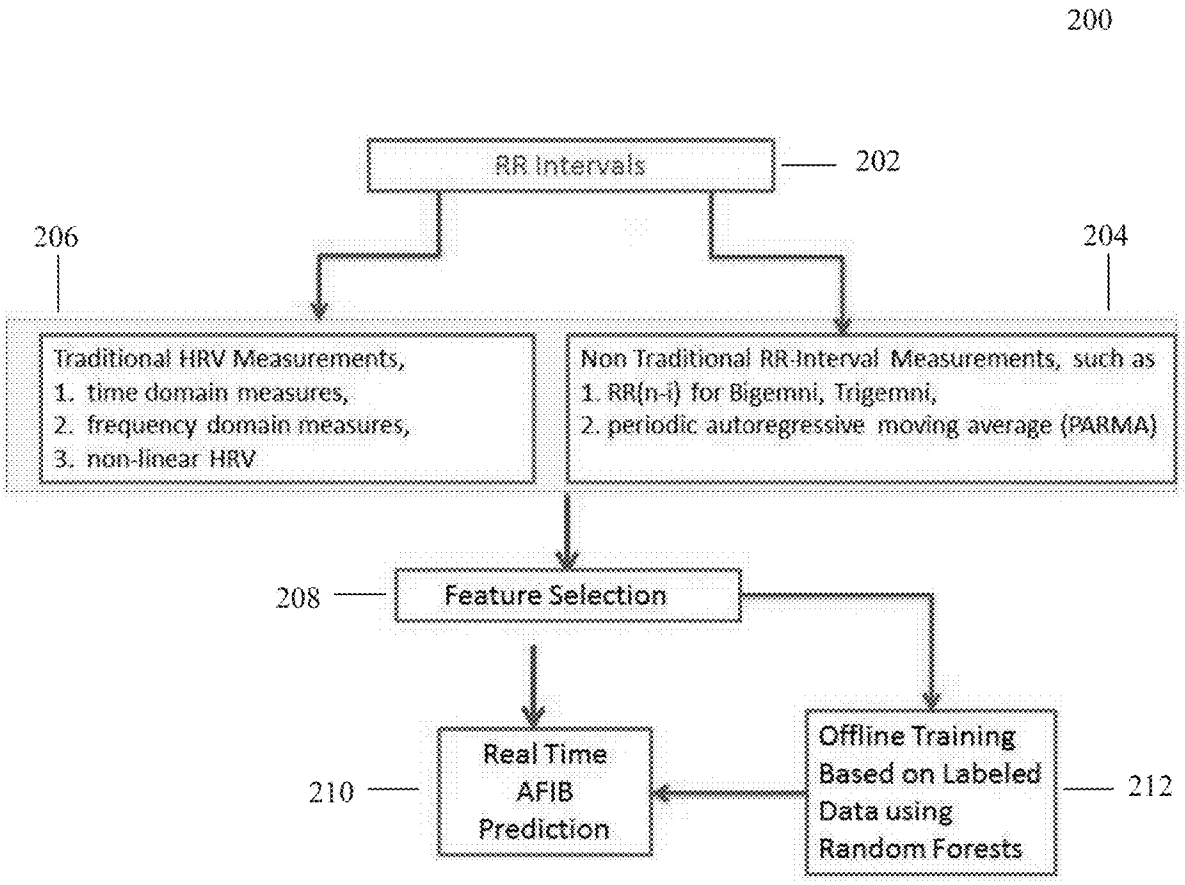
200
RR Intervals
202
206
204
Traditional HRV Measurements,
1. time domain measures,
2. frequency domain measures,
3. non-linear HRV
Non Traditional RR Interval Measurements, such as
1. RR(n-i) for Bigemni, Trigemni,
2. periodic autoregressive moving average (PARMA)
208
Feature Selection
Real Time
AFIB
Prediction
210
Offline Training
Based on Labeled
Data using
Random Forests
212

FIG. 2

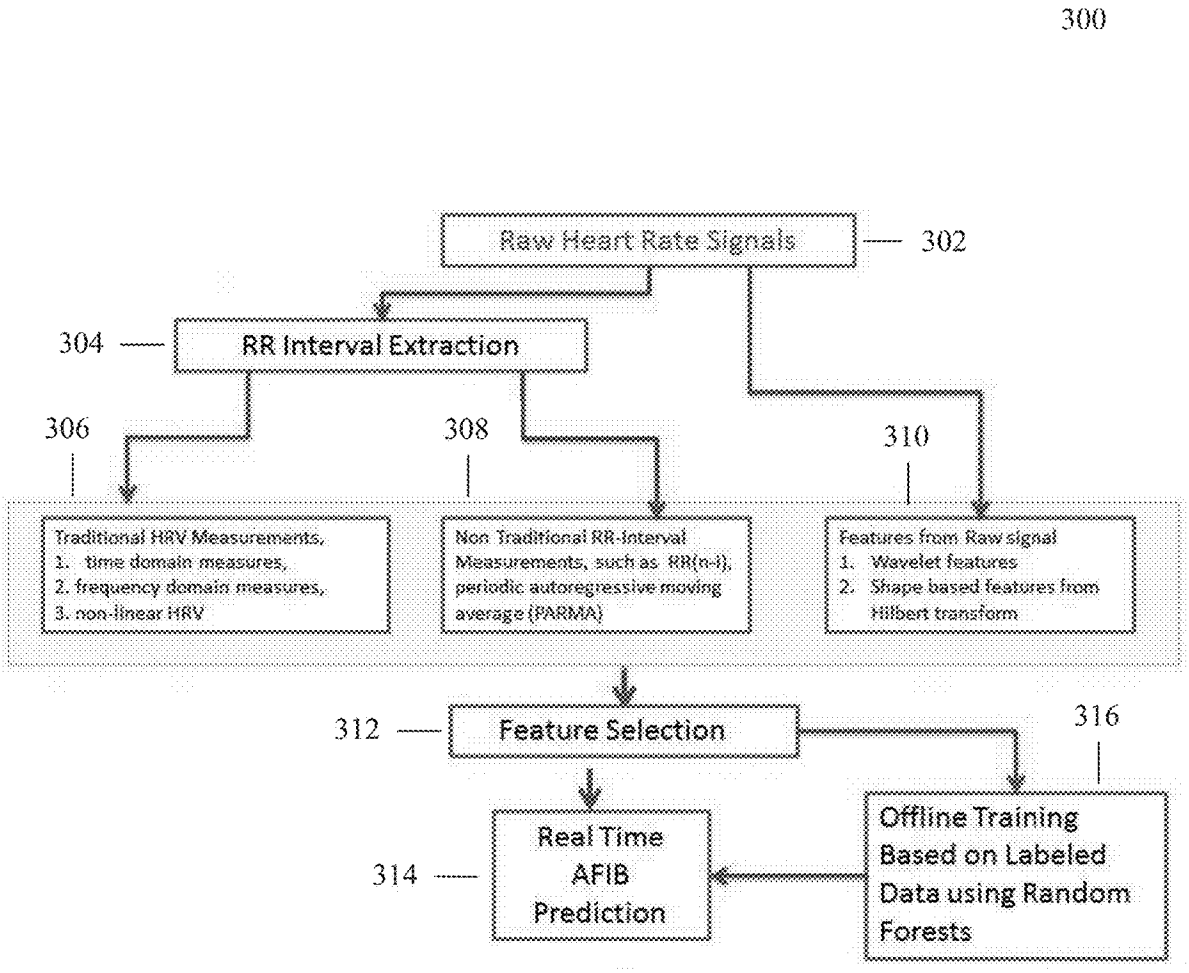
300
Raw Heart Rate Signals
302
304
RR Interval Extraction
306
308
310
Traditional HRV Measurements,
1. time domain measures,
2. frequency domain measures,
3. non-linear HRV
Non Traditional RR-Interval Measurements, such as RR(n-i), periodic autoregressive moving average (PARMA)
Features from Raw signal
1. Wavelet features
2. Shape based features from Hilbert transform
312
Feature Selection
316
314
Real Time AFIB Prediction
Offline Training Based on Labeled Data using Random Forests

FIG. 3

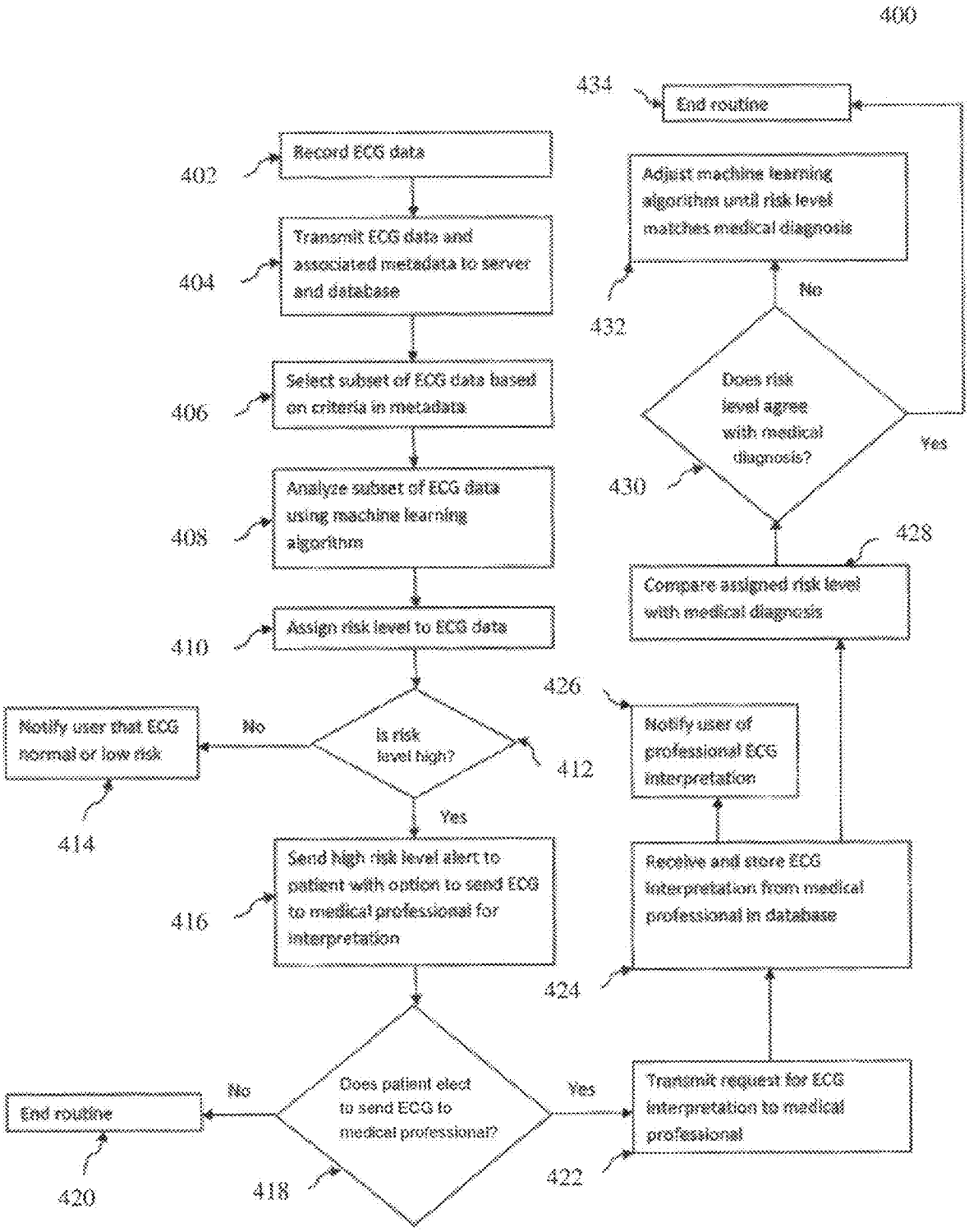
400
434
End routine
Record ECG data
402
Adjust machine learning algorithm until risk level matches medical diagnosis
Transmit ECG data and associated metadata to server and database
404
No
432
Select subset of ECG data based on criteria in metadata
406
Does risk level agree with medical diagnosis?
Yes
Analyze subset of ECG data using machine learning algorithm
408
430
428
Compare assigned risk level with medical diagnosis
Assign risk level to ECG data
410
426
Notify user that ECG normal or low risk
No
Is risk level high?
412
Notify user of professional ECG interpretation
414
Yes
Send high risk level alert to patient with option to send ECG to medical professional for interpretation
Receive and store ECG interpretation from medical professional in database
416
424
Does patient elect to send ECG to medical professional?
No
Yes
End routine
Transmit request for ECG interpretation to medical professional
420
418
422

FIG. 4

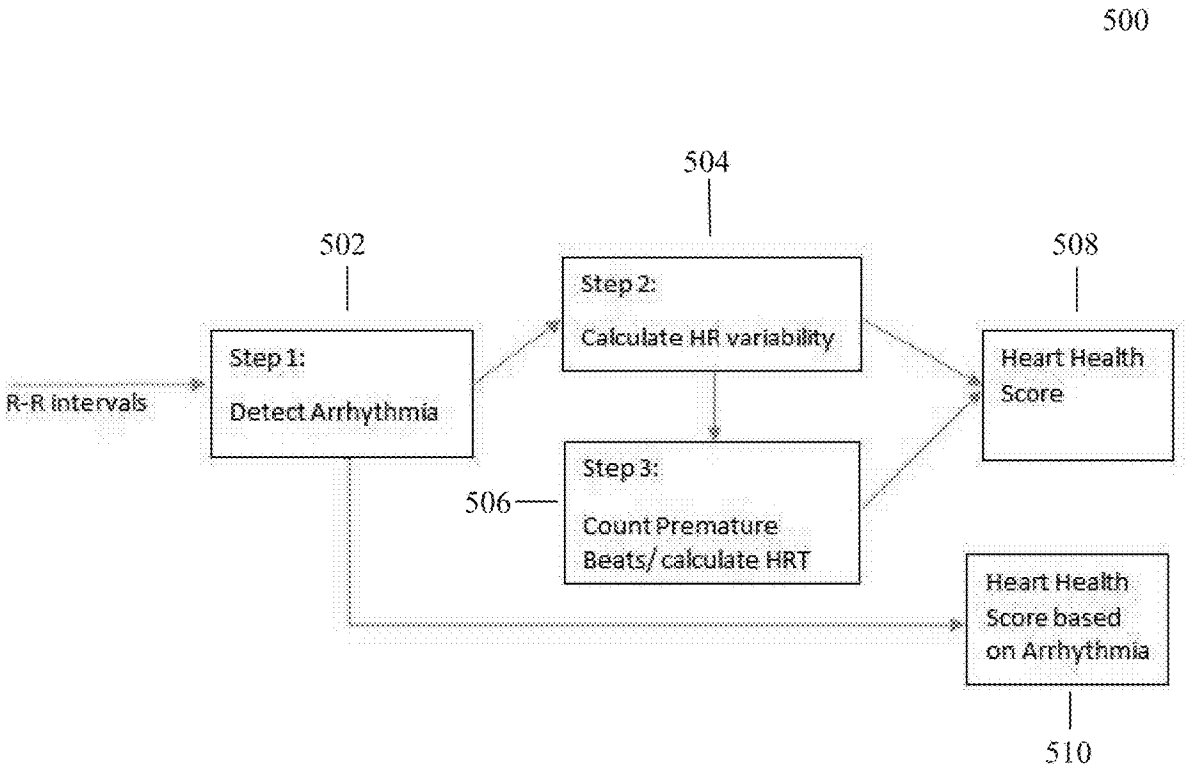
500
504
502
508
Step 2:
Calculate HR variability
Step 1:
Detect Arrhythmia
R-R intervals
Heart Health
Score
Step 3:
506
Count Premature
Beats/ calculate HRT
Heart Health
Score based
on Arrhythmia
510

FIG. 5

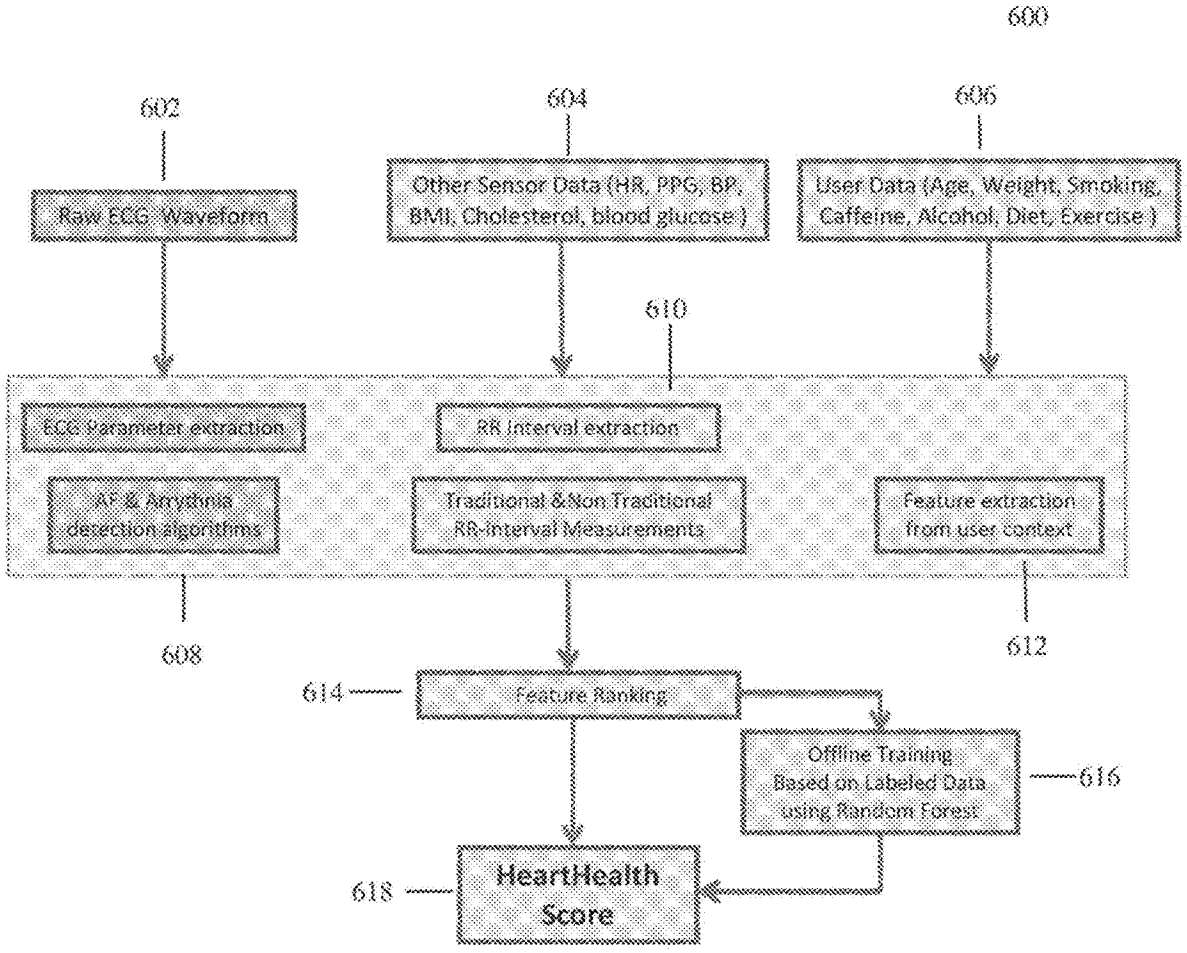
600
602
604
606
Raw ECG Waveform
Other Sensor Data (HR, PPG, BP, BMI, Cholesterol, blood glucose)
User Data (Age, Weight, Smoking, Caffeine, Alcohol, Diet, Exercise)
610
ECG Parameter extraction
RR Interval extraction
AF & Arrythmia detection algorithms
Traditional &Non Traditional RR-Interval Measurements
Feature extraction from user context
608
612
614
Feature Ranking
Offline Training Based on Labeled Data using Random Forest
616
618
HeartHealth Score

FIG. 6

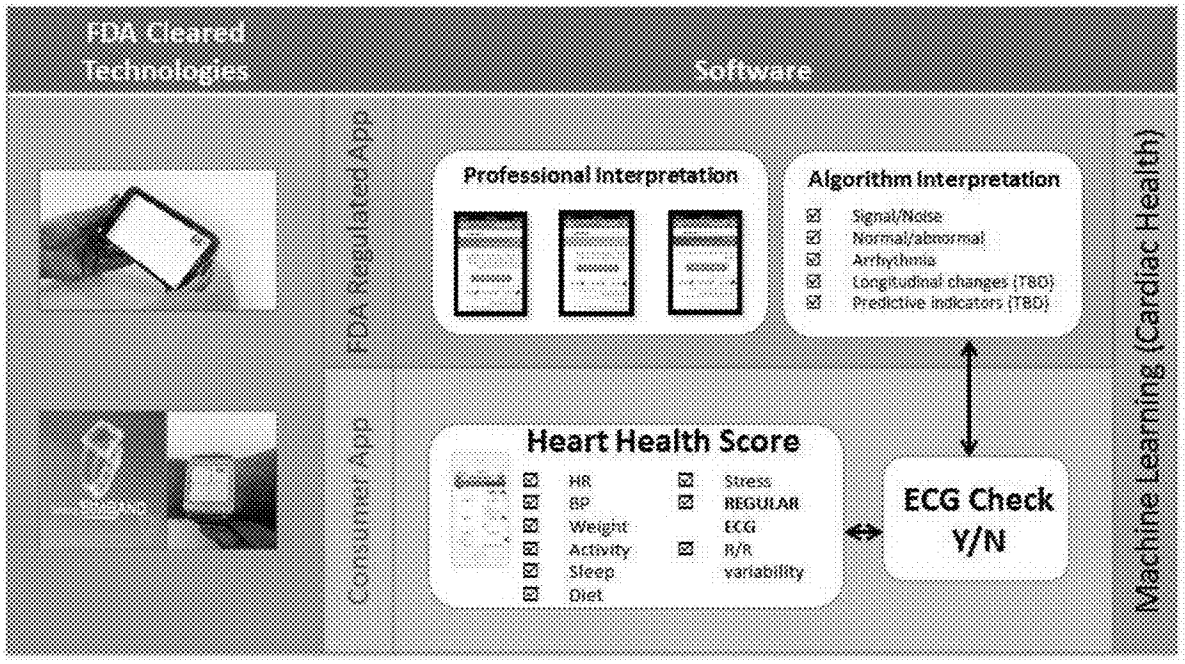
FDA Cleared Technologies
Software
FDA Regulated App
Professional Interpretation
Algorithm Interpretation
Signal/Noise
Normal/abnormal
Arrhythmia
Longitudinal changes (TBD)
Predictive indicators (TBD)
Consumer App
Heart Health Score
HR
BP
Weight
Activity
Sleep
Diet
Stress
REGULAR ECG
R/R variability
ECG Check Y/N
Machine Learning (Cardiac Health)

FIG. 7

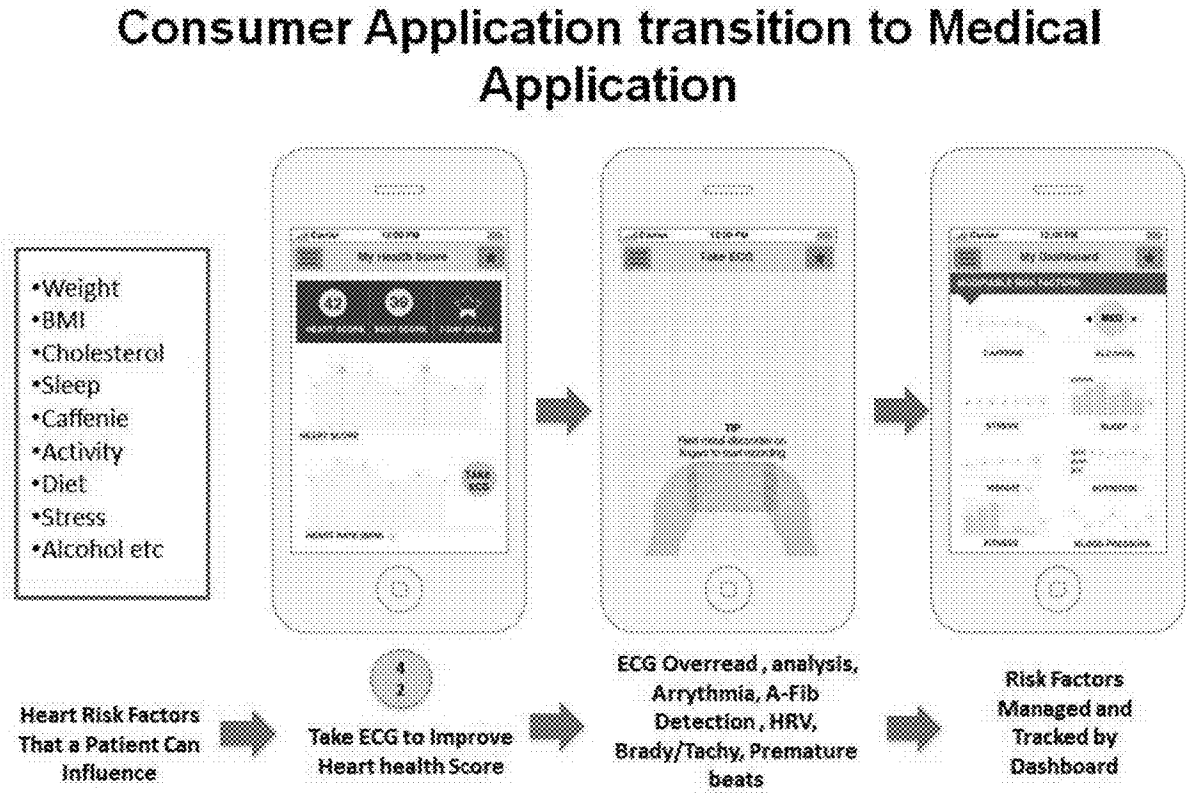
Consumer Application transition to Medical Application
•Weight
•BMI
•Cholesterol
•Sleep
•Caffenie
•Activity
•Diet
•Stress
•Alcohol etc
Heart Risk Factors That a Patient Can Influence
Take ECG to Improve Heart health Score
ECG Overread , analysis, Arrythmia, A-Fib Detection , HRV, Brady/Tachy, Premature beats
Risk Factors Managed and Tracked by Dashboard

