IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of:	Gopalakrishnan	
U.S. Patent No.:	9,572,499	Attorney Docket No.: 50095-0032IP1
Issue Date:	February 21, 2017	
Appl. Serial No.:	14/730,122	
Filing Date:	June 3, 2015	
Title:	METHODS AND SYSTEMS FOR ARRHYTHMIA TRACKING AND SCORING	

DECLARATION OF DR. BERNARD R. CHAITMAN

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I, Dr. Bernard R. Chaitman, of St. Louis, Missouri, declare that:

I. ASSIGNMENT

1. I have been retained on behalf of Apple Inc. ("Apple" or "Petitioner") to offer technical opinions related to U.S. Patent No. 9,572,499 ("The '499 patent") (APPLE-1001). I understand that Apple is requesting that the Patent Trial and Appeal Board ("PTAB" or "Board") to institute an *inter partes* review ("IPR") proceeding of the '499 patent.

2. I have been asked to provide my independent analysis of the '499 patent in light of the prior art publications cited in this declaration.

3. I am not and never have been, an employee of Apple. I received no compensation for this declaration beyond my normal hourly compensation based on my time actually spent analyzing the '499 patent, the prior art publications cited below, and issues related thereto, and I will not receive any added compensation based on the outcome of any IPR or other proceeding involving the '499 patent

II. QUALIFICATIONS

4. I am over the age of 18 and am competent to write this declaration. I have personal knowledge, or have developed knowledge of these technologies based upon education, training, or experience, of the matters set forth herein.

5. I am an Emeritus Professor of Medicine, and Director of Cardiovascular Research at St Louis University School of Medicine. I am also a

Board-Certified Cardiologist and have practiced Internal Medicine and Cardiovascular Disease for four decades. I am currently licensed in the State of Missouri and Florida. I also serve as the Chair for Clinical Event Committees and Data and Safety Monitoring Boards for numerous clinical trials sponsored by National Heart Lung and Blood Institute (NHLBI) and industry. I am currently a member of the Editorial Board of nine journals that include Circulation, Journal of the American College of Cardiology, and the European Heart Journal. I also founded and am the Medical Director of St Louis University Core ECG Laboratory that provides ECG analysis for numerous NHLBI and industry sponsored clinical trials that test various treatment strategies.

6. I received a Bachelor of Science degree in 1965 and a medical degree 1969, both from McGill University in Montreal, Canada. I completed my Internal Medicine training at McGill University and Royal Victoria Hospital in 1972. I then completed post-graduate training in Cardiovascular Diseases at the University of Oregon (from 1972-1974) and University of Montreal (from 1974-1975).

7. I have a long and distinguished career in academic medicine and have published more than 400 peer-reviewed papers and more than 600 abstracts, book chapters, and short communications. My areas of expertise in Cardiovascular Medicine include rest and exercise ECG analysis, diagnostic noninvasive testing, large scale multinational clinical trials testing different treatment strategies, and

drug development. I have received funding from the National Heart Lung and Blood Institute (NHLBI) for more than 3 decades and also funding by the Department of Defense. My experience is recognized internationally and I have lectured abroad and published frequently with cardiologists in Europe.

8. I have served as a consultant to the Food and Drug Administration on ECG related issues, and the use of the rest and exercise ECG as a diagnostic instrument. I also served as a committee member for the American Heart Association, American College of Cardiology, and the European Society of Cardiology in matters related to ECG analysis and the use of ECG analysis as a diagnostic and prognostic tool. I served on grant review committees for the NHLBI, the Veterans Administration Review Board, and the American Heart Association.

III. SUMMARY OF CONCLUSIONS FORMED

9. This Declaration explains the conclusions that I have formed based on my analysis. To summarize those conclusions:

- **Ground 1:** Based upon my knowledge and experience and my review of the prior art publications in this declaration, I believe that claims 1-6, 10-16 and 20 of the ’499 patent are rendered obvious by Shmueli in view of Osorio.
- **Ground 2**: Based upon my knowledge and experience and my review of the prior art publications in this declaration, I believe that claims 7-9 and 17-19

of the ’499 patent are rendered obvious by Shmueli in view of Osorio and Hu 1997.

IV. BACKGROUND KNOWLEDGE ONE OF SKILL IN THE ART WOULD HAVE HAD PRIOR TO THE PRIORITY DATE OF THE ’499 PATENT

10. I have been informed that a person of ordinary skill in the art is a hypothetical person who is presumed to have the skill and experience of an ordinary worker in the field at the time of the alleged invention. Based on my knowledge and experience in the field and my review of the ’499 patent and file history, I believe that a person of ordinary skill in the art in this matter would have had 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). Additional education or industry experience may compensate for a deficit in one of the other aspects of the requirements stated above.

11. My analysis and conclusions set forth in this declaration are based on the perspective of a person of ordinary skill in the art having this level of knowledge and skill as of the date of the alleged invention of the ’499 patent (“POSITA”). Based on instruction from Counsel, I have applied December 12, 2014 (“Critical Date”), as the date of the alleged invention of the ’499 patent.

However, my analysis of the prior art and the conclusions I have formed as set forth herein would also apply even if the date of the alleged invention as claimed was December 12, 2013 ("earliest possible effective filing date").

12. Based on my experiences, I have a good understanding of the capabilities of a POSITA. Indeed, I have taught, mentored, advised, and collaborated closely with many such individuals over the course of my career.

V. LEGAL PRINCIPLES

13. I am not a lawyer and I will not provide any legal opinions in this IPR. Although I am not a lawyer, I have been advised that certain legal standards are to be applied by technical experts in forming opinions regarding the meaning and validity of patent claims.

A. Claim construction

14. I understand that claim terms are generally given their plain and ordinary meaning in light of the patent's specification and file history as understood by a person of ordinary skill in the art at the time of the purported invention. In that regard, I understand that the best indicator of claim meaning is its usage in the context of the patent specification as understood by a POSITA. I further understand that the words of the claims should be given their plain meaning unless that meaning is inconsistent with the patent specification or the patent's history of examination before the Patent Office. I also understand that the words

of the claims should be interpreted as they would have been interpreted by a POSITA at the time of the invention was made (not today).

B. Priority

15. I understand that a continuation application is a later-filed application that has the same disclosure (specification and figures) as an earlier filed application to which the later-filed application claims priority. A continuation is generally entitled to the same priority date as the later-filed application to which it claims priority.

C. Anticipation

16. I understand that a patent claim is invalid as anticipated if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. I also understand that, to anticipate, the reference must teach all of the limitations arranged or combined in the same way as recited in the claim. I do not rely on anticipation in this declaration.

17. With respect to inherency, I understand that the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. Instead, the inherent characteristic must necessarily flow from the teaching of the prior art.

D. Obviousness

18. I understand that a patent claim is invalid if the claimed invention would have been obvious to a person of ordinary skill in the field at the time of the

purported invention, which is often considered the time the application was filed. Thus, even if all of the claim limitations are not found in a single prior art reference that anticipates the claim, the claim can still be invalid.

19. To obtain a patent, a claimed invention must have, as of the priority date, been nonobvious in view of the prior art in the field. I understand that an invention is obvious when 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.

20. I understand that, to prove that prior art or a combination of prior art renders a patent obvious it is necessary to: (1) identify the particular references that, singly or in combination, make the patent obvious; (2) specifically identify which elements of the patent claim appear in each of the asserted references; and (3) explain a motivation, teaching, need, market pressure or other legitimate reason that would have inspired a person of ordinary skill in the art to combine prior art references to solve a problem.

21. I also understand that certain objective indicia can be important evidence regarding whether a patent is obvious or nonobvious. Such indicia include:

- Commercial success of products covered by the patent claims;

- A long-felt need for the invention;
- Failed attempts by others to make the invention;
- Copying of the invention by others in the field;
- Unexpected results achieved by the invention as compared to the closest prior art;
- Praise of the invention by the infringer or others in the field;
- The taking of licenses under the patent by others;
- Expressions of surprise by experts and those skilled in the art at the making of the invention; and
- The patentee proceeded contrary to the accepted wisdom of the prior art.

22. To the extent these factors have been brought to my attention, if at all, I have taken them into consideration in rendering my opinions and conclusions.

VI. MATERIALS CONSIDERED

23. My analysis and conclusions set forth in this declaration are based on my educational background and experiences in the field (see Section IV). Based on my above-described experience, I believe that I am considered to be an expert in the field. Also, based on my experiences, I understand and know of the capabilities of persons of ordinary skill in the field during the early 1990s–2010s, and I taught, participated in organizations, and worked closely with many such persons in the field during that time frame.

24. As part of my independent analysis for this declaration, I have considered the following: the background knowledge/technologies that were commonly known to persons of ordinary skill in this art during the time before the earliest claimed priority date for the '499 patent; my own knowledge and experiences gained from my work experience in the field of the '499 patent and related disciplines; and my experience in working with others involved in this field and related disciplines.

25. In addition, I have analyzed the following publications and materials:

- U.S. Patent No. 9,572,499 to Gopalakrishnan ("the '499 patent") (APPLE-1001)
- the Prosecution History of the '499 patent ("the Prosecution History") (APPLE-1002)
- PCT Patent Publication WO2012/140559 ("Shmueli") (APPLE-1004)
- U.S. Patent Publication 2014/0275840 ("Osorio") (APPLE-1005)
- Li Q, Clifford GD, "Signal quality and data fusion for false alarm reduction in the intensive care unit," J Electrocardiol. 2012 Nov-Dec; 45(6):596-603 ("Li 2012") (APPLE-1006)
- U.S. Patent Publication 2008/0004904 ("Tran") (APPLE-1007)
- U.S. Patent Publication 2014/0107493 ("Yuen") (APPLE-1008)
- U.S. Patent Publication 2015/0119725 ("Martin") (APPLE-1009)

- U.S. Provisional Application No. 61/794,540 ("Osorio Provisional") (APPLE-1010)
- Lee J, Reyes BA, McManus DD, Mathias O, Chon KH. Atrial fibrillation detection using a smart phone. Annu Int Conf IEEE Eng Med Biol Soc. 2012; 2012:1177-800 ("Lee 2013") (APPLE-1011)
- Tsipouras MG, Fotiadis DI. Automatic arrhythmia detection based on time and time-frequency analysis of heart rate variability. Comput Methods Programs Biomed. 2004 May; 74(2):95-108 ("Tsipouras 2004") (APPLE-1012)
- Lu S, Zhao H, Ju K, Shin K, Lee M, Shelley K, Chon KH. Can photoplethysmography variability serve as an alternative approach to obtain heart rate variability information? J Clin Monit Comput. 2008 Feb; 22(1):23-9 ("Lu 2008") (APPLE-1013)
- Selvaraj N, Jaryal A, Santhosh J, Deepak KK, Anand S. Assessment of heart rate variability derived from finger-tip photoplethysmography as compared to electrocardiography. J Med Eng Technol. 2008 Nov-Dec; 32(6):479-84 ("Selvaraj 2008") (APPLE-1014)
- Lu G, Yang F, Taylor JA, Stein JF. A comparison of photoplethysmography and ECG recording to analyse heart rate variability in healthy subjects. J Med Eng Technol. 2009; 33(8):634-41 ("Lu 2009") (APPLE-1015)

- Suzuki T, Kameyama K, Tamura T. Development of the irregular pulse detection method in daily life using wearable photoplethysmographic sensor. Annu Int Conf IEEE Eng Med Biol Soc. 2009; 2009:6080-3 ("Suzuki 2009") (APPLE-1016)
- Reed MJ, Robertson CE, Addison PS. Heart rate variability measurements and the prediction of ventricular arrhythmias. QJM. 2005 Feb; 98(2):87-95 ("Reed 2005") (APPLE-1017)
- Schäfer A, Vagedes J. How accurate is pulse rate variability as an estimate of heart rate variability? A review on studies comparing photoplethysmographic technology with an electrocardiogram. Int J Cardiol. 2013 Jun 5; 166(1):15-29 ("Schafer 2013") (APPLE-1018)
- K. Douglas Wilkinson, "The Clinical Use of the Sphygmomanometer," The British Medical Journal, 1189-90 (Dec. 27, 1924) ("Wilkinson") (APPLE-1019)
- U.S. Pat. No. 6,095,984 ("Amano") (APPLE-1020)
- B.K. Bootsma et. al, "Analysis of R-R intervals with atrial fibrillation at rest and during exercise." Circulation 1970; 41:783-794 (APPLE-1021)
- Frits L. Meijler and Fred H. M. Wittkampf, "Role of the Atrioventricular Node in Atrial Fibrillation" Atrial Fibrillation: Mechanisms and Management, 2nd ed. 1997 ("Meijler") (APPLE-1022)

- Heart Diseases _ Definition of Heart Diseases by Merriam-Webster (APPLE-1023)
- Rajendra Acharya U, Paul Joseph K, Kannathal N, Lim CM, Suri JS. Heart rate variability: a review. Med Biol Eng Comput. 2006 Dec; 44(12):1031-51 ("Acharya 2006") (APPLE-1024)
- Saime Akdemir Akar, Sadık Kara, Fatma Latifoğlu, Vedat Bilgiç. Spectral analysis of photoplethysmographic signals: The importance of preprocessing. Biomedical Signal Processing and Control, 2013; 8(1):16-22 (Akar 2013) (APPLE-1025)
- U.S. Provisional Application No. 61/915,113 (APPLE-1026)
- U.S. Provisional Application No. 61/953,616 (APPLE-1027)
- U.S. Provisional Application No. 61/969,019 (APPLE-1028)
- U.S. Provisional Application No. 61/970,551 (APPLE-1029)
- U.S. Provisional Application No. 62/014516 (APPLE-1030)
- U.S. Patent Publication No. 2012/0203491 ("Sun") (APPLE-1031)
- U.S. Patent No. 9,808,206 ("Zhao") (APPLE-1032)
- Kleiger RE, Stein PK, Bigger JT Jr. Heart rate variability: measurement and clinical utility. Ann Noninvasive Electrocardiol. 2005 Jan; 10(1):88-101 ("Kleiger 2005") (APPLE-1033)
- Chen Z, Brown EN, Barbieri R. Characterizing nonlinear heartbeat

dynamics within a point process framework. IEEE Trans Biomed Eng. 2010 Jun; 57(6):1335-47 ("Chen 2010") (APPLE-1034)

- Karvonen, J., Vuorimaa, T. Heart Rate and Exercise Intensity During Sports Activities. Sports Medicine 5, 303–311 (1988) ("Karvonen 1988") (APPLE-1035)
- Yu C, Liu Z, McKenna T, Reisner AT, Reifman J. A method for automatic identification of reliable heart rates calculated from ECG and PPG waveforms. J Am Med Inform Assoc. 2006 May-Jun; 13(3):309-20 ("Yu 2006") (APPLE-1036)
- AliveCor v Apple ITC Complaint Exhibit 11 (499 Infringement Chart) (APPLE-1037)
- Tavassoli, & Ebadzadeh, Mohammad & Malek,. (2012). Classification of cardiac arrhythmia with respect to ECG and HRV signal by genetic programming. Canadian Journal on Artificial Intelligence, Machine Learning and Pattern Recognition. 3. 1-13 ("Tavassoli 2012") (APPLE-1038)
- Asl BM, Setarehdan SK, Mohebbi M. Support vector machine-based arrhythmia classification using reduced features of heart rate variability signal. Artif Intell Med. 2008 Sep;44(1):51-64 ("Asl 2008") (APPLE-1039)
- Yaghouby F., Ayatollahi A. (2009) An Arrhythmia Classification Method

Based on Selected Features of Heart Rate Variability Signal and Support Vector Machine-Based Classifier. In: Dössel O., Schlegel W.C. (eds) World Congress on Medical Physics and Biomedical Engineering, September 7 - 12, 2009, Munich, Germany. IFMBE Proceedings, vol 25/4. Springer, Berlin, Heidelberg ("Yaghouby 2009") (APPLE-1040)

- Dallali, Adel & Kachouri, Abdennaceur & Samet, Mounir. (2011). Integration of HRV, WT and neural networks for ECG arrhythmias classification. ARPN Journal of Engineering and Applied Sciences. VOL. 6. 74-82 ("Dallali 2011") (APPLE-1041)
- Sajda P. Machine learning for detection and diagnosis of disease. Annu Rev Biomed Eng. 2006;8:537-65 ("Sajda 2006") (APPLE-1042)
- Aarron Smith. Smartphone Ownership – 2013 Update. Pew Research Center. June 5, 2013 ("Smith 2013") (APPLE-1043)
- C. Narayanaswami and M. T. Raghunath, "Application design for a smart watch with a high resolution display," Digest of Papers. Fourth International Symposium on Wearable Computers, 2000, pp. 7-14 ("Narayanaswami 2000") (APPLE-1044)
- Thong, YK & Woolfson, M & Crowe, JA & Hayes-Gill, Barrie & Challis, Richard. (2002). Dependence of inertial measurements of distance on accelerometer noise," Meas. Measurement Science and Technology. 13.

1163 (“Thong 2002”) (APPLE-1045)

- AliveCor’s ITC Complaint filed on April 20, 2021 in “Certain Wearable Electronic Devices With ECG Capability and Components Thereof” ITC-337-3545-20210420 (“ITC Complaint”) (APPLE-1046)
- Marcovitch, Harvey. Black’s Medical Dictionary. London: A. & C. Black, 2005 (APPLE-1047)
- U.S. Pat. No. 7,894,888 (“Chan”) (APPLE-1048)
- Hu YH, Palreddy S, Tompkins WJ. A patient-adaptable ECG beat classifier using a mixture of experts approach. IEEE Transactions on Bio-medical Engineering. 1997 Sep;44(9):891-900 (“Hu 1997”) (APPLE-1049)
- Strath SJ, Swartz AM, Bassett DR Jr, et al. Evaluation of heart rate as a method for assessing moderate intensity physical activity. Medicine and Science in Sports and Exercise. 2000 Sep;32(9 Suppl):S465-70 (“Strath 2000”) (APPLE-1050)
- U.S. Provisional Application No. 61/895,995 (“Martin Provisional”) (APPLE-1054)
- AliveCor’s District Court Complaint filed on May 25, 2021 in *AliveCor, Inc. v. Apple Inc.*, 3:21-cv-03958 (N.D.Cal. May 25, 2021) (“Antitrust Complaint”) (APPLE-1055)

VII. TECHNOLOGY OVERVIEW

A. Arrhythmia

26. Cardiac arrhythmias refer to a group of disorders of the heart rate or heart rhythm. Atrial fibrillation is "the most common cardiac arrhythmia." APPLE-1001, 1:35-36. Arrhythmic activity can include the heart beating too fast (tachycardia), too slow (bradycardia), or irregularly (variations in heart rate). *Id.* While tachycardia and bradycardia may be diagnosed based on heart rate, variations in heart rate (e.g., atrial fibrillation) are diagnosed based on heart rate variability ("HRV") analysis. As a hypothetical example, when a patient goes into atrial fibrillation, a common rhythm disturbance, an HRV analysis would detect the irregularity, even though heart rate of the patient may stay with the normal range of between 60-100 bpm. For example, Tsipouras 2004 discloses detecting arrhythmia by training a machine learning algorithm (e.g., neural networks) with HRV data. APPLE-1012, Abstract. Tsipouras 2004 states that "Our study is based on the analysis of the RR-interval duration so the proposed method is capable of detecting arrhythmia types that produce irregularities on the RR intervals, the HRV or the heart rhythm." APPLE-1012, p. 106. Compared to looking at the raw heart rate signal (e.g., ECG), HRV analysis is more robust because it involves extracting the RR intervals and is less affected by noise. APPLE-1039, p. 52.

27. Since 1903, different detection techniques have been employed to

detect irregular pulse rhythms or irregular heartbeats. *See, e.g.*, APPLE-1019 (describing use of a sphygmomanometer as early as 1924 to make "obvious the variation in the sound heard over the artery" to identify pulse irregularity); APPLE-1020, 9:12-28 (describing use of "plethysmogram" in 1997 to detect arrhythmia). By 1977, both detecting possible atrial fibrillation using irregular pulse rhythms or heartbeats and techniques to quantitatively characterize irregularities were well-known. By 2009, examples of known arrhythmia detection techniques included: neural networks, wavelet transforms, support vector machines, fuzzy logic and rule-based algorithms. APPLE-1040, p. 1928. A POSITA would have understood that many of these techniques (e.g., support vector machines, neural networks) are machine learning algorithms.

B. Electrocardiography (ECG)

28. Eletrocardiography (ECG) measures the electrical activity of the heart, which can be indicative of various heart diseases. APPLE -1004, 1:14-17. ECG recording uses Ag/AgCl electrodes attached to specific anatomical positions. APPLE-1015, p. 635. Clinical ECG recording commonly uses 12 leads for determination of the complex temporal dynamics of each cardiac cycle. *Id*.

29. An 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 the ECG readout—P-wave, Q-wave, R-wave, S-wave,

and T-wave. 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. An R-R interval represents a time elapsed between successive R-waves of a QRS complex of the ECG that occur between successive heart beats. If R-R interval durations over a time period are close to one another in value, then ventricular rhythm is understood to be "regular." APPLE-1022, 110-112. 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*.

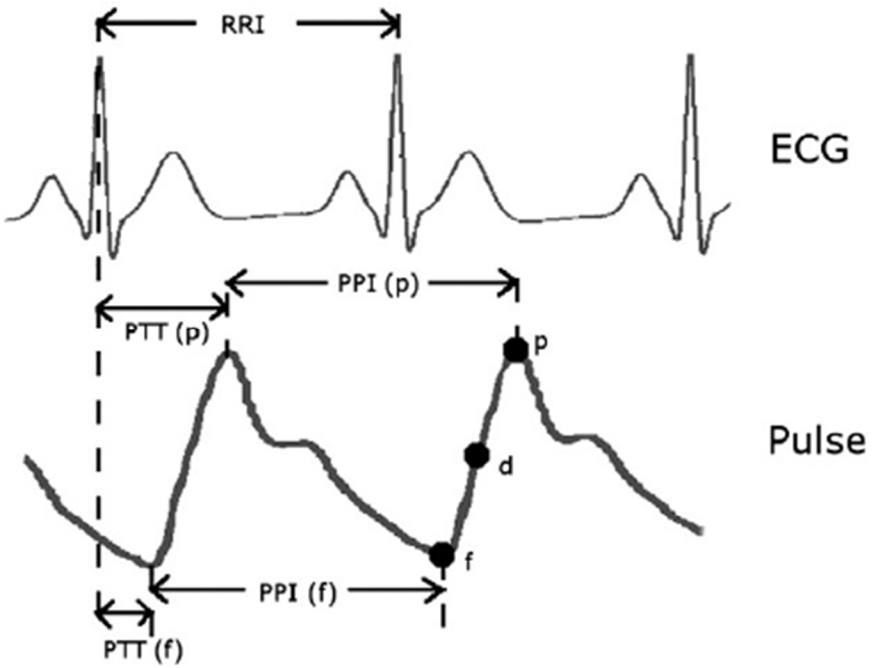
30. In conventional clinical practice, ECG and telemetry are used at a hospital to diagnose cardiac arrhythmias. APPLE-1016, p. 6080. As an irregular heartbeat caused by arrhythmia does not necessarily occur during examination at the hospital, a Holter ECG has been used for measuring one or more leads of an ECG in daily life. *Id*. A Holter ECG device is not ideal because it still requires attaching some electrodes to the patients' chest. *Id*. In addition, a Holter device typically only monitors the patient for a certain period (e.g., 24 hours, 48 hours or 72 hours) and thus it may not detect a cardiac arrhythmia if it does not occur during the monitoring period. APPLE-1004, 1:26-2:3.

C. Photoplethysmography (PPG)

31. Photoplethysmography (PPG) is a simple noninvasive optical

technique for monitoring beat-to-beat relative blood volume changes in the microvascular bed of peripheral tissues. APPLE-1014, p. 479. PPG is sometimes also referred to as blood oxygen saturation, pulse oximeter, oximetry, and SpO2. APPLE-1004, 7:25-27. Its basic principle requires a light source to illuminate subcutaneous tissue and a photo detector with spectral characteristics matching those of the light source. APPLE-2018, p. 16.

32. As the pulse period derived from PPG data is directly related to cardiac activity, the physiological information derived from RR intervals of ECG can also be derived from the pulse period of a PPG reading. APPLE-1014, p. 480. This is because under normal conditions, the electrical impulse of the heart (ECG) stimulates a cardiac contraction resulting in a spread of the pulsatile wave of blood to the periphery (PPG). APPLE-1014, p. 480. Thus, a PPG signal includes information about both heart rate and heart rate variability. APPLE-1025, p. 16. Many studies verify the high correlation between RR intervals (RRI) obtained from ECG and PP intervals (PPI) obtained from PPG. APPLE-1025, p. 16; APPLE-1018, Fig. 1.



APPLE-1018, Fig. 1.

33. Compared to ECG, PPG is attractive because it only requires attaching a single sensor to the hand of the user. APPLE-1018, p.16.

D. Heart Rate (HR)

34. Heart rate (HR) is the reciprocal of the RR interval and measures the number of heartbeats per unit of time. APPLE-1034, p. 5. It was long recognized that an individual's heart rate varies with his/her activity level (exercise intensity). APPLE-1035, p. 303. As discussed above, an individual's heart rate and the corresponding RR interval can be determined using either ECG or PPG data. APPLE-1036, Abstract and Fig. 1.

E. Heart Rate Variability (HRV)

35. 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. APPLE-1025, p. 16; APPLE-1012, p. 95. HRV analysis is an important tool in cardiology used to diagnose various types of arrhythmias. APPLE-1012, Abstract and pp. 95-96 ("Therefore, HRV analysis became a critical tool in cardiology for the diagnosis of heart diseases."). HRV analysis has become popular because heart rate (HR) is a nonstationary signal and its variation may contain indicators of heart diseases. APPLE-1024, Abstract.

36. By the Critical Date, it was known that HRV can be accurately determined based on either ECG data or PPG data. *See*, *e.g.*, APPLE-1013, Abstract ("Our results demonstrate that the parameters of PPGV are highly correlated with the parameters of HRV."); APPLE-1014, Abstract ("HRV can also be reliably estimated from the PPG based PP interval method."); APPLE-1015, Abstract ("Our results confirm that PPG provides accurate interpulse intervals from which HRV measures can be accurately derived in healthy subjects under ideal conditions, suggesting this technique may prove a practical alternative to ECG for HRV analysis."). As described in the '499 patent, R-R intervals may be extracted from the raw heart rate signals (from PPG or ECG) and the R-R intervals may be used to calculate heart rate variability (HRV) in various ways using time-domain methods, geometric methods, frequency-domain methods, non-linear methods, long term correlations, or the like, as known in the art. APPLE-1001,

8:54-59 and Fig. 3. Kleiger 2005 discloses that methods for quantifying HRV are categorized as: time domain, spectral or frequency domain, geometric, and nonlinear. APPLE-1033, p. 88. SDNN, the standard deviation of all normal RR intervals during a 24-hour period, is a commonly used time domain measure of HRV. *Id*.

37. If the RR intervals over a time period are close to each other in value, then ventricular rhythm is understood to be "regular." APPLE-1022, 110-112. 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*.

F. Machine Learning Algorithms

38. Machine learning, a subdiscipline in the field of artificial intelligence (AI), focuses on 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. APPLE-1042, p. 538. Machine learning and statistical pattern recognition have been the subject of tremendous interest in the biomedical community because they offer promise for improving the sensitivity and/or specificity of detection and diagnosis of disease, while at the same time increasing objectivity of the decision-making process. *Id*. Machine learning offers a principled approach for developing sophisticated, automatic, and objective algorithms for analysis of high-dimensional and multimodal biomedical

data. *Id*., Abstract.

VIII. OVERVIEW OF THE '499 PATENT

39. The '499 patent, titled "Methods and systems for arrhythmia tracking and scoring," claims a two-staged arrhythmia detection method where the first step uses a heart rate monitor and the second step uses an ECG monitor. APPLE-1001, claim 1. Specifically, the '499 patent claims a method that includes: (1) sensing a heart rate with a heart rate sensor; (2) determining a heart rate variability ("HRV") based on the heart rate; (3) sensing an activity level with a motion sensor; (4) comparing the HRV to the activity level; and (5) alerting the user to sense an electrocardiogram ("ECG") in response to an irregular HRV.[1] *Id.*, claim 1. The '499 patent explains that the heart rate can be detected by using photoplethysmography. APPLE-1001, 8:41-45. The '499 patent further explains that an advisory condition for recording an ECG may occur due to large continuing fluctuations in heart rate, or when a measured heart rate increases rapidly without a corresponding increase in activity level. APPLE-1001, 25:17-22.

40. As shown below, Figure 10 depicts an example where the heart rate is

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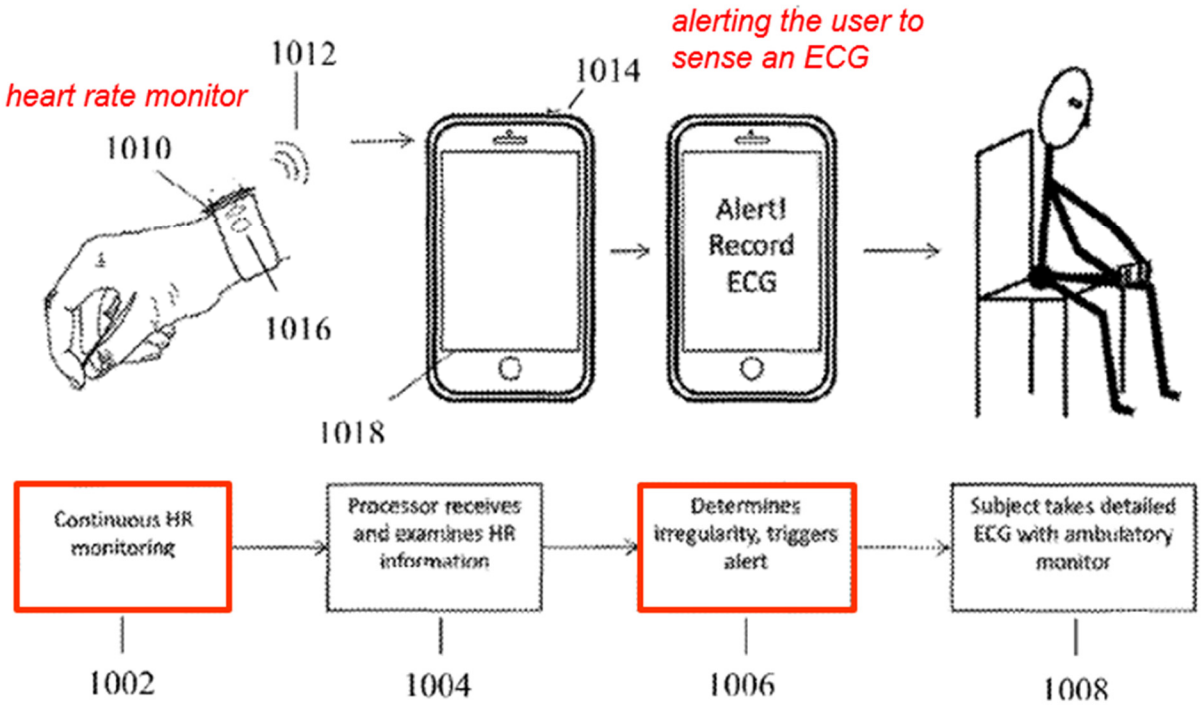
[1] As detailed below, the Applicant made clear during prosecution that the claimed "heart rate sensor" is not an ECG sensor that is used to "sense an electrocardiogram." APPLE-1002, 342-347.

detected using a heart rate monitor 1010, an irregularity is detected, and an alert is provided for the user to record an ECG. APPLE-1001, 23:14-26 ("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 to their body (e.g. chest, between arms, etc.) 1008 to record ECGs that can then be saved and/or transmitted for analysis.").



APPLE-1001, Figure 10 (annotated)

IX. OVERVIEW OF THE PROSECUTION HISTORY

41. Applicant filed U.S. Patent Application 14/730,122 ("the '122 application") on June 3, 2015. APPLE-1001, Cover. The '122 application is a continuation application of U.S. Patent Application No. 14/569,513, filed on December 12, 2014, which claims priority to provisional application No. 61/915,113, filed on December 12, 2013, provisional application No 61/953,616, filed on March 14, 2014, provisional application No. 61/969,019, filed on March 21, 2014, provisional application No. 61/970,551, filed on March 26, 2014, and provisional application No. 62/014,516, filed on June 19, 2014. *Id*.

42. The Office rejected claims 1-20 under 35 USC § 102(b) based on U.S. Patent Publication No. 2012/0197148 (Levitan). APPLE-1002, 491-497 (Office action, 2016-2-24). In response, Applicant argued that the prior art did not disclose "determining a heart rate variability value **based on the user's heart rate**" or "that **the user is alerted to sense an electrocardiogram in response to a determined heart rate variability value**" (emphasis in original). APPLE-1002, 374-375 (Applicant's response, 2016-5-23).

43. In a Final Rejection, the Office rejected claims 1-20 under 35 USC § 102(b) based on U.S. Patent Publication No. 2012/0197148 (Levitan). APPLE-1002, 358-363 (Office Action, 2016-6-13). In response, Applicant amended the

claims (including amending claim 1 to require "***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***") and argued that the prior art did not disclose added features of "**a motion sensor**, **sensing an activity level of a user**, and **comparing an activity level of the user to an HRV value of the user**." APPLE-1002, 342-347 (Applicant's response, 2016-11-14). Applicant also distinguished prior art by arguing that the claimed "heart rate sensor" is different from the ECG sensor in the prior art. *Id*. (Applicant's response, 2016-11-14).

44. Later, the Office allowed the application and noted that the cited art of record did not provide the claimed method, and specifically highlighted the newly added limitation in the Examiner's statement of reason for allowance. APPLE-1002, 52-58 (Notice of Allowance, 2016-12-6). The '499 patent issued on February 21, 2017 and includes 20 claims, of which claims 1 and 11 are independent. APPLE-1001, Cover. As explained below, the limitations added to gain allowance (a motion sensor, sensing an activity level; and comparing an activity level to an HRV), which according to the Examiner were missing from the art of record, are expressly disclosed in Shmueli and/or Osorio.

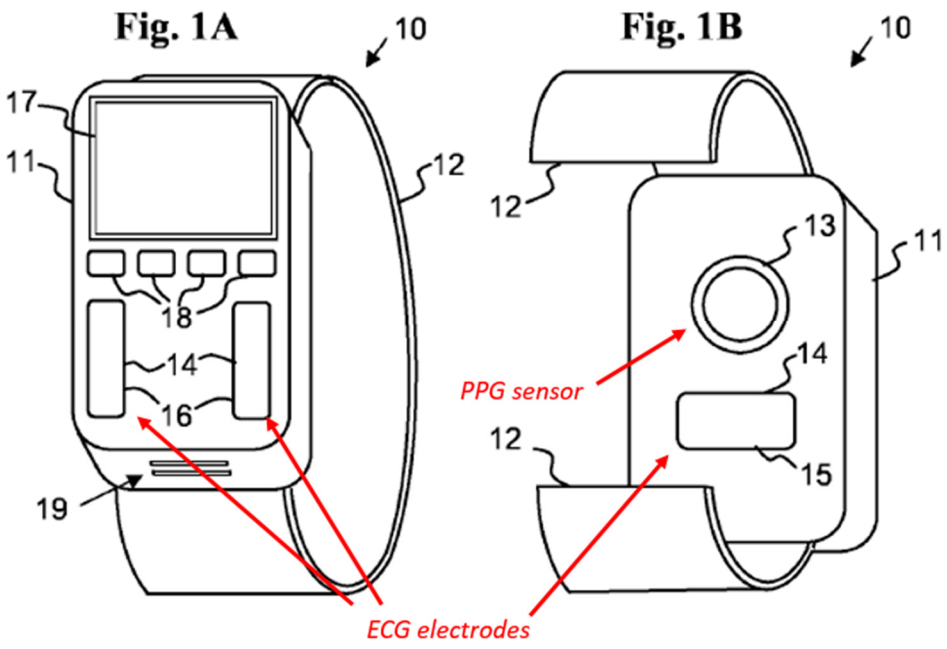
X. SUMMARY OF THE PRIOR ART

A. Shmueli

(a) *Monitoring Device*

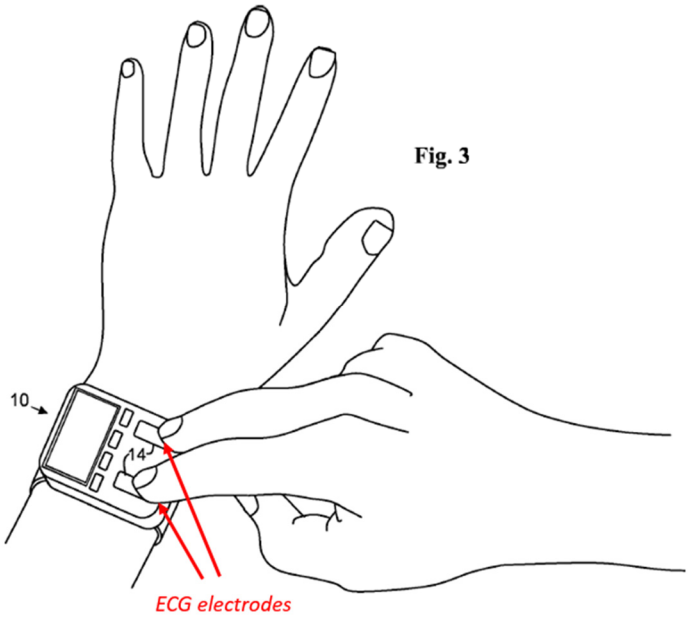
45. Shmueli is titled "Pulse oximetry measurement triggering ECG measurement." APPLE-1004, Cover. Shmueli's heart monitoring device includes an "oximetry measuring unit" for measuring oxygen saturation (SpO_2), which Shmueli describes as being the same as PPG. APPLE-1004, 7:25-27 ("In this document, unless otherwise specified, the terms 'oxygen saturation in the blood', 'blood oxygen saturation', 'pulse oximeter', oximetry, SpO2, and photoplethysmography[(PPG)] have the same meaning and may be used interchangeably"). The heart monitoring device also includes an "ECG measuring unit" with electrical contacts for measuring ECG, and a "processor" to control both types of measurements. APPLE-1004, 4:1-9 ("a wrist-mounted physiological parameters measuring device including: an SpO2 measuring unit attached to a wrist of a subject the SpO2 measuring unit being operative to continuously measure SpO2 at the wrist of the subject, an ECG measuring unit attached to the wrist of the subject for measuring ECG signal at least partially at the wrist, and a processor operative to control both the SpO2 measuring and the ECG measuring unit"), 9:8-16, 11:10-21.

46. Shmueli's heart monitoring device has a wrist-mounted form factor. *See* APPLE-1004, FIGS. 1A, 1B, 2-5.



APPLE-1004, Figs. 1A, 1B (annotated)

47. Figure 3 shows an example of a user using Shmueli's heart monitoring device on his/her wrist to collect an ECG measurement.



APPLE-1004, Fig. 3 (annotated)

(b) *Monitoring Technique*

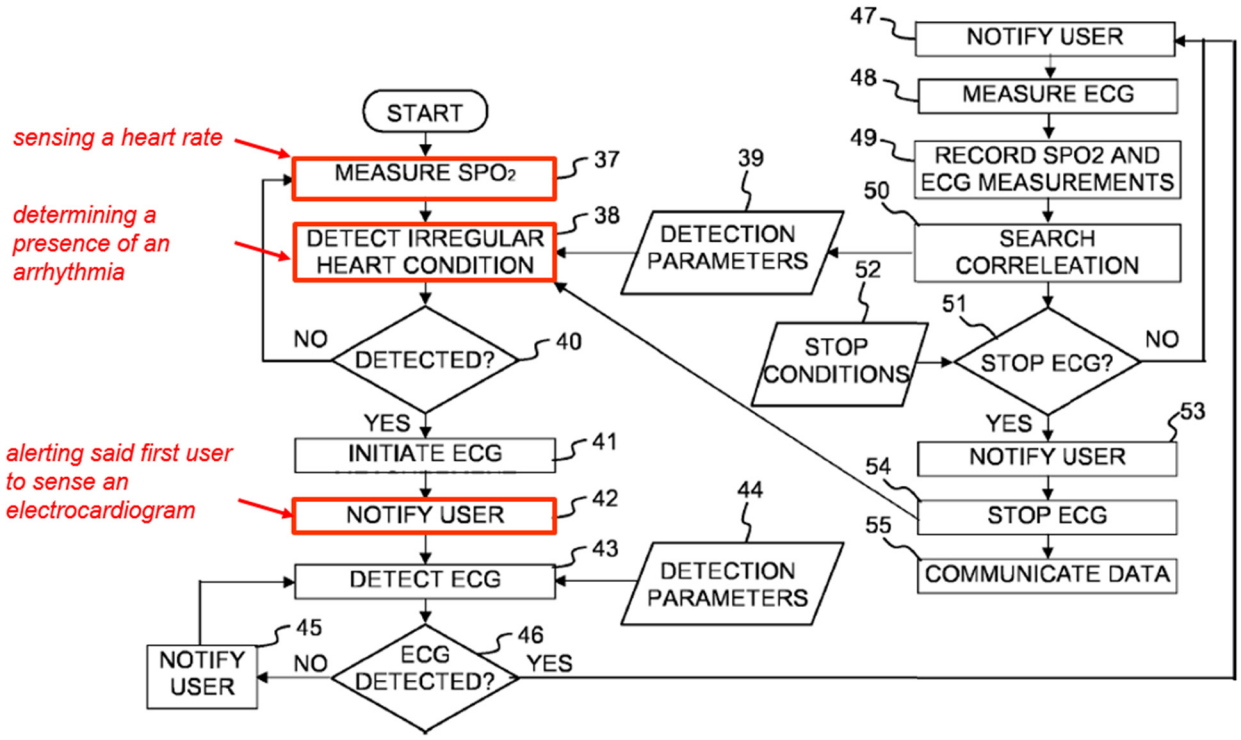
48. Shmueli's heart monitoring device performs a monitoring technique that involves "continuously measuring [oxygen saturation (SpO_2)] at the wrist of the user, detecting an **irregular heart condition** from the SpO_2 measurement, notifying the user to perform an ECG measurement, and initiating the ECG measurement at least partially at the wrist." APPLE-1004, Abstract (emphasis added). PPG also is referred to as pulse oximetry SpO_2 (oxygen saturation). APPLE-1004, 7:25-27.