FIG. 8

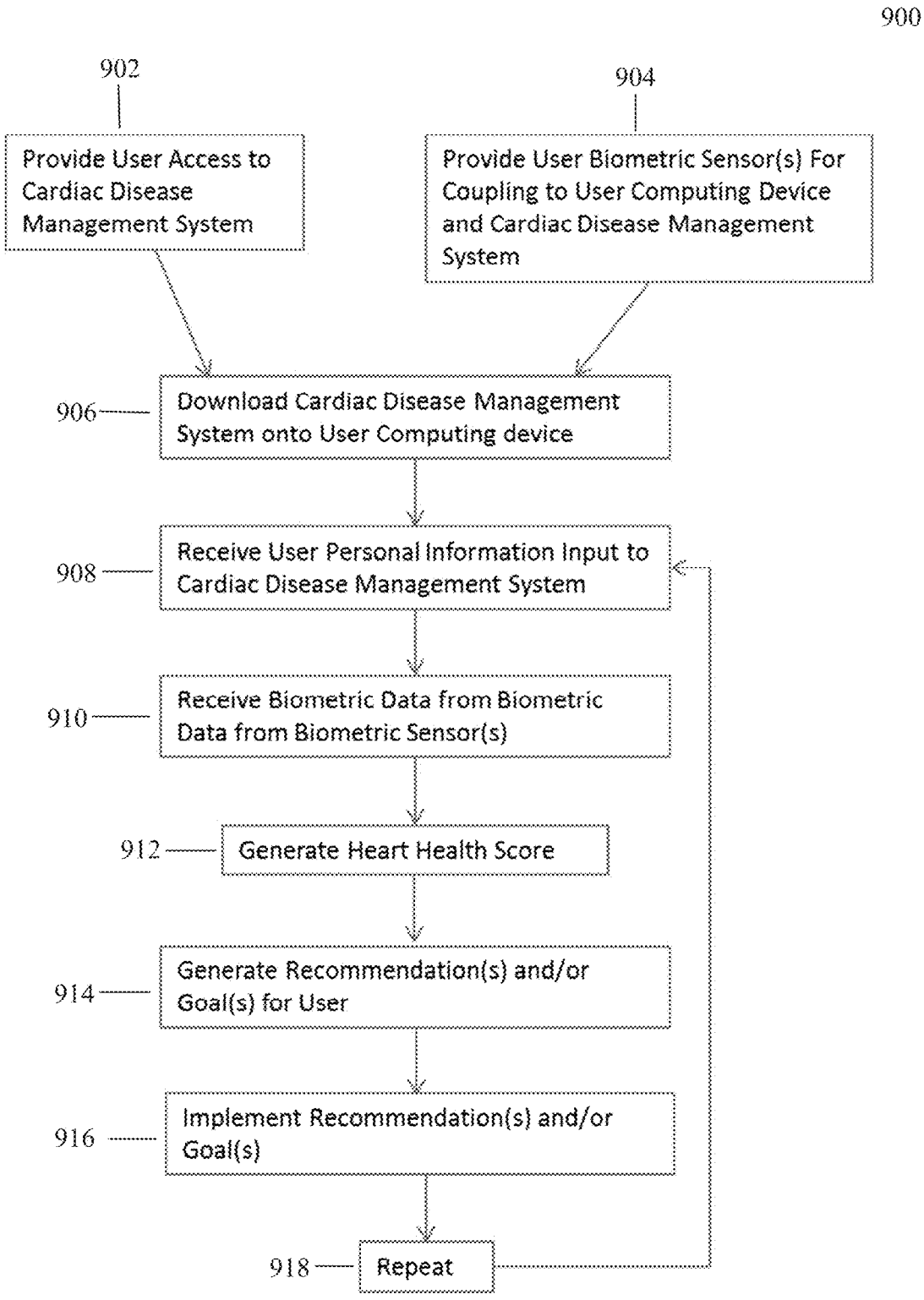
900
902
Provide User Access to Cardiac Disease Management System
904
Provide User Biometric Sensor(s) For Coupling to User Computing Device and Cardiac Disease Management System
906
Download Cardiac Disease Management System onto User Computing device
908
Receive User Personal Information Input to Cardiac Disease Management System
910
Receive Biometric Data from Biometric Data from Biometric Sensor(s)
912
Generate Heart Health Score
914
Generate Recommendation(s) and/or Goal(s) for User
916
Implement Recommendation(s) and/or Goal(s)
918
Repeat

FIG. 9

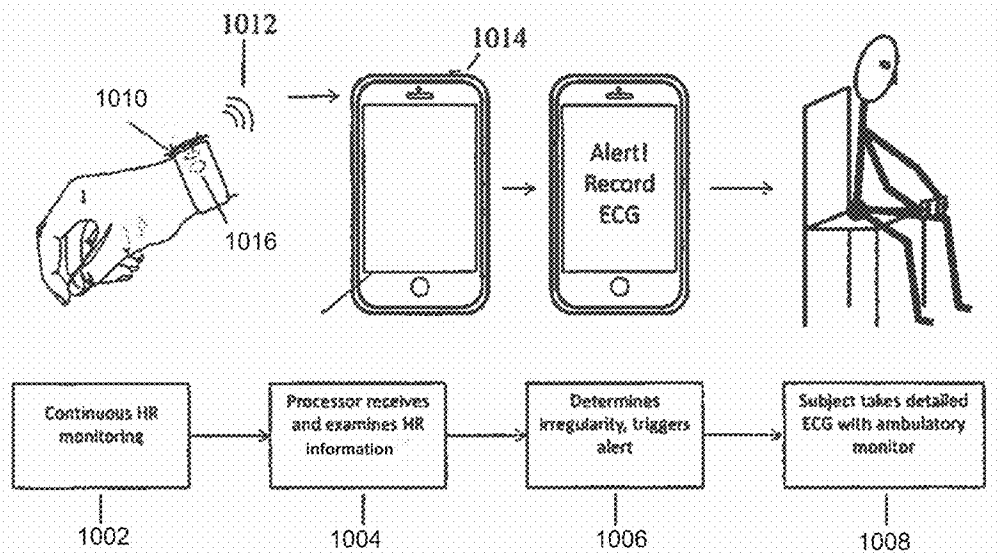
1012
1014
1010
1016
Alert! Record ECG
Continuous HR monitoring
Processor receives and examines HR information
Determines irregularity, triggers alert
Subject takes detailed ECG with ambulatory monitor
1002
1004
1006
1008

FIG. 10

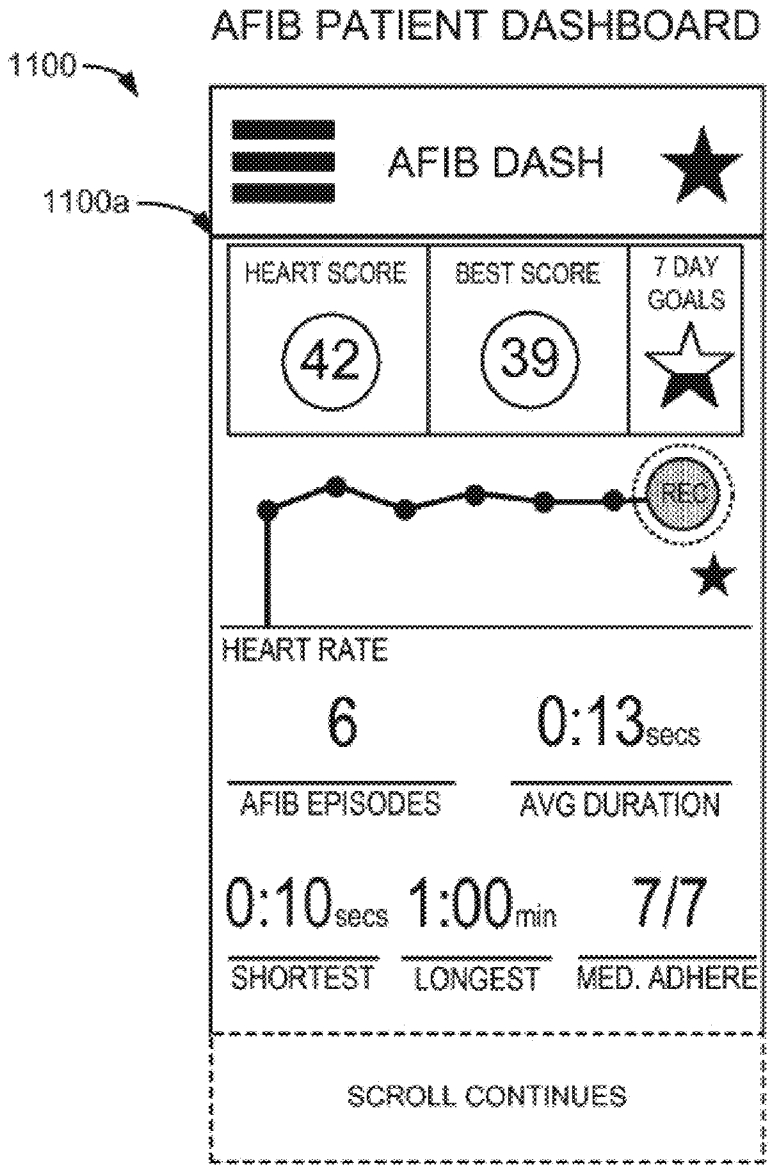
AFIB PATIENT DASHBOARD
1100
1100a
AFIB DASH
HEART SCORE
42
BEST SCORE
39
7 DAY GOALS
HEART RATE
6
AFIB EPISODES
0:13secs
AVG DURATION
0:10secs
SHORTEST
1:00min
LONGEST
7/7
MED. ADHERE
SCROLL CONTINUES

FIG. 11

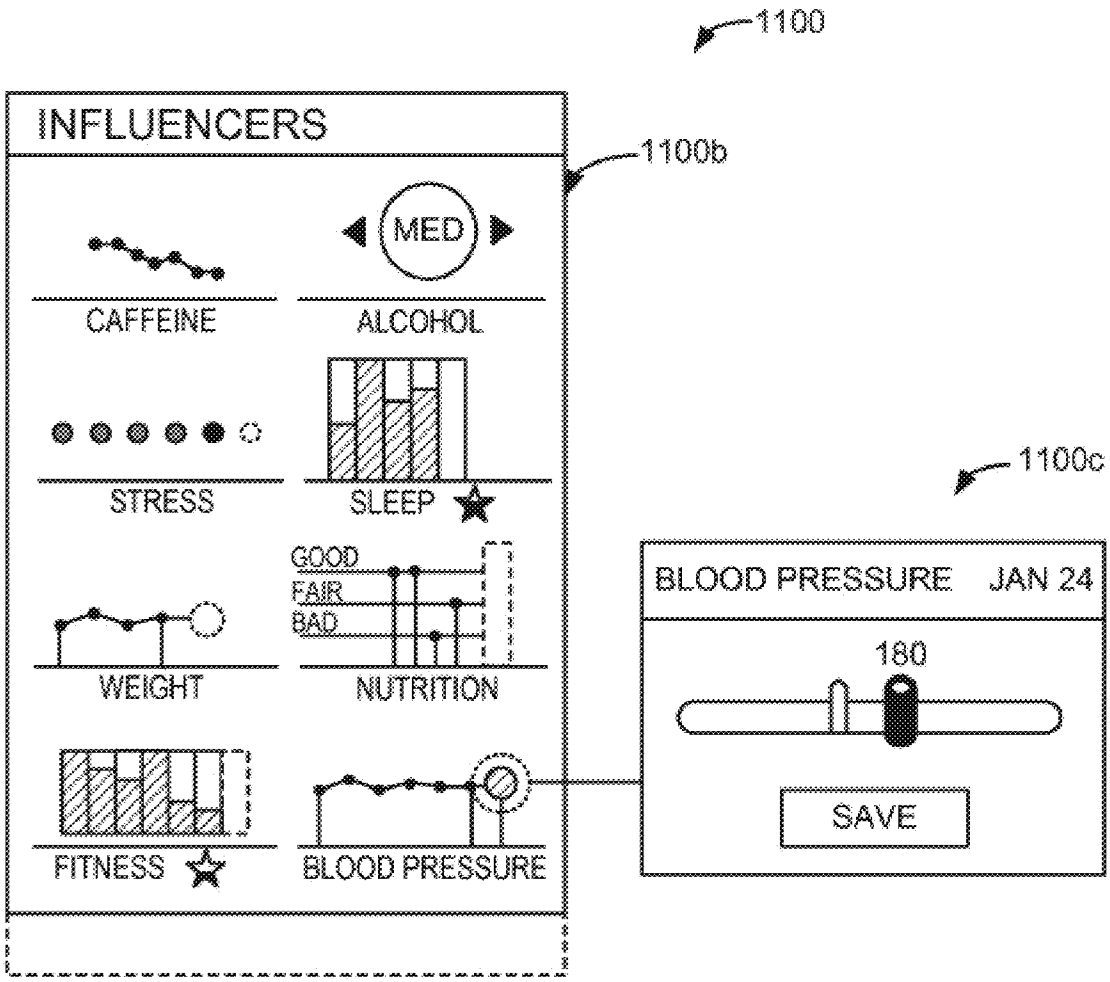
1100
INFLUENCERS
1100b
MED
CAFFEINE
ALCOHOL
STRESS
SLEEP
1100c
GOOD
FAIR
BAD
WEIGHT
NUTRITION
BLOOD PRESSURE JAN 24
180
SAVE
FITNESS
BLOOD PRESSURE

FIG. 11A

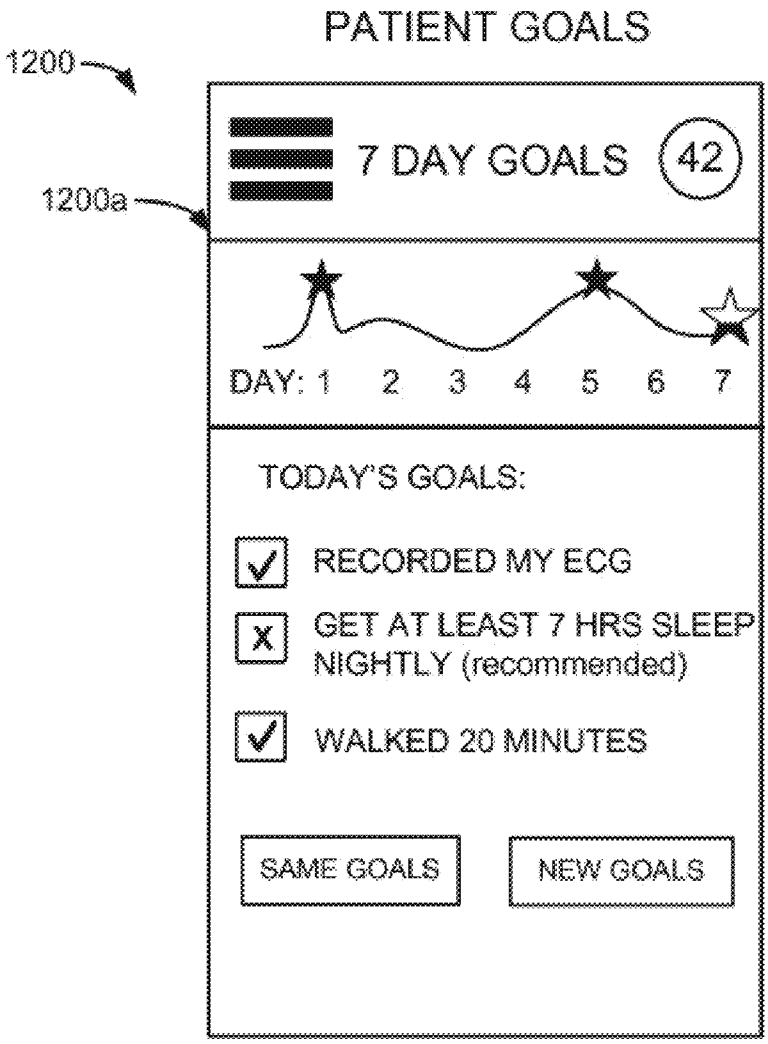
PATIENT GOALS
1200
1200a
7 DAY GOALS
42
DAY: 1 2 3 4 5 6 7
TODAY'S GOALS:
RECORDED MY ECG
GET AT LEAST 7 HRS SLEEP NIGHTLY (recommended)
WALKED 20 MINUTES
SAME GOALS
NEW GOALS

FIG. 12

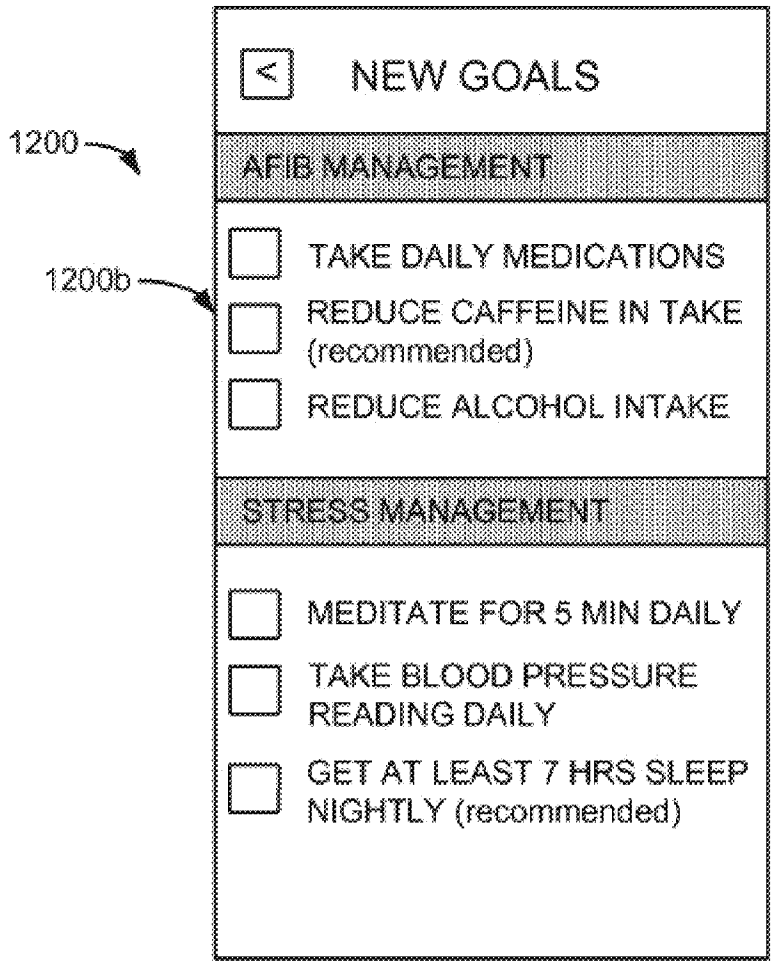
NEW GOALS
1200
AFIB MANAGEMENT
1200b
TAKE DAILY MEDICATIONS
REDUCE CAFFEINE IN TAKE (recommended)
REDUCE ALCOHOL INTAKE
STRESS MANAGEMENT
MEDITATE FOR 5 MIN DAILY
TAKE BLOOD PRESSURE READING DAILY
GET AT LEAST 7 HRS SLEEP NIGHTLY (recommended)

FIG. 12A

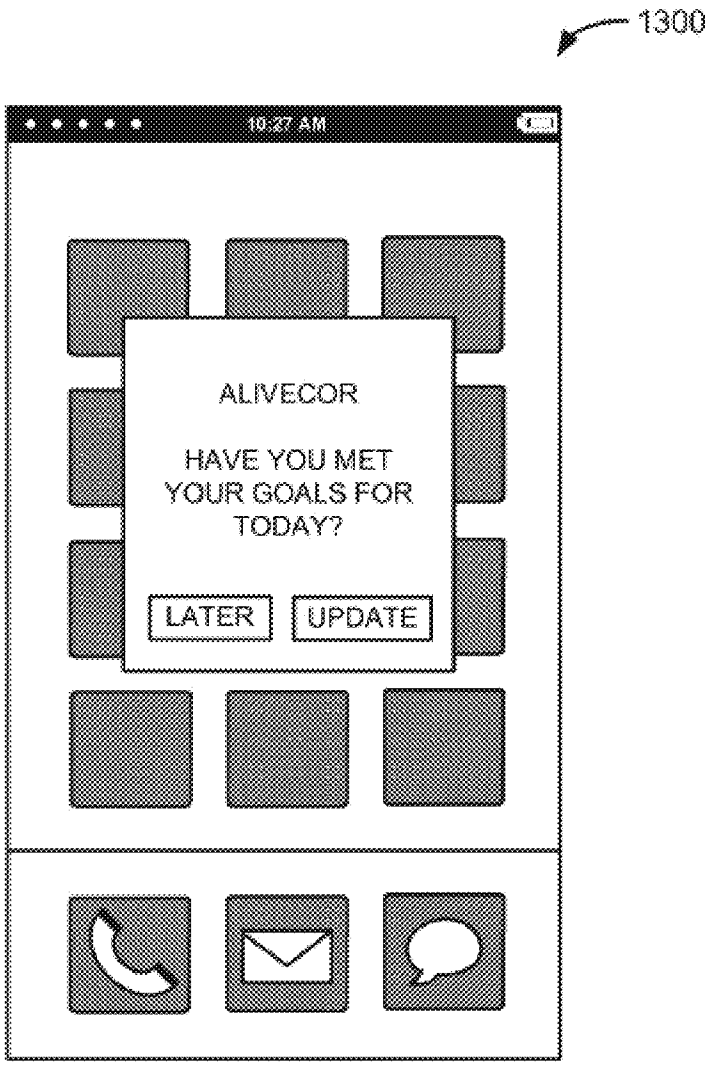
1300
10:27 AM
ALIVECOR
HAVE YOU MET YOUR GOALS FOR TODAY?
LATER
UPDATE

FIG. 13

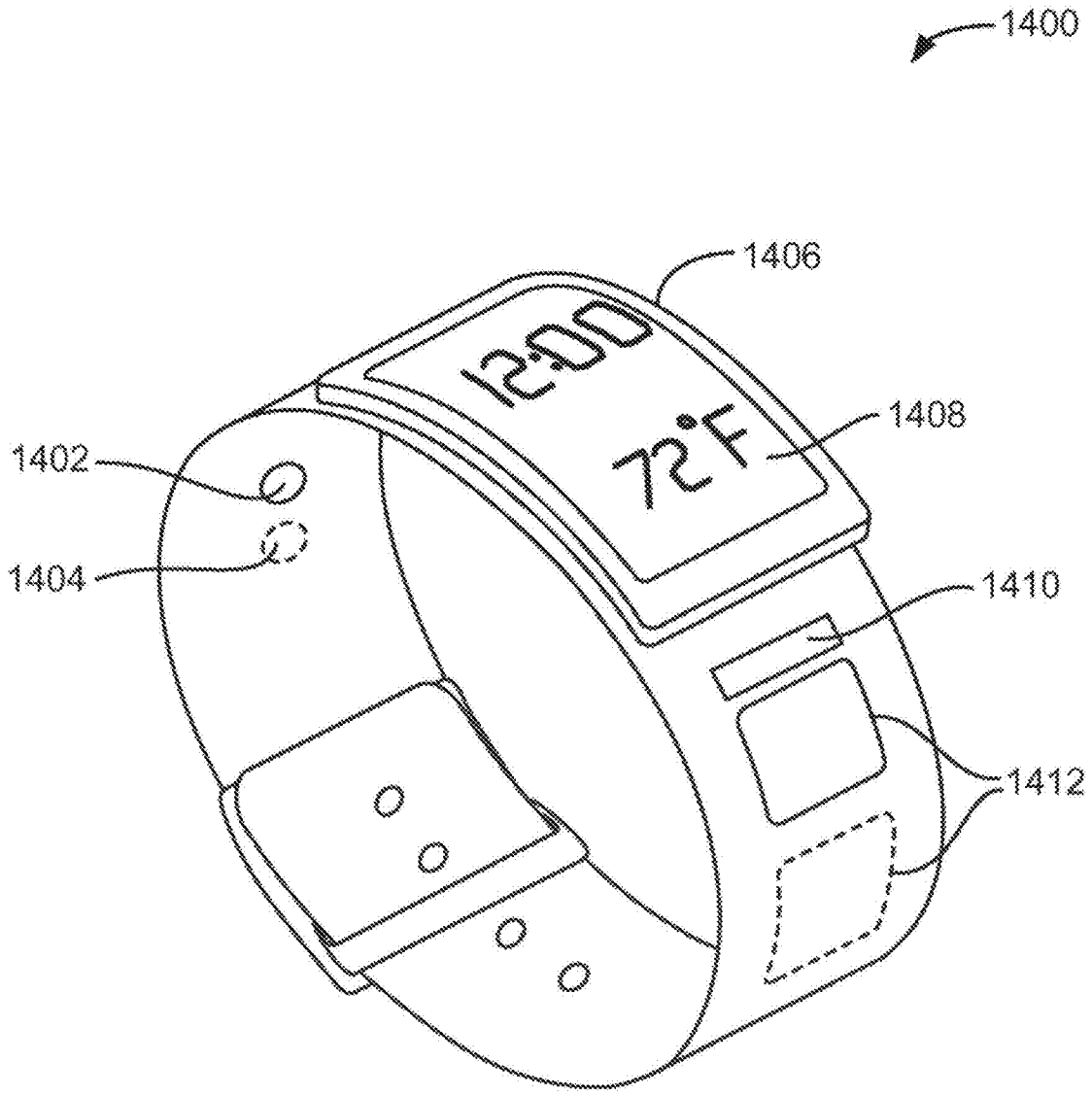

FIG. 14

METHODS AND SYSTEMS FOR ARRHYTHMIA TRACKING AND SCORING

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 16/153,446, filed Oct. 5, 2018, now U.S. Pat. No. 10,426,359, issued Oct. 1, 2019, which is a continuation of U.S. application Ser. No. 15/393,077, filed Dec. 28, 2016, now U.S. Pat. No. 10,159,415, issued Dec. 25, 2018, which is a continuation of U.S. application Ser. No. 14/730,122, filed Jun. 3, 2015, now U.S. Pat. No. 9,572,499, issued Feb. 21, 2017, which is a continuation of U.S. application Ser. No. 14/569,513 filed Dec. 12, 2014, now U.S. Pat. No. 9,420,956, issued Aug. 23, 2016, which claims the benefit of U.S. Provisional Application No. 61/915,113, filed Dec. 12, 2013, which application is incorporated herein by reference, U.S. Provisional Application No. 61/953,616 filed Mar. 14, 2014, U.S. Provisional Application No. 61/969,019, filed Mar. 21, 2014, U.S. Provisional Application No. 61/970,551 filed Mar. 26, 2014 which application is incorporated herein by reference, and U.S. Provisional Application No. 62/014,516, filed Jun. 19, 2014, which application is incorporated herein by reference.

BACKGROUND

The present disclosure relates to medical devices, systems, and methods. In particular, the present disclosure relates to methods and systems for managing health and disease such as cardiac diseases including arrhythmia and atrial fibrillation.

Cardiovascular diseases are the leading cause of death in the world. In 2008, 30% of all global death can be attributed to cardiovascular diseases. It is also estimated that by 2030, over 23 million people will die from cardiovascular diseases annually. Cardiovascular diseases are prevalent in the populations of high-income and low-income countries alike.

Arrhythmia is a cardiac condition in which the electrical activity of the heart is irregular or is faster (tachycardia) or slower (bradycardia) than normal. Although many arrhythmias are not life-threatening, some can cause cardiac arrest and even sudden cardiac death. Atrial fibrillation is the most common cardiac arrhythmia. In atrial fibrillation, electrical conduction through the ventricles of heart is irregular and disorganized. While atrial fibrillation may cause no symptoms, it is often associated with palpitations, shortness of breath, fainting, chest, pain or congestive heart failure. Atrial fibrillation is also associated with atrial clot formation, which is associated with clot migration and stroke.

Atrial fibrillation is typically diagnosed by taking an electrocardiogram (ECG) of a subject, which shows a characteristic atrial fibrillation waveform

To treat atrial fibrillation, a patient may take medications to slow heart rate or modify the rhythm of the heart. Patients may also take anticoagulants to prevent atrial clot formation and stroke. Patients may even undergo surgical intervention including cardiac ablation to treat atrial fibrillation.

Often, a patient with arrhythmia or atrial fibrillation is monitored for extended periods of time to manage the disease. For example, a patient may be provided with a Holter monitor or other ambulatory electrocardiography device to continuously monitor a patient's heart rate and rhythm for at least 24 hours.

Current ambulatory electrocardiography devices such as Holter monitors, however, are typically bulky and difficult for subjects to administer without the aid of a medical professional. For example, the use of Holter monitors requires a patient to wear a bulky device on their chest and precisely place a plurality of electrode leads on precise locations on their chest. These requirements can impede the activities of the subject, including their natural movement, bathing, and showering. Once an ECG is generated, the ECG is sent to the patient's physician who may analyze the ECG and provide a diagnosis and other recommendations. Currently, this process often must be performed through hospital administrators and health management organizations and many patients do not receive feedback in an expedient manner.

SUMMARY

Disclosed herein are devices, systems, and methods for managing health and disease such as cardiac diseases, including arrhythmia and atrial fibrillation. In particular, a cardiac disease and/or rhythm management system, according to aspects of the present disclosure, allows a user to conveniently document their electrocardiograms (ECG) and other biometric data and receive recommendation(s) and/or goal(s) generated by the system or by a physician in response to the documented data. The cardiac disease and/or rhythm management system can be loaded onto a local computing device of the user, where biometric data can be conveniently entered onto the system while the user may continue to use the local computing device for other purposes. A local computing device may comprise, for example, a computing device worn on the body (e.g. a head-worn computing device such as a Google Glass, a wrist-worn computing device such as a Samsung Galaxy Gear Smart Watch, etc.), a tablet computer (e.g. an Apple iPad, an Apple iPod, a Google Nexus tablet, a Samsung Galaxy Tab, a Microsoft Surface, etc.), a smartphone (e.g. an Apple iPhone, a Google Nexus phone, a Samsung Galaxy phone, etc.)

A portable computing device or an accessory thereof may be configured to continuously measure one or more physiological signals of a user. The heart rate of the user may be continuously measured. The continuously measurement may be made with a wrist or arm band or a patch in communication with the portable computing device. The portable computing device may have loaded onto (e.g. onto a non-transitory computer readable medium of the computing device) and executing thereon (e.g. by a processor of the computing device) an application for one or more of receiving the continuously measured physiological signal(s), analyzing the physiological signal(s), sending the physiological signal(s) to a remote computer for further analysis and storage, and displaying to the user analysis of the physiological signal(s). The heart rate may be measured by one or more electrodes provided on the computing device or accessory, a motion sensor provided on the computing device or accessory, or by imaging and lighting sources provided on the computing device or accessory. In response to the continuous measurement and recordation of the heart rate of the user, parameters such as heart rate (HR), heart rate variability (R-R variability or HRV), and heart rate turbulence (HRT) may be determined. These parameters and further parameters may be analyzed to detect and/or predict one or more of atrial fibrillation, tachycardia, bradycardia, bigeminy, trigeminy, or other cardiac conditions. A quantitative heart health score may also be generated from the determined parameters. One or more of the heart health score, detected heart conditions, or recommended user

action items based on the heart health score may be displayed to the user through a display of the portable computing device.

The biometric data may be uploaded onto a remote server where one or more cardiac technicians or cardiac specialists may analyze the biometric data and provide ECG interpretations, diagnoses, recommendations such as lifestyle recommendations, and/or goals such as lifestyle goals for subject. These interpretations, diagnoses, recommendations, and/or goals may be provided to the subject through the cardiac disease and/or rhythm management system on their local computing device. The cardiac disease and/or rhythm management system may also include tools for the subject to track their biometric data and the associated interpretations, diagnoses, recommendations, and/or goals from the cardiac technicians or specialists.

An aspect of the present disclosure includes a dashboard centered around arrhythmia or atrial fibrillation tracking. The dashboard includes a heart score that can be calculated in response to data from the user such as their ECG and other personal information such as age, gender, height, weight, body fat, disease risks, etc. The main driver of this heart score will often be the incidence of the user's atrial fibrillation. Other drivers and influencing factors include the aforementioned personal information. The heart score will be frequently related to output from a machine learning algorithm that combines and weights many if not all of influencing factors.

The dashboard will often display and track many if not all of the influencing factors. Some of these influencing factors may be entered directly by the user or may be input by the use of other mobile health monitoring or sensor devices. The user may also use the dashboard as an atrial fibrillation or arrhythmia management tool to set goals to improve their heart score.

The dashboard may also be accessed by the user's physician (e.g. the physician prescribing the system to the user, another regular physician, or other physician) to allow the physician to view the ECG and biometric data of the user, view the influencing factors of the user, and/or provide additional ECG interpretations, diagnoses, recommendations, and/or goals.

Another aspect of the present disclosure provides a method for managing cardiac health. Biometric data of a user may be received. A cardiac health score may be generated in response to the received biometric data. One or more recommendations or goals for improving the generated cardiac health score may be displayed to the user. The biometric data may comprise one or more of an electrocardiogram (ECG), dietary information, stress level, activity level, gender, height, weight, age, body fat percentage, blood pressure, results from imaging scans, blood chemistry values, or genotype data. The recommendations or goals may be updated in response to the user meeting the displayed recommendations or goals. The user may be alerted if one or more recommendations or goals have not been completed by the user, for example if the user has not completed one or more recommendations or goals for the day.

The analysis applied may be through one or more of the generation of a heart health score or the application of one or more machine learning algorithms. The machine learning algorithms may be trained using population data of heart rate. The population data may be collected from a plurality of the heart rate monitoring enabled portable computing devices or accessories provided to a plurality of users. The training population of users may have been previously identified as either having atrial fibrillation or not having atrial fibrillation prior to the generation of data for continuously measured heart rate. The data may be used to train the machine learning algorithm to extract one or more features from any continuously measured heart rate data and identify atrial fibrillation or other conditions therefrom. After the machine learning algorithm has been trained, the machine learning algorithm may recognize atrial fibrillation from the continuously measured heart rate data of a new user who has not yet been identified as having atrial fibrillation or other heart conditions. One or more of training population data or the trained machine learning algorithm may be provided on a central computing device (e.g. be stored on a non-transitory computer readable medium of a server) which is in communication with the local computing devices of the users and the application executed thereon (e.g. through an Internet or an intranet connection.)

A set of instructions for managing cardiac health may be downloaded from the Internet. These set of instructions may be configured to automatically generate the cardiac health score. The cardiac health score may be generated using a machine learning algorithm. The machine learning algorithm may generate the cardiac health score of the user and/or the recommendations and/or goals in response to biometric data from a plurality of users. The set of instructions may be configured to allow a medical professional to access the received biometric data. The cardiac health score and/or the recommendations and/or goals may be generated by the medical professional.

The set of instructions may be stored on a non-transitory computer readable storage medium of one or more of a body-worn computer, a tablet computer, a smartphone, or other computing device. These set of instructions may be capable of being executed by the computing device. When executed, the set of instructions may cause the computing device to perform any of the methods described herein, including the method for managing cardiac health described above.

Another aspect of the present disclosure provides a system for managing cardiac health. The system may comprise a sensor for recording biometric data of a user and a local computing device receiving the biometric data from the sensor. The local computing device may be configured to display a cardiac health score and one or more recommendations or goals for the user to improve the cardiac health score in response to the received biometric data.

The system may further comprise a remote server receiving the biometric data from the local computing device. One or more of the local computing device or the remote server may comprise a machine learning algorithm which generates one or more of the cardiac health score or the one or more recommendations or goals for the user. The remote server may be configured for access by a medical professional. Alternatively, or in combination, one or more of the cardiac health score or one or more recommendations or goals may be generated by the medical professional and provided to the local computing device through the remote server.

The sensor may comprise one or more of a hand-held electrocardiogram (ECG) sensor, a wrist-worn activity sensor, a blood pressure monitor, a personal weighing scale, a body fat percentage sensor, a personal thermometer, a pulse oximeter sensor, or any mobile health monitor or sensor. Often, the sensor is configured to be in wireless communication with the local computing device. The local computing device comprises one or more of a personal computer, a laptop computer, a palmtop computer, a tablet computer, a smartphone, a body-worn computer, or the like. The biometric data may comprise one or more of an electrocardio-

gram (ECG), dietary information, stress level, activity level, gender, height, weight, age, body fat percentage, or blood pressure.

Other physiological signals or parameters such as physical activity, heart sounds, blood pressure, blood oxygenation, blood glucose, temperature, activity, breath composition, weight, hydration levels, an electroencephalograph (EEG), an electromyography (EMG), a mechanomyogram (MMG), an electrooculogram (EOG), etc. may also be monitored. The user may also input user-related health data such as age, height, weight, body mass index (BMI), diet, sleep levels, rest levels, or stress levels. One or more of these physiological signals and/or parameters may be combined with the heart rate data to detect atrial fibrillation or other conditions. The machine learning algorithm may be configured to identify atrial fibrillation or other conditions in response to heart rate data in combination with one or more of the other physiological signals and/or parameters for instance. Triggers or alerts may be provided to the user in response to the measured physiological signals and/or parameters. Such triggers or alerts may notify the user to take corrective steps to improve their health or monitor other vital signs or physiological parameters. The application loaded onto and executed on the portable computing device may provide a health dash board integrating and displaying heart rate information, heart health parameters determined in response to the heart rate information, other physiological parameters and trends thereof, and recommended user action items or steps to improve health.

INCORPORATION BY REFERENCE

All publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

The novel features of the subject matter disclosed herein are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present disclosure will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the disclosure are utilized, and the accompanying drawings of which:

FIG. **1** shows a system for cardiac disease and rhythm management;

FIG. **2** shows a flow chart of a method **200** for predicting and/or detecting atrial fibrillation from R-R interval measurements;

FIG. **3** shows a flow chart of a method for predicting and/or detecting atrial fibrillation from R-R interval measurements and for predicting and/or detecting atrial fibrillation from raw heart rate signals;

FIG. **4** shows an embodiment of the system and method of the ECG monitoring described herein;

FIG. **5** shows a flow chart of an exemplary method to generate a heart health score in accordance with many embodiments;

FIG. **6** shows an exemplary method of generating a heart score;

FIG. **7** shows a schematic diagram of the executed application described herein;

FIG. **8** shows exemplary screenshots of the executed application;

FIG. **9** shows an exemplary method for cardiac disease and rhythm management;

FIG. **10** shows an exemplary method for monitoring a subject to determine when to record an electrocardiogram (ECG);

FIG. **11** shows an exemplary screenshot of a first aspect of a dashboard application;

FIG. **11**A shows an exemplary screenshot of a second aspect of a dashboard application;

FIG. **12** shows an exemplary screenshot of a first aspect of a goals and recommendations page of the cardiac disease and rhythm management system interface or mobile app;

FIG. **12**A shows an exemplary screenshot of a second aspect of a goals and recommendations page of the cardiac disease and rhythm management system interface or mobile app;

FIG. **13** shows an exemplary screenshot of a user's local computing device notifying the user with a pop-up notice to meet their daily recommendations and goals; and

FIG. **14** shows an embodiment comprising a smart watch which includes at least one heart rate monitor and at least one activity monitor.

DETAILED DESCRIPTION

Devices, systems, and methods for managing health and disease such as cardiac diseases, including arrhythmia and atrial fibrillation, are disclosed. In particular, a cardiac disease and/or rhythm management system, according to aspects of the present disclosure, allows a user to conveniently document their electrocardiograms (ECG) and other biometric data and receive recommendation(s) and/or goal(s) generated by the system or by a physician in response to the documented data.

The term "atrial fibrillation," denoting a type of cardiac arrhythmia, may also be abbreviated in either the figures or description herein as "AFIB."

FIG. **1** shows a system **100** for cardiac disease and rhythm management. The system **100** may be prescribed for use by a user or subject such as being prescribed by the user or subject's regular or other physician or doctor. The system **100** may comprise a local computing device **101** of the user or subject. The local computing device **101** may be loaded with a user interface, dashboard, or other sub-system of the cardiac disease and rhythm management system **100**. For example, the local computing device **101** may be loaded with a mobile software application ("mobile app") **101***a* for interfacing with the system **100**. The local computing device may comprise a computing device worn on the body (e.g. a head-worn computing device such as a Google Glass, a wrist-worn computing device such as a Samsung Galaxy Gear Smart Watch, etc.), a tablet computer (e.g. an Apple iPad, an Apple iPod, a Google Nexus tablet, a Samsung Galaxy Tab, a Microsoft Surface, etc.), a smartphone (e.g. an Apple iPhone, a Google Nexus phone, a Samsung Galaxy phone, etc.).

The local computing device **101** may be coupled to one or more biometric sensors. For example, the local computing device **101** may be coupled to a handheld ECG monitor **103**. The handheld ECG monitor **103** may be in the form of a smartphone case as described in co-owned U.S. patent application Ser. No. 12/796,188 (now U.S. Pat. No. 8,509,882), Ser. Nos. 13/107,738, 13/420,520 (now U.S. Pat. No. 8,301,232), Ser. Nos. 13/752,048, 13/964,490, 13/969,446, 14/015,303, and 14/076,076, the contents of which are incorporated herein by reference.

In some embodiments, the handheld ECG monitor **103** may be a handheld sensor coupled to the local computing device **101** with an intermediate protective case/adapter as described in U.S. Provisional Application No. 61/874,806, filed Sep. 6, 2013, the contents of which are incorporated herein by reference. The handheld ECG monitor **103** may be used by the user to take an ECG measurement which the handheld ECG monitor **103** may send to the local computing device by connection **103***a*. The connection **103***a* may comprise a wired or wireless connection (e.g. a Wi-Fi connection, a Bluetooth connection, a NFC connection, an ultrasound signal transmission connection, etc.). The mobile software application **101***a* may be configured to interface with the one or more biometric sensors including the handheld ECG monitor **103**.

The local computing device **101** may be coupled to a wrist-worn biometric sensor **105** through a wired or wireless connection **105***a* (e.g. a Wi-Fi connection, a Bluetooth connection, a NFC connection, an ultrasound signal transmission connection, etc.). The wrist-worn biometric sensor **105** may comprise an activity monitor such as those available from Fitbit Inc. of San Francisco, Calif. or a Nike FuelBand available from Nike, Inc. of Oregon. The wrist-worn biometric sensor **105** may also comprise an ECG sensor such as that described in co-owned U.S. Provisional Application No. 61/872,555, the contents of which is incorporated herein by reference.

The local computing device **101** may be coupled to other biometric devices as well such as a personal scale or a blood pressure monitor **107**. The blood pressure monitor **107** may communicate with the local device **101** through a wired or wireless connection **107***a* (e.g. a Wi-Fi connection, a Bluetooth connection, a NFC connection, an ultrasound signal transmission connection, etc.).

The local computing device **101** may directly communicate with a remote server or cloud-based service **113** through the Internet **111** via a wired or wireless connection **111***a* (e.g. a Wi-Fi connection, a cellular network connection, a DSL Internet connection, a cable Internet connection, a fiber optic Internet connection, a T1 Internet connection, a T3 Internet connection, etc.). Alternatively, or in combination, the local computing device **101** may first couple with another local computing device **109** of the user, such as a personal computer of the user, which then communicates with the remote server or cloud-based service **113** via a wired or wireless connection **109***a* (e.g. a Wi-Fi connection, a cellular network connection, a DSL Internet connection, a cable Internet connection, a fiber optic Internet connection, a T1 Internet connection, a T3 Internet connection, etc.) The local computing device **109** may comprise software or other interface for managing biometric data collected by the local computing device **101** or the biometric data dashboard loaded on the local computing device **101**.

Other users may access the patient data through the remote server or cloud-based service **113**. These other users may include the user's regular physician, the user's prescribing physician who prescribed the system **100** for use by the user, other cardiac technicians, other cardiac specialists, and system administrators and managers. For example, a first non-subject user may access the remote server or cloud-based service **113** with a personal computer or other computing device **115** through an Internet connection **115***a* (e.g. a Wi-Fi connection, a cellular network connection, a DSL Internet connection, a cable Internet connection, a fiber optic Internet connection, a T1 Internet connection, a T3 Internet connection, etc.). Alternatively, or in combination, the first non-subject user may access the remote server or cloud-based service **113** with a local computing device such as a tablet computer or smartphone **117** through an Internet connection **117***a*. The tablet computer or smartphone **117** of the first non-subject user may interface with the personal computer **115** through a wired or wireless connection **117***b* (e.g. a Wi-Fi connection, a Bluetooth connection, a NFC connection, an ultrasound signal transmission connection, etc.). Further, a second non-subject user may access the remote server or cloud-based service **113** with a personal computer or other computing device **119** through an Internet connection **119***a* (e.g. a Wi-Fi connection, a cellular network connection, a DSL Internet connection, a cable Internet connection, a fiber optic Internet connection, a T1 Internet connection, a T3 Internet connection, etc.). Further, a third non-subject user may access the remote server or cloud-based service **113** with a tablet computer or smartphone **121** through an Internet connection **121***a* (e.g. a Wi-Fi connection, a cellular network connection, a DSL Internet connection, a cable Internet connection, a fiber optic Internet connection, a T1 Internet connection, a T3 Internet connection, etc.). Further, a fourth non-subject user may access the remote server or cloud-based service **113** with a personal computer or other computing device **123** through an Internet connection **123***a* (e.g. a Wi-Fi connection, a cellular network connection, a DSL Internet connection, a cable Internet connection, a fiber optic Internet connection, a T1 Internet connection, a T3 Internet connection, etc.). The first non-subject user may comprise an administrator or manager of the system **100**. The second non-subject user may comprise a cardiac technician. The third non-subject user may comprise a regular or prescribing physician of the user or subject. And, the fourth non-subject user may comprise a cardiac specialist who is not the user or subject's regular or prescribing physician. Generally, many if not all of the communication between various devices, computers, servers, and cloud-based services will be secure and HIPAA-compliant.

Aspects of the present disclosure provide systems and methods for detecting and/or predicting atrial fibrillation or other arrhythmias of a user by applying one or more machine learning-based algorithms. A portable computing device (or an accessory usable with the portable computing device) may provide R-R intervals and/or raw heart rate signals as input to an application loaded and executed on the portable computing device. The raw heart rate signals may be provided using an electrocardiogram (ECG) in communication with the portable computing device or accessory such as described in U.S. Ser. No. 13/964,490 filed Aug. 12, 2013, Ser. No. 13/420,520 filed Mar. 14, 2013, Ser. No. 13/108,738 filed May 16, 2011, and Ser. No. 12/796,188 filed Jun. 8, 2010. Alternatively, or in combination, the raw heart rate signals may be provided using an on-board heart rate sensor of the portable computing device or by using photoplethysmography implemented by an imaging source and a light source of the portable computing device. Alternatively, or in combination, the raw heart rate signals may be from an accessory device worn by the user or attached to the user (e.g. a patch) and which is in communication with the portable computing device. Such wearable accessory devices may include Garmin's Vivofit Fitness Band, Fitbit, Polar Heart Rate Monitors, New Balance's Balance Watch, Basis BI Band, MIO Alpha, Withings Pulse, LifeCORE Heart Rate Monitor strap, and the like.

R-R intervals may be extracted from the raw heart rate signals. The R-R intervals may be used to calculate heart rate variability (HRV) which may be analyzed in many ways such as using time-domain methods, geometric methods,

frequency-domain methods, non-linear methods, long term correlations, or the like as known in the art. Alternatively, or in combination, the R-R intervals may be used for non-traditional measurements such as (i) determining the interval between every other or every three R-waves to evaluate for bigeminy or trigeminy or (ii) the generation of a periodic autoregressive moving average (PARMA).

The machine learning based algorithm(s) may allow software application(s) to identify patterns and/or features of the R-R interval data and/or the raw heart rate signals or data to predict and/or detect atrial fibrillation or other arrhythmias. These extracted and labelled features may be features of HRV as analyzed in the time domain such as SDNN (the standard deviation of NN intervals calculated over a 24 hour period), SDANN (the standard deviation of the average NN intervals calculated over short periods), RMSSD (the square root of the mean of the sum of the squares of the successive differences between adjacent NNs), SDSD (the standard deviation of the successive differences between adjacent NNs), NN50 (the number of pairs of successive NNs that differ by more than 50 ms), pNN50 (the proportion of NN50 divided by total number of NNs), NN20 (the number of pairs of successive NNs that differ by more than 20 ms), pNN20 (the proportion of NN20 divided by the total number of NNs), EBC (estimated breath cycle), NNx (the number of pairs of successive NNs that differ by more than x ms), pNNx (the proportion of NNx divided by the number of NNs), or other features known in the art. Alternatively, or in combination, the extracted and labelled features may comprise a nonlinear transform of R-R ratio or R-R ratio statistics with an adaptive weighting factor. Alternatively, or in combination, the extracted and labelled features may be features of HRV as analyzed geometrically such as the sample density distribution of NN interval durations, the sample density distribution of differences between adjacent NN intervals, a Lorenz plot of NN or RR intervals, degree of skew of the density distribution, kurtosis of the density distribution, or other features known in the art. Alternatively, or in combination, the extracted and labelled features may be features of HRV in the frequency domain such as the power spectral density of different frequency bands including a high frequency band (HF, from 0.15 to 0.4 Hz), low frequency band (LF, from 0.04 to 0.15 Hz), and the very low frequency band (VLF, from 0.0033 to 0.04 Hz), or other frequency domain features as known in the art. Alternatively, or in combination, the extracted and labelled features may be non-linear features such as the geometric shapes of a Poincare plot, the correlation dimension, the nonlinear predictability, the pointwise correlation dimension, the approximate entropy, and other features as known in the art. Other features from the raw heart rate signals and data may also be analyzed. These features include for example a generated autoregressive (AR) model, a ratio of consecutive RR intervals, a normalized ratio of consecutive RR intervals, a standard deviation of every 2, 3, or 4 RR intervals, or a recurrence plot of the raw HR signals, among others.

The features of the analysis and/or measurement may be selected, extracted, and labelled to predict atrial fibrillation or other arrhythmias in real time, e.g. by performing one or more machine learning operation. Such operations can be selected from among an operation of ranking the feature(s), classifying the feature(s), labelling the feature(s), predicting the feature(s), and clustering the feature(s). Alternatively, or in combination, the extracted features may be labelled and saved for offline training of a machine learning algorithm or set of machine learning operations. For example, the operations may be selected from any of those above. Any number of machine learning algorithms or methods may be trained to identify atrial fibrillation or other conditions such as arrhythmias. These may include the use of decision tree learning such as with a random forest, association rule learning, artificial neural network, inductive logic programming, support vector machines, clustering, Bayesian networks, reinforcement learning, representation learning, similarity and metric learning, sparse dictionary learning, or the like.