49. A POSITA would have understood that the term "irregular heart condition" refers to arrhythmia for several reasons. First, Shmueli's disclosure supports this understanding since Shmueli discloses both detecting the "irregular heart condition" based on PPG data and confirming the diagnosis with an ECG measurement. APPLE-1004, Abstract, FIG. 8; 8:23-28 ("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 event."). Although "irregular heart condition" is not a standard term in medicine, a POSITA would have understood that this term refers to arrhythmia, which is one of the most obvious (if not the most obvious) types of "irregular heart condition[s]" that can be determined

using PPG and ECG data. APPLE-1016, p. 6081; APPLE-1020, Abstract, 44:29-32; APPLE-1011, Abstract. Indeed, the Merriam-Webster Dictionary defines "heart disease" as "an abnormal condition of the heart or of the heart and circulation (such as coronary heart disease, **arrhythmia**, or heart-valve defect)." APPLE-1023, 2. Similarly, the Black Medical Dictionary lists "**arrhythmia**" as the first condition under the heading "Heart, Disease of." APPLE-1047, 320-321. Likewise, the '499 patent describes arrhythmia as "a **cardiac condition** in which the electrical activity of the heart is **irregular**..." APPLE-1001, 1:31-33. Shmueli also recognizes that "[d]eriving heart rate from oximetry" was known in the art and was commonly understood to be used in detection of arrhythmias. APPLE-1004, 8:11-13. Shmueli also offers an expansive definition of the term "irregular heart condition." APPLE-1004, 15:3-5 ("It is expected that during the life of this patent many relevant methods and systems will be developed and the scope of the terms herein, particularly of the term 'irregular heart condition' are intended to include all such new technologies a priori."). If you google the term "irregular heart condition," the first page only refers to arrhythmias. A POSITA would assume that when this term is used in the patent, it is referring to a cardiac arrhythmia.

50. Like the '499 patent, Shmueli's heart monitoring device detects arrhythmia using PPG. APPLE-1004, Abstract. Shmueli's Figure 7 provides an example of its cardiac monitoring technique.

Fig. 7



APPLE-1004, Fig. 7 (annotated)

51. As shown above, Shmueli's heart monitoring device uses PPG data to detect an irregular heart condition (arrhythmia) at elements 37-38. APPLE-1004, 12:9-22 ("The software program proceeds to element 38 to derive from the SpO2 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."). If arrhythmia is detected at element 40, the heart monitoring device triggers an ECG measurement at element 41 by providing a notification to the user to take the ECG measurement at element 42. *Id.*, 12:23-32.

52. A POSITA 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. *Id.*, 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 POSITA 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. *See* APPLE-1004, 13:16-21 (describing that developing correlations between PPG data and ECG data provides the ability to "produce new detection parameters, or modify existing detection parameters, so as to enhance the detection algorithms of the irregular heart conditions").

B. Osorio

53. Osorio is titled "Pathological state detection using dynamically determined body data variability range values." APPLE-1005, Cover. Osorio's monitoring technique includes receiving a body signal of the patient and determining a body data variability (BDV) from the body signal. *Id.*, Abstract, [0003]. Osorio describes the body signal can be heart rate ("HR") and the BDV

can be heart rate variability ("HRV"). *Id.*, [0042]-[0043]; [0080] ("the body index value may be heart rate and the BDV may be HRV."). Osorio's monitoring technique also includes determining an activity level of a patient based on data from an activity sensor (e.g., accelerometer). *Id.* at [0035]. Osorio describes detecting a pathological state (e.g., arrhythmia) by comparing the current BDV value to a BDV non-pathological range that is determined based on the activity level. *Id.*, [0003] ("the present disclosure relates to a method of detecting a pathological body state of a patient, comprising receiving a body signal of the patient; determining a first body data variability (BDV) from said body signal; determining an activity level of said patient; determining a non-pathological range for said first BDV, based at least in part on said activity level; comparing said first BDV to said non-pathological range for said first BDV; and detecting a pathological body state when said BDV is outside said non- pathological range."). Figure 8 shows an example of Osorio's monitoring technique:

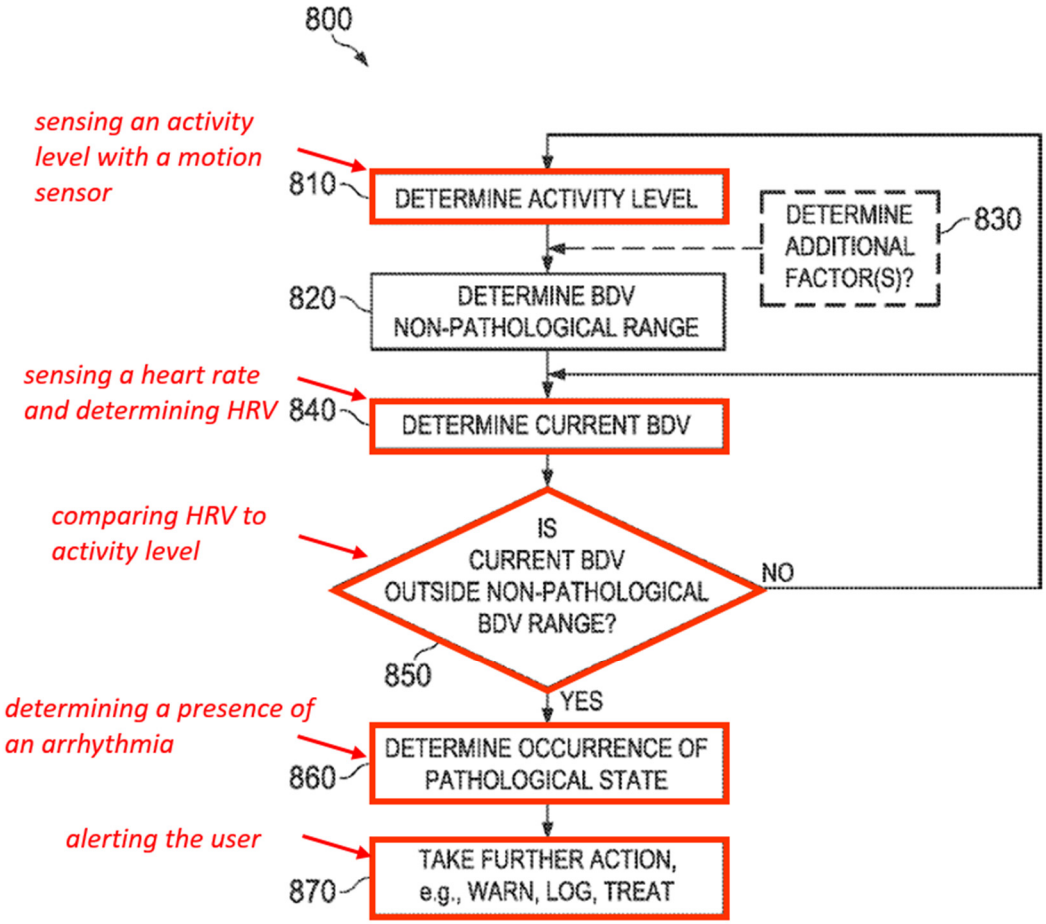


FIG. 8

APPLE-1005, Fig. 8 (annotated)

54. As shown above, an activity level is determined at 810, and a non-pathological BDV range is determined at 820 based on the activity level. APPLE-1005, [0077]. A current BDV is determined at 840 and compared to the non-pathological BDV range at 850. APPLE-1005, [0078]. If the current BDV is outside the non-pathological range, then a pathological state is determined at 860. *Id*. Thereafter, a further action, such as warning, treating, or logging the occurrence and/or severity of the pathological state is taken at 870. *Id*..

55. Osorio's detection of a pathological state encompasses detecting arrhythmia. APPLE-1005, [0046] (discussing detecting "a **tachycardia** episode."); [0071] (discussing detecting "**the emergence of one or more cardiac arrhythmias**"). A POSITA would have therefore understood and/or found obvious that Osorio's detection of a pathological state involves detecting an arrhythmia.

56. Osorio explains that accurate detection of a pathological condition (e.g., arrhythmia) based on a patient's HR should also consider the patient's activity level:

> This disclosure recognizes that to determine (using body systems and their features) whether a body system is functioning pathologically or non-pathologically with a clinically worthwhile degree of accuracy and reliability, **one must take into account the type and/or level of activity being performed by a subject at the time the pathological/non-pathological determination is made**. For example, if the objective is to determine if and when a patient is in a seizure state that manifests with increases in heart rate, it is imperative to know whether or not a given increase in heart rate is associated with a change in activity (e.g., physical or emotional) and if such a change in activity is occurring, **to determine if the heart rate increase is commensurate with said activity type and level**. This may be accomplished by a dynamical adjustment of value ranges of body signal features to avoid false diagnoses.

APPLE-1005, [0029].

57. Based on this disclosure, a POSITA would have understood that accurate detection of a pathological condition (e.g., arrhythmia) benefits from monitoring body data (e.g., HR) and activity level in tandem. Osorio recognizes that both HR and activity level affect the non-pathological BDV range and, thus, affect the detection of a pathological condition (e.g., arrhythmia) using the non-pathological BDV range. APPLE-1005, [0058] (describing that "[b]oth the upper and lower bounds of the [non-pathological] HR range increase as activity level increases (e.g., from a sleep state to a resting, awake state) and reach their highest values for strenuous exertion.").

58. Osorio's Figure 4A (below) show examples of HR variability as a function of activity level, which is then used to determine different non-pathological BDV ranges at different activity levels:

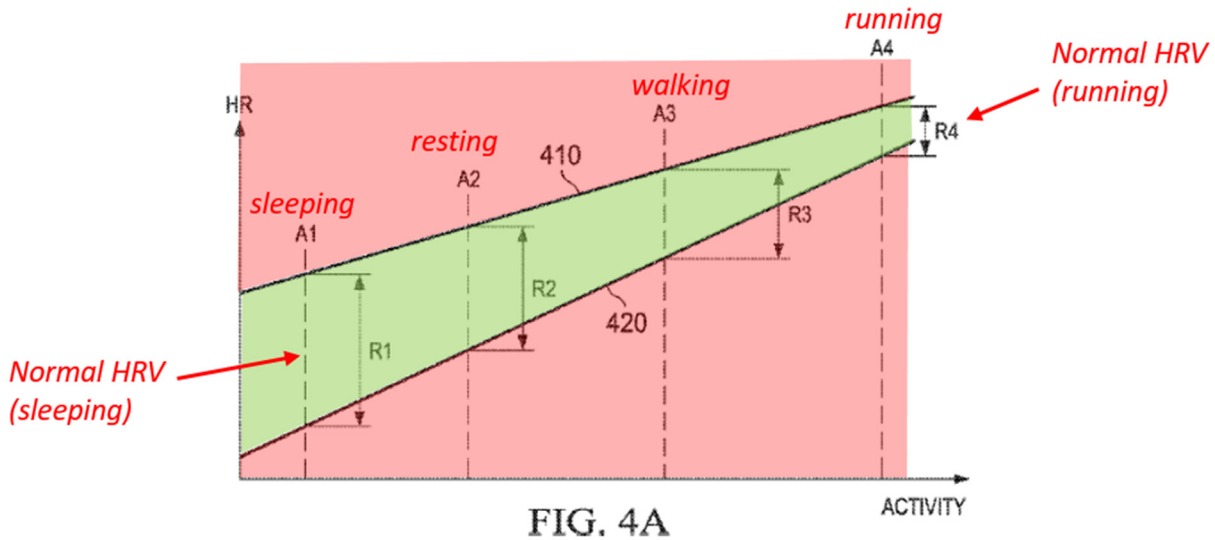


FIG. 4A

APPLE-1005, Figs. 4A (annotated)

59. As shown, a patient's activity level is shown on the x-axis and the patient's HR is shown on the y-axis. APPLE-1005, [0057]. BDV is represented by HRV, which is represented in Figure 4A by bars R1-R4. *Id.* Non-pathological BDV (HRV) ranges are illustrated in green and BDV (HRV) values outside the non-pathological BDV ranges are illustrated in red. *Id.* In Figure 4A, a unique non-pathological BDV (HRV) range (R1, R2, R3, R4) is determined for each of four different activity levels A1, A2, A3, A4 represented by sleeping, resting, walking, and running, respectively. *Id.* The dynamic relationship between HR, HRV, and activity level is used to detect pathological states by "determining when the patient's HRV is incommensurate with the patient's activity level and/or heart rate." APPLE-1005, [0066] ("The dynamic relationship between non-pathological HRVs and activity levels may be exploited to detect pathological states such as epileptic seizures by determining when the patient's HRV is incommensurate with the patient's activity level and/or heart rate.").

C. Hu 1997 Overview

60. Hu 1997, titled "A patient-adaptable ECG beat classifier using a mixture of experts approach," discloses a machine learning method to detect arrhythmia by training the algorithm using both user-specific historical data (local expert) and historical data from other users (global expert). APPLE-1049, pp. 891-

892.

61. Hu 1997 recognizes that "One major problem faced by today's automatic ECG analysis machine is the wild variations in the morphologies of ECG waveforms of different patients and patient groups." APPLE-1049, p. 891. As a result, An ECG beat classifier which performs well for a given training database often fails miserably when presented with a different patient's ECG waveform. *Id*. One obvious approach to alleviate this problem is to use as much training data as possible to develop the ECG classifier (using data from many patients). *Id*. However, this approach suffers from several pitfalls: 1) this approach it is not possible to cover every ECG waveform of all potential patients; 2) the complexity of the classifier grows as the size of the training database grows; and 3) it is practically impossible to make the classifier learn to correct errors during normal clinical use. *Id*.

62. Hu 1997 solves this problem using a mixture of experts ("MOE") approach, where two classifiers are modeled as two experts on ECG beat classification. APPLE-1049, p. 892. The original classifier, called the *Global expert* (GE) in this work, knows how to classify ECG beats for many other patients whose ECG records are part of the in-house, large ECG database. *Id*. The patient-specific classifier, called the *local expert* (LE) in this work, is trained specifically with the ECG record of the patient. *Id*. A gating function, based on the feature

vector presented, dynamically weights the classification results of the GE's and the LE's to reach a combined decision. *Id*. The process is analogous to two human experts arriving at a consensus based on their own expertise. *Id*.

63. Hu 1997 tested its MOE method and showed that the performance of the MOE classier is able to gain significant performance enhancement with a small amount of annotated patient specific training data. APPLE-1049, p. 895. Specifically, the MOE approach significantly enhanced the performance of an ECG beat classifier over the global classifier, confirming that patient-specific training data significantly enhances the performance of a general purpose ECG classifier. APPLE-1049, p. 898. In other words, Hu 1997 shows that training the machine learning algorithm with both general population data and user-specific data can significantly improve performance comparing to training with general population alone.

XI. ANALYSIS OF SHMUELI IN VIEW OF OSORIO

64. For the reasons articulated in detail below, and based on my review of the '499 patent, the file history, and the prior art references cited here, it is clear that a POSITA would have readily understood that the teachings of Shmueli in view of Osorio provide all the elements of claims 1-6, 10-16 and 20.

A. The Combination of Shmueli and Osorio

65. As discussed above, Shmueli's wrist-mounted heart monitoring device

detects an irregular heart condition (arrhythmia) based on PPG and ECG measurements taken at a person's wrist. Though Shmueli's detection method does not expressly account for a user's activity level, 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. APPLE-1005, [0029]; APPLE-1035, p. 303; APPLE-1050, p. S465. For example, as early as 1988, it was recognized that "variations in heart rate during exercise correlate with changes of exercise intensity." APPLE-1035, p. 303. In fact, based on this well-recognized correlation between heart rate and activity level, heart rate has been commonly employed as an objective method of assessing physical activity. APPLE-1050, p. S465. This is because heart rate is a physiological parameter known to have a strong positive association with energy expenditure during large muscle dynamic exercise. *Id*. A POSITA would have been aware that the normal heart rate ranges from 60-100bpm, and that failure to account for physical activity or stress, that might elevate heart rates above 100 bpm during normal daily activity would result in triggered alerts from physiologic and not pathologic events that occur during normal daily activity. Indeed, Osorio explicitly describes the benefits (e.g., improved accuracy, reliability, and reduced false detection) of using activity level to detect an irregular heart condition. APPLE-1005, [0029], [0036]. With these benefits in mind, a POSITA would have been motivated to incorporate Osorio's

activity sensor and activity level analysis techniques into Shmueli's heart monitoring device. APPLE-1005, [0029].

66. In implementing the Shmueli-Osorio device, a POSITA would have modified Shmueli's heart monitoring device to incorporate two types of teachings from Osorio—(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). As discussed below, the combined Shmueli-Osorio device would have been advantageous for use in detecting pathological events.

(a) *Activity Level Monitoring*

67. A POSITA would have been motivated to modify Shmueli to incorporate Osorio's activity level monitoring to enable more sophisticated cardiac monitoring that improves accuracy of detecting a pathological event (e.g., arrhythmia). For example, as discussed above, Osorio teaches that activity level information can be used to avoid "false diagnoses." APPLE-1005, [0029]. Osorio also recognizes that, "to determine (using body systems and their features) whether a body system is functioning pathologically or non-pathologically with a ***clinically worthwhile degree of accuracy and reliability***, one must take into account ***the type and/or level of activity being performed by a subject*** at the time the pathological/non-pathological determination is made." APPLE-1005, [0029]. As

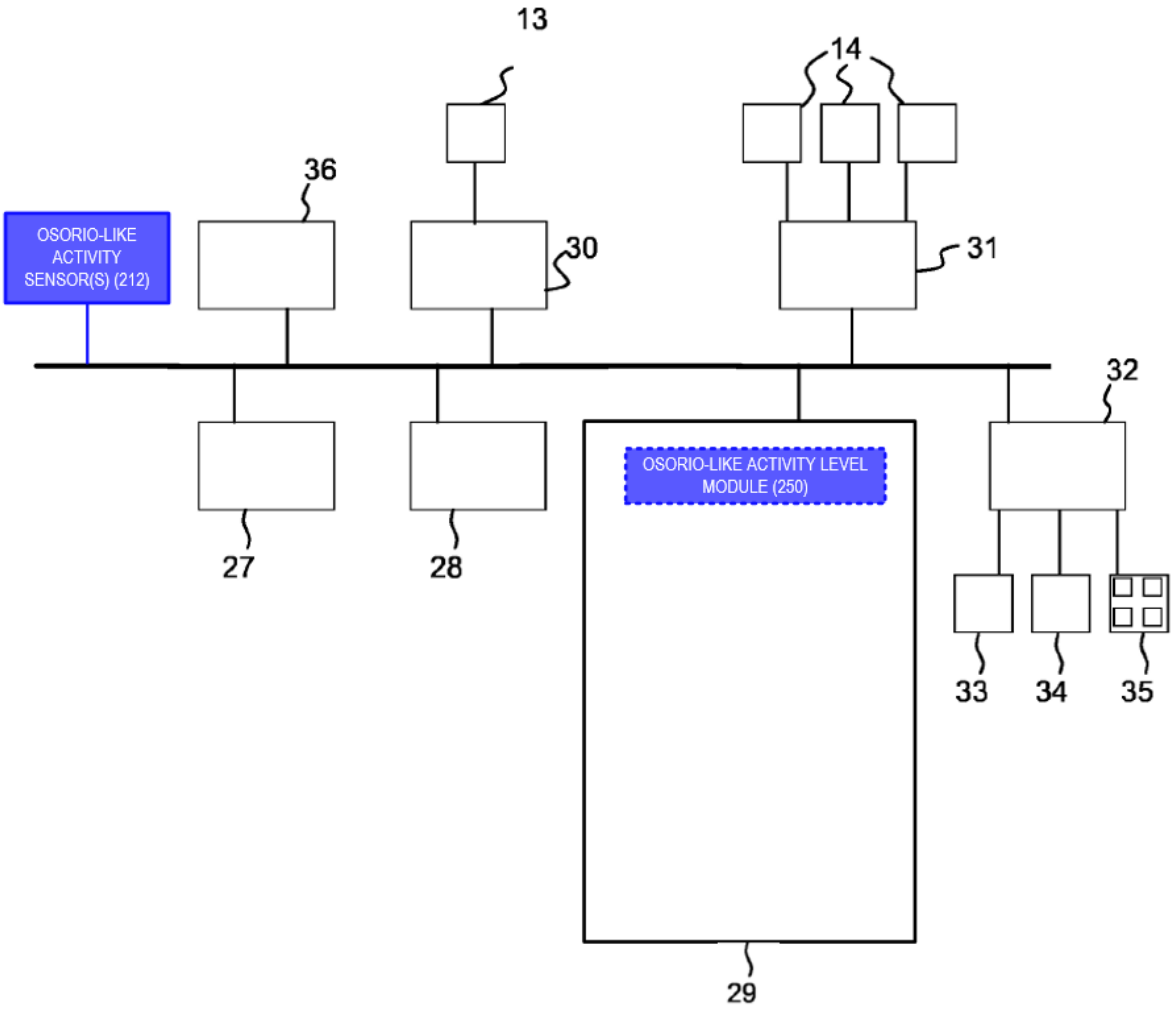
Osorio explains, "it is imperative to know whether or not ***a given increase in heart rate is associated with a change in activity*** (e.g., physical or emotional) and if such a change in activity is occurring, to determine if the heart rate increase is commensurate with said activity type and level." *Id*. In this regard, Osorio confirms 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***." *Id.*, [0036].

68. A POSITA would have found the modification of Shmueli's heart monitoring device to incorporate Osorio's activity level monitoring techniques to have been obvious since, by the Critical Date, it was well-known that activity level was related to HR and, therefore, activity level would have been considered an option for improving Shmueli's detection of irregular heart conditions. APPLE-1005, [0029]; APPLE-1035, 303; APPLE-1050, S465. This is consistent with Shmueli's primary focus on enabling a convenient yet comfortable device to measure ECG only upon detection of an irregular heart condition using PPG data. APPLE-1004, 1:6-2:13.

69. To implement the modification discussed above, a POSITA would have incorporated the following teachings from Osorio into Shmueli's heart monitoring device: (a) hardware elements used for measuring activity level, such as Osorio's activity sensors 212 (e.g., motion sensors) and (b) software-related

techniques for processing sensed data to determine an activity level of a patient, such as those performed by Osorio's activity level module 250.

70. A POSITA would have found it obvious to implement this modification in several ways, consistent with the disclosures of both references. For example, a POSITA would have found it obvious to modify Shmueli's heart monitoring device to include activity level sensors (similar to Osorio's activity sensors 212) that sense body signal data representing user activity. APPLE-1005, [0033]. A POSITA also would have found it obvious to configure processor 29 in Shmueli's heart monitoring device to execute operations related to activity level monitoring that are performed by Osorio's activity level module 250, such as determining activity level based on body signal data sensed by activity level sensors 212. *Id.*, [0034]. A visual representation of this modification is shown in Shmueli's Figure 6 below (modification in blue):



Shmueli's Heart Monitoring Device (Modified To Incorporate Osorio's Activity Level Monitoring)

71. A POSITA would have had a reasonable expectation of success in modifying Shmueli's heart monitoring device based on Osorio in the manner shown above. Both Shmueli and Osorio are directed to detecting a pathological event (e.g., irregular heart condition, pathological condition, both of which include arrhythmia) based on sensed data (e.g., HR). APPLE-1004, Abstract; APPLE-1005, Abstract. Shmueli's heart monitoring device uses an oximetry sensor for an

initial diagnosis and an ECG sensor for confirmation. APPLE-1004, Abstract, 2:16-21, 11:22-13:21, Fig. 7. Osorio similarly teaches a monitoring device that tracks HR using a HR sensor. APPLE-1005, [0033], Fig. 1. In assessing Osorio's disclosure when reviewing Shmueli, a POSITA would have viewed Shmueli's heart monitoring device as a similar type of external or body-worn medical device described in Osorio. Accordingly, a POSITA would have viewed Osorio's activity level sensor 212 as being readily able to be incorporated into Shmueli's heart monitoring device.

72. Moreover, given the overlapping subject matter between Shmueli and Osorio, a POSITA would have expected the processing capabilities of Shmueli's processor 29 to be able to perform (or be able to be upgraded with routine skill) to implement the operations performed by Osorio's software modules. APPLE-1031, [0001], [0028]-[0029], Figs. 1-2 (discussing processing data from multiple sensors including PPG, ECG, and motion sensors); APPLE-1032, 19:54-22:3, Fig. 8A (discussing processing data from multiple sensors including PPG, ECG, and motion sensors). For example, Sun discloses a system containing PPG, ECG and motion sensors to provide context-aware control of sensors and sensor data to monitor cardiovascular diseases. APPLE-1031, [0028]-[0029], [0034] (describing sensors including accelerometer, ECG sensor, and PPG sensor) and Figs. 1 and 2. Sun discloses that the system 100 uses an individual's physical activity level to

boost the accuracy of sensor data interpretation as well as to reduce energy consumption by turning the physiological sensor off or other restricting its functions under conditions (e.g., high levels of movement) when the collected data would not be accurate. APPLE-1031, [0034]. As another example, Zhao discloses a method of improving the quality of vital signs data including concurrently sensing data form a plurality of vital signs sensors over a period of time, determining a plurality of vital sign values; and fusing at least two vital sign values. APPLE-1032, Abstract. Fig. 8A of Zhao illustrates Zhao's device that contains an processor 840 that receives signals from accelerometer 885, a pulse oximetry sensor 880, and an ECG sensor 860. APPLE-1032, 19:54-22:3 and Fig. 8A. Zhao further discloses that the processor 840 includes a processor memory 841 to store instructions to control the sensors in the system to obtain the sensor data and process the information obtained. APPLE-1032, 20:60-67.Thus, a POSITA would have been motivated to modify Shmueli's device to include a motion sensor to detect activity level in order to improve accuracy of arrhythmia detection and would have had a reasonable expectation of success in doing so.

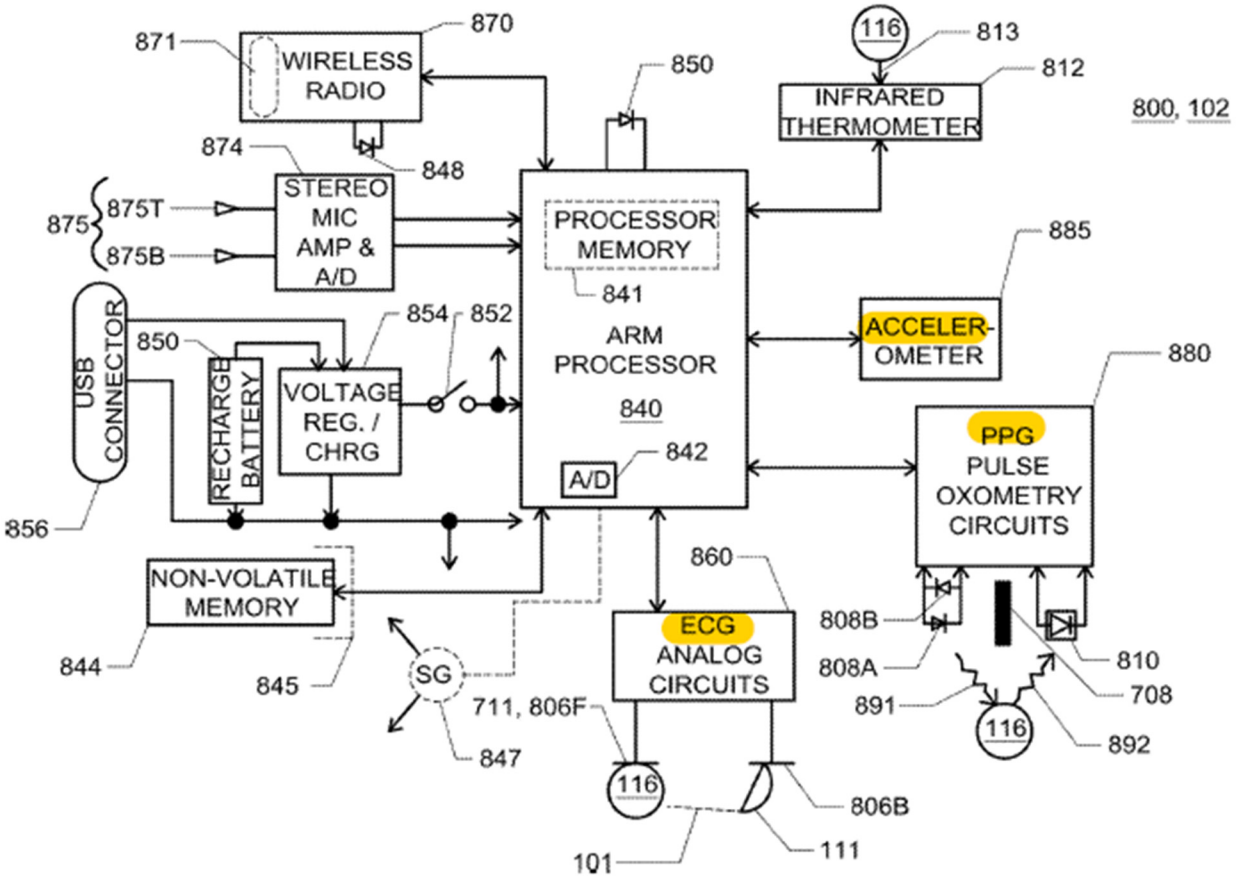


FIG. 8A

APPLE-1032, Fig. 8A (annotated)

This is expressly contemplated by Shmueli's explanation that "[i]t is expected that during the life of this patent many relevant methods and systems will be developed" and that its scope is intended to capture those developments. APPLE-1004, 15:3-5. Thus, a POSITA would have understood that incorporating Osorio's activity level monitoring techniques into Shmueli's heart monitoring device would have involved use of a known technique (e.g., monitoring activity level in detecting a pathological event) to known devices (e.g., monitoring devices

disclosed in Shmueli and Osorio), ready for improvement to yield predictable results.

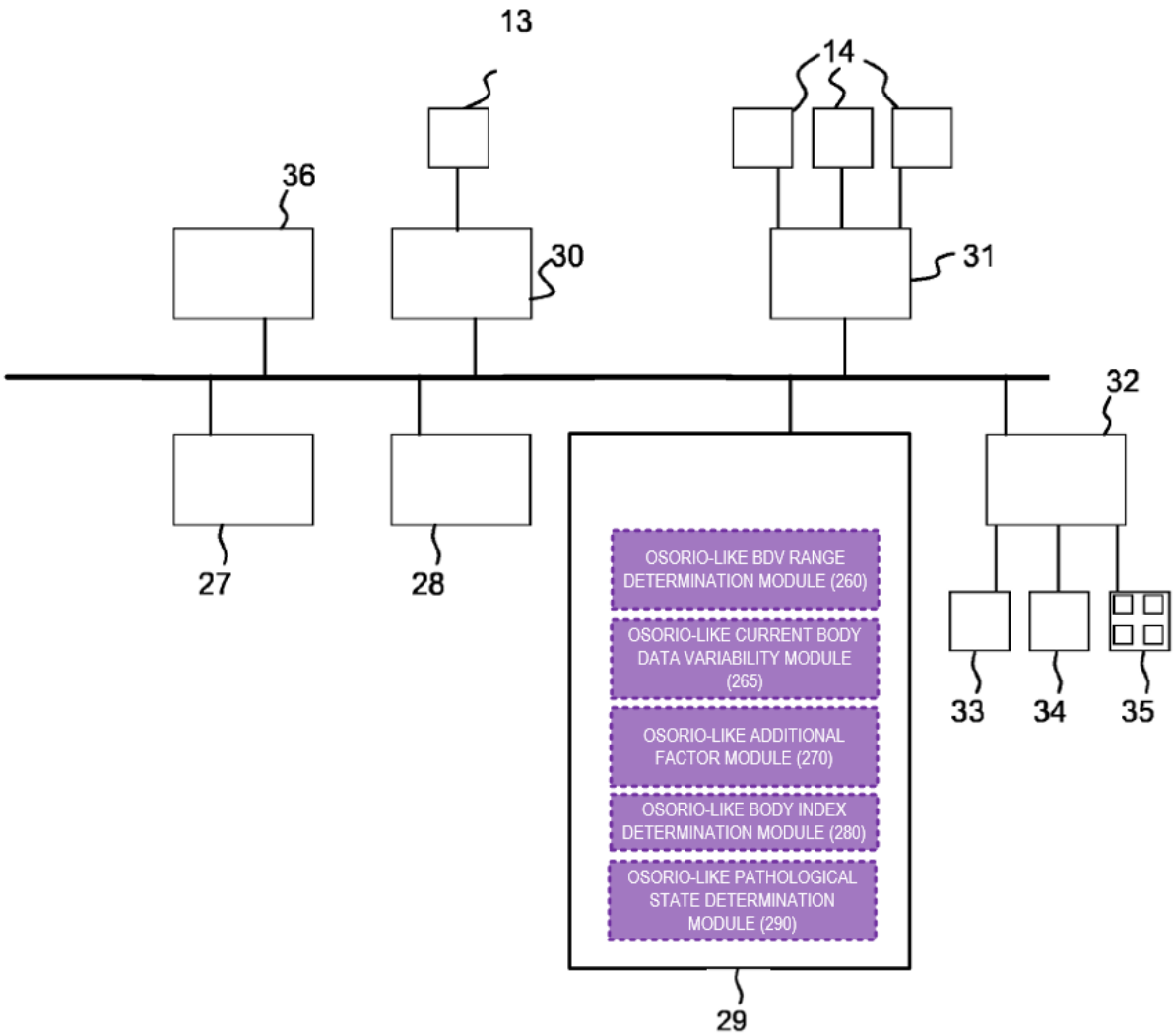
(b) *HRV Monitoring*

73. While incorporating Osorio's activity sensor and corresponding techniques for monitoring activity level, a POSITA would have found it natural to incorporate other aspects of Osorio's monitoring techniques for detecting a pathological condition (e.g., arrhythmia) based on HR and activity level. Examples of such aspects include deriving HRV from HR, and detecting a pathological state (e.g., arrhythmia) by comparing a current HRV to a non-pathological HRV range determined based on the activity level. APPLE-1005, [0003], Fig. 8. A POSITA also would have been motivated to incorporate Osorio's HRV analysis because it is less affected by noise. APPLE-1039, 52 ("This is a more robust method since the R-R time intervals are less affected by the noise.").

74. To implement this modification, a POSITA would have incorporated, into Shmueli's heart monitoring device, Osorio's software elements for processing data related to body indices and BDVs, including BDV determination module 260, BDV module 265, additional factor module 270, body index determination module 280, and pathological state determination module 290.

75. A POSITA would have found it obvious to implement this modification in several ways, consistent with the disclosures of both references.

For example, a POSITA would have found it obvious to configure processor 29 in Shmueli's heart monitoring device to execute operations related to BDV range monitoring, such as determining an HRV value from HR, comparing an HRV value with a non-pathological HRV range, and determining a pathological condition based on the comparison. *See* APPLE-1005, [0003], [0043], [0053], [0055], [0056], [0065], [0066], [0080], Figs. 1 and 8. A visual representation of this modification is shown in Shmueli's Figure 6 below (modification in purple):



Shmueli's Heart Monitoring Device (Modified Based on Osorio's HRV Monitoring)

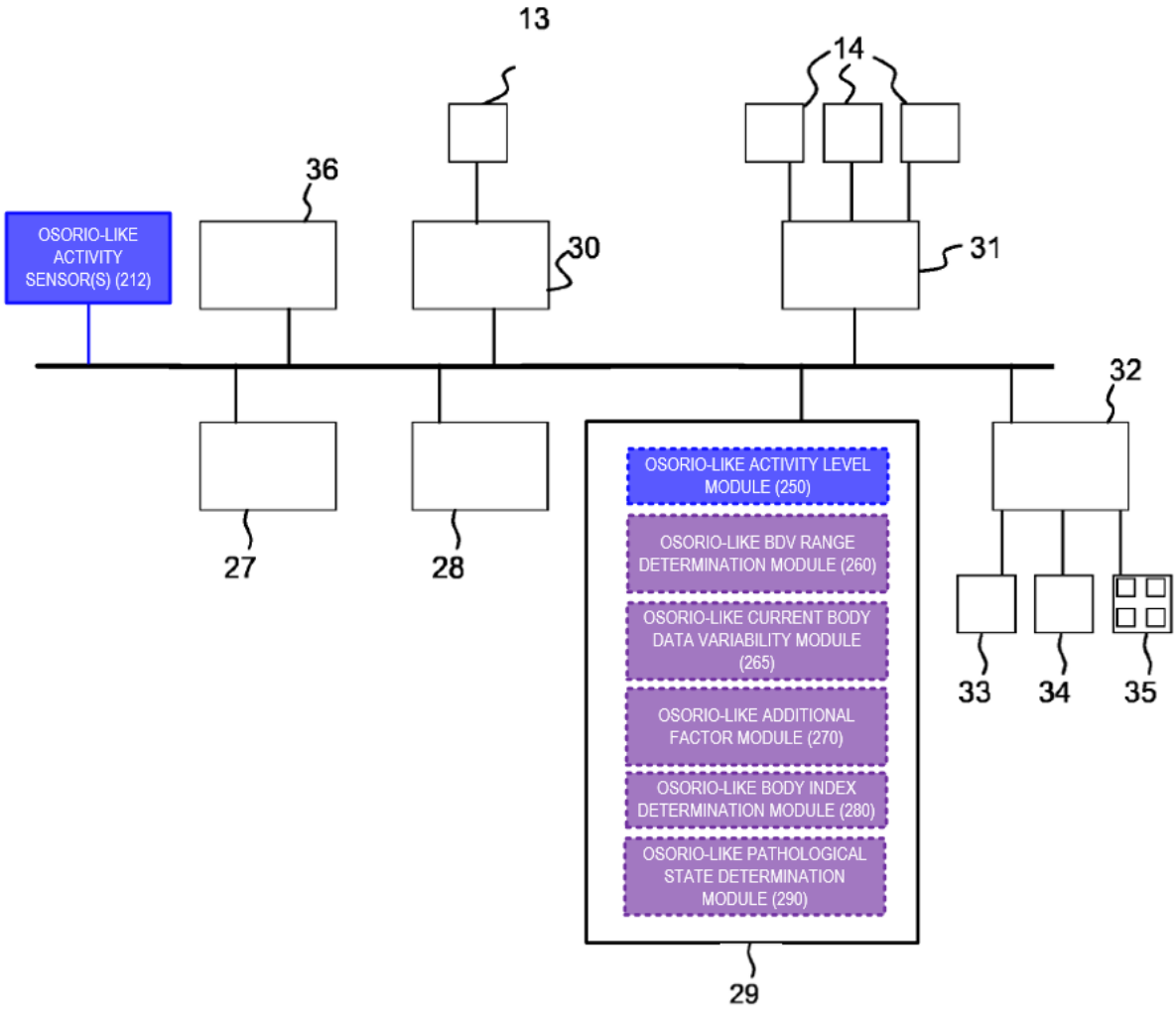
76. A POSITA would have been motivated to incorporate Osorio's software modules into Shmueli's heart monitoring device since doing so would have enabled use of HRV, which improves the pathological event detection capabilities compared to Shmueli's unmodified heart monitoring device. For example, although certain arrhythmias (e.g., tachycardia, bradycardia) are sufficiently detectable based on absolute heart rate values, detection of more frequently-occurring arrhythmias (e.g., atrial fibrillation) is improved when using HRV to prevent false detections. Thus, a POSITA would have understood that use of HRV by the Shmueli-Osorio device would have improved the detection of different types of arrhythmias.

77. A POSITA would have understood that the use of HRV analysis by the Shmueli-Osorio device would have been a simple application of a known technique to a known device to yield predictable results. Indeed, a POSITA would have found the use of HRV and a non-pathological HRV range as one of a finite number of identified, predictable solutions for detecting irregular heart conditions and would have had a reasonable expectation of success of implementing such detection in Shmueli, particularly in view of Osorio's disclosure of the same. For example, Asl-2008 describes two categories of arrhythmia detection techniques,

one based on the raw heart rate signal (e.g., ECG) and one based on HRV analysis. APPLE-1039, 52. A POSITA would have been motivated to choose HRV analysis because HRV extracted 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*. ("This is a more robust method since the R-R time intervals are less affected by the noise."). A POSITA also would have been motivated to employ Osorio's HRV analysis because, although certain types of arrhythmias (e.g., tachycardia or bradycardia) can be detected by absolute heart rate values, diagnosis of other types of arrhythmias (e.g., atrial fibrillation, the most common cardiac arrhythmia) uses HRV analysis.

78. Finally, a POSITA would have found it obvious that Osorio's technique of determining HRV from HR was conventional and it could have been applied to derive HRV from HR based on PPG data collected by Shmueli's oximetry sensor 13. APPLE-1005, [0042]. This is because (1) Shmueli teaches a software program that derives physiological parameters (pulse rate, pulse amplitude, pulse shape) from oximetry data (APPLE-1004, 12:14-22) and (2) Shmueli recognizes that "[d]eriving heart beat rate from oximetry, as well as other artifacts of the heart activity and blood flow, is also known in the art…" (*Id.*, 8:11-13). Indeed, a POSITA would have found it obvious that HRV is one example of the "artifacts of the heart activity and blood flow" addressed in Shmueli.

79. The figure below provides a visual depiction of the Shmueli-Osorio combination based on the modifications discussed above.



The Shmueli-Osorio Device

80. In the Shmueli-Osorio device, Shmueli would have been modified to incorporate Osorio's activity sensor and Osorio's monitoring technique to detect a pathological condition (e.g., arrhythmia) based on a user's HR, HRV, and activity level. Shmueli's oximetry sensor 13 would have determined HR information, and Osorio's activity sensor would have determined the user's activity level. The

combined device then would determine a current HRV based on the HR information, determine the non-pathological HRV range based on the user's activity level, and compare the HRV to the non-pathological HRV range to detect an arrhythmia, as taught by Osorio. APPLE-1005, Fig. 8, [0077]-[0080]; APPLE-1010, [0042]-[0050]. Upon detection of arrhythmia based on HRV and activity level, the combined device would have notified the user to take an ECG measurement using Shmueli's ECG sensor. APPLE-1004, Fig. 7 and 12:6-30.

81. As discussed above, the Shmueli-Osorio device would have used Osorio's activity sensor to detect arrhythmia with increased accuracy by accounting for the user's activity level. APPLE-1005, [0029]. Moreover, using Shmueli's two-staged detection of irregular heart conditions using PPG data and ECG data, the Shmueli-Osorio device would have continuously monitored heart rhythm with an oximetry sensor and triggered an ECG measurement when an irregularity was detected. APPLE-1004, Abstract and Fig. 7. By accounting for activity level in determining when to notify the user to take an ECG, the Shmueli-Osorio device would have provided improved accuracy in determining when an ECG is needed, resulting in improved user satisfaction since the user would have been less bothered by false positives.