The systems and methods for detecting and/or predicting atrial fibrillation or other conditions such as arrhythmias described herein may be implemented as software provided as a set of instructions on a non-transitory computer readable medium. A processor of a computing device (e.g. a tablet computer, a smartphone, a smart watch, a smart band, a wearable computing device, or the like) may execute this set of instructions to receive the input data and detect and/or predict atrial fibrillation therefrom. The software may be downloaded from an online application distribution platform such as the Apple iTunes or App Store, Google Play, Amazon App Store, and the like. A display of the computing device may notify the user whether atrial fibrillation or other arrhythmias has been detected and/or if further measurements are required (e.g. to perform a more accurate analysis). The software may be loaded on and executed by the portable computing device of the user such as with the processor of the computing device.

The machine learning-based algorithms or operations for predicting and/or detecting atrial fibrillation or other arrhythmias may be provided as a service from a remote server which may interact or communicate with a client program provided on the computing device of the user, e.g. as a mobile app. The interaction or communication may be through an Application Program Interface (API). The API may provide access to machine learning operations for ranking, clustering, classifying, and predicting from the R-R interval and/or raw heart rate data, for example.

The machine learning-based algorithms or operations, provided through a remote server and/or on a local application on a local computing device, may operate on, learn from, and make analytical predictions from R-R interval data or raw heart rate data, e.g. from a population of users. The R-R interval or raw heart rate data may be provided by the local computing device itself or an associated accessory, such as described in U.S. Ser. No. 13/964,490 filed Aug. 12, 2013, Ser. No. 13/420,520 filed Mar. 14, 2013, Ser. No. 13/108,738 filed May 16, 2011, and Ser. No. 12/796,188 filed Jun. 8, 2010. Thus, atrial fibrillation and other arrhythmias or other heart conditions can be in a convenient, user-accessible way.

FIG. **2** shows a flow chart of a method **200** for predicting and/or detecting atrial fibrillation from R-R interval measurements. In a step **202**, an R-R interval of a user is obtained. In a step **204**, the obtained R-R interval is analyzed using one or more traditional heart rate variability measurements such as, for example, time domain measures, frequency domain measures, and non-linear heart rate variability. In a step **206**, the obtained R-R interval is analyzed using one or more non-traditional heart rate variability measurements such as, for example, RR (n-i) for Bigeminy and Trigeminy detection, and the generation of a periodic autoregressive moving average (PARMA). In a step **208**, a feature selection occurs. In a step **210**, a real time prediction or detection of atrial fibrillation, and/or in a step **212**, the heart rate variability measurements may be labelled and saved for offline training of a machine learning algorithm or set of

machine learning operations, and then may be subsequently used to make a real time prediction and/or detection of atrial fibrillation.

FIG. **3** shows a flow chart of a method **300** for predicting and/or detecting atrial fibrillation from R-R interval measurements and for predicting and/or detecting atrial fibrillation from raw heart rate signals. In a step **302**, raw heart rate signals are obtained from, for example, an ECG of a user. In a step **304**, R-R intervals are obtained from the obtained raw hearth signals. In a step **306**, the obtained R-R interval is analyzed using one or more traditional heart rate variability measurements such as, for example, time domain measures, frequency domain measures, and non-linear heart rate variability. In a step **308**, the obtained R-R interval is analyzed using one or more non-traditional heart rate variability measurements such as, for example, RR (n-i) for bigeminy and trigeminy detection, and the generation of a periodic autoregressive moving average (PARMA). In a step **310**, features from the obtained heart rate features are analyzed using one or more of wavelet features and shape based features from a Hilbert transform. In a step **312**, a feature selection occurs. In a step **314**, a real time prediction or detection of atrial fibrillation, and/or in a step **316**, the heart rate variability measurements may be labelled and saved for offline training of a machine learning algorithm or set of machine learning operations, and then may be subsequently used to make a real time prediction and/or detection of atrial fibrillation.

Although the above steps show methods **200** and **300** in accordance with many embodiments, a person of ordinary skill in the art will recognize many variations based on the teaching described herein. The steps may be completed in a different order. Steps may be added or deleted. Some of the steps may comprise sub-steps. Many of the steps may be repeated as often as beneficial to the user or subject.

One or more of the steps of method **200** and **300** may be performed with circuitry, for example, one or more of a processor or a logic circuitry such as a programmable array logic for a field programmable gate array. The circuitry may be programmed to provide one or more of the steps of methods **200** and **300**, and the program may comprise program instructions stored on a non-transitory computer readable medium or memory or programmed steps of the logic circuitry such as the programmable array logic or the field programmable gate array, for example.

Aspects of the present disclosure provide systems and methods for monitoring one or more physiological parameters and providing a trigger message to the user if the one or more physiological parameter meets a pre-determined or learned threshold(s). Two or more of the physiological parameters may be combined to provide a trigger message. That is, a particular trigger message may be provided to the user if two or more pre-determined threshold(s) for the physiological parameter(s) are met.

Table 1 below shows an exemplary table of physiological parameters that may be measured (left column), features of interest to be measured or threshold types to be met (middle column), and exemplary trigger messages (right column).

TABLE 1

Physiological Parameter	Measurements/Threshold	Sample Trigger Messages
Heart Rate	Heart Rate Variability (HRV), Non-linear Transformation of RR Intervals	Measure ECG; See Your Doctor
Heart Sound	Sound Features	Abnormal Heart Sound; Measure ECG; See Your Doctor
Blood Pressure	Upper and Lower Thresholds	High/Low Blood Pressure; Take BP Medication; Exercise; See Your Doctor
Blood Oxygenation	O2 Saturation, O2 Saturation Variability	High Risk of Hypoventilation; High Risk of Sleep Disorder such as Apnea; See Your Doctor
Blood Glucose	Upper and Lower Thresholds	High Risk of Hypoglycemia; See Your Doctor
Temperature	Temperature, Temperature Changes	Fever; Take OTC Fever Medication; See Your Doctor
Physical Activity (accelerometer data)	Gait, Chest Compressions, Speed, Distance	Monitor Senior or Infant Posture, e.g. if senior/infant has fallen
Electrocardiogram (ECG)	ECG Features (E.g. QT, QRS, PR intervals, HRV, etc.	High Risk of Certain Cardiac Diseases; Sleep apnea; See Your Doctor
Breath Content (Breathalyzer data)	Percentage of the Certain Chemicals	High Risk of Certain Dental Disease, Diabetes, etc.; See Your Doctor

The machine learning based algorithms or operations as described herein may be used to determine the appropriate trigger thresholds in response to the raw physiological data input and/or user-input physiological parameters (e.g. age, height, weight, gender, etc.). Features of the raw physiological data input may be selected, extracted, labelled, clustered, and/or analyzed. These processed features may then be analyzed using one or more machine learning operation such as ranking the feature(s), classifying the feature(s), predicting the feature(s), and clustering the feature(s). The various machine learning algorithms described herein may be used to analyze the features to detect and predict health conditions and generate recommendations or user action items to improve the health of the user. For instance, the machine learning algorithms may be trained to identify atrial fibrillation or other conditions in response to the non-heart rate physiological parameter(s) such as age, gender, body mass index (BMI), activity level, diet, and others in combination with the raw heart rate data and HRV that can be extracted therefrom.

The systems and methods for monitoring one or more physiological parameters and providing a trigger message to the user if the one or more physiological parameter meets a

pre-determined threshold(s) described herein may be implemented as software provided as a set of instructions on a non-transitory computer readable medium. A processor of a computing device (e.g. a tablet computer, a smartphone, a smart watch, a smart band, a wearable computing device, or the like) may execute this set of instructions to receive the input data and detect and/or predict atrial fibrillation therefrom. The software may be downloaded from an online application distribution platform such as the Apple iTunes or App Store, Google Play, Amazon App Store, and the like. The software may be loaded on and executed by the portable computing device of the user such as with the processor of the computing device. The software may also provide both the triggering application described herein and the heart rate monitoring and analysis for detecting atrial fibrillation or other heart conditions described herein.

In an embodiment, a method and system for longitudinal monitoring of a patient's or any consumer's (after referred to as "patient") health using various ECG monitoring devices is described herein. The ECG monitoring devices generate ECG signal data which can be stored in a database for further analysis. The ECG data, which can be stored in a database along with other patient information, can be analyzed by a processing device, such as a computer or server, using various algorithms.

Various ECG monitoring or recording devices, hereinafter referred to as ECG monitoring devices, can be used to record the ECG data. For example, the ECG monitoring device can be a handheld, portable, or wearable smartphone based device, as described in U.S. Pat. No. 8,301,232, which is herein incorporated by reference in its entirety for all purposes. A smartphone based device, or a device having wireless or cellular telecommunication capabilities, can transmit the ECG data to a database or server directly through the internet. These types of ECG monitoring devices as well as other ECG monitoring devices include portable devices, wearable recording devices, event recorders, and Holter monitors. Clinical or hospital based ECG recording devices can also be used and integrated into the system. Such devices may be able to transmit stored ECG data through a phone line or wirelessly through the internet or cellular network, or may need to be sent to a data collection center for data collection and processing. The ECG data can be tagged with the type of ECG monitoring device used to record the data by, for example, including it in metadata for indexing and searching purposes.

The ECG monitoring devices can be single lead devices or multiple lead devices, where each lead generally terminates with an electrode. Some embodiments may even be leadless and have electrodes that are integrated with the body or housing of the device, and therefore have a predetermined relationship with each other, such as a fixed spacing apart from each other. The orientation and positioning of the single lead in a single lead device or of each lead of the multiple lead device or of the electrodes of the leadless device can be transmitted with the ECG data. The lead and/or electrode placement may be predetermined and specified to the patient in instructions for using the device. For example, the patient may be instructed to position the leads and/or electrodes with references to one or more anatomical landmarks on the patient's torso. Any deviation from the predetermined lead and/or electrode placement can be notated by the patient or user when transmitting the ECG data. The lead and electrode placement may be imaged using a digital camera, which may be integrated with a smart phone, and transmitted with the ECG data and stored in the database. The lead and electrode placement may be marked on the patient's skin for imaging and for assisting subsequent placement of the leads and electrodes. The electrodes can be attached to the skin using conventional methods which may include adhesives and conducting gels, or the electrodes may simply be pressed into contact with the patient's skin. The lead and electrode placement may be changed after taking one recording or after recording for a predetermined or variable amount of time. The ECG data can be tagged with the numbers of leads and/or electrodes and the lead and/or electrode placement, including whether adhesives and/or conducting gels were used. Again, this information can be including in metadata for indexing and searching purposes.

The ECG signal data can be continuously recorded over a predetermined or variable length of time. Continuous ECG recording devices can record for up to 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, or 14 days. Alternatively, or additionally, the ECG data can be recorded on demand by the patient at various discrete times, such as when the patient feels chest pains or experiences other unusual or abnormal feelings. The on demand ECG recorder can have a memory buffer that can record a predetermined amount of ECG data on a rolling basis, and when activated by the patient to record a potential event, a predetermined amount of ECG data can be saved and/or transmitted. The predetermined amount of ECG data can include a predetermined amount of ECG data before activation and a predetermined amount of ECG data after activation such that a window of ECG data is captured that encompasses the potential event. The time period between ECG recordings may be regular or irregular. For example, the time period may be once a day, once a week, once a month, or at some other predetermined interval. The ECG recordings may be taken at the same or different times of days, under similar or different circumstances, as described herein. One or more baseline ECGs can be recorded while the patient is free of symptoms. The baseline ECGs can be periodically recorded and predetermined intervals and/or on-demand. The same ECG recording device or different ECG recording devices may be used to record the various ECG of a particular patient. All this information may be tagged to or associated with the ECG data by, for example, including it in the metadata for indexing and searching purposes.

The ECG data can be time stamped and can be annotated by the patient or health care provider to describe the circumstances during which the ECG was recorded, preceding the ECG recording, and/or following the ECG recording. For example, the system and device can have a user interface for data entry that allows the patient to enter in notes regarding the conditions and circumstances surrounding the ECG recording. This additional data can be also included as metadata for indexing and searching purposes. For example, location, food, drink, medication and/or drug consumption, exercise, rest, sleep, feelings of stress, anxiety, pain or other unusual or abnormal feelings, or any other circumstance that may affect the patient's ECG signal can all be inputted into the device, smart phone, computer or other computing device to be transmitted to the server or database along with the ECG data. The annotated data can also include the patient's identity or unique identifier as well as various patient characteristics including age, sex, race, ethnicity, and relevant medical history. The annotated data can also be time stamped or tagged so that the ECG data can be matched or correlated with the activity or circumstance of interest. This also allows comparison of the ECG before, after and during the activity or circumstance so that the effect on the ECG can be determined.

The ECG data and the associated metadata can be transmitted from the device to a server and database for storage and analysis. The transmission can be real-time, at regular intervals such as hourly, daily, weekly and any interval in between, or can be on demand. The metadata facilitates the searching, organizing, analyzing and retrieving of ECG data. Comparison and analysis of a single patient's ECG data can be performed, and/or comparison of ECG data between patients can be performed. For example, the metadata can be used to identify and select a subset of ECG data where an activity or circumstance, such as the taking of medication, occurred within a predetermined amount of time to the ECG data. The components of the ECG signal data, such as the P wave, T wave, and QRS complex and the like, the amplitudes of the components, the ratios between the components, the width of the components, and the delay or time separation between the components, can be extracted, compared, analyzed, and stored as ECG features. For example, the P wave and heart rate can be extracted and analyzed to identify atrial fibrillation, where the absence of P waves and/or an irregular heart rate may indicate atrial fibrillation. The extracted ECG features can also be included in the metadata for indexing and searching.

The changes in the ECG signal over time in view of the activities and circumstances can be compared with changes over time and circumstances observed within a database of ECG's. Comparisons may include any comparison of data derived from any other ECG signal or any database of ECG's or any subset of ECG data, or with data derived from any database of ECG's. Changes in any feature of the ECG signal over time may be used for a relative comparison with similar changes in any ECG database or with data derived from an ECG database. The ECG data from the baseline ECG and the ECG data from a potential adverse event can be compared to determine the changes or deviations from baseline values. In addition, both the baseline ECG and the ECG data recorded from the patient can be compared to one or more predetermined template ECGs which can represent a normal healthy condition as well as various diseased conditions, such as myocardial infarction and arrhythmias.

The comparisons and analysis described herein can be used to draw conclusions and insights into the patient's health status, which includes potential health issues that the patient may be experiencing at the time of measurement or at future times. Conclusions and determinations may be predictive of future health conditions or diagnostic of conditions that the patient already has. The conclusions and determinations may also include insights into the effectiveness or risks associated with drugs or medications that the patient may be taking, have taken or may be contemplating taking in the future. In addition, the comparisons and analysis can be used to determine behaviors and activities that may reduce or increase risk of an adverse event. Based on the comparisons and analysis described herein, the ECG data can be classified according to a level of risk of being an adverse event. For example, the ECG data can be classified as normal, low risk, moderate risk, high risk, and/or abnormal. The normal and abnormal designation may require health care professional evaluation, diagnosis, and/or confirmation.

Diagnosis and determination of an abnormality, an adverse event, or a disease state by physicians and other health care professionals can be transmitted to the servers and database to be tagged with and associated with the corresponding ECG data. The diagnosis and determination may be based on analysis of ECG data or may be determined using other tests or examination procedures. Professional diagnosis and determinations can be extracted from the patient's electronic health records, can be entered into the system by the patient, or can be entered into the system by the medical professional. The conclusions and determinations of the system can be compared with actual diagnosis and determinations from medical professions to validate and/or refine the machine learning algorithms used by the system. The time of occurrence and duration of the abnormality, adverse event or disease state can also be included in the database, such that the ECG data corresponding with the occurrence and/or the ECG data preceding and/or following the abnormality, adverse event or disease state can be associated together and analyzed. The length of time preceding or following the abnormality may be predetermined and be up to 1 to 30 days, or greater than 1 to 12 months. Analysis of the time before the abnormality, adverse event or disease state may allow the system to identify patterns or correlations of various ECG features that precede the occurrence of the abnormality, adverse event or disease state, thereby providing advance detection or warning of the abnormality, adverse event or disease state. Analysis of the time following the abnormality, adverse event or disease state can provide information regarding the efficacy of treatments and/or provide the patient or physician information regarding disease progression, such as whether the patient's condition in improving, worsening or staying the same. The diagnosis and determination can also be used for indexing by, for example, including it in the metadata associated with the corresponding ECG data.

As described herein, various parameters may be included in the database along with the ECG data. These may include the patient's age, gender, weight, blood pressure, medications, behaviors, habits, activities, food consumption, drink consumption, drugs, medical history and other factors that may influence a patient's ECG signal. The additional parameters may or may not be used in the comparison of the changes in ECG signal over time and circumstances.

The conclusions, determinations, and/or insights into the patient's health generated by the system may be communicated to the patient directly or via the patient's caregiver (doctor or other healthcare professional). For example, the patient can be sent an email or text message that is automatically generated by the system. The email or text message can be a notification which directs the patient to log onto a secure site to retrieve the full conclusion, determination or insight, or the email or text message can include the conclusion, determination or insight. Alternatively, or additionally, the email or text message can be sent to the patient's caregiver. The notification may also be provided via an application on a smartphone, tablet, laptop, desktop or other computing device.

As described herein, the system can identify behaviors, habits, activities, foods, drinks, medications, drugs, and the like which are associated with the patient's abnormal ECG readings. In addition to informing the patient of these associations, the system can provide instructions or recommendations to the patient to avoid these behaviors, habits, activities, foods, drinks, medications, drugs, and the like which are associated with the patient's abnormal ECG readings. Similarly, the system can identify behaviors, habits, activities, foods, drinks, medications, drugs, and the like which are associated with normal or improving ECG readings, and can instruct or recommend that the patient perform these behaviors, habits, and activities and/or consume these foods, drinks, medications, and drugs. The patient may avoid a future healthcare issue, as instructed or recommended by the system, by modifying their behavior, habits

or by taking any course of action, including but not limited to taking a medication, drug or adhering to a diet or exercise program, which may be a predetermined course of action recommended by the system independent of any analysis of the ECG data, and/or may also result from insights learned through this system and method as described herein. In addition, the insights of the system may relate to general fitness and or mental wellbeing.

The ECG data and the associated metadata and other related data as described herein can be stored in a central database, a cloud database, or a combination of the two. The data can be indexed, searched, and/or sorted according to any of the features, parameters, or criteria described herein. The system can analyze the ECG data of a single patient, and it can also analyze the ECG data of a group of patients, which can be selected according to any of the features, parameters or criteria described herein. When analyzing data from a single patient, it may be desirable to reduce and/or correct for the intra-individual variability of the ECG data, so that comparison of one set of ECG data taken at one particular time with another set of ECG data taken at another time reveals differences resulting from changes in health status and not from changes in the type of ECG recording device used, changes in lead and electrode placement, changes in the condition of the skin (i.e. dry, sweaty, conductive gel applied or not applied), and the like. As described above, consistent lead and electrode placement can help reduce variability in the ECG readings. The system can also retrieve the patient's ECG data that were taken under similar circumstances and can analyze this subset of ECG data.

FIG. **4** illustrates an embodiment of the system and method **400** of ECG monitoring described herein. The system can be implemented on a server or computer having a processor for executing the instructions described herein, which can be stored in memory. In step **402**, ECG data can be recorded using any of the devices described herein for one or more patients. In step **404**, the ECG data is transmitted along with associated metadata to a server and database that stores the ECG data. In step **406**, a subset of the ECG data can be selected based on criteria in the metadata, such as user identity, time, device used to record the ECG data, and the like. In step **408**, the subset of ECG data can be analyzed using a machine learning algorithm, which can assign a risk level to the ECG data in step **410**. The system can then determine whether the risk level is high, as shown in step **412**. If the risk level is low, the user can be notified that the ECG is normal or low risk, as shown in step **414**. If the risk level is high, a high risk level alert can be sent to the patient with the option of sending the ECG to the medical professional for interpretation, as shown in step **416**. The system then waits for the user's response to determine whether the patient elects to send the ECG to the medical professional for interpretation, as shown in step **418**. If the patient does not wish to send the ECG to the medical professional for interpretation, the system can end the routine at this point, as shown in **420**. If the patient does elect to send the ECG to the medical professional for interpretation, the request can be transmitted to the medical professional in step **422**. The request to the medical professional can be sent to a workflow auction system as described in U.S. Provisional Application No. 61/800,879, filed Mar. 15, 2013, which is herein incorporated by reference in its entirety for all purposes. Once the medical professional has interpreted the ECG, the system can receive and store the ECG interpretation from the medical professional in the database, as shown in step **424**. The system can then notify the user of the professional ECG interpretation, which can be sent to or accessed by the user, as shown in step **426**. Additionally, the system can compare the assigned risk level with the medical diagnosis in step **428** and can determine whether the risk level determined by the system agrees with the medical diagnosis in step **430**. If the risk level does not agree with the medical diagnosis, the machine learning algorithm can be adjusted until the risk level matches the medical diagnosis, as shown in step **432**. If the risk level does agree with the medical diagnosis, the routine can be ended as shown in step **434**.

Although the above steps show a method **400** in accordance with many embodiments, a person of ordinary skill in the art will recognize many variations based on the teaching described herein. The steps may be completed in a different order. Steps may be added or deleted. Some of the steps may comprise sub-steps. Many of the steps may be repeated as often as beneficial to the user or subject.

One or more of the steps of a method **400** may be performed with circuitry, for example, one or more of a processor or a logic circuitry such as a programmable array logic for a field programmable gate array. The circuitry may be programmed to provide one or more of the steps of a method **400**, and the program may comprise program instructions stored on a non-transitory computer readable medium or memory or programmed steps of the logic circuitry such as the programmable array logic or the field programmable gate array, for example.

Aspects of the present disclosure provide systems and methods for generating a heart health score in response to continuously measured or monitored physiological parameter(s). The score may be given a quantitative value such as be graded from A to F or 0 to 100 for example (e.g. a great score may be an A or 100, a good score may be a B or 75, a moderate score may be a C or 50, a poor score may be a D or 25, and a failing score may be an F or 0.) If an arrhythmia is detected, the score may be below 50 for example. Other scoring ranges such as A to Z, 1 to 5, 1 to 10, 1 to 1000, etc. may also be used. Arrhythmia may be detecting using the machine learning based operations or algorithms described herein.

FIG. **5** shows a flow chart of an exemplary method **500** to generate a heart health score in accordance with many embodiments.

In a step **502**, an arrhythmia is detected. If an arrhythmia is detected (e.g. using the methods and/or algorithms disclosed herein), then the heart health score generated will be below 50. Depending on the severity of the arrhythmia detected, the heart score may be calculated or assigned within the ranges according to the table below in Table 2.

TABLE 2

Arrhythmia	Heart Health score
ATRIAL FIBRILLATION, HR below 100	30-45
ATRIAL FIBRILLATION, HR above 100	15-30
Sinus Tachycardia	20-40
Supraventricular Tachycardia	20-40
Bradycardia	20-40
Bigeminy, Trigeminy	30-50
Short runs of High Heart Rate (VTACH suspect)	10-30

In a step **504** a Heart Rate Variability (HRV) is calculated. HRV can be an indicator of heart health. The value for HRV value for a healthy heart is typically higher than HRV for an unhealthy heart. Also, HRV typically declines with age and may be affected by other factors, like stress, lack of physical

activity, etc. HRV may be measured and analyzed using the methods described above. HRV may be calculated in the absence of arrhythmia, which may improve the accuracy of the HRV measurement. HRV may be determined and further analyzed as described above.

In a step **506**, premature beats are counted and Heart Rate Turbulence (HRT) is calculated. Premature beats in the sequence of R-R intervals may be detected. Also, R-R intervals typically tend to recover at a certain pace after a premature beat. Using these two parameters (prematurity and pace of R-R recovery), HRT parameters may be calculated. There may be known deviations of HRT parameters associated with patients with risk of Congestive Heart Failure (CHF). These deviations, however, may be used to estimate an inverse measure. The number of premature beats per day (or per hour) may also be used as a measure of heart health. A low number of premature beats may indicate better heart health. In summary, the heart health score may be generated by combining at least heart rate variability (HRV), the number of premature beats, and heart rate turbulence (HRT). This combination (in the absence of arrhythmia) may provide an accurate estimate of how healthy the heart of the user is.

In a step **508**, a heart health score is generated, and in a step **510**, a hearth health score is generated based on an arrhythmia. To initially generate the score, a few hours (e.g. 2-5 hours) of measured R-R intervals may be required. A more accurate score may be generated after a week of continuous R-R interval measurements. Longer data sets may be required to detect significant arrhythmias as they may usually be detected within the first 7-8 days of monitoring.

Although the above steps show a method **500** in accordance with many embodiments, a person of ordinary skill in the art will recognize many variations based on the teaching described herein. The steps may be completed in a different order. Steps may be added or deleted. Some of the steps may comprise sub-steps. Many of the steps may be repeated as often as beneficial to the user or subject.

One or more of the steps of a method **500** may be performed with circuitry, for example, one or more of a processor or a logic circuitry such as a programmable array logic for a field programmable gate array. The circuitry may be programmed to provide one or more of the steps of a method **500**, and the program may comprise program instructions stored on a non-transitory computer readable medium or memory or programmed steps of the logic circuitry such as the programmable array logic or the field programmable gate array, for example.

FIG. **6** shows a further method **600** of generating a heart score. In addition to the parameters which may be derived from the heart rate data described above, the heart health score may also be generated in response to further physiological parameters as shown in FIG. **6**.

In a step **602**, a raw ECG waveform is obtained. In a step **608**, ECG parameters are extracted from the raw ECG waveform data and arrhythmia prediction and/or detection algorithms are run to analyze the obtained raw ECG waveform data.

In a step **604**, physiological parameters may be measured using a sensor of the user's local computing device or an accessory thereof. Such measured physiological parameters may include blood pressure, user activity and exercise level, blood oxygenation levels, blood sugar levels, an electrocardiogram, skin hydration or the like of the user. These physiological parameters may be measured over time such as over substantially the same time scale or length as the measurement of heart rate. In a step **610**, an R-R interval is extracted and both traditional and non-traditional heart rate measures are used to analyze the measured heart rate and physiological parameters.

In a step **606**, additional physiological parameters for determining the heart health score may be input by the user. These parameters may include the age, the gender, the weight, the height, the body type, the body mass index (BMI), the personal medical history, the family medical history, the exercise and activity level, the diet, the hydration level, the amount of sleep, the cholesterol level, the alcohol intake level, the caffeine intake level, the smoking status, and the like of the user. For example, the heart health score may be weighted by age and/or gender to provide the user an accurate assessment of his or her heart health in response to the heart rate data. In a step **612**, feature extraction is used to analyze the inputted physiological parameters.

In a step **614** feature ranking and/or feature selection occurs. In a step **618**, a real time prediction or detection of atrial fibrillation, and/or in a step **616**, the heart rate variability measurements may be labelled and saved for offline training of a machine learning algorithm or set of machine learning operations, and then may be subsequently used to make a real time prediction and/or detection of atrial fibrillation. A plurality of heart health scores may be generated by a plurality of users to generate a set of population data. This population data may be used to train the machine learning algorithms described herein such that the trained algorithm may be able to detect and predict atrial fibrillation or other health conditions from user data.

Although the above steps show a method **600** in accordance with many embodiments, a person of ordinary skill in the art will recognize many variations based on the teaching described herein. The steps may be completed in a different order. Steps may be added or deleted. Some of the steps may comprise sub-steps. Many of the steps may be repeated as often as beneficial to the user or subject.

One or more of the steps of a method **600** may be performed with circuitry, for example, one or more of a processor or a logic circuitry such as a programmable array logic for a field programmable gate array. The circuitry may be programmed to provide one or more of the steps of a method **600**, and the program may comprise program instructions stored on a non-transitory computer readable medium or memory or programmed steps of the logic circuitry such as the programmable array logic or the field programmable gate array, for example.

The systems and methods for generating a heart health score in response to continuously measured or monitored physiological parameter(s) may comprise a processor of a computing device and software. A processor of a computing device (e.g. a tablet computer, a smartphone, a smart watch, a smart band, a wearable computing device, or the like) may execute this set of instructions to receive the input data and detect and/or predict atrial fibrillation therefrom. The software may be downloaded from an online application distribution platform such as the Apple iTunes or App Store, Google Play, Amazon App Store, and the like. A display of the computing device may notify the user of the calculated heart health score and/or if further measurements are required (e.g. to perform a more accurate analysis).

FIG. **7** shows a schematic diagram of the executed application described herein. The heart health score may be provided on a software application such as a mobile app downloaded from an application distribution platform and executed on a local computing device of the user as described above. This executed application may instruct the

user to take active steps in response to a poor or moderate heart health score. For example, the instructions to the user may be to make a corrective measure such as to modify his or her diet, exercise pattern, sleep pattern, or the like. Alternatively, or in combination, the instructions to the user may be to take a further step such as to take an electrocardiogram (e.g. to verify the presence of an arrhythmia), enroll in an electrocardiogram over-read service, or schedule an appointment with a physician or other medical specialist. If the heart health score is below a desired threshold for good heart health, the executed application may link the user to a second execute application with further application features. Alternatively, or in combination, these further features may be unlocked on the first executed application if the heart health score is below the threshold. In at least some cases, a prescription or verification from a medical professional may also be required to unlock the further application features.

FIG. **8** shows screenshots of the executed application. The further features unlocked may include the ability to read electrocardiogram (ECG) data from a sensor coupled to the local computing device and display the electrocardiogram (ECG) in real-time and/or detect and alert for atrial fibrillation based on the electrocardiogram (ECG) in real-time (e.g. as described in U.S. application Ser. Nos. 12/796,188, 13/108,738, 13/420,540, and 13/964,490). As shown in FIG. **8**, these further features may include an electrocardiogram (ECG) over-read service such as that described in U.S. application Ser. No. 14/217,032. The first executed application may comprise a consumer software application and the second executed application may comprise a medical professional or regulated software application or set of features of the first executed application. As described herein and shown in FIG. **8**, the executed application may provide a dash board to track the heart health of the user and show risk factors which may be monitored and tracked by the user. The dash board may be provided with further features such as that described in U.S. Ser. No. 61/915,113 (filed Dec. 12, 2013).

FIG. **9** shows a method **900** for cardiac disease and rhythm management, which may, for example, be implemented with the system **100** described herein. In a step **902**, a user or subject is provided access to a cardiac disease and/or rhythm management system such as system **100**. Step **902** may comprise prescribing the use of the system **100** for the user or subject. In a step **904**, the user or subject is provided one or more biometric sensors. These biometric sensor(s) may couple to a computing device of the user or subject, e.g. a personal desktop computer, a laptop computer, a tablet computer, a smartphone, etc., and associated software loaded thereon.

In a step **906**, the user or subject downloads the cardiac disease and/or rhythm management system software onto their computing device. For example, the system software may comprise a mobile software application ("mobile app") downloaded from the Apple App Store, Google Play, Amazon Appstore, BlackBerry World, Nokia Store, Windows Store, Windows Phone Store, Samsung Apps Store, and the like. The downloaded system software, e.g. mobile app **101***a*, may be configured to interface with the biometric sensors provided to the user or subject in the step **154**.

In a step **908**, personal information input to the cardiac disease management system is received. For example, the user or subject may enter his or her gender, height, weight, diet, disease risk factors, etc. into the mobile app **101***a*. Alternatively, or in combination, this personal information may be input on behalf of the user or subject, for example, by a physician of the user or subject.

In a step **910**, biometric data is received from the biometric sensors provided to the user or subject. For example, the system **100** and the mobile app **101***a* may receive ECG data and heart rate from handheld sensor **103**, activity data from wrist-worn activity sensor **105**, blood pressure and heart rate data from mobile blood pressure monitor **107***a*, and other data such as weight and body fat percentage data from a "smart" scale in communication with the local computing device **101**.

In a step **912**, a cardiac health score is generated. The cardiac health score can be generated by considering and weighing one or more influencing factors including the incidence of atrial fibrillation or arrhythmia as detected by the handheld ECG monitor, the heart rate of the user or subject, the activity of the user or subject, hours of sleep and rest of the user or subject, blood pressure of the user or subject, etc. Often, the incidence of atrial fibrillation or arrhythmia will be weighed the most. The cardiac health score may be generated by a physician or a machine learning algorithm provided by the remote server or cloud-based service **113**, for example. A plurality of users and subject may concurrently use the cardiac health and/or rhythm management system **100** and the machine learning algorithm may, for example, consider population data and trends to generate an individual user or subject's cardiac health score.

In a step **914**, one or more recommendations or goals is generated for the user or subject based on or in response to the generated cardiac health score. These recommendation(s) and/or goal(s) may be generated automatically based on or in response to the biometric and personal information of the user or subject. For example, the machine learning algorithm may generate these recommendation(s)/goal(s). Alternatively, or in combination, a physician or other medical specialist may generate the recommendation(s) and/or goal(s), for example, based on or in response to the biometric and personal information of the user or subject. The physician or other medical professional may access the patient data through the Internet as described above.

In a step **916**, the patient implements many if not all of the recommendation(s) and/or goal(s) provided to him or her. And in a step **916**, steps **908** to **916** may be repeated such that the user or subject may iteratively improve their cardiac health score and their overall health.

Although the above steps show method **900** of managing cardiac disease and/or rhythm in accordance with many embodiments, a person of ordinary skill in the art will recognize many variations based on the teaching described herein. The steps may be completed in a different order. Steps may be added or deleted. Some of the steps may comprise sub-steps. Many of the steps may be repeated as often as beneficial to the user or subject.

One or more of the steps of the method **900** may be performed with circuitry, for example, one or more of a processor or a logic circuitry such as a programmable array logic for a field programmable gate array. The circuitry may be programmed to provide one or more of the steps of the method **900**, and the program may comprise program instructions stored on a non-transitory computer readable medium or memory or programmed steps of the logic circuitry such as the programmable array logic or the field programmable gate array, for example.

In some embodiments, the heart rate information (or an extracted portion of HR information) may be used to compare to a database of similar information that has been correlated with cardiac events. For example, heart rate

information may be compared to a database of HR information extracted for ECG recordings of patients known to be experiencing cardiac problems. Thus, patterns of heart rate information taken from a subject may be compared to patterns of cardiac information in a database. If there is a match (or a match within a reasonable closeness of fit), the patient may be instructed to record an ECG, e.g. using an ambulatory ECG monitor. This may then provide a more detailed view of the heart. This method may be particularly useful, as it may allow recording and/or transmission and/or analysis of detailed electrical information about the heart at or near the time (or shortly thereafter) when a clinically significant cardiac event is occurring. Thus, the continuous monitoring may allow a subject to be alerted immediately upon an indication of the potential problem (e.g. an increase in HRV suggestive of a cardiac dysfunction). This may allow the coupling of continuous HR monitoring with ECG recording and analysis for disease diagnosis and disease management.

FIG. **10** illustrates one variation of a method for monitoring a subject to determine when to record an electrocardiogram (ECG). In FIG. **10**, a subject is wearing a continuous heart rate monitor (configured as a watch **1010**, including electrodes **1016**), shown in step **1002**. The heart rate monitor transmits (wirelessly **1012**) heart rate information that is received by the smartphone **1018**, as shown in step **1004**. The smartphone includes a processor that may analyze the heart rate information **1004**, and when an irregularity is determined, may indicate **1006** to the subject that an ECG should be recorded. In FIG. **10**, an ambulatory ECG monitor **1014** is attached (as a case having electrodes) to the phone **1018**. The user may apply the ECG monitor as to their body (e.g. chest, between arms, etc.) **1008** to record ECGs that can then be saved and/or transmitted for analysis.

FIGS. **11** and **11**A show screenshots of an atrial fibrillation dashboard **1100** of a user interface for the cardiac disease and/or rhythm management system **100**. FIG. **11** shows a top portion **1100***a* of the atrial fibrillation dashboard **1100** while FIG. **10**A shows a bottom portion **1100***b* of the atrial fibrillation dashboard **1100**.

The top portion **1100***a* of the atrial fibrillation dashboard **1100** as shown in FIG. **10** may display the current cardiac health score of the user or subject, a recent best cardiac health score of the user or subject, and a completion percentage of recommendation(s) and/or goal(s) for the user or subject. The user or subject may tap any one of the cardiac health score displays or the recommendation(s) and/or goal(s) displays to access more detailed information regarding the calculated health score(s) or recommendation(s) and/or goal(s), respectively. The top portion **1100***a* may also show an ECG of the user or subject and a button which may be tapped to record the ECG of the user or subject for the day. As discussed with reference to FIG. **1**, the ECG may be recorded with a handheld sensor **103** in communication with the local computing device **100**. The top portion **1000***a* may also show the number of atrial fibrillation episodes and the average duration of these atrial fibrillation episodes. This number and duration may be generated automatically by software or logic of the mobile app **101***a* based on or in response to the ECG measurements taken by the user or subject. Alternatively, or in combination, a physician may access the atrial fibrillation dashboard **1100** of an individual user or subject, evaluate his or her ECGs, and provide the number of atrial fibrillation episodes and their duration to the mobile app **101***a* or other software loaded on the local computing device **101** of the user or subject. The shortest and longest durations of the atrial fibrillation episodes may also be shown by the top portion **1100***a* as well as the user or subject's daily adherence to a medication regime.

The bottom portion **1100***b* of the atrial fibrillation dashboard **1100** as shown in FIG. **10**A may display one or more influencers which influence how the cardiac health score is generated. These influencers may include, for example, caffeine intake, alcohol intake, stress levels, sleep levels, weight, nutrition, fitness and activity levels, and blood pressure. Data for these influencers may be input automatically by one or more biometric sensors coupled to the local computing device **101** and/or the mobile app **101***a*. Alternatively, or in combination, the data for these influencers may be input manually by the user or subject by tapping on the respective influencer display. For example, tapping on the blood pressure display area may cause a slider input **1100***c* for blood pressure to pop up. The user or subject may use the slider to enter and save his or her blood pressure for the day. Similar pop-ups or user-selected inputs may be provided for the other influencers. For example, the user or subject may enter his or her daily caffeine or alcohol intake, stress and sleep levels, nutrition levels, or activity and fitness levels (e.g. low/bad, medium/so-so, or high/good based on the user's age, gender, height, weight, etc. as can be indicated by an instruction page of the mobile app **101***a*). The influencer displays may also show the goal progression of the user or subject.

FIGS. **12** and **12**A show screenshots of a goals and recommendations page **1200** of the cardiac disease and rhythm management system interface or mobile app **101***a*. A top portion **1200***a* of the goals and recommendations page **1100** may comprise a listing of 7-day goals for the user or subject. The top portion **1200***a* may further comprise everyday goals for the user or subject which often cannot be removed or changed. The user or subject can check off these goals or recommendations as he or she meets them. The top portion **1200***a* may track goal completion percentage over a 7-day period. The user or subject can set the same goals for the next day and/or set new goals.

A bottom portion **1200***b* of the goals and recommendations page **1200** may comprise a listing of new goals which the user or subject may add. The new goals may be categorized into goals or recommendations for atrial fibrillation management, stress management, and/or other categories. For example, goals for atrial fibrillation management may include taking daily medications, reducing caffeine intake, and reducing alcohol intake. And, goals for stress management may include meditate for 5 minutes daily, take blood pressure reading daily, and getting at least 7 hours of sleep nightly. Using the goals and recommendations page **1200**, the user or subject can set their goals for the week. One or more of these goals may be automatically recommended to the user or subject or be recommended by a physician having access to the dashboard **1100**. For example, goals may be recommended based on last week's progress. The completion of recommended goals can result in the user or subject earning more "points," in effect gamifying health and cardiac rhythm management for the user or subject. Alternatively, or in combination, the goals may be set by a physician having access to the dashboard **1100**.

FIG. **13** shows a screenshot of a user's local computing device notifying the user with a pop-up notice **1300** to meet their daily recommendations and goals. By tapping on the pop-up notice, **1300**, the user or subject can be taken to the atrial fibrillation dashboard where the user or subject can update or otherwise manage their cardiac health.

FIG. **14** shows an embodiment comprising a smart watch **1400** which includes at least one heart rate monitor **1402** and

at least one activity monitor **1404**. One or more processors are coupled to one or more non-transitory memories of the smart watch and configured to communicate with the heart rate monitor **1402** and the activity monitor **1404**. The one or more processors are further coupled to an output device **1408**. Processor executable code is stored on the one or more memories and when executed by the one or more processors causes the one or more processors to determine if heart rate and activity measurements represent an advisory condition for recording an ECG, and generate and send notification signals through the output device **1408** when an advisory condition for recording an ECG is determined.

For example, presently available smart watches include motion sensors such as pedometers. Pedometers can be based on an accelerometer or electromechanical mechanism such as a pendulum, magnetic reed proximity switch, and a spring suspended lever arm with metal-on-metal contact. Modern accelerometers are often small micro electro-mechanical systems and are well known by those skilled in the art. Heart rate monitors are readily available with smart phones as well as smart watches. One type uses an optical sensor to detect the fluctuation of blood flow. The signal can be amplified further using, for example, a microcontroller to count the rate of fluctuation, which is actually the heart rate.

An advisory condition for recording an ECG may occur due to, for example, large continuing fluctuations in heart rate. An advisory condition for recording an ECG can also occur when a measured heart rate increases rapidly without a corresponding increase in activity monitored by, for example, an accelerometer. By comparing measured heart rate changes with measured activity changes, the presently disclosed software or "app" minimizes false alarms are minimized. ECG devices are described in U.S. Ser. No. 12/796,188, filed Jun. 8, 2010, now U.S. Pat. No. 8,509,882, hereby expressly incorporated herein by reference in its entirety. The ECG device can be present in a smart watch band or a smart phone. In one embodiment, the ECG device includes an electrode assembly configured to sense heart-related signals upon contact with a user's skin, and to convert the sensed heart-related signals to an ECG electric signal. The ECG device transmits an ultrasonic frequency modulated ECG signal to a computing device such as, for example, a smartphone. Software running on the computing device or smartphone digitizes and processes the audio in real-time, where the frequency modulated ECG signal is demodulated. The ECG can be further processed using algorithms to calculate heart rate and identify arrhythmias. The ECG, heart rate, and rhythm information can be displayed on the computer or smartphone, stored locally for later retrieval, and/or transmitted in real-time to a web server via a 2G/3G/4G, Wi-Fi or other Internet connection. In addition to the display and local processing of the ECG data, the computer or smartphone can transmit, in real-time, the ECG, heart rate and rhythm data via a secure web connection for viewing, storage and further analysis via a web browser interface.

In another embodiment, the converter assembly of an ECG device is integrated with, and electrically connected to the electrode assembly and is configured to convert the electric ECG signal generated by electrode assembly to a frequency modulated ECG ultrasonic signal having a carrier frequency in the range of from about 18 kHz to about 24 kHz. It is sometimes desirable to utilize a carrier frequency in the 20 kHz to 24 kHz range. The ultrasonic range creates both a lower noise and a silent communication between the acquisition electronics and the computing device such as the smartphone, notebook, smart watch and the like.

A kit can include downloadable software such as an "app" for detecting an advisory condition for recording an ECG and an ECG device. The ECG device can be present on a watch band for replacing a specific band on a smart watch. The ECG device can also be provided on a smart phone back plate for replacing an existing removable smartphone back. In another configuration, the ECG device is usable as a smartphone protective case.

Software on the smartphone or smart watch can also combine data and signals from other sensors built into the smartphone or smart watch such as a GPS.

While preferred embodiments of the present disclosure have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the subject matter described herein. It should be understood that various alternatives to the embodiments of the subject matter described herein may be employed in practicing the subject matter described herein. It is intended that the following claims define the scope of the disclosure and that methods and structures within the scope of these claims and their equivalents be covered thereby.

What is claimed is:

1. A smart watch to detect the presence of an arrhythmia of a user, comprising:

a processing device;

a photoplethysmography ("PPG") sensor operatively coupled to the processing device;

an ECG sensor, comprising two or more ECG electrodes, the ECG sensor operatively coupled to the processing device;

a display operatively coupled to the processing device; and

a memory, operatively coupled to the processing device, the memory having instructions stored thereon that, when executed by the processing device, cause the processing device to:

receive PPG data from the PPG sensor;

detect, based on the PPG data, the presence of an arrhythmia;

receive ECG data from the ECG sensor; and

confirm the presence of the arrhythmia based on the ECG data.

2. The smart watch of claim **1**, further comprising a motion sensor operatively coupled to the processing device, wherein to detect the presence of the arrhythmia, the processing device is configured to:

receive motion sensor data from the motion sensor; and

determine, from motion sensor data, that the user is at rest.

3. The smart watch of claim **2**, wherein to detect the presence of the arrhythmia, the processing device is configured to input the PPG data into a machine learning algorithm trained to detect arrhythmias.

4. The smart watch of claim **2**, wherein to detect the presence of the arrhythmia, the processing device is configured to:

determine heartrate variability ("HRV") data from the PPG data; and

detect, based on the HRV data, the presence of the arrhythmia.

5. The smart watch of claim **4**, wherein to detect the presence of the arrhythmia, the processing device is configured to input the HRV data into a machine learning algorithm trained to detect arrhythmias.

6. The smart watch of claim 5, wherein to detect the presence of the arrhythmia, the processing device is further configured to input the motion sensor data with the HRV data into the machine learning algorithm trained to detect arrhythmias.

7. The smart watch of claim 1, wherein the processing device is further configured to:

extract one or more features from the PPG data; and

detect, based on the one or more features, the presence of the arrhythmia.

8. The smart watch of claim 7, wherein the one or more features correspond to an HRV signal analyzed in a time domain.

9. The smart watch of claim 7, wherein the one or more features comprise a nonlinear transform of R-R ratio or R-R ratio statistics with an adaptive weighting factor.

10. The smart watch of claim 7, wherein the one or more features are features of an HRV signal analyzed geometrically.

11. The smart watch of claim 7, wherein the one or more features are features of an HRV signal analyzed in the frequency domain.

12. The smart watch of claim 1, wherein the processing device is further configured to generate a notification of the detected arrhythmia.

13. The smart watch of claim 1, further comprising a biometric data sensor, wherein the processing device is further configured to:

receive biometric data of the user from the biometric data sensor; and

detect, based on the biometric data, the presence of the arrhythmia.

14. The smart watch of claim 13, wherein the biometric data comprises at least one of: a temperature, a blood pressure, or an inertial data of the user.

15. The smart watch of claim 1, the processing device further configured to display an ECG rhythm strip from the ECG data.

16. The smart watch of claim 1, the processing device further to receive the ECG data from the ECG sensor in response to receiving an indication of a user action.

17. A method to detect the presence of an arrhythmia of a user on a smart watch, comprising:

receiving PPG data from a PPG sensor of the smartwatch;

detecting by a processing device, based on the PPG data, the presence of an arrhythmia;

receiving ECG data from an ECG sensor of the smartwatch; and

confirming the presence of the arrhythmia based on the ECG data.

18. The method of claim 17, wherein detecting the presence of the arrhythmia comprises:

receiving motion sensor data from a motion sensor of the smartwatch; and

determine, from motion sensor data, that the user is at rest.

19. The method of claim 18, wherein detecting the presence of the arrhythmia comprises inputting the PPG data into a machine learning algorithm trained to detect arrhythmias.

20. The method of claim 18, wherein detecting the presence of the arrhythmia comprises:

determining heartrate variability ("HRV") data from the PPG data; and

detecting, based on the HRV data, the presence of the arrhythmia.

21. The method of claim 20, wherein detecting the presence of the arrhythmia comprises inputting the HRV data into a machine learning algorithm trained to detect arrhythmias.

22. The method of claim 21, wherein detecting the presence of the arrhythmia comprises inputting the motion sensor data with the HRV data into the machine learning algorithm trained to detect arrhythmias.

23. The method of claim 17, further comprising generating a notification of the detected arrhythmia.

24. The method of claim 17, further comprising receiving the ECG data from the ECG sensor in response to receiving an indication of a user action.

25. A non-transitory computer-readable storage medium including instructions that, when executed by a processing device, cause the processing device to:

receive PPG data from a PPG sensor of the smartwatch;

detect by the processing device, based on the PPG data, the presence of an arrhythmia;

receive ECG data from an ECG sensor of the smartwatch; and

confirm the presence of the arrhythmia based on the ECG data.

26. The non-transitory computer-readable storage medium of claim 25, wherein the processing device is further configured to:

extract one or more features from the PPG data; and

detect, based on the one or more features, the presence of the arrhythmia.

27. The non-transitory computer-readable storage medium of claim 26, wherein the one or more features correspond to an HRV signal analyzed in a time domain.

28. The non-transitory computer-readable storage medium of claim 26, wherein the one or more features comprise a nonlinear transform of R-R ratio or R-R ratio statistics with an adaptive weighting factor.

29. The non-transitory computer-readable storage medium of claim 26, wherein the one or more features are features of an HRV signal analyzed geometrically or in the frequency domain.

30. The non-transitory computer-readable storage medium of claim 25, the processing device further to receive the ECG data from the ECG sensor in response to receiving an indication of a user action.

* * * * *

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

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(45) **Date of Patent: *May 5, 2020**

(54) **DISCORDANCE MONITORING**

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

This patent is subject to a terminal disclaimer.

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(63) Continuation of application No. 15/656,745, filed on Jul. 21, 2017, now Pat. No. 10,537,250, which is a continuation of application No. 15/154,849, filed on May 13, 2016, now Pat. No. 9,839,363.

(60) Provisional application No. 62/161,092, filed on May 13, 2015.

(51) **Int. Cl.**

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A61B 5/024	(2006.01)
A61B 5/11	(2006.01)
A61B 5/046	(2006.01)
A61B 5/0464	(2006.01)
A61B 5/0408	(2006.01)

(52) **U.S. Cl.**

CPC ***A61B 5/0205*** (2013.01); ***A61B 5/681*** (2013.01); ***A61B 5/7267*** (2013.01); *A61B 5/02405* (2013.01); *A61B 5/02438* (2013.01); *A61B 5/046* (2013.01); *A61B 5/0464* (2013.01); *A61B 5/04085* (2013.01); *A61B 5/1118* (2013.01); *A61B 2562/0219* (2013.01)

(58) **Field of Classification Search**

None

See application file for complete search history.

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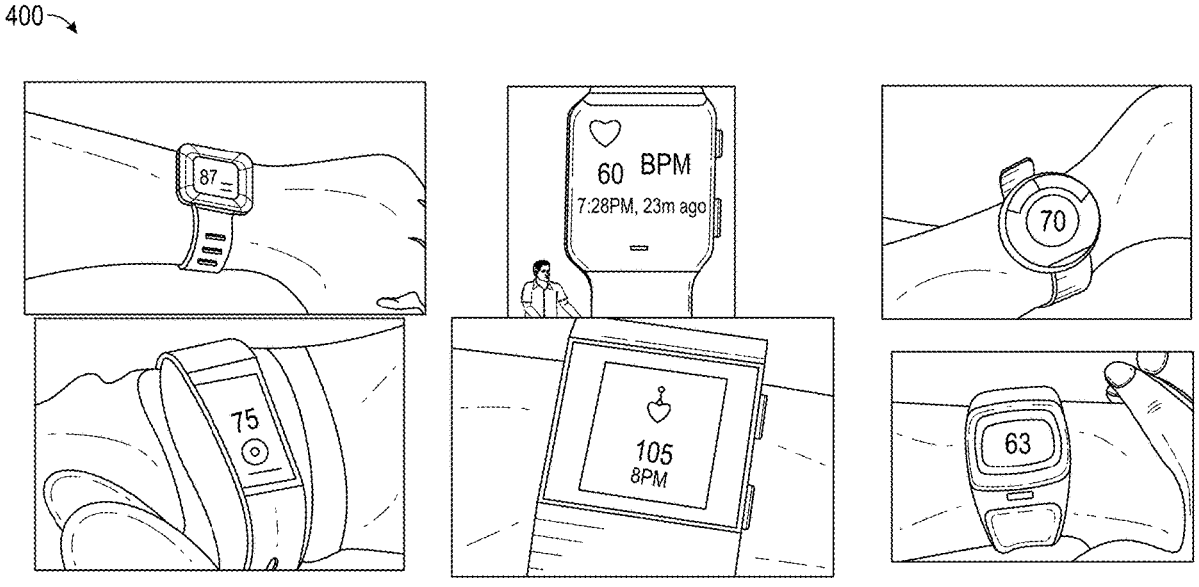
(57) **ABSTRACT**

Described herein are systems, devices, and methods for cardiac monitoring. In particular, the systems, devices, and methods described herein may be used to conveniently sense the presence of an intermittent arrhythmia in an individual. The systems, devices, and methods described herein may be further configured to sense an electrocardiogram.