B. Claim 1

[1.0] A method of determining a presence of an arrhythmia of a first user, said method comprising

82. It is my opinion that the Shmueli-Osorio combination renders obvious element [1.0].

83. Shmueli teaches "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." APPLE-1004, Abstract. The Merriam-Webster Dictionary defines "heart disease" as "an abnormal condition of the heart or of the heart and circulation (such as coronary heart disease, arrhythmia, or heart-valve defect)." APPLE-1023, p.2. Similarly, the Black Medical Dictionary lists arrhythmia as the first condition under the heading "Heart, Disease of." APPLE-1047, pp. 320-321. The '499 patent also defines arrhythmia as an irregular heart condition. APPLE-1001, 1:31-33 ("Arrhythmia is a ***cardiac condition*** in which the electrical activity of the heart is ***irregular***…"). A POSITA would have understood the term "irregular heart condition" refers to arrhythmia. Indeed, Shmueli offers an expansive meaning for the term "irregular heart condition," explaining that "[i]t is expected that during the life of this patent many relevant methods and systems will be developed and the scope of the terms herein, particularly of the term 'irregular heart condition' are intended to include all such new technologies a priori." APPLE-1004, 15:3-5.

84. A POSITA would have found it obvious to use Shmueli's SpO2

measurement to detect arrhythmia as the irregular heart condition because using PPG data to detect arrhythmia was well-known and arrhythmia was a well-known heart condition. APPLE-1016, p. 6081 (discussing detecting arrhythmia using PPG data); APPLE-1020, Abstract and 44:29-32. In addition, Shmueli discloses both detecting the "irregular heart condition" based on PPG data and confirming the diagnosis with an ECG measurement. APPLE-1004, Abstract ("The method including the steps of: ***continuously measuring SpO2*** at the wrist of the user, detecting an irregular heart condition from the SpO2 measurement, notifying the user to perform an ECG measurement, and ***initiating the ECG measurement*** at least partially at the wrist.") and Fig. 8. An irregular heart condition is not a standard term in medicine. If you google the term, the first page only refers to arrhythmias. A POSITA would assume that when this term is used in the patent, it is referring to a cardiac arrhythmia. Arrhythmia is one of the most obvious (if not the most obvious) types of "irregular heart condition[s]" that can be determined using both PPG and ECG data. Indeed, ECG measurements are taken to detect rhythm abnormalities (e.g., arrhythmias) of a patient's heart. Because Shmueli uses ECG to confirm the irregular heart condition detected using PPG data, a POSITA would have understood that Shmueli inherently discloses and/or renders obvious that Shmueli's detection of irregular heart conditions using PPG data includes detection of arrhythmias. Otherwise, Shmueli likely would not confirm

the irregular heart condition using ECG measurements because one of the basic functions of obtaining an ECG is to determine rhythm. For example, Lee 2013 discloses using PPG data and ECG data to detect atrial fibrillation, one of the most common types of arrhythmia. APPLE-1011, Abstract. For these reasons, based on Shmueli's disclosure of a method of detecting an irregular heart condition from SpO2 and ECG measurements, Shmueli renders obvious a method of determining a presence of an arrhythmia of a first user.

85. In addition to Shmueli, Osorio also discloses using heart rate data to determine arrhythmia. APPLE-1005, [0046] and [0071]. For example, Osorio discloses "if the body signal is heart rate, then an instantaneous heart rate above the non-pathological heart rate range determined by the BDV range determination module 260 may indicate a tachycardia episode." APPLE-1005, [0046]. Osorio further discloses that "the severity 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.)." APPLE-1005, [0071].

86. As discussed in Section XI.A (above), in the Shmueli-Osorio 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 obtained from the PPG, determines the non-pathological HRV range based on the user's activity level (accelerometer), and compares the HRV to the non-pathological HRV range to determine the presence of arrhythmia, as taught by Osorio. APPLE-1005, Fig. 8 and [0077]-[0080]; APPLE-1010, [0042]-[0050]. Thus, the Shmueli-Osorio combination renders obvious [1.0].

[1.1] sensing a heart rate of said first user with a heart rate sensor coupled to said first user;

87. It is my opinion that the Shmueli-Osorio combination renders obvious element [1.1].

88. The '499 patent teaches sensing a heart rate with a PPG sensor. APPLE-1001, 8:41-45. During prosecution, Applicant distinguished prior art by arguing that the claimed "heart rate sensor" is different from the ECG sensor in the prior art. APPLE-1002, 342-347. Specifically, Applicant argued:

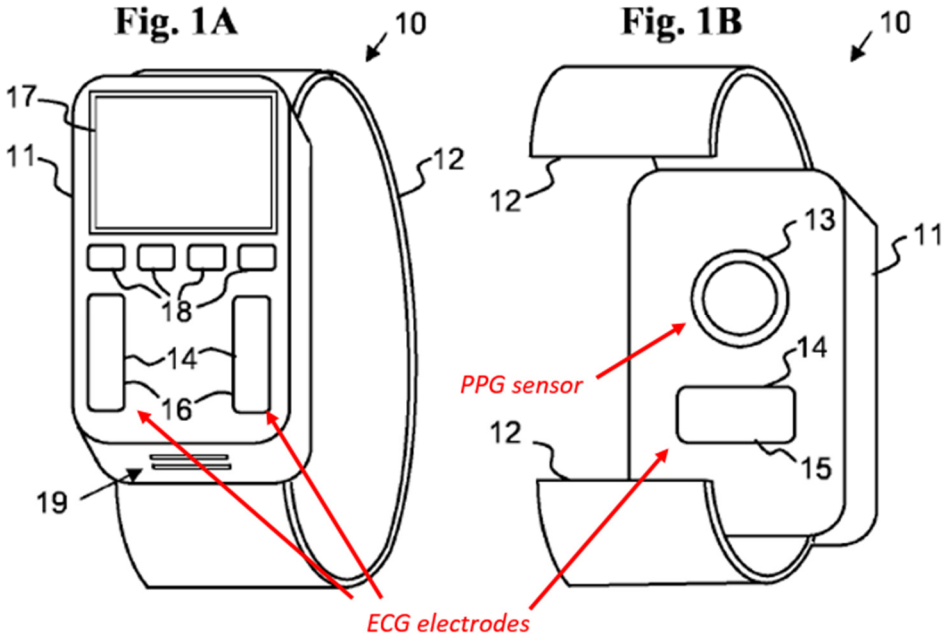
> Claims 1 and 11 recite a ***specific*** rather than a generic sensor type. Namely, claims 1 and 11 recite a "heart rate sensor." Levitan describes a "data collection subsystem" for collecting ECG data ***only***. See e.g., para [0058]. That is, Levitan describes a method for determining HRV from peak to peak interval data taken form a sensed ECG (i.e. using a data collection system), and does not describe use of ***a heart rate sensor*** in determining an HRV as recited by claims 1 and 11.

APPLE-1002, 342-347 (emphasis in original).

89. Similar to the '499 patent, Shmueli discloses measuring SpO_2 with a PPG sensor. APPLE-1004, 9:8-10 (disclosing "an oximetry sensor"); 7:25-27

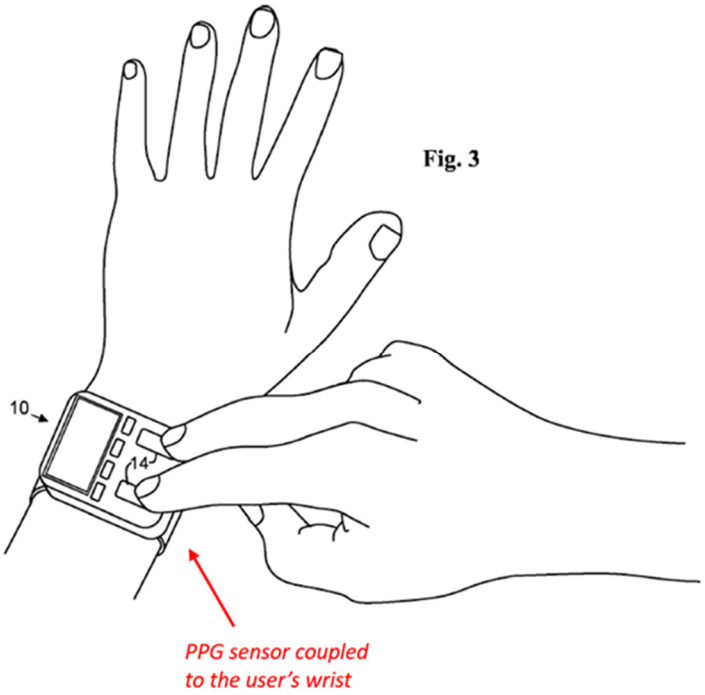
(explaining that the terms oximetry and photoplethysmography have the same meaning). In addition, Shmueli explains that "[d]eriving heart beat rate from oximetry" was known in the art. APPLE-1004, 8:11-13. From this disclosure, Shmueli renders obvious sensing a heart rate of the first user with a heart rate sensor (e.g., PPG sensor).

90. Shmueli also discloses that the PPG sensor is coupled to the user through a wrist-worn device. APPLE-1004, 4:1-9 ("According to yet another aspect of the present invention there is provided a **wrist-mounted** physiological parameters measuring device including: **an SpO2 measuring unit attached to a wrist of a subject** the SpO2 measuring unit being operative to continuously measure SpO2 at the wrist of the subject"). Figs. 1A and 1B illustrate an example of Shmueli's device.



APPLE-1004, Figs. 1A and 1B (annotated).

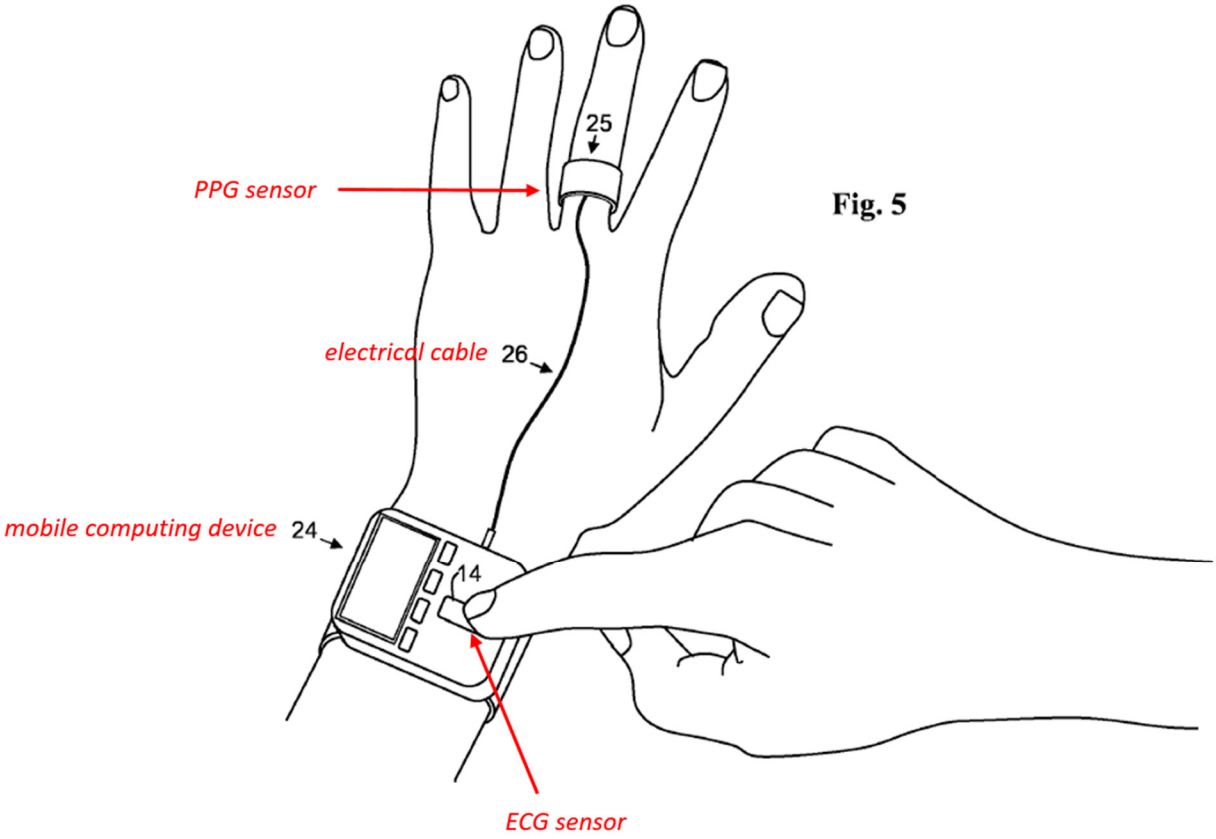
91. Fig. 3 of Shmueli shows an example of a user wearing the device of FIG. 1A/1B where the heart rate sensor (PPG sensor) is coupled to the user at the user's wrist through Shmueli's wrist-mounted device.



APPLE-1004, Fig. 3 (annotated).

92. Shmueli further discloses that the PPG sensor can also be mounted on the inner side of a ring or a clip worn on a finger of the hand wearing the heart monitoring device. APPLE-1004, 9:20-22 ("It is further appreciated that the oximetry (SpO2) measuring unit can be mounted on the inner side of a ring or a clip worn on a finger of the hand wearing the heart monitoring device 10."). As shown in Fig. 5 below, the PPG measuring unit (i.e., heart rate sensor) is coupled

to the user's finger and connected to Shmueli's wrist-worn device (e.g., mobile computing device) through an electrical cable 26. APPLE-1004, Fig. 5 and 10:28-11:2 ("As seen, the wrist-mounted heart monitoring device 24 of Fig. 5 includes the oximeter (not shown) mounted inside a ring 25 warn [sic] on a finger of the hand wearing the heart monitoring device 24. The oximeter in the ring 24 is preferably connected to the heart monitoring device 24, preferably by an electrical cable 26."). In Fig. 5, a POSITA would have understood that Shmueli's device is configured to transmit, through the cable 26, heart rate data from the oximetry (PPG) sensor to a mobile computing device (wrist-worn device), which is configured to sense an ECG.



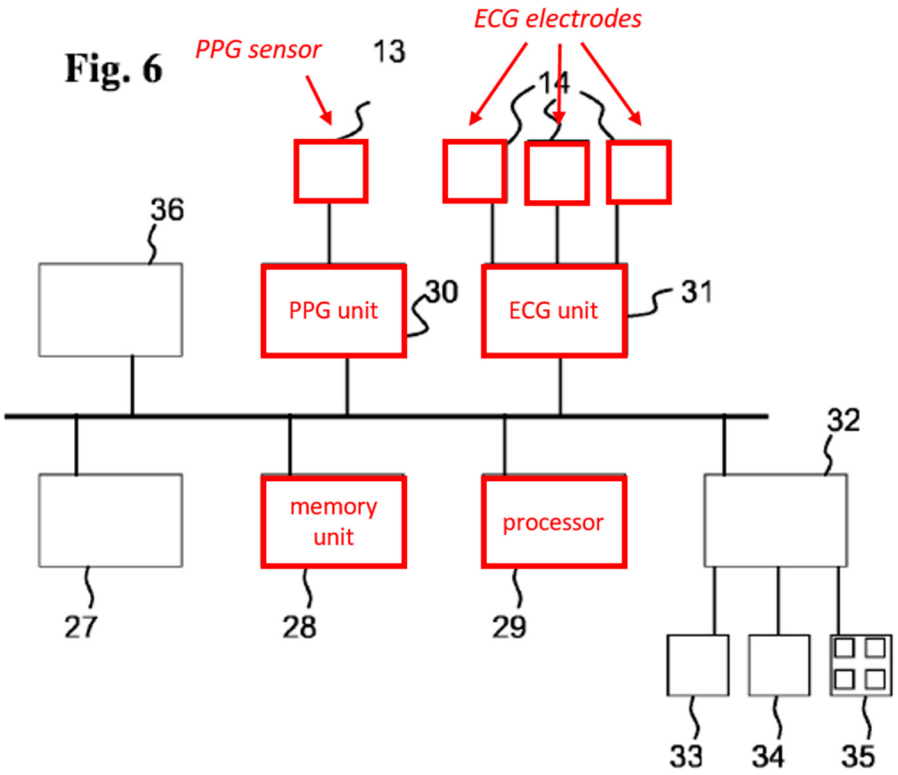
APPLE-1004, Fig. 5 (annotated).

93. As discussed in Section XI.A (above), in the Shmueli-Osorio 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. Thus, the Shmueli-Osorio combination renders obvious [1.1].

[1.2] transmitting said heart rate of said first user to a mobile computing device, wherein said mobile computing device is configured to sense an electrocardiogram;

94. It is my opinion that the Shmueli-Osorio combination renders obvious element [1.2].

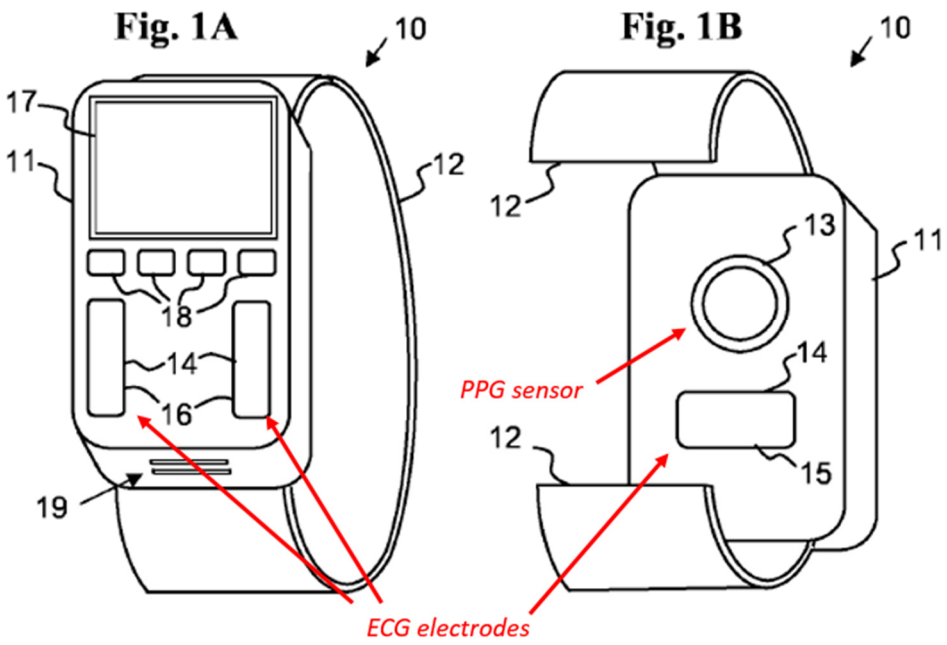
95. As shown in Fig. 6, Shmueli's heart monitoring device "preferably includes a power supply unit such as a battery 27, ***a memory unit 28, a processor 29, an oximetry measuring unit 30 with the oximetry sensor 13, an ECG measuring unit 31 with three ECG contact sensors 14***, a user interface unit 32 preferably containing output devices such as a display 33 and a sound producing device 34, and a user input device 35 for example including buttons, and optionally a communication unit 36." APPLE-1004, 11:10-15. Shmueli also discloses that this heart monitoring device is a wrist-mounted device worn by the user. APPLE-1004, Abstract ("The system includes a SpO2 measuring unit and an ECG measuring unit both ***embedded in a wrist-mounted device warren by the user***.") and Fig. 4. A POSITA would have understood that Shmueli's device is a "mobile computing device" that is "configured to sense an electrocardiogram" because it is a wrist-mounted device that has a memory and a processor, coupled to an ECG measuring unit with three ECG contact sensors.



APPLE-1004, Fig.6 (annotated).

96. As discussed above in element [1.1], Shmueli's device includes a heart rate monitor in the form of an oximetry (PPG) sensor. As shown below in Figs. 1A and 1B, the oximetry (PPG) sensor 13 can be mounted on the back of the monitoring device and facing the skin of the subject. APPLE-1004, 9:8-11 ("As shown in Figs. 1A and IB, the heart monitoring device 10 is preferably equipped with two types of sensing devices: and [sic] ***oximetry (SpO2) measuring unit*** and an ***ECG measuring unit***. The oximetry measuring unit preferably includes an ***oximetry sensor 13*** mounted in the back side of the monitoring unit 11 and facing the skin of the subject. ***The ECG measuring unit preferably includes at least***

three areas 14, each providing electrical contact with the subject.").



APPLE-1004, Figs. 1A and 1B (annotated).

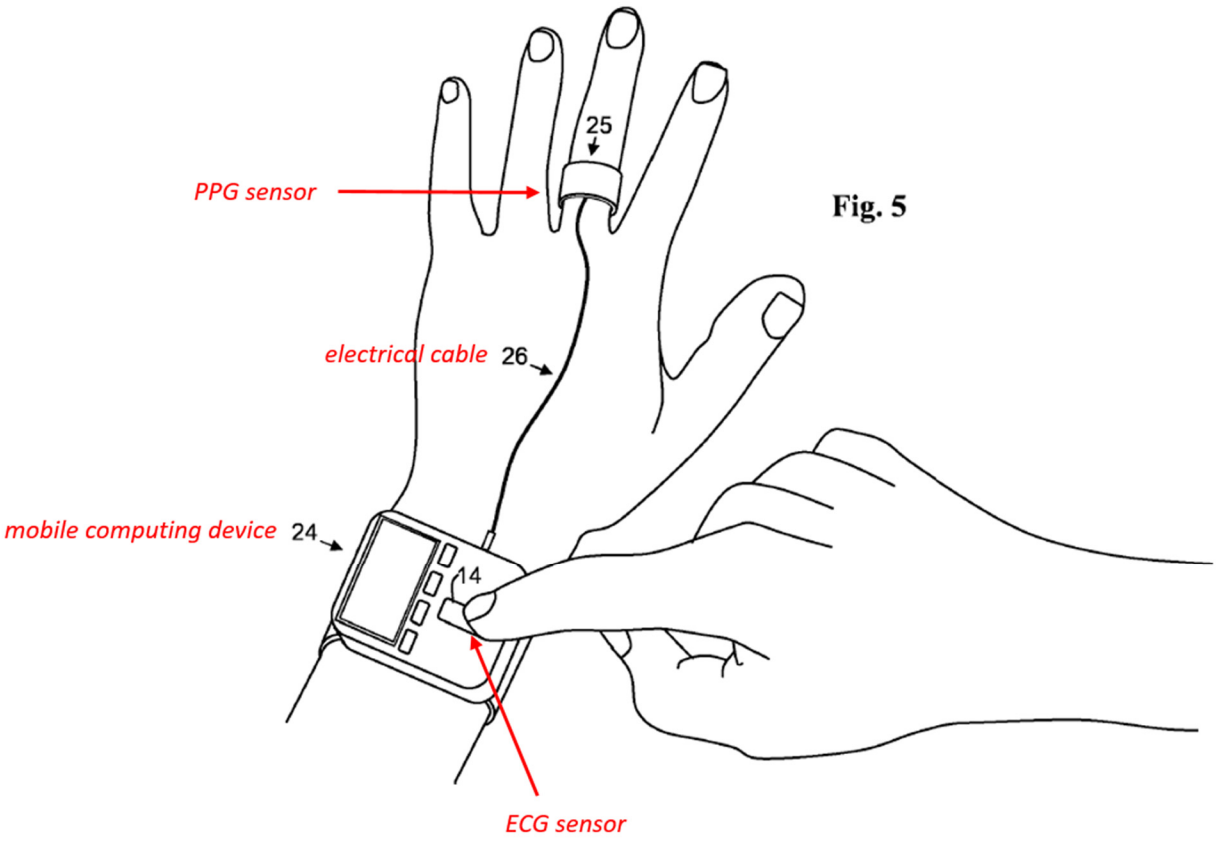
97. A POSITA would have understood that Shmueli's device is configured to transmit heart rate data from the PPG sensor to a mobile computing device (wrist-worn device), which is configured to sense an ECG. This is consistent with AliveCor's infringement contentions regarding this limitation, which cover transmission of a heart rate from a sensor to an electrical device to which the sensor is attached. APPLE-1037, pp. 2-3.

1.2	transmitting said heart rate of said first user to a mobile computing device, wherein said mobile	The Accused Products transmit the rate of said first user to a mobile computing device, wherein said mobile computing device is configured to sense an electrocardiogram. For example, Apple's documentation states,

	computing device is configured to sense an electrocardiogram;	How to check your heart rate You can check your heart rate any time using the Heart Rate app. Open the app, then wait for Apple Watch to measure your heart rate. You can also view https://support.apple.com/en-us/HT204666. The Accused Products are configured to sense an electrocardiogram of the user. As Apple states, "The ECG app can record your heartbeat and rhythm using the electrical heart sensor on Apple Watch Series 4, Series 5, or Series 6 and then check the recording for atrial fibrillation (AFib), a form of irregular rhythm." https://support.apple.com/en-us/HT208955.

APPLE-1037, pp. 2-3.

98. Shmueli further discloses that the oximetry (PPG) sensor can be mounted on the inner side of a ring or a clip worn on a finger of the hand wearing the heart monitoring device. APPLE-1004, 9:20-22 ("It is further appreciated that the oximetry (SpO2) measuring unit can be mounted on the inner side of a ring or a clip worn on a finger of the hand wearing the heart monitoring device 10."). As shown in Fig. 5 below, the PPG measuring unit (i.e., heart rate sensor) is connected to Shmueli's wrist-worn device (e.g., mobile computing device) through an electrical cable 26. APPLE-1004, Fig. 5 and 10:28-11:2 ("As seen, the wrist-mounted heart monitoring device 24 of Fig. 5 includes the oximeter (not shown) mounted inside a ring 25 warn on a finger of the hand wearing the heart monitoring device 24. ***The oximeter in the ring 24 is preferably connected to the heart monitoring device 24, preferably by an electrical cable 26***."). As shown in Fig. 5, A POSITA would have understood that Shmueli's device is configured to transmit, through the cable 26, heart rate data from the oximetry (PPG) sensor to a mobile computing device (wrist-worn device), which is configured to sense an ECG.

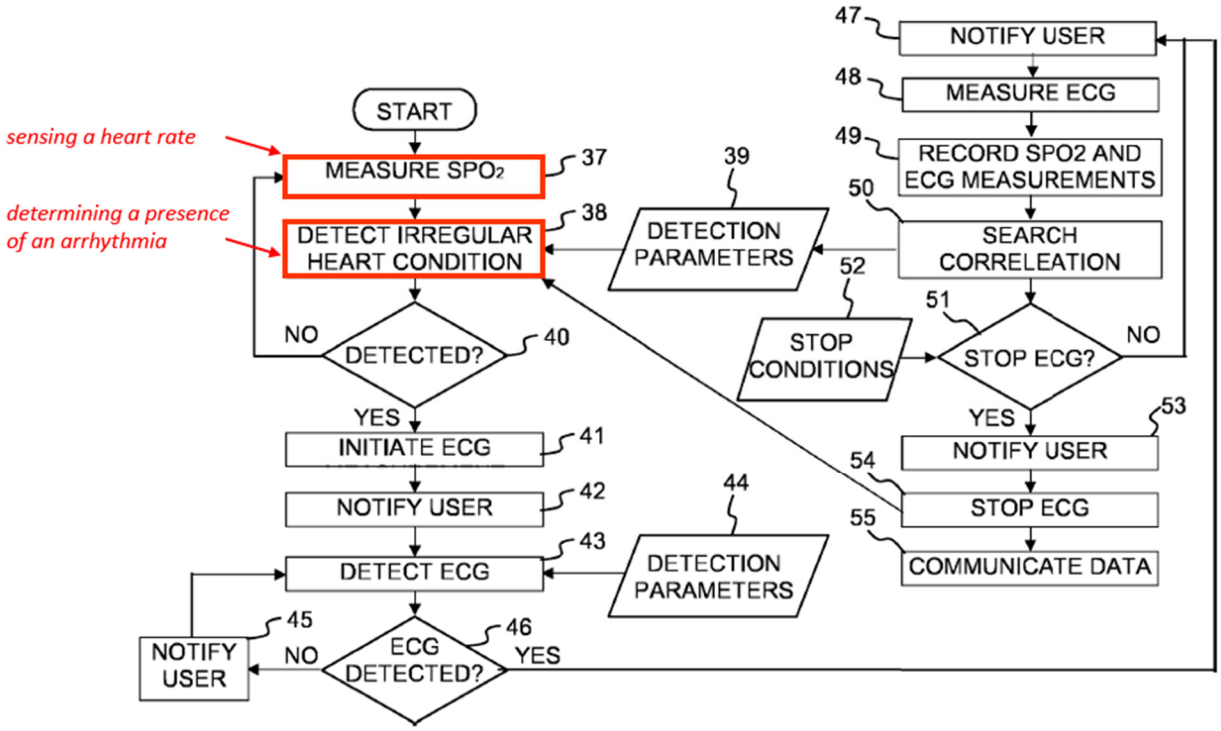


APPLE-1004, Fig. 5 (annotated).

99. Shmueli's Fig. 7 provides a flow chart of a software program executed by this "mobile computing device." APPLE-1004, 12:6-8 ("Reference is now made to Fig. 7, which is a simplified flow chart of a ***software program preferably executed by the processor 29*** of the wrist-mounted heart monitoring device according to a preferred embodiment of the present invention."). As shown in Fig. 7, the software program "starts in element 37 by measuring SpO2" and then "proceeds to element 38 to derive from the SpO2 measurement physiological parameters" and "to detect various irregularities of the heart condition." APPLE-

1004, 12:9-17 ("The software program proceeds to ***element 38 to derive from the SpO2 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 scanning for an irregular heart condition preferably uses heart-irregularity detection parameters (element 39) stored in the memory unit 28. When an irregular heart condition is detected (element 40) the software program continues to element 41. However, the SpO2 measurement (element 37) preferably continues and optionally also the derivation of physiological parameters as well as the detection of irregular heart conditions (element 38).").

Fig. 7



APPLE-1004, Fig. 7 (annotated)

100. As shown above in Fig. 5, the PPG sensor is connected to the wrist-worn mobile computing device through an electrical cable. A POSITA would have understood that element 38 in Fig. 7 results in transmission of the heart rate data from the PPG sensor to the wrist-worn mobile computing device in order for the mobile computing device (using its memory and processor) to detect irregular heart conditions based on the heart rate data from PPG sensor. APPLE-1004, Fig. 7.

101. Figure 1B shows another embodiment of this same configuration where the PPG sensor is integrated into the wrist-worn device. A POSITA would have understood that the PPG sensor in Figure 1 is likewise connected to the computing device through connections housed inside the wrist-worn device.

102. As discussed in Section XI.A (above), in the Shmueli-Osorio 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. The heart rate information is transmitted to the combined device to determine the current HRV. Then, the combined device determines the current HRV based on the heart rate information, determines the non-pathological HRV range based on the user's activity level, and compares the current HRV to the non-pathological HRV range to determine an irregularity, as taught by Osorio. APPLE-1005, Fig. 8 and [0077]-[0080]; APPLE-1010, [0042]-[0050]. Once an irregularity is detected in the

Shmueli-Osorio combination, the user is notified to take an ECG at the wrist-worn device, which is configured to sense an ECG, as described by Shmueli. APPLE-1004, Abstract ("The method including the steps of: continuously measuring SpO2 at the wrist of the user, detecting an irregular heart condition from the SpO2 measurement, ***notifying the user to perform an ECG measurement***, and initiating the ECG measurement at least partially at the wrist."), 12:23-13:9, and Fig. 7. Thus, the Shmueli-Osorio combination renders obvious [1.2].

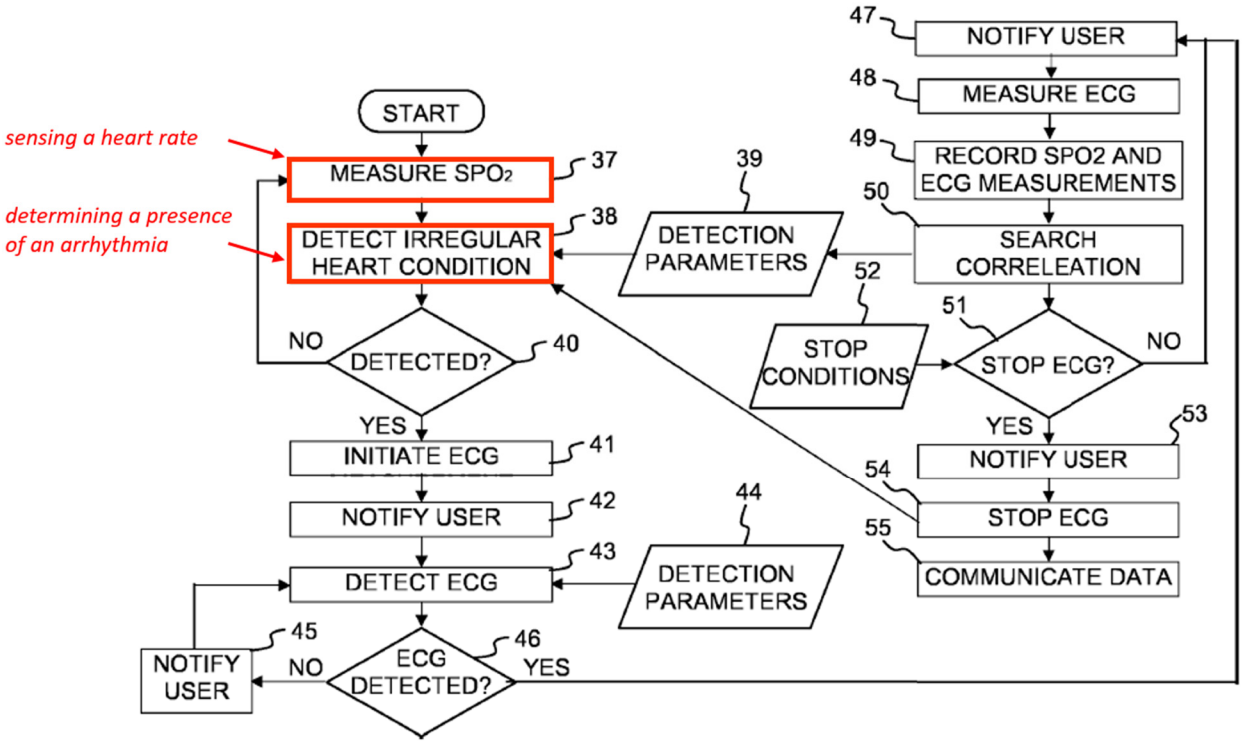
[1.3] determining, using said mobile computing device, a heart rate variability of said first user based on said heart rate of said first user;

103. It is my opinion that the Shmueli-Osorio combination renders obvious element [1.3].

104. As discussed above for element [1.2], Shmueli's device includes a mobile computing device that executes the software program in Fig. 7. As shown in Fig. 7 below, the software program "starts in element 37 by measuring SpO2" and then "proceeds to element 38 to derive from the SpO2 measurement **physiological parameters such as pulse rate**, pulse amplitude, pulse shape, rate of blood flow, etc." and "to detect various irregularities of the heart condition." APPLE-1004, 12:9-17 ("The software program proceeds to ***element 38 to derive from the SpO2 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 scanning for an irregular heart condition preferably uses heart-irregularity detection parameters (element 39) stored in the memory unit 28. When an irregular heart condition is detected (element 40) the software program continues to element 41. However, the SpO2 measurement (element 37) preferably continues and optionally also the derivation of physiological parameters as well as the detection of irregular heart conditions (element 38).").

Fig. 7



APPLE-1004, Fig. 7 (annotated).

105. As discussed for element [1.1], the PPG sensor is a "heart rate monitor" within the meaning of the '499 patent that detects heart rate of the user. Thus, in element 38, Shmueli's method derives the user's heart rate from the SpO2

measurement in element 37. A POSITA 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. HRV analysis is an important tool in cardiology used to help diagnose various types of arrhythmia. APPLE-1012, Abstract; pp. 95-96 ("Therefore, HRV analysis became a critical tool in cardiology for the diagnosis of heart diseases."). In addition, a POSITA would have been motivated to determine HRV based on heart rate data because, although certain types of arrhythmias (e.g., tachycardia or bradycardia) can be detected by absolute heart rate values, diagnosis of other types of arrhythmias (e.g., atrial fibrillation, one of the most common cardiac arrhythmia) requires HRV analysis. As a hypothetical example, if only heart rate were measured, a patient in atrial fibrillation with a heart rate between 60-100 bpm (normal range) would not be detected unless a method such as HRV analysis was used to assess R-R interval variation. By the Critical Date, it was well-known that HRV can be accurately derived from heart rate sensed using either PPG or ECG data. APPLE-1013, Abstract ("Our results demonstrate that the parameters of PPGV are highly correlated with the parameters of HRV."); APPLE-1014, Abstract ("HRV can also be reliably estimated from the PPG based PP interval method."); APPLE-1015, Abstract ("Our results confirm that PPG provides accurate interpulse intervals from which HRV measures can be

accurately derived in healthy subjects under ideal conditions, suggesting this technique may prove a practical alternative to ECG for HRV analysis."). Thus, while Shmueli does not provide a detailed disclosure of how to detect irregular heart conditions (e.g., arrhythmia) based on heart rate sensed using the PPG sensor, a POSITA would have known how and found it obvious to use Shmueli's wrist-worn device to determine HRV from the sensed heart rate in order to detect the irregular heart condition (e.g., arrhythmia) based on their knowledge, training, and experience in the field as of the Critical Date.

106. In addition, Osorio also discloses determining HRV from the sensed heart rate from the heart rate sensor. APPLE-1005, Fig. 1, [0033], [0042] ("The body index may be heart rate (instantaneous or in a short-term or long-term time window), heart rate rhythm, ***heart rate variability…***"), [0043] ("The current BDV module 265 may be configured to determine at least one ***body data variability*** selected from a heart rhythm variability, ***a heart rate variability (HRV)…***"), [0053] ("For example, the current BDV module 265 may comprise an HRV module 310 configured to ***determine HRV from heart rate data***.") and [0080] ("***the body index value may be heart rate and the BDV may be HRV***."); APPLE-1010, [0035] ("For example, the body data variability module 165 may comprise an HRV module 310 configured ***to determine HRV from heart rate data***."). As shown below in Fig. 1, Osorio discloses determining a body index at a body index

determination module 280 based on a body signal from a body signal sensor 282, and then determining a current BDV at a current BDV module 265 based on the body index. APPLE-1005, Fig. 1, [0033], [0042] ("The body index may be ***heart rate*** (instantaneous or in a short-term or long-term time window), heart rate rhythm, ***heart rate variability…***") and [0043] ("The current BDV module 265 may be configured to determine at least one ***body data variability*** selected from a heart rhythm variability, ***a heart rate variability (HRV)…***"). Osorio discloses that the body index value may be heart rate and the BDV value may be HRV. APPLE-1005, [0080] ("***the body index value may be heart rate and the BDV may be HRV***."); APPLE-1010, [0035] ("For example, the body data variability module 165 may comprise an HRV module 310 configured ***to determine HRV from heart rate data***."). Osorio also discloses "the current BDV module 265 may comprise a **HRV module 310 configured to determine HRV from heart rate data**." APPLE-1005, [0053] ("For example, the current BDV module 265 may comprise an HRV module 310 configured to ***determine HRV from heart rate data***."). Thus, Osorio discloses determining HRV from the sensed heart rate from the heart rate sensor.

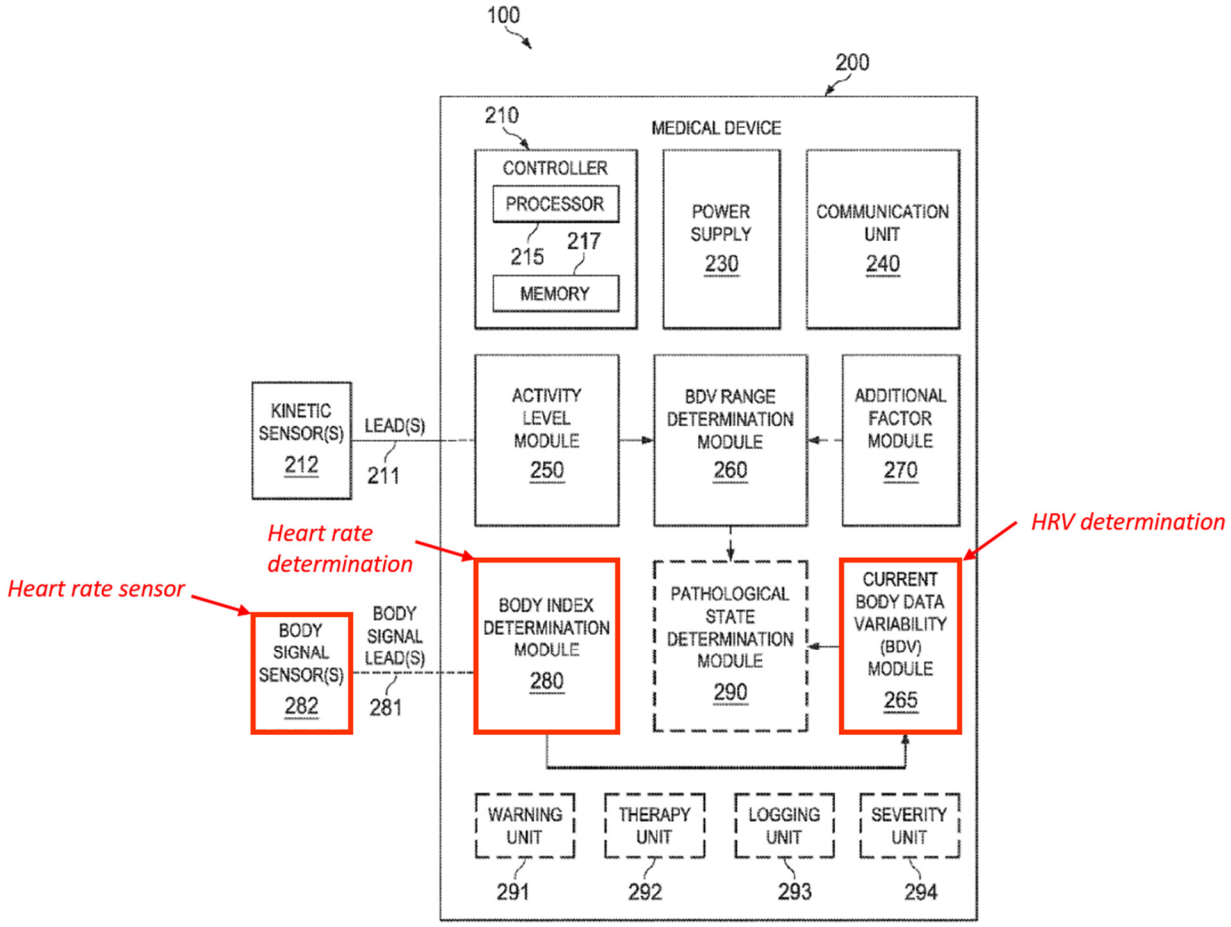


FIG. 1

APPLE-1005, Fig. 1 (annotated).