23 Claims, 7 Drawing Sheets



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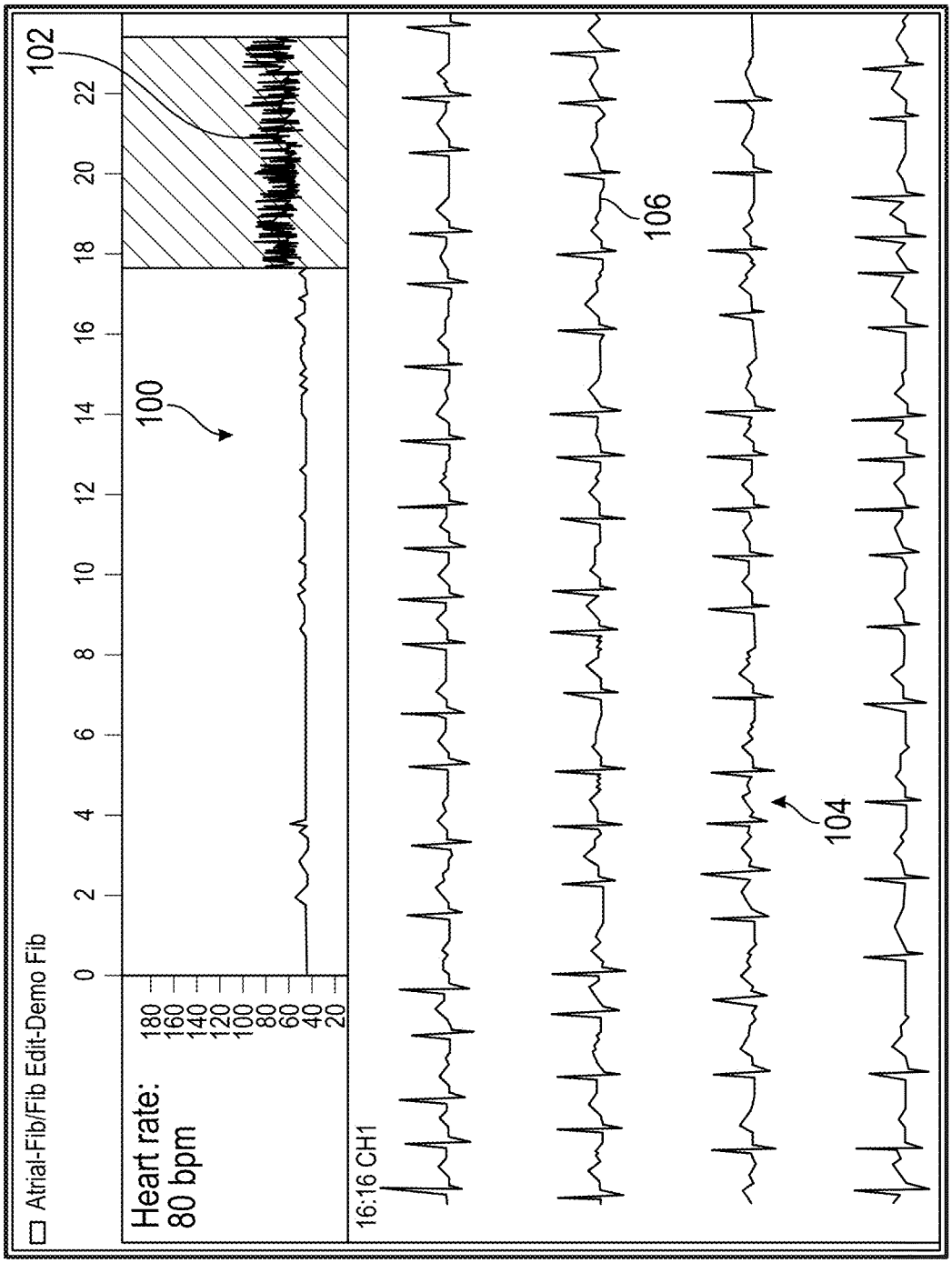
Atrial-Fib/Fib Edit-Demo Fib
Heart rate:
80 bpm
16:16 CH1
100
102
104
106

FIG. 1

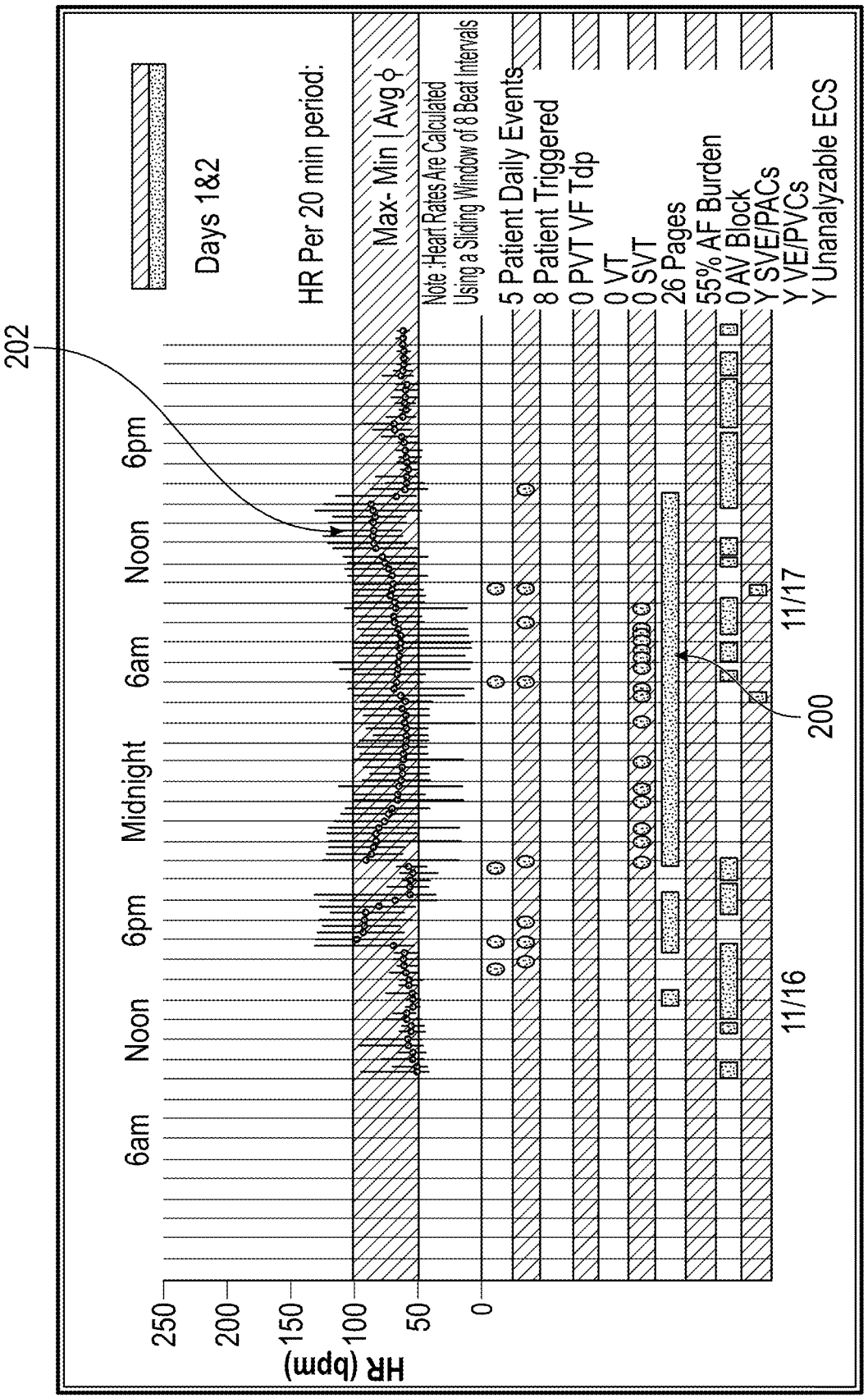
202
Days 1&2
HR Per 20 min period:
Max- Min | Avg
Note :Heart Rates Are Calculated
Using a Sliding Window of 8 Beat Intervals
5 Patient Daily Events
8 Patient Triggered
0 PVT VF Tdp
0 VT
0 SVT
26 Pages
55% AF Burden
0 AV Block
Y SVE/PACs
Y VE/PVCs
Y Unanalyzable ECS
6am
Noon
6pm
Midnight
6am
Noon
6pm
11/16
11/17
200
250
200
150
100
50
0
HR (bpm)

FIG. 2

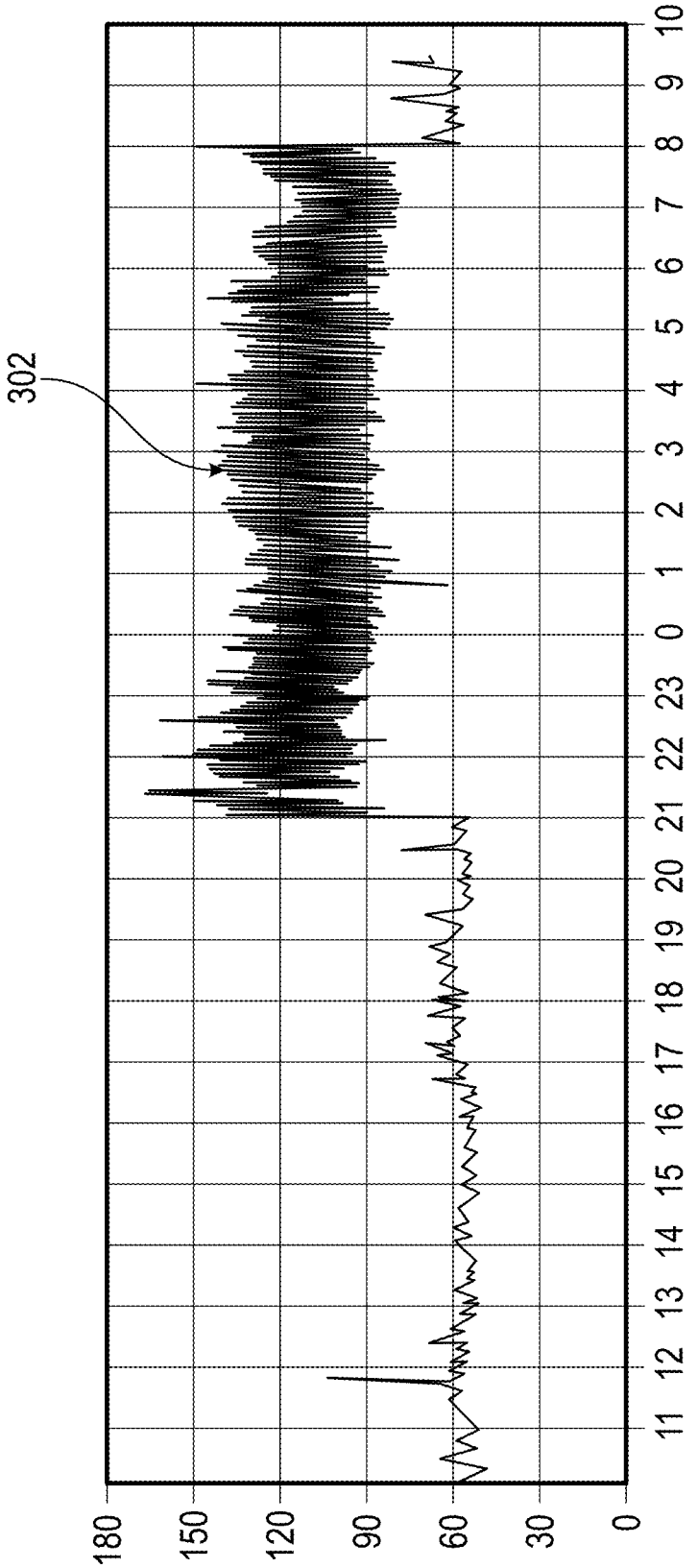
302
10
9
8
7
6
5
4
3
2
1
0
23
22
21
20
19
18
17
16
15
14
13
12
11
180
150
120
90
60
30
0

FIG. 3

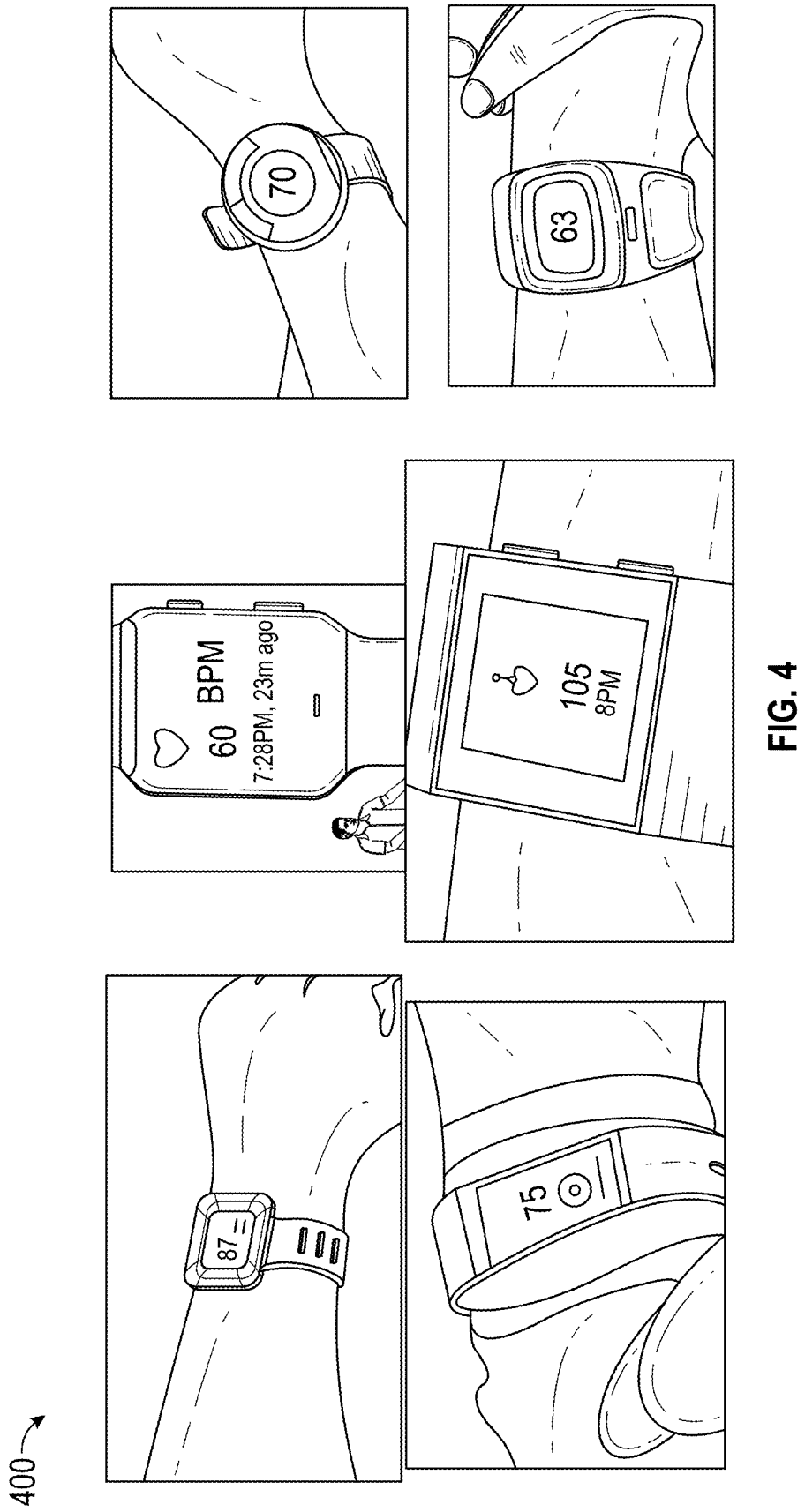

FIG. 4

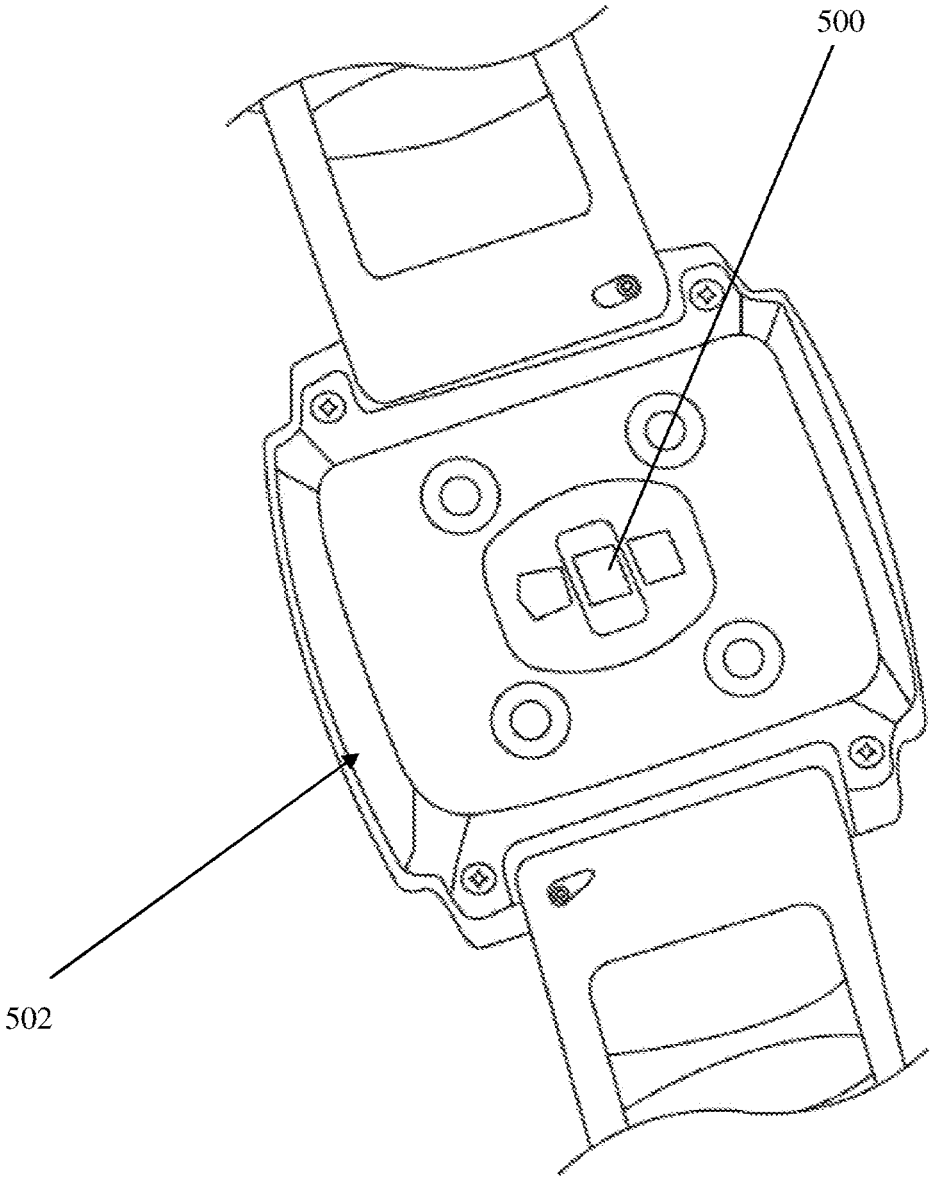

FIG. 5

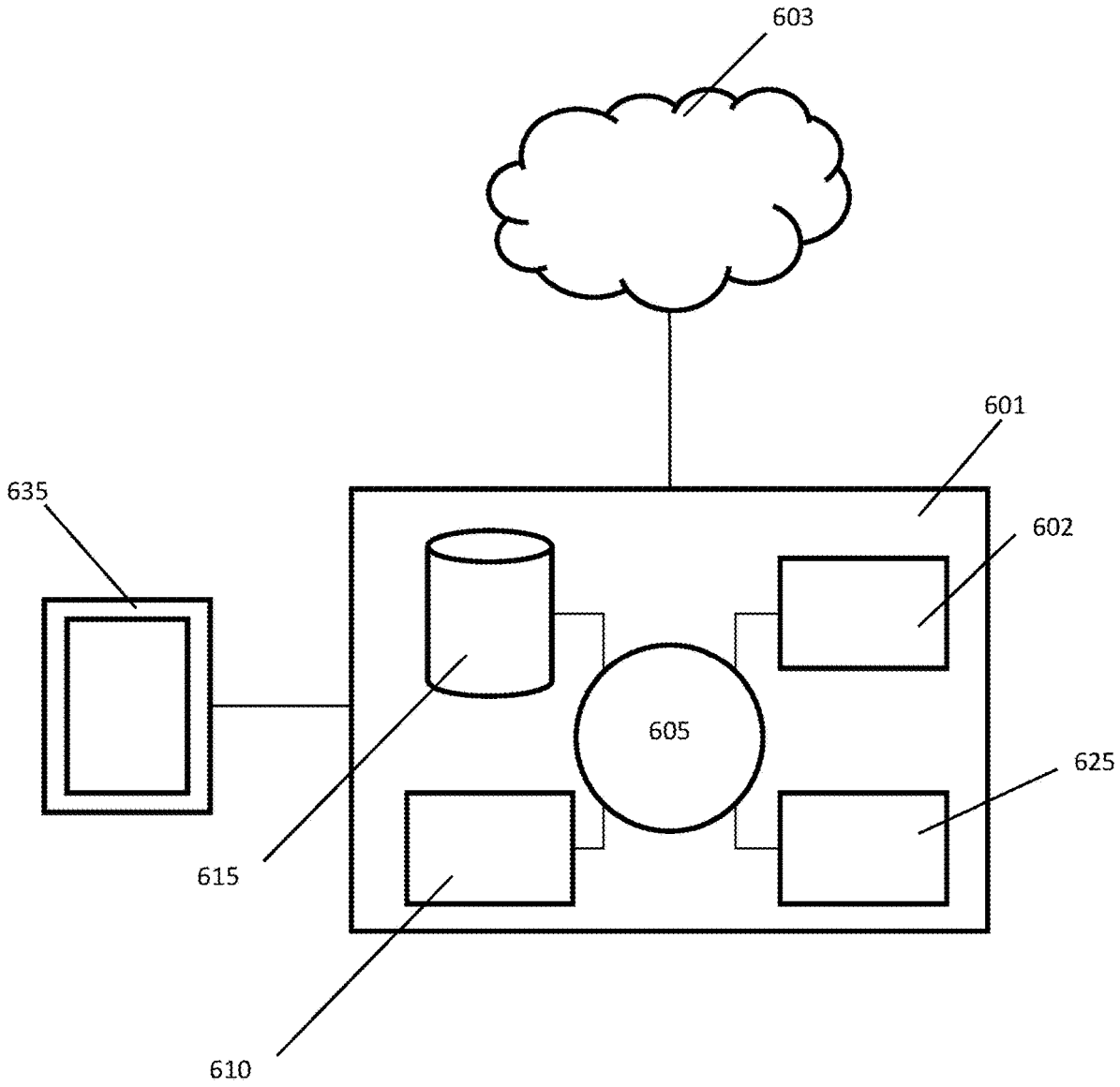

FIG. 6

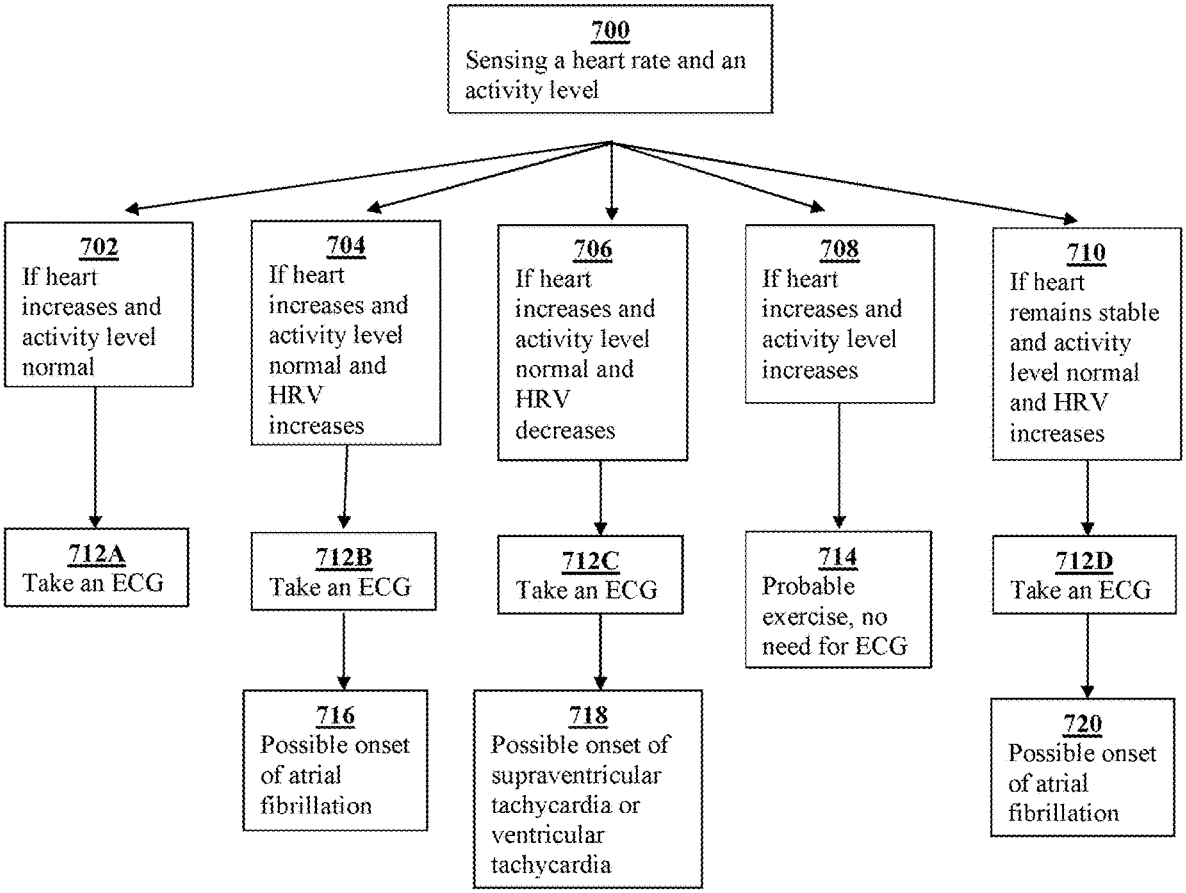
700
Sensing a heart rate and an activity level
702
If heart increases and activity level normal
704
If heart increases and activity level normal and HRV increases
706
If heart increases and activity level normal and HRV decreases
708
If heart increases and activity level increases
710
If heart remains stable and activity level normal and HRV increases
712A
Take an ECG
712B
Take an ECG
712C
Take an ECG
714
Probable exercise, no need for ECG
712D
Take an ECG
716
Possible onset of atrial fibrillation
718
Possible onset of supraventricular tachycardia or ventricular tachycardia
720
Possible onset of atrial fibrillation

FIG. 7

DISCORDANCE MONITORING

CROSS-REFERENCE

This application is a continuation of U.S. patent application Ser. No. 15/656,745, filed Jul. 21, 2017, entitled "DISCORDANCE MONITORING", which is a continuation of U.S. patent application Ser. No. 15/154,849, filed May 13, 2016, entitled "DISCORDANCE MONITORING", now issued as U.S. Pat. No. 9,839,363 on Dec. 12, 2017, which claims the benefit of U.S. Provisional Application No. 62/161,092, filed May 13, 2015, both of which are incorporated herein by reference in its entirety.