107. As discussed in Section XI.A (above), in the Shmueli-Osorio 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. The combined device (e.g., Shmueli's wrist-worn device modified to perform Osorio's activity level and HRV analysis) then ***determines current HRV based on the heart rate information***, determines the non-pathological HRV range based on the user's activity level, and compares the HRV to the non-pathological HRV range to

determine if there is an irregularity, as taught by Osorio. APPLE-1005, Fig. 8 and [0077]-[0080]; APPLE-1010, [0042]-[0050]. Thus, the Shmueli-Osorio combination renders obvious [1.3].

[1.4] sensing an activity level of said first user with a motion sensor;

108. It is my opinion that the Shmueli-Osorio combination renders obvious element [1.4].

109. As discussed above in Section XI.A (above), a POSITA would have been motivated to add Osorio's motion sensor and activity level analysis to Shmueli's device because Osorio teaches that considering activity level improves detection of a pathological condition (e.g., arrhythmia) based on heart rate. APPLE-1005, [0029] ("This disclosure recognizes that to determine (using body systems and their features) whether a body system is functioning pathologically or non-pathologically with a clinically worthwhile degree of accuracy and reliability, ***one must take into account the type and/or level of activity being performed*** by a subject at the time the pathological/non-pathological determination is made.").

110. Osorio discloses monitoring the user's activity level using a kinetic sensor. APPLE-1005, Abstract, [0003]-[0006] and [0028] ("a medical device capable of monitoring an ***activity type and/or level*** of a patient and dynamically determining a non-pathological BDV range based upon an activity type and/or level of the patient. … ***An activity level or state (e.g., awake or asleep)*** of the

patient may in some embodiments be determined from a ***kinetic sensor such as an accelerometer***."), [0033] (discussing an activity sensor 212), [0057] ("Fig. 4A shows a dynamic relationship between non-pathological patient ***activity levels (e.g., as determined from a tri-axial accelerometer)*** and an exemplary ***body data and BDV (e.g., heart rate and HRV***)."), [0061] and Fig. 1; APPLE-1010, [0025]-[0026] ("The medical device 200 may comprise at least one ***activity level sensor(s)*** 114, each configured to collect at least one body signal from a patient relating to an activity level of the patient. For example, each activity level sensor(s) 114 may be selected from an ***accelerometer***…") and [0045]-[0050] ("In some embodiments, the method 700 may further comprise ***determining an activity level*** of the patient (not shown). In some embodiments, determining the activity level may comprise determining a kinetic index from an output of at least one of an ***accelerometer***…").

111. A POSITA would have understood that Osorio's "kinetic sensor" (e.g., accelerometer) is a motion sensor within the meaning of the '499 patent. For example, the '499 patent discloses "[a]n 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**." APPLE-1001, 25:19-22. Thus, as shown in Fig. 1 below, Osorio discloses a motion sensor.

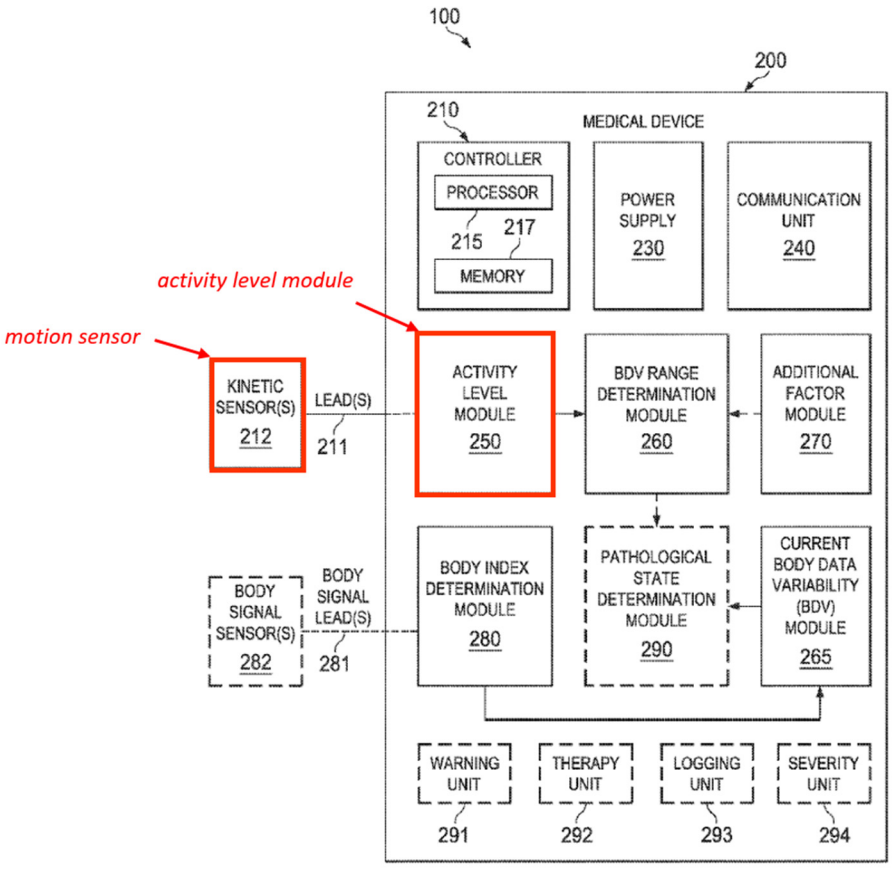


FIG. 1

APPLE-1005, Fig. 1 (annotated). *See also*, APPLE-1010, Fig. 1.

112. Osorio also discloses sensing an activity level using the activity level module. APPLE-1005, [0035]-[0036] (discussing an "***activity level module 250***, configured to determine an activity type and/or level of the patient, based on at least in part on body signal data collected by activity sensor(s) 212."); APPLE-1010, [0025]-[0026] ("The medical device 200 may comprise an ***activity level module 180***, configured to determine an activity level from a body signal collected by activity level sensor(s) 114.") and [0045]-[0050] ("In some embodiments, the

method 700 may further comprise ***determining an activity level*** of the patient (not shown).”). Osorio “recognizes that to determine (using body systems and their features) whether a body system is functioning pathologically or non-pathologically with a ***clinically worthwhile degree of accuracy and reliability***, one must take into account ***the type and/or level of activity being performed by a subject*** at the time the pathological/non-pathological determination is made.” APPLE-1005, [0029]. As Osorio explains, “it is imperative to know whether or not ***a given increase in heart rate is associated with a change in activity*** (e.g., physical or emotional) and if such a change in activity is occurring, to determine ***if the heart rate increase is commensurate with said activity type and level***.” *Id.* Thus, Osorio discloses sensing an activity level of said first user with a motion sensor.As discussed in Section XI.A (above), in the Shmueli-Osorio 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, determines the non-pathological HRV range based on the user’s activity level and compares the HRV to the non-pathological HRV range to determine if there is an irregularity, as taught by Osorio. APPLE-1005, Fig. 8 and [0077]-[0080]; APPLE-1010, [0042]-[0050]. Thus, the Shmueli-Osorio combination renders obvious [1.4].

[1.5] comparing, using said mobile computing device, said heart rate variability of said first user to said activity level of said first user; and

113. It is my opinion that the Shmueli-Osorio combination renders obvious element [1.5].

114. As discussed above in Section XI.A (above), a POSITA would have been motivated to add Osorio's motion sensor and activity level analysis to Shmueli's device because Osorio teaches that considering activity level improves detection of a pathological condition (e.g., arrhythmia) based on heart rate. APPLE-1005, [0029] ("This disclosure recognizes that to determine (using body systems and their features) whether a body system is functioning pathologically or non-pathologically with a clinically worthwhile degree of accuracy and reliability, ***one must take into account the type and/or level of activity being performed*** by a subject at the time the pathological/non-pathological determination is made.").

115. FIG. 4A of Osorio shows a dynamic relationship between non-pathological patient activity levels and an exemplary set of body data and BDV (heart rate and HRV). APPLE-1005, [0057] ("Fig. 4A shows a dynamic relationship between non-pathological patient ***activity levels (e.g., as determined from a tri-axial accelerometer)*** and an exemplary ***body data and BDV (e.g., heart rate and HRV***)."). "The patient's ***activity level*** is shown on the x-axis, HR is on the y-axis, and ***HRV*** is represented by bars R1-R4." *Id*. Osorio discloses that this dynamic relationship between non-pathological HRVs and activity levels may be

exploited to detect pathological states, such as tachycardia, by "determining when the patient's HRV is incommensurate with the patient's activity level and/or heart rate." APPLE-1005, [0066] ("The dynamic relationship between non-pathological HRVs and activity levels may be exploited to detect pathological states such as epileptic seizures by determining when the patient's HRV is incommensurate with the patient's activity level and/or heart rate."); APPLE-1010, [0042]-[0050] ("If the patient's activity level is determined at 920 not to be commensurate with one or more of the time of day, the patient's body data, or with one or more body indices appropriate for determining a non-pathological state, the pathological statement be confirmed (930).").

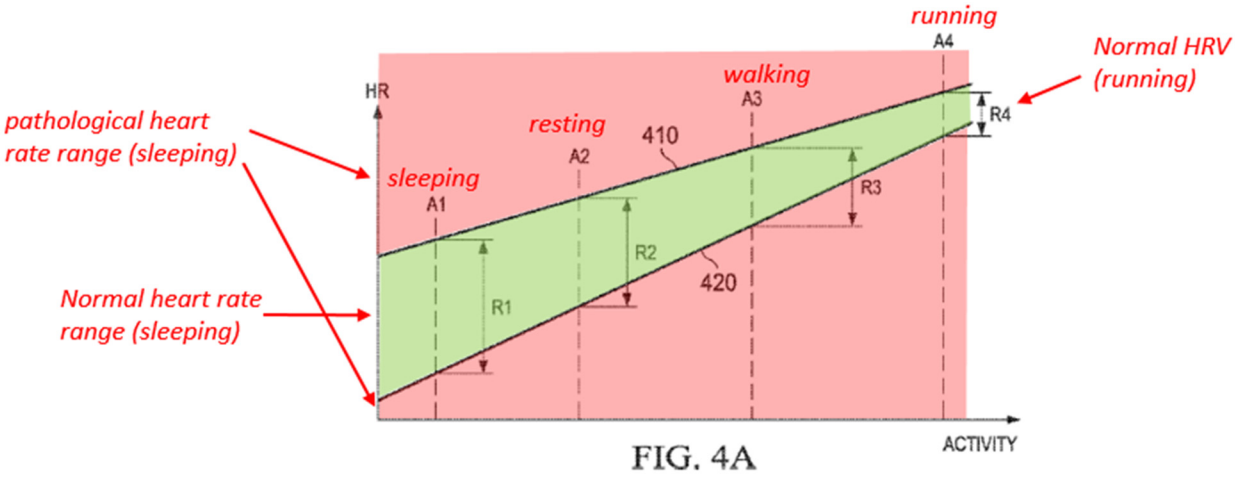


FIG. 4A

APPLE-1005, Fig. 4A (annotated).

116. Fig. 11 of Osorio shows an example of comparing the patient's HRV to the non-pathological ranges dynamically determined based on the activity level. As shown in Fig. 11, HRV values that fall below 0.5 bpm and above 4 bpm are

always pathological when activity level is low (e.g., resting or walking). APPLE-1005, [0091] ("FIG. 11 shows a conceptual depiction of pathological and non-pathological BDV (e.g., HRV) value ranges. ***Certain HRV ranges, such as below 0.5 bpm and above 4 bpm, are essentially always pathological*** when seen in patients having normal levels of physical fitness and either resting or engaged in mild activity (e.g., walking). ***Intermediate HRV ranges, such as from 0.5-4 bpm, may be pathological, or may be non-pathological***, depending on the kinetic and/or emotional/ cognitive activity levels of the patient."). Intermediate HRV values (0.5-4 bpm) may be pathological depending on the activity level of the patient. *Id*.

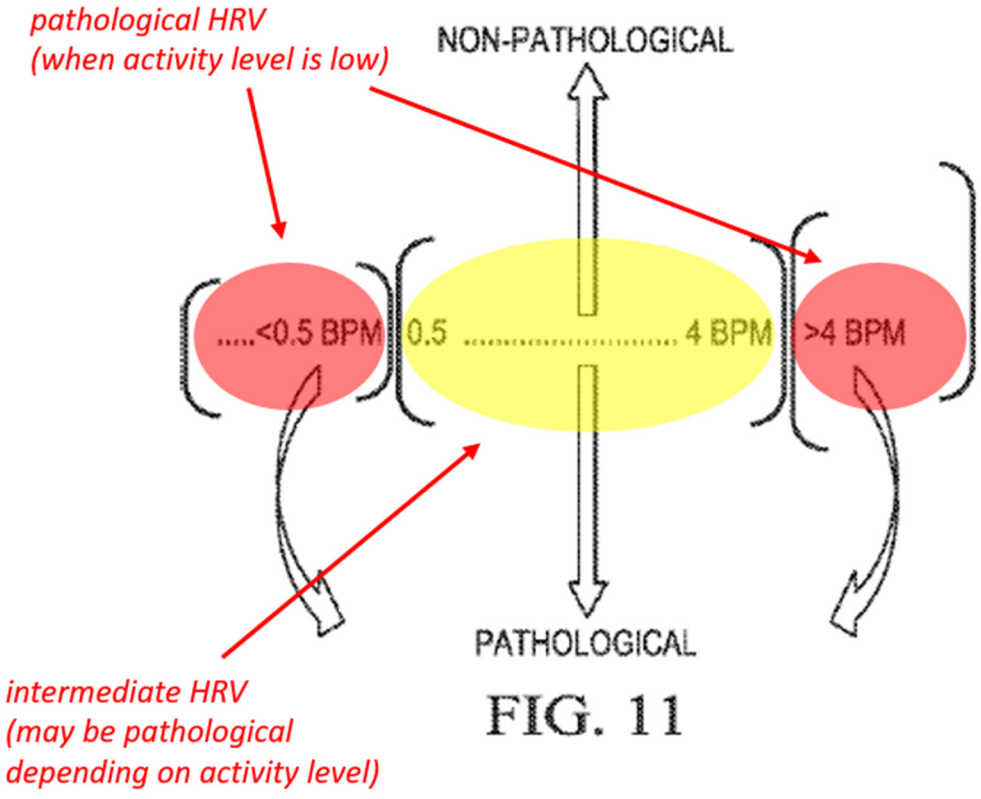


FIG. 11

APPLE-1005, Fig. 11 (annotated).

117. Osorio further discloses that the method in Fig. 8 below "may be governed by instructions that are stored in a non-transitory computer readable storage medium and that are executed by, e.g., a processor 217 of the medical device 200." APPLE-1005, [0095].

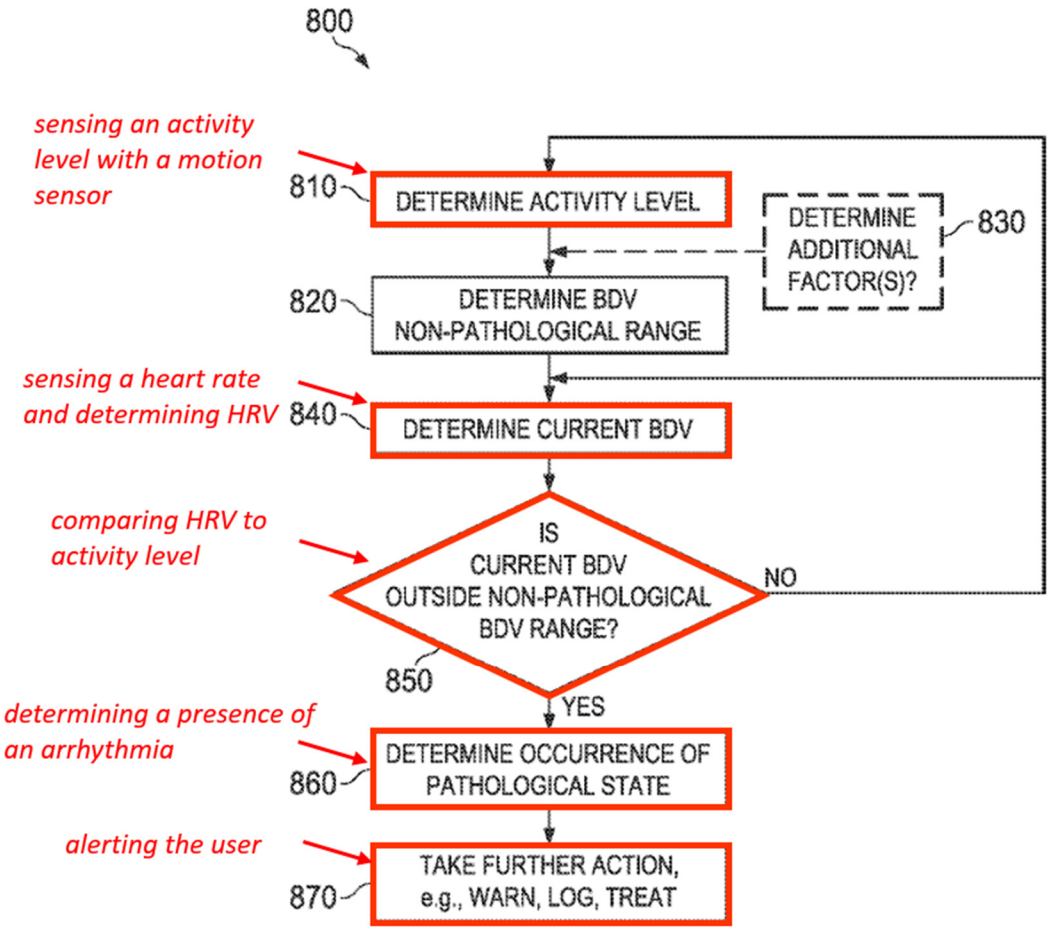


FIG. 8

APPLE-1005, Fig. 8 (annotated).

118. As shown in Fig. 8, an activity level is determined at 810, and a non-pathological BDV range (e.g., HRV range) is determined at 820, based on the activity level. APPLE-1005, [0077]. A current BDV (e.g., HRV) is determined at

840 and compared to the non-pathological BDV range. APPLE-1005, [0078]. If the current BDV is outside the non-pathological range, then a pathological state is determined at 860. APPLE-1005, [0078]. Osorio discloses "the body index value may be heart rate and the BDV value may be HRV." APPLE-1005, [0080] ("***the body index value may be heart rate and the BDV may be HRV***."); APPLE-1010, [0035] ("For example, the body data variability module 165 may comprise an HRV module 310 configured ***to determine HRV from heart rate data***."). Osorio also discloses: "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. APPLE-1005, [0066] ("The dynamic relationship between non-pathological HRVs and activity levels may be exploited to detect pathological states such as epileptic seizures by determining when the patient's HRV is incommensurate with the patient's activity level and/or heart rate."); APPLE-1010, [0042]-[0050] ("If the patient's activity level is determined at 920 not to be commensurate with one or more of the time of day, the patient's body data, or with one or more body indices appropriate for determining a non-pathological state, the pathological statement be confirmed (930).").

119. A POSITA would have understood that Osorio's method to detect arrhythmia involves "comparing" HRV to activity level within the meaning of the '499 patent. The '499 patent discloses that "[a]n advisory condition for

recording an ECG may occur due to, for example, large continuing fluctuations in heart rate" or "***when a measured heart rate increases rapidly without a corresponding increase in activity*** monitored by, for example, an accelerometer." APPLE-1001, 25:17-22. The '499 patent also discloses that, "[b]y comparing measured heart rate changes with measured activity changes, the presently disclosed software or 'app' minimizes false alarms." APPLE-1001, 25:22-25. Osorio uses the activity level in the same way to reduce false alarms. APPLE-1005, [0029] ("This disclosure recognizes that to determine (using body systems and their features) whether a body system is functioning pathologically or non-pathologically with a clinically worthwhile degree of accuracy and reliability, ***one must take into account the type and/or level of activity being performed*** by a subject at the time the pathological/non-pathological determination is made.") and [0036] ("false negative and false positive detection of pathological events may be reduced by dynamically determining pathological or non-pathological ranges for particular body indices based on ***activity type and level***").

120. In addition, Osorio also discloses in Fig. 12 a method that involves comparing HRV to activity level to determine "whether the patient's ***activity level*** is commensurate with the ***BDV***." APPLE-1005, [0092] ("A non-pathological BDV range value may be determined (e.g., from patient data, and taken into account an assumed activity level of the patient) at 1210, and a current BDV may be

determined at 1215. If the BDV is found to be inside the non-pathological range at 1220, flow returns to 1210. If the BDV value is found to be outside the range at 1220, then a determination may be made at 1230 whether the patient's activity level is commensurate with the BDV. If the activity level is commensurate, then the non-pathological BDV range may be (re)determined at 1210. If the activity level is not commensurate with the current BDV, then a detection of a pathological state may be issued at 1250, with flow then returning to 1215."). Osorio discloses "the body index value may be heart rate and the BDV value may be ***HRV***." APPLE-1005, [0080] ("***the body index value may be heart rate and the BDV may be HRV***."); APPLE-1010, [0035] ("For example, the body data variability module 165 may comprise an HRV module 310 configured ***to determine HRV from heart rate data***."). As shown in Fig. 12, the device determines a nonpathological BDV (e.g., HRV) range based on an assumed activity level at 1210, and determines a current BDV (e.g., HRV) at 1215. APPLE-1005, [0092]. If the BDV (e.g., HRV) is found to be outside the non-pathological BDV range at 1220, then a determination is made at 1230 on "whether the patient's ***activity level*** is commensurate with the ***BDV***." *Id*. If the activity level is not commensurate with the current BDV (e.g., HRV), then a detection of a pathological state is issued at 1250. *Id*.