BACKGROUND

Irregular heartbeats and arrhythmias are associated with significant morbidity and mortality in patients. Arrhythmias may occur continuously or may occur intermittently. Types of arrhythmia include atrial fibrillation and supraventricular tachycardia. Non-invasive cardiac monitoring is useful in diagnosing cardiac arrhythmia.

SUMMARY

Described herein are systems, devices, and methods for cardiac monitoring. The systems, devices, and methods described herein for cardiac monitoring may comprise portable computing devices such as smartphones, smartwatches, laptops, and tablet computers. Cardiac monitoring using the systems, devices, and methods described herein may be used to predict or identify the occurrence of arrhythmias.

Arrhythmias may occur continuously or may occur intermittently. Continuously occurring arrhythmias may be diagnosed using a number of different techniques including, for example, palpating a radial pulse of an individual, auscultating heart sounds of an individual, recording a heart rate of an individual, and recording an electrocardiogram of an individual. Because a continuous or essentially continuous arrhythmia is always present or essentially always present in the patient, any of the aforementioned diagnosis techniques may be applied at any time in order to make a diagnosis. For intermittent arrhythmia diagnosis any of the aforementioned diagnosis techniques may also be used, however, because intermittent arrhythmias do not always present, the diagnostic technique cannot be applied at any time, but must be applied at the time when the individual is experiencing the arrhythmia. Thus, diagnosing, intermittent arrhythmias may be difficult, because, for example, it is not practical to be prepared to apply one of the aforementioned diagnostic modalities at the exact time that an individual experiences an intermittent arrhythmia. This particular difficulty may also be compounded when an individual is not aware that they are experiencing an intermittent arrhythmia so that they would not, for example, seek out a health care provider during the intermittent arrhythmia.

However, certain parameter values may be conveniently sensed continuously such as, for example, heart rate and activity level, and analyzed to predict or determine the presence of an arrhythmia. One or more conveniently continuously sensed parameter values such as, for example, heart rate and activity level may be analyzed to determine the future onset of or the presence of an arrhythmia by identifying discordance between these two parameter values. For example, discordance between two sensed values may indicate the future onset of or the presence of an arrhythmia. In response to the identification of the future onset of or presence of an arrhythmia an electrocardiogram may be caused to be sensed.

Additional sensed parameters may also be used in an analysis as part of the cardiac monitoring systems, devices, and methods described herein. For example, a determined heart rate variability may be compared to a sensed heart rate and activity level to determine the presence of, for example, atrial fibrillation or supraventricular tachycardia.

Described herein is a method for cardiac monitoring, comprising: sensing an activity level value of an individual with a first sensor of a wearable device worn by said individual; sensing a heart rate value of said individual with a second sensor of said wearable device; determining a heart rate variability value with a processor of said wearable device; determining if a discordance is present between two or more of said activity level value, said heart rate value, and said heart rate variability value with said processor; and indicating to said individual with said wearable device to record an electrocardiogram when said discordance is determined to be present. In some embodiments, said first sensor comprises an accelerometer. In some embodiments, said first sensor comprises a gyroscope. In some embodiments, said second sensor comprises a photosensor. In some embodiments, said discordance is determined to be present when said activity level value is normal and said heart rate value is elevated. In some embodiments, said discordance is determined to be present when said activity level value is normal, said heart rate value is elevated, and said heart rate variability value is increased. In some embodiments, said method comprises indicating a presence of atrial fibrillation. In some embodiments, said discordance is determined to be present when said activity level value is normal, said heart rate value is elevated, and said heart rate variability value is decreased. In some embodiments, said method comprises indicating a presence of a supraventricular tachycardia. In some embodiments, setting one or more threshold values based on said activity level value, said heart rate value, and said heart rate variability value. In some embodiments, said one or more threshold values is determined using a machine learning algorithm.

Described herein is wearable device for cardiac monitoring, comprising: a processor; a first sensor configured to sense an activity level value of an individual, wherein said first sensor is coupled to said processor; a second sensor configured to sense a heart rate value of an individual, wherein said second sensor is coupled to said processor; a first electrode and a second electrode configured to sense an electrocardiogram; a non-transitory computer readable storage medium encoded with a computer program including instructions executable by said processor to cause said processor to: determine if a discordance is present between said activity level value of said individual and said heart rate value of said individual; and indicate that said electrocardiogram be recorded when said discordance is determined to be present. In some embodiments, said first sensor comprises an accelerometer. In some embodiments, said first sensor comprises a gyroscope. In some embodiments, said second sensor comprises a photosensor. In some embodiments, said discordance is determined to be present when said activity level value is normal and said heart rate value is elevated. In some embodiments, said computer program includes instructions that cause said processor to determine a heart rate variability value. In some embodiments, said discordance is determined to be present when said activity level value is normal, said heart rate value is elevated, and said heart rate variability value is increased. In some

embodiments, said computer program includes instructions that cause said processor to indicate a presence of atrial fibrillation. In some embodiments, said discordance is determined to be present when said activity level value is normal, said heart rate value is elevated, and said heart rate variability value is elevated. In some embodiments, said computer program includes instructions that cause said processor to indicate a presence of a supraventricular tachycardia. In some embodiments, said computer program includes instructions that cause said processor to set one or more threshold values based on said activity level value, and said heart rate value.

In some embodiments, said one or more threshold values is determined using a machine learning algorithm.

Described herein is a method for cardiac monitoring, comprising: sensing an activity level value of an individual with a first sensor of a wearable device worn by said individual; sensing a heart rate value of said individual with a second sensor of said wearable device; determining if a discordance is present between two or more of said activity level value and said heart rate value by using an activity level threshold and a heart rate threshold with a processor of said wearable device; and adjusting said activity level threshold and said heart rate level threshold using a machine learning algorithm executed by said processor.

BRIEF DESCRIPTION OF THE DRAWINGS

The novel features of the individual matter described herein are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present individual matter described herein will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the individual matter described herein are utilized, and the accompanying drawings of which:

FIG. **1** shows a heart rate tracing with a corresponding electrocardiogram (ECG) tracing both sensed from the same individual over the same period.

FIG. **2** shows a graphic showing both heart rate and rhythm analysis over a period of time in an individual who experienced different arrhythmias.

FIG. **3** shows a close up of a heart rate tracing sensed over a period of paroxysmal atrial fibrillation.

FIG. **4** shows available technologies for continuously sensing a heart rate or an activity level.

FIG. **5** shows a photosensor commonly used to measure heart rates integrated with a smartwatch.

FIG. **6** exemplifies a computer system that is programmed or otherwise configured to sense one or more physiologic parameters of an individual.

FIG. **7** shows a schematic of an algorithm for discordance monitoring.

DETAILED DESCRIPTION

Cardiac Monitoring

Described herein are systems, devices, and methods for use in cardiac monitoring. Cardiac monitoring typically comprises monitoring of the heart function of an individual for changes in, for example, heart rate or heart rhythm.

Heart rate may vary between, for example, bradycardia which typically is defined as a heart rate of less than 60 beats per minute, normal resting heart rate which typically is defined as a heart rate of between 60-100 beats per minute, and tachycardia which typically is defined as a heart rate of greater than 100 beats per minute. Variance of heart rate over a period of time may be referred to as Heart Rate Variability (HRV).

Heart function is also measured in terms of regularity of rhythm. A normal heart rhythm comprises of a systole (ejection phase) and diastole (filling phase). During the phases of systole and diastole, the ventricles of the heart act in concert in a regular manner that is repeated with every single heartbeat. When there is an abnormality of rhythm, the condition is typically referred to as an arrhythmia. Examples of arrhythmias include atrial fibrillation, WPW syndrome, prolonged QT syndrome, and premature ventricular contractions.

Many arrhythmias occur intermittently and relatively infrequently. Thus, in order to monitor and capture an intermittent arrhythmia, continuous monitoring is typically required. ECGs can be measured continuously in the ambulatory patient using holter monitoring, but this type of monitoring is cumbersome for the patient and is thus not widely used. A device or system configured to take an intermittent ECG is much more convenient for users. Such devices or systems comprise a mobile computing device that includes one or more electrodes that sense an ECG when contacted by a skin surface of the patient. Such devices are light and portable and don't necessarily require the user to be in continuous physical contact with one or more electrodes as they would with a holter type monitor. Intermittent arrhythmias can be recorded with these devices and systems when a user is given an indication that an intermittent arrhythmia is occurring. HRV sensing is used in combination with these devices or systems to indicate to a user when to contact one or more electrodes in order to sense an ECG.

FIG. **1** shows a heart rate tracing **100** with a corresponding electrocardiogram (ECG) tracing **104** both sensed from the same individual over the same period. As is shown in the ECG tracing **104**, the individual experienced a period of intermittent atrial fibrillation **106** during the time that the ECG was sensed. As is also shown in the heart rate tracing **100**, the heart rate of the individual rapidly increased **102** during the period of intermittent atrial fibrillation. As such, the HRV of the individual increased during the period of intermittent atrial fibrillation as the heart rate of the individual increased from a resting heart rate to an increased heart rate **102**. HRV changes are therefore associated with atrial fibrillation, wherein increased HRV is found during periods of intermittent atrial fibrillation.

FIG. **2** shows a graphic showing both heart rate **202** and rhythm analysis **200** over a period of time in an individual who experienced different arrhythmias. As shown, the measured heart rate **202** tended to increase above 100 beats per minute during the periods of sensed atrial fibrillation **200**. Thus, elevated heart rate above resting heart rate occurred in this individual during the period of arrhythmia.

FIG. **3** shows a close up of a heart rate tracing sensed over a period of paroxysmal atrial fibrillation. As shown, there was a substantial step increase from a normal heart of between 60-100 beats per minute to above 100 beats per minute **302** during the period of atrial fibrillation.

FIG. **4** shows available technologies **400** for continuously sensing a heart rate or an activity level. Shown are smartwatches made available by manufactures such as, for example, Apple. A wearer of one of the shown smartwatch technologies **400** may conveniently and continuously wear one or more sensors that are either coupled to or integrated with the watch throughout the day, thus, effectively continuously monitoring one or more parameter values via the one or more sensors that are either coupled to or integrated with

the smartwatch. Thus, one of the smartwatch technologies **400** are an example of a type of device in the form of a wearable that conveniently provides continuous monitoring of one or more parameters of a user. Non-limiting examples of wearable devices that may have one or more sensors either coupled to them or integrated with them include watches (e.g. smartwatches), eyeglasses, wristbands, necklaces, and clothing. The one or more continuously sensed parameters of the user of such a technology as, for example, shown in FIG. **4**, are then used to indicate to the user to use a device or system to sense an ECG. For example, a user wearing a smartwatch having a heart rate sensor is alerted by the smartwatch to record an ECG when the HRV of the user increases.

FIG. **5** shows a photosensor **500** commonly used to measure heart rates integrated with a smartwatch **502**.

Activity level is correlated with arrhythmia in many individuals who have a predisposition to develop arrhythmia wherein increased activity level is associated with onset of arrhythmia. In other individuals an increased activity level that is detected by one or more activity sensors in the presence of increased HRV is likely normal and is not associated with arrhythmia. Thus, as described herein, the addition of continuous heart rate monitoring along with continuous activity level monitoring may achieve the same results, in terms of arrhythmia monitoring, as continuous electrocardiogram monitoring. Using one or more sensors associated with the devices or systems described herein two parameter values of heart rate and activity level may be conveniently and accurately continuously and simultaneously sensed.

Devices and Systems

FIG. **6** exemplifies a computer system **601** that is programmed or otherwise configured to sense one or more physiologic parameters of an individual. Non-limiting examples of physiologic parameters include heart rate, blood pressure, temperature, oxygen saturation, ECG, HRV, and activity level. The computer system **601** comprises an electronic device of a user **635**, or comprises a computer system that is remotely located with respect to the electronic device **635**. Electronic devices suitable for use with the system **601** include mobile electronic devices such as smartphones, smartwatches, tablets, and laptops. The electronic device **601** comprises one or more sensors configured to sense a physiologic parameter. Numerous sensors are known for measuring heart rate. Non-limiting examples of suitable sensors include light based sensors such as, for example, infrared sensor/emitter, ultrasound sensors, and tactile sensors. Sensors for measuring rhythm include electrodes for measuring electrocardiograms (ECG) and light based sensors for measuring photoplethysmograms.

The computer system **601** includes a central processing unit (CPU, also "processor" and "computer processor" herein) **605**, which can be a single core or multi core processor, or a plurality of processors for parallel processing. The computer system **601** also includes memory or memory location **610** (e.g., random-access memory, read-only memory, flash memory), electronic storage unit **615** (e.g., hard disk), communication interface **602** (e.g., network adapter) for communicating with one or more other systems, and peripheral devices **625**, such as cache, other memory, data storage and/or electronic display adapters. The memory **610**, storage unit **615**, interface **602** and peripheral devices **625** are in communication with the CPU **605** through a communication bus (solid lines), such as a motherboard. The storage unit **615** can be a data storage unit (or data repository) for storing data. The computer system **601** can be operatively coupled to a computer network ("network") **603** with the aid of the communication interface **602**. The network **603** can be the Internet, an internet and/or extranet, or an intranet and/or extranet that is in communication with the Internet. The network **603** in some cases is a telecommunication and/or data network. The network **603** can include one or more computer servers, which can enable distributed computing, such as cloud computing. The network **603**, in some cases with the aid of the computer system **601**, can implement a peer-to-peer network, which may enable devices coupled to the computer system **601** to behave as a client or a server.

The CPU **605** can execute a sequence of machine-readable instructions, which can be embodied in a program or software. The instructions may be stored in a memory location, such as the memory **610**. The instructions can be directed to the CPU **605**, which can subsequently program or otherwise configure the CPU **605** to implement methods of the present disclosure. Examples of operations performed by the CPU **605** can include fetch, decode, execute, and writeback.

The CPU **605** can be part of a circuit, such as an integrated circuit. One or more other components of the system **601** can be included in the circuit. In some cases, the circuit is an application specific integrated circuit (ASIC).

The storage unit **615** can store files, such as drivers, libraries and saved programs. The storage unit **615** can store user data, e.g., user preferences and user programs. The computer system **601** in some cases can include one or more additional data storage units that are external to the computer system **601**, such as located on a remote server that is in communication with the computer system **601** through an intranet or the Internet.

The computer system **601** can communicate with one or more remote computer systems through the network **603**. For instance, the computer system **601** can communicate with a remote computer system of a user (e.g., mobile device, server, etc.). Examples of remote computer systems include personal computers (e.g., portable PC), slate or tablet PC's (e.g., Apple® iPad, Samsung® Galaxy Tab), telephones, Smart phones (e.g., Apple® iPhone, Android-enabled device, Blackberry®), or personal digital assistants. The user can access the computer system **601** via the network **603**.

Methods as described herein can be implemented by way of machine (e.g., computer processor) executable code stored on an electronic storage location of the computer system **601**, such as, for example, on the memory **610** or electronic storage unit **615**. The machine executable or machine readable code can be provided in the form of software. During use, the code can be executed by the processor **605**. In some cases, the code can be retrieved from the storage unit **615** and stored on the memory **610** for ready access by the processor **605**. In some situations, the electronic storage unit **615** can be precluded, and machine-executable instructions are stored on memory **610**.

The code can be pre-compiled and configured for use with a machine have a processor adapted to execute the code, or can be compiled during runtime. The code can be supplied in a programming language that can be selected to enable the code to execute in a pre-compiled or as-compiled fashion.

Aspects of the systems and methods provided herein, such as the computer system **601**, can be embodied in programming. Various aspects of the technology may be thought of as "products" or "articles of manufacture" typically in the form of machine (or processor) executable code and/or associated data that is carried on or embodied in a type of

machine readable medium. Machine-executable code can be stored on an electronic storage unit, such memory (e.g., read-only memory, random-access memory, flash memory) or a hard disk. "Storage" type media can include any or all of the tangible memory of the computers, processors or the like, or associated modules thereof, such as various semiconductor memories, tape drives, disk drives and the like, which may provide non-transitory storage at any time for the software programming. All or portions of the software may at times be communicated through the Internet or various other telecommunication networks. Such communications, for example, may enable loading of the software from one computer or processor into another, for example, from a management server or host computer into the computer platform of an application server. Thus, another type of media that may bear the software elements includes optical, electrical and electromagnetic waves, such as used across physical interfaces between local devices, through wired and optical landline networks and over various air-links. The physical elements that carry such waves, such as wired or wireless links, optical links or the like, also may be considered as media bearing the software. As used herein, unless restricted to non-transitory, tangible "storage" media, terms such as computer or machine "readable medium" refer to any medium that participates in providing instructions to a processor for execution.

Hence, a machine readable medium, such as computer-executable code, may take many forms, including but not limited to, a tangible storage medium, a carrier wave medium or physical transmission medium. Non-volatile storage media include, for example, optical or magnetic disks, such as any of the storage devices in any computer(s) or the like, such as may be used to implement the databases, etc. shown in the drawings. Volatile storage media include dynamic memory, such as main memory of such a computer platform. Tangible transmission media include coaxial cables; copper wire and fiber optics, including the wires that comprise a bus within a computer system. Carrier-wave transmission media may take the form of electric or electromagnetic signals, or acoustic or light waves such as those generated during radio frequency (RF) and infrared (IR) data communications. Common forms of computer-readable media therefore include for example: a floppy disk, a flexible disk, hard disk, magnetic tape, any other magnetic medium, a CD-ROM, DVD or DVD-ROM, any other optical medium, punch cards paper tape, any other physical storage medium with patterns of holes, a RAM, a ROM, a PROM and EPROM, a FLASH-EPROM, any other memory chip or cartridge, a carrier wave transporting data or instructions, cables or links transporting such a carrier wave, or any other medium from which a computer may read programming code and/or data. Many of these forms of computer readable media may be involved in carrying one or more sequences of one or more instructions to a processor for execution

The computer system **601** can include or be in communication with an electronic display **535** that comprises a user interface (UI) **640** for providing, for example, distributions of magnetic fields, distributions of electrical currents, distributions of local myocardial activities, etc. Examples of UI's include, without limitation, a graphical user interface (GUI) and web-based user interface.

Methods and systems of the present disclosure can be implemented by way of one or more algorithms. An algorithm can be implemented by way of software upon execution by the central processing unit **605**. The algorithm, for example, is used to analyze a sensed physiologic parameter.

A device as described herein is in some embodiments configured to sense two or more physiologic parameters. For example, a device configured to measure the heart rate of an individual as described herein is also in some embodiments configured to sense the electrocardiogram of said individual. In these embodiments, a device as described herein includes one or more electrodes configured to sense an electrocardiogram of an individual. In some embodiments, a device as described herein comprises two electrodes. In some embodiments, a device as described herein comprises three electrodes. In some embodiments, a device as described herein comprises four electrodes. In some embodiments, a device as described herein comprises five electrodes. In some embodiments, a device as described herein comprises six electrodes. In some embodiments, a device as described herein comprises seven electrodes. In some embodiments, a device as described herein comprises eight electrodes. In some embodiments, a device as described herein comprises nine electrodes. In some embodiments, a device as described herein comprises ten electrodes. Electrodes of the device described herein are configured to sense an electrocardiogram of an individual and transmit the sensed electrocardiogram data to a processor integrated with the device or part of the system described herein. In some embodiments, the processor is configured to display the electrocardiogram on a display of the device described herein. In some embodiments, the device is configured to sense and/or display a single lead electrocardiogram. In some embodiments, the single lead comprises any of Lead I, Lead II, Lead aVR, Lead aVL, Lead aVF, Lead V1, Lead V2, Lead V3, Lead V4, Lead V5, and Lead V6. In some embodiments, the device is configured to sense and/or display two leads comprising any two of Lead I, Lead II, Lead aVR, Lead aVL, Lead aVF, Lead V1, Lead V2, Lead V3, Lead V4, Lead V5, and Lead V6. In some embodiments, the device is configured to sense and/or display two leads comprising any three of Lead I, Lead II, Lead aVR, Lead aVL, Lead aVF, Lead V1, Lead V2, Lead V3, Lead V4, Lead V5, and Lead V6. In some embodiments, the device is configured to sense and/or display three leads comprising any three of Lead I, Lead II, Lead aVR, Lead aVL, Lead aVF, Lead V1, Lead V2, Lead V3, Lead V4, Lead V5, and Lead V6. In some embodiments, the device is configured to sense and/or display four leads comprising any four of Lead I, Lead II, Lead aVR, Lead aVL, Lead aVF, Lead V1, Lead V2, Lead V3, Lead V4, Lead V5, and Lead V6. In some embodiments, the device is configured to sense and/or display five leads comprising any five of Lead I, Lead II, Lead aVR, Lead aVL, Lead aVF, Lead V1, Lead V2, Lead V3, Lead V4, Lead V5, and Lead V6. In some embodiments, the device or system is configured to sense and/or display six leads comprising any six of Lead I, Lead II, Lead aVR, Lead aVL, Lead aVF, Lead V1, Lead V2, Lead V3, Lead V4, Lead V5, and Lead V6. In some embodiments, the device is configured to sense and/or display seven leads comprising any seven of Lead I, Lead II, Lead aVR, Lead aVL, Lead aVF, Lead V1, Lead V2, Lead V3, Lead V4, Lead V5, and Lead V6. In some embodiments, the device is configured to sense and/or display eight leads comprising any eight of Lead I, Lead II, Lead aVR, Lead aVL, Lead aVF, Lead V1, Lead V2, Lead V3, Lead V4, Lead V5, and Lead V6. In some embodiments, the device is configured to sense and/or display nine leads comprising any nine of Lead I, Lead II, Lead aVR, Lead aVL, Lead aVF, Lead V1, Lead V2, Lead V3, Lead V4, Lead V5, and Lead V6. In some embodiments, the device is configured to sense and/or display ten leads comprising any ten of Lead I, Lead II, Lead aVR, Lead aVL, Lead aVF, Lead V1, Lead V2,

Lead V3, Lead V4, Lead V5, and Lead V6. In some embodiments, the device is configured to sense and/or display eleven leads comprising any eleven of Lead I, Lead II, Lead aVR, Lead aVL, Lead aVF, Lead V1, Lead V2, Lead V3, Lead V4, Lead V5, and Lead V6. In some embodiments, the device is configured to sense and/or display twelve leads comprising any twelve of Lead I, Lead II, Lead aVR, Lead aVL, Lead aVF, Lead V1, Lead V2, Lead V3, Lead V4, Lead V5, and Lead V6. In some embodiments, the device includes software configured to cause a processor of said device to analyze the sensed electrocardiogram. An analysis of a sensed electrocardiogram performed by the processor of the device identifies the presence of an abnormal heart condition. For example, an analysis performed by a processor of a device, in some embodiments, identifies arrhythmias by, for example, analysis of the PQRST waveform and/or comparing multiple PQRST waveforms within an electrocardiogram. In some embodiments, the processor carries out an analysis of an electrocardiogram by comparing one or more PQRST waveforms of an individual against a one or more PQRST waveforms of other individuals from a database containing electrocardiograms of other individuals. In some embodiments of the devices described herein, an individual is alerted to sense an electrocardiogram by, for example, engaging one or more electrodes when the device senses one or more physiologic parameters. For example, in some embodiments, a device as described herein is configured to sense a blood pressure of an individual, and in some of these embodiments, the device is configured to sense a second physiologic parameter of the individual such as for example a heart rate. An accelerated heart rate of an individual sensed by the device in addition to, for example, a low blood pressure of the individual concurrently sensed by the device, triggers the processor of the device to indicate to the individual to engage with the electrodes of the device in order to sense an electrocardiogram.

The combination of a sensed accelerated heart rate and low blood pressure typically indicate an abnormality, however, other physiologic conditions may also produce an elevated heart rate accompanied by low blood pressure including, for example, dehydration. Thus, in some embodiments, accuracy is enhanced when physiologic parameters such as, for example, heart rate, blood pressure, oxygen saturation, and temperature are compared to baseline values of the individual or to a data from a database containing the physiological parameters of other individuals. Some elite athletes, for example, have physiologic parameter values that would be abnormal in another individual such as, for example, very low heart rates or increased heart rate variability (e.g. during a period of exercise).

A device as described herein is in some embodiments configured to sense a photophletysmogram of an individual. A photopletysmogram, for example, provides cardiac cycle information and may, for example, be analyzed by a processor of a device described herein to determine a presence of a premature ventricular contraction.

In some embodiments, a device as described herein is configured to sense a pulse oxygenation of an individual. A device as described herein is configured to sense a pulse oxygenation of an individual in some embodiments.

Analysis

In some embodiments, a device as described herein is configured to sense and/or analyze a number of additional physiologic parameters. Non-limiting examples of parameter values sensed and/or analyzed by the devices and systems described herein include heart rate, activity level, blood pressure, temperature, pulse oxygen, and heart rate variability. Analysis includes in some embodiments the comparison of a first sensed physiologic parameter to a second sensed physiologic and determining if a discordance exists between the first and second sensed parameter values.

In some embodiments, a device as described herein is configured to monitor for arrhythmia in an individual, wherein monitoring may comprise the identification of onset of an arrhythmia. In some embodiments, cardiac monitoring carried out by the devices described herein comprises, for example, monitoring for the presence or onset of arrhythmia in an individual who has not previously been identified to have an arrhythmia. In some embodiments, cardiac monitoring carried out by the devices described herein comprises the identification of onset of a known or suspected intermittent arrhythmia. In some embodiments, the devices described herein are configured to predict an onset of an arrhythmia in an individual. The onset of an arrhythmia is, for example, predicted due to a sudden and significant shift in the value of a sensed physiologic parameter such as heart rate. A prediction of arrhythmia is more accurate when two or more physiologic parameters are concurrently sensed and analyzed with respect to one another. For example, sensing of heart rate changes with respect to a sensed activity level provides contextual information for the sensed heart rate.

A subset of arrhythmias are sometimes termed tachyarrhythmias. Tachyarrhythmias typically comprise a tachycardic heart rate which may comprise a heart rate above 100 beats per minute. Tachyarrhythmias may comprise, for example, certain types of atrial fibrillation and supraventricular tachycardia. In some embodiments, the devices as described herein are configured to identify the presence or onset of a tachyarrhythmia, such as, for example, atrial fibrillation or supraventricular tachycardia. In some embodiments, the devices as described herein are configured to identify the presence or onset of a tachyarrhythmia. In some embodiments, the devices as described herein are configured to predict the onset of a tachyarrhythmia.

In some embodiments, the devices as described herein are configured to provide continuous cardiac monitoring. In some embodiments, the devices as described herein are configured to provide continuous cardiac monitoring for a period of up to one year. In some embodiments, the devices as described herein are configured to provide continuous cardiac monitoring for a period of up to 12 months. In some embodiments, the devices described herein are configured to provide continuous cardiac monitoring for a period of up to 6 months. In some embodiments, the devices described herein are configured to provide continuous cardiac monitoring for a period of up to 3 months. In some embodiments, the devices described herein are configured to provide continuous cardiac monitoring for a period of up to 1 month. In some embodiments, the devices described herein are configured to provide continuous cardiac monitoring for a period of up to 2 weeks. In some embodiments, the devices described herein are configured to provide continuous cardiac monitoring for a period of up to 1 weak. In some embodiments, the devices described herein are configured to provide continuous cardiac monitoring for a period of up to 72 hours. In some embodiments, the devices described herein are configured to provide continuous cardiac monitoring for a period of up to 48 hours. In some embodiments, the devices described herein are configured to provide continuous cardiac monitoring for a period of up to 24 hours. In some embodiments, the devices described herein are configured to provide continuous cardiac monitoring for a period of up to 12 hours. In some embodiments, the devices

described herein are configured to provide continuous cardiac monitoring for a period of up to 8 hours. In some embodiments, the devices described herein are configured to provide continuous cardiac monitoring for a period of up to 4 hours. In some embodiments, the devices described herein are configured to provide continuous cardiac monitoring for a period of up to 2 months.

In some embodiments, the devices described herein are configured to provide intermittent cardiac monitoring. In some embodiments, intermittent cardiac monitoring is initiated in response to one or more sensed parameter values. Non-limiting examples of the one or more sensed parameter value that may cause initiation of intermittent cardiac monitoring may comprise, for example, a heart rate of an individual, a blood pressure of an individual, an activity level an individual, a temperature of an individual, a pulse oximetry of an individual, or any other sensed biometric parameter of an individual. In some embodiments, an electrocardiogram of an individual may be sensed in response to one or more sensed parameters. For example, an electrocardiogram may be caused to be sensed in response to a heart rate value.

In some embodiments, one or more continuous sensors may sense one or more parameters that cause the initiation of intermittent cardiac monitoring by one or more sensors. In some embodiments, a heart rate of an individual is sensed continuously. In some embodiments, an activity level of an individual is sensed continuously. In some embodiments, a heart rate variability of an individual is sensed continuously. In some embodiments, an electrocardiogram of an individual is sensed intermittently. In some embodiments, an intermittently sensed electrocardiogram is caused to be sensed in response to a continuously measured heart rate of an individual. In some embodiments, an intermittently sensed electrocardiogram is caused to be sensed in response to an activity level of an individual. In some embodiments, an intermittently sensed electrocardiogram is caused to be sensed in response to both a continuously measured heart rate and a continuously measured activity level. In some embodiments, an intermittently sensed electrocardiogram is caused to be sensed in response to a continuously sensed heart rate, a continuously sensed activity level, and a continuously sensed heart rate variability.

In some embodiments, a device or system as described herein comprises one or more sensors configured for continuous cardiac monitoring. In some embodiments, a device or system as described herein comprises one or more sensors configured for intermittent cardiac monitoring. In some embodiments, a device or system as described herein comprises one or more heart rate sensors, which may, for example, comprise a photosensor. In some embodiments, a device or system as described herein comprises one or more activity level sensors, which may, for example, comprise an accelerometer or a gyroscope. In some embodiments, a device or system as described herein comprises one or more electrocardiogram sensors, which may, for example, comprise one or more electrodes. Non-limiting examples of other sensors suitable for use with the devices, systems, and methods described herein further comprise blood pressure sensors, temperature sensors, and pulse oximetry sensors.

In some embodiments, a device or system as described herein comprises a processor. In some embodiments, a process is coupled with one or more sensors that are configured to sense continuously and one or more sensors that are configured to sense intermittently. In some embodiments, a processor is configured to receive parameter values from one or more sensors. In some embodiments, a processor is configured to activate one or more sensors or to initiate the sensing of a parameter value. In some embodiments, a processor is configured to analyze a parameter value. In some embodiments, a processor is configured to compare a first parameter value with a second parameter value. In some embodiments, a first and a second parameter value to be compared are simultaneously or essentially simultaneously sensed.

In some embodiments, a device or system as described herein further comprises software in the form of a program or application. In some embodiments, the program or application may be configured to cause a processor to carry out one or more functions. In some embodiments, the program or application may be configured to cause a processor to receive parameter values from one or more sensors. In some embodiments, the program or application may be configured to cause a processor to activate one or more sensors or to initiate the sensing of a parameter value. In some embodiments, the program or application may be configured to cause a processor to analyze a parameter value. In some embodiments, the program or application may be configured to cause a processor to compare a first parameter value with a second parameter value. In some embodiments, a first and a second parameter value to be compared are simultaneously or essentially simultaneously sensed.

In some embodiments, the devices described herein are configured to carry out an analysis, wherein the analysis is performed by a processor. In some embodiments, an analysis of one or more parameter values carried out by the devices described herein comprises a comparison of a sensed parameter value to a threshold or range. For example, an analysis may comprise determining whether a sensed heart rate value falls within one or more ranges. For example, in some embodiments, a sensed heart rate may be determined to be within a heart rate range comprising a range between 60-100 beats per minute. For example, in some embodiments, a sensed heart rate may be determined to be in a heart rate range comprising a range of values less than 60 beats per minute. For example, in some embodiments, a sensed heart rate may be determined to be within a heart rate range comprising a range of values above 100 beats for minute.

In some embodiments, an analysis of one or more parameter values carried out by the devices described herein comprises a comparison of a first sensed parameter to a second sensed parameter. For example, in some embodiments, a heart rate value is compared to a sensed activity level of an individual.

In some embodiments, a first sensed value is compared to a second sensed value, and it is determine whether a discordance exists between the two values. For example, in some embodiments, an elevated heart rate value would be expected to be present during a period of elevated activity, thus an elevated heart rate and an elevated activity level that are simultaneously sensed would not be found to be in discordance with one another.

A discordance may be identified when a first sensed parameter value would not be expected to coincide with a second sensed parameter value. For example, an elevated heart rate value would not be expected to be present with a normal or resting activity level and thus the two values are in discordance with one another. For example, in some embodiments, when a heart rate sensor senses a heart rate above 100 beats per minute and a simultaneously sensed activity level is determined to be a resting activity level, an analysis of the two sensed values determines that they are in discordance with one another.

In some embodiments, an analysis carried out by the devices and systems described herein comprises the deter-

mination of an increase in a heart rate variability. In some embodiments, an analysis carried out by the devices and systems described herein comprises comparing a heart rate variability with one or more sensed parameter values. For example, in some embodiments, a heart rate variability is compared to concurrently or essentially concurrently sensed heart rate and activity level values.

In some embodiments, an analysis carried out by the devices and systems described herein comprises the prediction of or the identification of the initiation of an arrhythmia using an identified discordance as described herein. In some embodiments, a discordance comprising a simultaneously or essentially simultaneously sensed elevated heart rate and resting or normal activity level is determined to indicate the imminent initiation of an arrhythmia or the presence of an arrhythmia. In particular, because the heart rate is elevated, the arrhythmia with this type of discordance typically comprises a tachyarrhythmia.

In some embodiments, a simultaneously sensed increase in heart rate variability, an elevated heart rate, and a resting or normal activity rate is determined to indicate the future onset or presence of atrial fibrillation. In some embodiments, a sensed increased heart rate variability, normal resting heart rate, and resting or normal activity rate may also be determined to indicate the future onset of or the presence of atrial fibrillation. In some embodiments, a simultaneously sensed decrease in heart rate variability, an elevated heart rate, and a resting or normal activity rate is determined to indicate the future onset or presence of supraventricular tachycardia. In some embodiments, when an arrhythmia is determined to be imminent or present, an electrocardiogram is recorded. In some embodiments, an individual is instructed or signaled by a cardiac monitoring device or system described herein to engage one or more electrodes in order to sense in electrocardiogram. In some embodiments, one or more electrodes may be positioned on a surface of a cardiac monitoring device so that the individual may, for example, comfortably engage a first electrode with a skin surface of a first extremity while simultaneously engaging a second electrode with a skin surface of a second extremity. In some embodiments, one or more electrodes may be affixed to an individual's body and are automatically engaged to sense an electrocardiogram by a cardiac monitoring device or system when an arrhythmia is determined to be imminent or present in the individual. For example, a first electrode may be positioned on smartwatch worn by the individual on a first extremity and a second electrode may be positioned on a wristlet worn by the individual on a second extremity. In this example, the first electrode on the smartwatch and the second electrode on the wristlet are both in communication with and controlled by the cardiac monitoring device.

In some embodiments, the devices described herein are configured to carry out machine learning. In some embodiments, the devices, systems, and methods described herein comprise machine learning algorithms which analyze parameter values sensed from an individual over period of time. In some embodiments, the devices, systems, and methods described herein comprise machine learning algorithms which analyze parameter values sensed from a plurality of individuals. In some embodiments, a machine learning algorithm causes the devices, systems, and methods described herein to more accurately identify or predict the presence of an arrhythmia in a given individual. For example, in some embodiments, sensed electrocardiogram data may be compared back to parameter values such as, for example, sensed heart rates and activity levels that triggered the sensing of said electrocardiograms. When, for example, sensed electrocardiograms confirm the presence of an arrhythmia, the presence of which was indicated by, for example, a discordance between other parameter values, the machine algorithm causes the device or system described herein to learn from that data. Similarly, when, for example, sensed electrocardiograms do not confirm the presence of an arrhythmia, the presence of which was indicated by, for example, a discordance between other parameter values, the machine algorithm causes the device or system described herein to learn from that data as well. That is, in some embodiments, the machine learning algorithm correlates the sensed electrocardiogram with the discordance between parameter values that caused it (i.e. the electrocardiogram) to be sensed. The presence or absence of an arrhythmia on the electrocardiogram either respectively reinforces the correlation of an arrhythmia with the discordance that caused the electrocardiogram to be sensed or contradicts the presence of a correlation of an arrhythmia with the discordance. For example, when a heart rate of 110 is sensed and simultaneously a resting activity is sensed, an electrocardiogram is caused to be sensed, and when the sensed electrocardiogram does not indicate a presence of an arrhythmia the machine learning algorithm causes the device or system as described herein to learn that for that individual a heart rate of 110 at rest does not necessarily indicate a presence of an arrhythmia. In some embodiments, the machine learning algorithm continues to cause the storing of parameter value data, such as, for example, heart rate, activity level, and heart rate variability, and compare the parameter values to the associated electrocardiogram data over time. Thus, in some embodiments, with multiple parameter values sensed over time and compared to associated electrocardiogram data, a cardiac monitoring device or system improves its ability to predict or identify the onset of arrhythmia based on a discordance between parameter values for a specific individual. In some embodiments, a machine learning algorithm may obviate the need to sense an electrocardiogram when a particular discordance is present between parameter values of a specific individual, because of an extremely high likelihood of a presence or absence of an arrhythmia based on the parameter values as determined by the machine learning algorithm.

Any of the devices, systems, and methods for cardiac monitoring described herein may comprise one or more of a smartphone, a laptop or desktop computer, a smartwatch, or a tablet computer.

Discordance Monitoring

FIG. **7** shows a schematic of an algorithm for discordance monitoring. In a step **700**, a heart rate and an activity level are sensed by, for example, a device or system as described herein. In some embodiments, an activity level is sensed with a gyroscope or an accelerometer that is. Heart rate is sensed with a light based or other commonly used heart rate sensors. The device that measures the heart rate and the activity level may be the same device or more than one device. For example, a smartwatch or other wearable device may be configured to include a heart rate sensor as well as an activity level sensor.

If, as shown in a step **702**, an increased heart rate is sensed together with a normal or resting activity level, the two values are determined to be in discordance by the device or system processor. That is, the elevated heart rate does no match the sensed stable activity level. Determination of the presence of the discordance is done by a processor of either the device or system as described herein. The identified discordance may indicate the presence of an arrhythmia. As such, an ECG is caused to be sensed in a step **712**A. The step

712A, may, for example, comprise indicating to the user through the device or system that sensed the heart rate and activity level to contact one or more electrodes of an ECG sensing device and thus sense the ECG. The ECG sensing device may be the device or part of the system used to sense the heart rate and activity level or may be a separate device. For example, a user wearing a smartwatch with heart rate and activity level monitoring receives an audible and/or visual indication from the smartwatch to sense an ECG when a discordance is present between a sensed heart rate value and a sensed activity level value. In some embodiments, the smartwatch comprises one or more electrodes and a user contacts one electrode with the left side of their body and one electrode with the right side of their body when an indication is received to do so from the smartwatch because a discordance is present thus sensing an ECG. In some embodiments, a smartphone comprises one or more electrodes and a user contacts one electrode with the left side of their body and one electrode with the right side of their body when an indication is received to do so from the smartwatch because a discordance is present thus sensing an ECG.

If, as shown in step **704**, an increased heart rate is sensed together with an increased heart rate variability, and a normal or resting activity level is sensed. The increased heart rate and HRV are in discordance with the normal or resting activity level, and a presence of a discordance is determined by the device or system processor. Once the discordance is determined, an ECG is caused to be sensed in a step **712**B as, for example, described herein with respect to step **712**A. As shown, in step **716**, this particular discordance may be indicative of the presence of atrial fibrillation and it should be confirmed with the ECG **712**B.

If, as shown in step **706**, an increased heart rate is sensed together with a decreased heart rate variability and a normal or resting activity level is sensed. The increased heart rate, decreased heart rate variability, and normal or resting activity level are in discordance with each other, and a presence of a discordance is determined by the device or system processor. Once the discordance is determined, an ECG is caused to be sensed in a step **712**C as, for example, described herein with respected to step **712**A. As shown, in a step **718**, supraventricular tachycardia may be present and it should be confirmed with the ECG of **712**C.

If, as shown in a step **708**, an increased heart rate is sensed together with an increased activity level, the device or system processor determines that no discordance is present, and an ECG is not recorded as the individual is probably exercising **714**.

If, as shown in a step **710**, a regular heart rate is sensed (e.g. 60-100 beats per minute) and an increased heart rate variability is sensed together with a normal or resting activity level. The normal heart rate, increased heart rate variability, and normal or resting activity level are in discordance with each other, and a presence of a discordance is determined by the device or system processor. Once the discordance is determined, an ECG is caused to be sensed in a step **712**D as, for example, described herein with respect to step **712**A. As shown, in a step **720**, atrial fibrillation may be present and it should be confirmed with the ECG of **712**D.

In some embodiments, a determination of the presence of a discordance is based on a comparison of two or more sensed physiologic parameters with each other. That is, for example, an elevated heart rate of 110 is compared to a resting activity level as sensed by an accelerometer which measures that the individual is traveling at 0 miles/hr. The 110 heart rate is elevated whereas the activity level of 0 miles/hr is a resting level, which indicates a discordance between the sensed heart rate and activity level. In some embodiments, a processor determines that the value of a sensed physiologic parameter is either above or below a threshold value or range of values. In some embodiments, the threshold value or range of values are deemed to be normal or resting values in the population. In some embodiments, the thresholds are specific to the biometric data of the user so that the user is, for example, age-matched or gender matched to the appropriate threshold from the general population. For example, an activity level is determined to be increased in a 70 year old user but would not be increased in a 7 year old user. Thus, a discordance is determined by qualifying if a sensed physiologic parameter is elevated, decreased, or normal (or resting) and then comparing that qualified value to a qualified value of another sensed physiologic parameter. That is, for example, a value that is qualified as either increased, decreased, or normal (or resting) is compared to a value that is also qualified as increased, decreased, or normal (or resting).

In some embodiments, there is the added step (not shown in FIG. **7**) of the devices and systems described herein running machine learning algorithms so that the threshold values and ranges used to determine whether a sensed physiologic parameter is increased, decreased, normal (or resting) are adjusted to more accurately fit the user. That is, for example, a user who was determined, through ECG, to have an arrhythmia at a heart rate of 80 will have their heart rate threshold lowered so that a heart of 85 (which is normal in some) would be determined to be an increased rate. The machine learning algorithm more accurately sets the thresholds over time so that discordances are more accurately determined resulting in more accurate (and efficient) recording of ECGs in response to the determination of the presence of the discordance.

Table 1 below presents some of the information found in FIG. **7** in table form.

TABLE 1

HR Data	Activity Level Data	HRV Data	Action
HR increases	Activity level stable		Take an ECG, possible arrhythmia
HR increases	Activity level stable	HRV increases	Take an ECG, possible atrial fibrillation
HR increases	Activity level stable	HRV decreases	Take an ECG, possible supraventricular tachycardia or ventricular tachycardia
HR increases	Activity level increases		Don't take an ECG, probable exercise
HR stable	Activity level stable	HRV increases	Take an ECG, possible atrial fibrillation

While preferred embodiments of the present individual matter described herein have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the individual matter described herein. It should be understood that various alternatives to the embodiments of the individual matter described herein described herein may be employed in practicing the individual matter described herein. It is intended that the following claims define the scope of the individual matter described herein and that methods and structures within the scope of these claims and their equivalents be covered thereby.

What is claimed is:

1. A method of cardiac monitoring, comprising:

sensing an activity level of a user with a first sensor on a smartwatch worn by the user;

when the activity level is resting, sensing a heart rate parameter of the user with a second sensor on the smartwatch;

determining, by a processing device, that a discordance is present between the activity level value and the heart rate parameter;

based on the presence of the discordance, indicating to the user, using the smartwatch, a possibility of an arrhythmia being present; and

receiving electric signals of the user from an electrocardiogram sensor ("ECG") on the smartwatch to confirm a presence of the arrhythmia, wherein the ECG sensor comprises a first electrode and a second electrode.

2. The method according to claim 1, wherein the heart rate parameter comprises an indication of a heart rate variability, and wherein the arrhythmia is atrial fibrillation.

3. The method according to claim 1, wherein the heart rate parameter comprises an indication of a heart rate variability and a heart rate value, and wherein the arrhythmia is atrial fibrillation.

4. The method according to claim 1, wherein the heart rate parameter comprises an indication a heart rate value, and wherein the arrhythmia is atrial fibrillation.

5. The method according to claim 1, wherein indicating to the user further comprises: instructing the user to record an ECG using the smartwatch.

6. The method according to claim 1, wherein the arrhythmia is selected from a group consisting of atrial fibrillation, supraventricular tachycardia, and ventricular tachycardia.

7. The method according to claim 1, wherein the heartrate parameter is a PPG signal.

8. The method according to claim 7, wherein the heart rate parameter is a heartrate variability ("HRV") value, wherein the HRV value is derived from the PPG signal.

9. The method according to claim 7, wherein the heart rate parameter is a heartrate, wherein the heartrate is derived from the PPG signal.

10. The method according to claim 1 further comprising:

displaying an ECG rhythm strip from the electric signals on the smartwatch.

11. The method according to claim 1, wherein the first electrode is located on the smartwatch in a location where the first electrode contacts a first side of the user's body while the user wears the smartwatch, and the second electrode is located on the smartwatch in a location where the user must actively contact the second electrode with a second side of the user's body opposite from the first side.

12. A smartwatch, comprising:

a processor;

a first sensor configured to sense an activity level value of a user, wherein the first sensor is coupled to the processor;

a photoplethysmogram ("PPG") sensor configured to sense a heart rate parameter of the user when the activity level value is resting, wherein the PPG sensor is coupled to the processor;

an electrocardiogram ("ECG") sensor configured to sense electrical signals of a heart, wherein the ECG sensor comprises a first electrode and a second electrode, and wherein the ECG sensor is coupled to the processor; and

a non-transitory computer readable storage medium encoded with a computer program including instructions executable by the processor to cause the processor to:

determine if a discordance is present between the activity level value of the user and the heart rate parameter of the user;

based on the presence of the discordance, indicate to the user a possibility of an arrhythmia being present; and

receive electric signals of the user from the ECG sensor to confirm the presence of the arrhythmia.

13. The smartwatch or wristlet according to claim 12, wherein the heart rate parameter comprises an indication of a heart rate variability, and wherein the arrhythmia is atrial fibrillation.

14. The smartwatch or wristlet according to claim 12, wherein the heart rate parameter comprises an indication of a heart rate variability and a heart rate value, and wherein the arrhythmia is atrial fibrillation.

15. The smartwatch or wristlet according to claim 12, wherein the heart rate parameter comprises an indication of a heart rate value, and wherein the arrhythmia is atrial fibrillation.

16. The smartwatch or wristlet according to claim 12, wherein indicating to the user further comprises: instructing the user to record an ECG using the ECG sensor.

17. The smartwatch or wristlet according to claim 12, wherein the arrhythmia is selected from a group consisting of atrial fibrillation, supraentricular tachycardia, and ventricular tachycardia.

18. The smartwatch according to claim 12, wherein the heart rate parameter is a PPG signal.

19. The smartwatch according to claim 18, wherein the heart rate parameter is a heartrate variability ("HRV") value, wherein the HRV value is derived from the PPG signal.

20. The smartwatch according to claim 18, wherein the heart rate parameter is a heartrate, wherein the heartrate is derived from the PPG signal.

21. The smartwatch according to claim 12, the processor further to: display an ECG rhythm strip from the electric signals.

22. The smartwatch according to claim 12, wherein the PPG sensor is located on a back of the smartwatch.

23. The smartwatch according to claim 12, wherein the first electrode is located on the smartwatch where the first electrode contacts a first side of the user's body while the user wears the smartwatch, and the second electrode is located on the smartwatch where the user must actively contact the second electrode with a second side of the user's body opposite from the first side.

* * * * *

CERTIFICATE OF COMPLIANCE

Counsel for Appellant AliveCor, Inc. certifies that the brief contained herein has a proportionally spaced 14-point typeface, and contains 13,745 words, based on the "Word Count" feature of Word for Microsoft 365 MSO, including footnotes and endnotes, excluding the parts of the brief exempted by Fed. R. App. 32(a)(7) and Fed. Cir. R. 32(b).

Dated: May 26, 2023

/s/ *Sean S. Pak*
Sean S. Pak