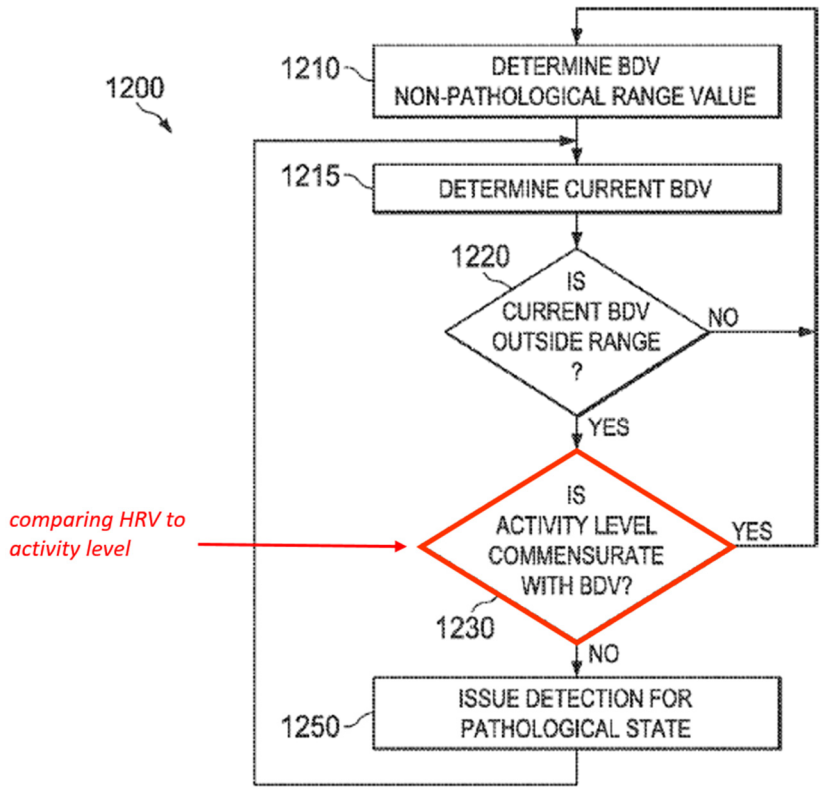


FIG. 12

APPLE-1005, Fig. 12 (annotated). A POSITA would have understood that Osorio's method in Fig. 12 involves "comparing" HRV to activity level within the meaning of the '499 patent. Indeed, a POSITA would have understood and found obvious that Osorio's comparison of HRV to an HRV range that corresponds to actvity level is a compariosn of HRV to activity level because it compares whether the HRV measurement is commensuate with the activity level.

121. Correspondingly, Osorio Provisional also discloses determining the user's activity level and determine whether the activity level is commensurate with the body data. APPLE-1010, [0042]-[0050] ("If the patient's activity level is

determined at 920 not to be commensurate with one or more of the time of day, the patient's body data, or with one or more body indices appropriate for determining a non-pathological state, the pathological statement be confirmed (930).”)..

122. As discussed in Section XI.A (above), in the Shmueli-Osorio 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. The combined device then determines current HRV based on the heart rate information, determines the non-pathological HRV range based on the user’s activity level, and ***compares the HRV to the non-pathological HRV range*** to determine if there is an irregularity, as taught by Osorio. APPLE-1005, Fig. 8 and [0077]-[0080]; APPLE-1010, [0042]-[0050]. Thus, the Shmueli-Osorio combination renders obvious [1.5].

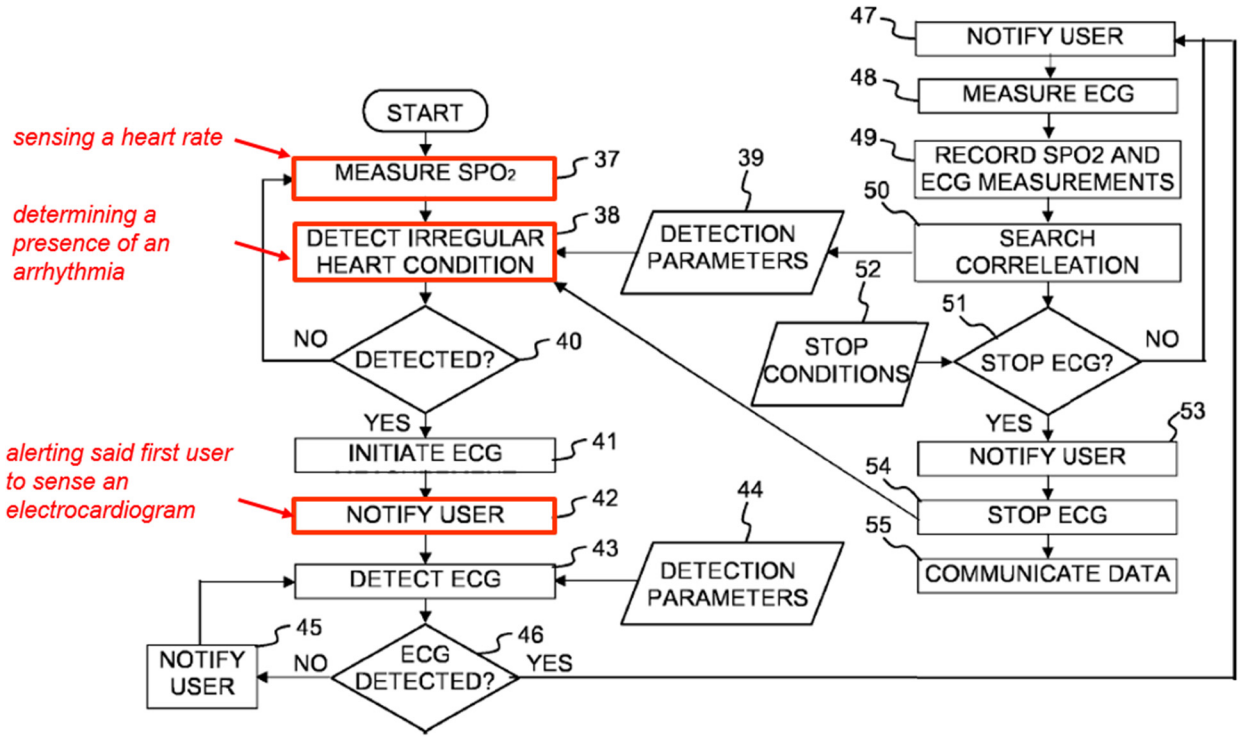
[1.6] alerting said first user to sense an electrocardiogram of said first user, using said mobile computing device, in response to an irregularity in said heart rate variability of said first user.

123. It is my opinion that the Shmueli-Osorio combination renders obvious element [1.6].

124. As discussed above in Section III.A.1, Shmueli’s method first detects arrhythmia based on the SpO2 measurement, which is also known as PPG or pulse oximetry. APPLE-1004, Abstract (“The method including the steps of: ***continuously measuring SpO2*** at the wrist of the user, detecting an irregular heart condition from the SpO2 measurement, notifying the user to perform an ECG

measurement, and ***initiating the ECG measurement*** at least partially at the wrist."). If the SpO2 measurement indicates an irregular heart condition, Shmueli's method then notifies the user to take an ECG measurement to confirm the diagnosis. *Id*. Fig. 7 is an example of Shmueli's method:

Fig. 7



APPLE-1004, Fig. 7 (annotated). As Fig. 7 shows, Shmueli's method measures SpO2 (element 37) and detects an irregular heart condition based on the PPG data (element 38). APPLE-1004, Fig. 7 and 12:6-30.

> Reference is now made to Fig. 7, which is a simplified flow chart of a software program preferably executed by the processor 29 of the wrist-mounted heart monitoring device according to a preferred embodiment of the present invention. ***As shown in Fig. 7, the software program starts in element 37 by measuring SpO2***. The element of measuring SpO2 (e.g. oxygen saturation in the blood). The SpO2 measurement is preferably executed continuously as long as the heart monitoring device

> is operative. Preferably, the SpO2 measurement is executed using the oximetry measuring unit 30 and the oximetry sensor 13. ***The software program proceeds to element 38 to derive from the SpO2 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 scanning for an irregular heart condition preferably uses heart-irregularity detection parameters (element 39) stored in the memory unit 28. When an irregular heart condition is detected (element 40) the software program continues to element 41. However, the SpO2 measurement (element 37) preferably continues and optionally also the derivation of physiological parameters as well as the detection of irregular heart conditions (element 38). ***In element 41 the software program preferably initiates ECG measurement, preferably by operating ECG measuring unit 31.*** The software program preferably proceeds to element 42 to notify the user to perform an ECG measurement, preferably making use of the ECG monitoring device as described and illustrated with reference to Figs. 3 and 4. The software program preferably proceeds to element 43 to detect and ECG signal. Preferably, determining that the ECG signal is present and appropriately detected by the ECG measuring unit 31 is made using ECG detection parameters (element 44) stored in the memory unit 28. The user is preferably notified (element 45) until an ECG signal is properly detected (element 46), in which case the software program proceeds to element 47 to notify the user that the ECG signal is detected.

APPLE-1004, 12:6-30. If an irregular heart condition is detected (element 40), the device initiates ECG measurement (element 41) and notifies the user to perform an ECG measurement (element 42), preferably using the ECG monitoring device in Figs. 3 and 4. *Id*. Shmueli further discloses this notification to the user to start the ECG measurement may be "visual and/or audible." APPLE-1004, 14:4-8 ("The notifications to the user, such as the various notifications to start the ECG measurement (element 42), notifications of ongoing ECG measurement (element

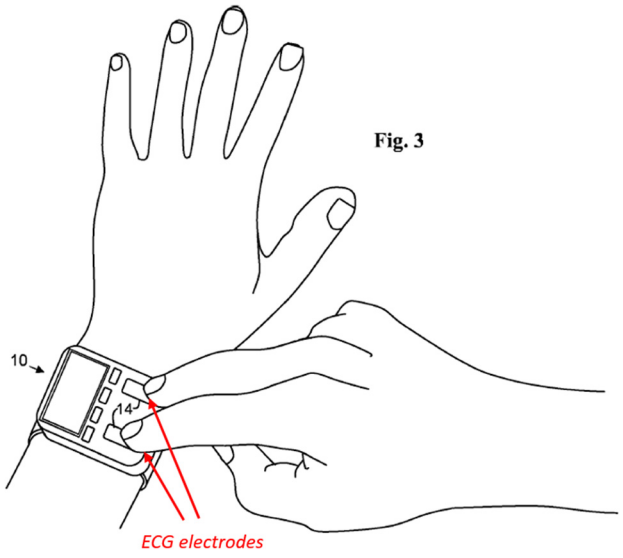
47), and notification that the ECG measurement has stopped (element 53) may be ***visual*** and/or audible, and/or ***graphic***, and/or textual, and/or using sound, and/or using speech, and/or using vibration, etc.").

125. As discussed above for element [1.3], although Shmueli does not specifically disclose how to detect irregular heart conditions (e.g., arrhythmia) based on heart rate sensed using the PPG sensor, a POSITA would have found it obvious to use Shmueli's wrist-worn device to determine HRV from the sensed heart rate in order to detect the irregular heart condition (e.g., arrhythmia). This is because HRV is a common physiological parameter derived from heart rate measurements to detect irregular heart conditions. HRV analysis is an important tool in cardiology used to help diagnose various types of arrhythmia. APPLE-1012, Abstract; pp. 95-96 ("Therefore, HRV analysis became a critical tool in cardiology for the diagnosis of heart diseases."). In addition, a POSITA would have been motivated to determine HRV based on heart rate data because, although certain types of arrhythmias (e.g., tachycardia or bradycardia) can be detected by absolute heart rate values, diagnosis of other types of arrhythmias (e.g., atrial fibrillation, one of the most common cardiac arrhythmia) requires HRV analysis. By the Critical Date, it was well-known that HRV can be accurately derived from heart rate sensed using either PPG or ECG data. APPLE-1013, Abstract ("Our results demonstrate that the parameters of PPGV are highly correlated with the parameters

of HRV."); APPLE-1014, Abstract ("HRV can also be reliably estimated from the PPG based PP interval method."); APPLE-1015, Abstract ("Our results confirm that PPG provides accurate interpulse intervals from which HRV measures can be accurately derived in healthy subjects under ideal conditions, suggesting this technique may prove a practical alternative to ECG for HRV analysis."). In addition, Osorio also discloses determining HRV from the sensed heart rate from the heart rate sensor. APPLE-1005, Fig. 1, [0033], [0042] ("The body index may be heart rate (instantaneous or in a short-term or long-term time window), heart rate rhythm, ***heart rate variability…***"), [0043] ("The current BDV module 265 may be configured to determine at least one ***body data variability*** selected from a heart rhythm variability, ***a heart rate variability (HRV)…***"), [0053] ("For example, the current BDV module 265 may comprise an HRV module 310 configured to ***determine HRV from heart rate data***.") and [0080] ("***the body index value may be heart rate and the BDV may be HRV***."); APPLE-1010, [0035] ("For example, the body data variability module 165 may comprise an HRV module 310 configured ***to determine HRV from heart rate data***."). Thus, in the Shmueli-Osorio combination, it would have been obvious that the combined device notifies the user to take an ECG measurement upon detection of an irregular heart condition based on an irregularity in HRV.

126. To implement Shmueli's method, Shmueli uses a wrist-worn device

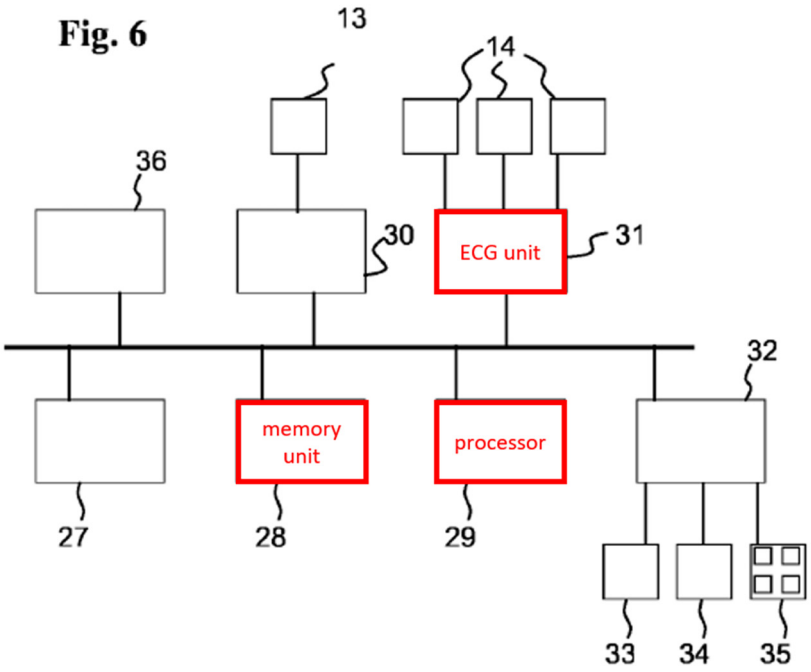
with a heart rate sensor (oximetry sensor for SpO2 measurement) and an ECG sensor (electrical contacts for ECG measurement). APPLE-1004, 4:1-9 (discussing a "wrist-mounted physiological parameters measuring device including: an SpO2 measuring unit," "an ECG measuring unit" and a "processor operative to control both the SpO2 measuring and the ECG measuring unit."), Figs. 3-6. As shown in Fig. 3 below, Shmueli's device contains an ECG sensor with ECG electrodes.



APPLE-1004, Fig. 3 (annotated).

127. As shown in Fig. 6 below, Shmueli's heart monitoring device includes "**a memory unit 28**, **a processor 29**," and "**an ECG measuring unit 31 with three ECG contact sensors 14**, a user interface unit 32 preferably containing output devices such as a **display 33** and a **sound producing device 34**." APPLE-1004, 11:10-15. A POSITA would have understood that Shmueli's wrist-worn device is a "mobile computing device" that is configured to sense an

electrocardiogram because it has a memory and a processor, coupled to an ECG measuring unit with three ECG contact sensors.



APPLE-1004, Fig.6 (annotated).

128. As discussed in Section XI.A (above), in the Shmueli-Osorio 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, determines the non-pathological HRV range based on the user's activity level, and compares the HRV to the non-pathological HRV range to determine if there is an irregularity, as taught by Osorio. APPLE-1005, Fig. 8 and [0077]-[0080]; APPLE-1010, [0042]-[0050]. Upon detection of arrhythmia based on HRV and activity

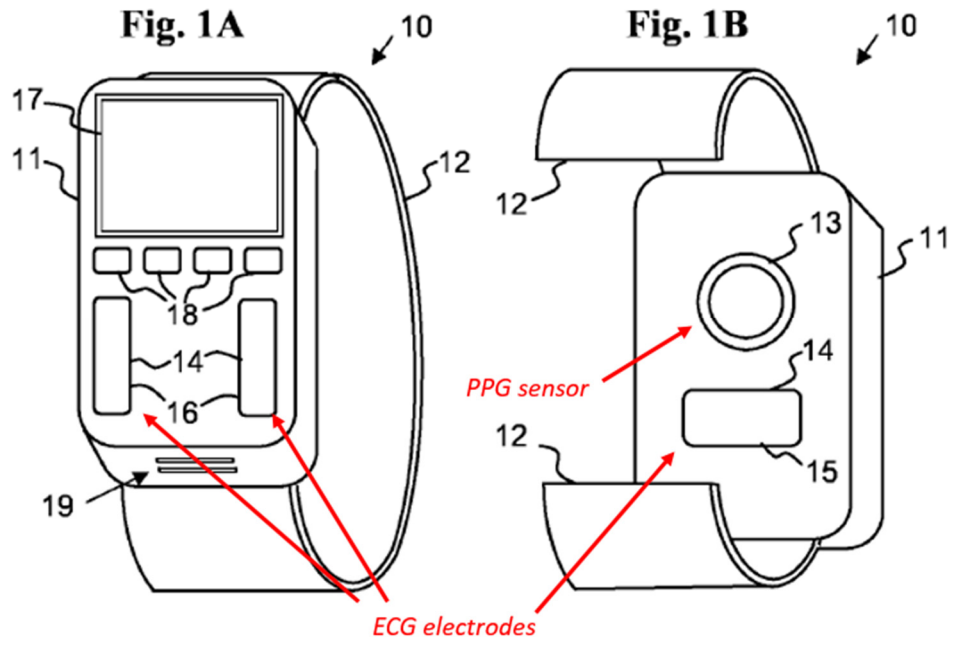
level, the combined device notifies the user to take an ECG measurement using Shmueli's ECG sensor. APPLE-1004, Fig. 7 and 12:6-30. Thus, the Shmueli-Osorio combination renders obvious [1.6].

C. Claim 2

[2.0] The method of claim 1, wherein said heart rate sensor comprises one or more of a patch, a wristband, and an armband.

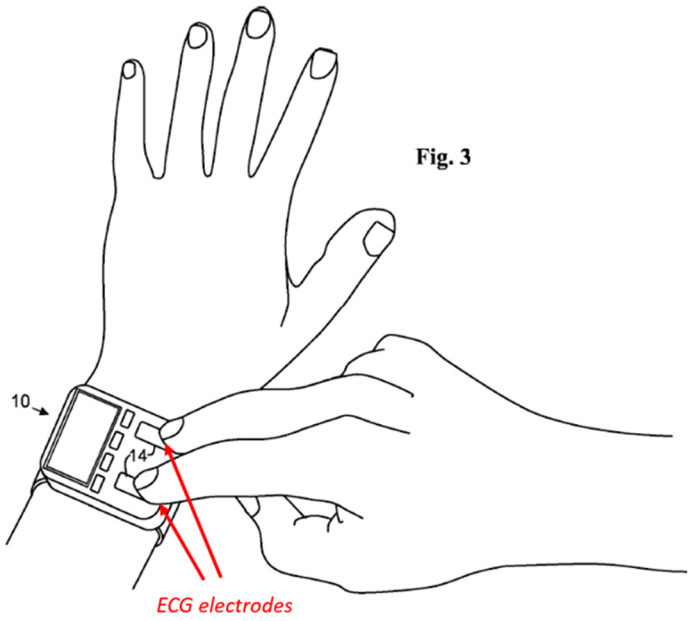
129. It is my opinion that the Shmueli-Osorio combination renders obvious element [2.0].

130. Like the '499 patent, Shmueli teaches a wrist-worn device with a heart rate sensor (oximetry sensor for SpO2 measurement) and an ECG sensor (electrical contacts for ECG measurement) under the control of a processor. *See* APPLE-1004, 4:1-9 (discussing a "wrist-mounted physiological parameters measuring device including: an SpO2 measuring unit," "an ECG measuring unit" and a "processor operative to control both the SpO2 measuring and the ECG measuring unit."). Figs. 1A and 1B illustrate an example of Shmueli's device.



APPLE-1004, Figs. 1A and 1B (annotated).

131. Fig. 3 of Shmueli shows an example of a user using the device of FIG. 1A/1B. It clearly shows that Shmueli's heart monitor device is a wristband.



APPLE-1004, Fig. 3 (annotated).

132. Shmueli's wrist-worn device includes a heart rate sensor that comprises a wristband in a manner similar to the examples described in the '499 patent. For example, the '499 patent describes "a wrist-worn computing device such as a Samsung Galaxy Gear Smart Watch" and a "wrist-worn biometric sensor," "such as those available from Fitbit … or a Nike FuelBand." APPLE-1001, 6:40-43; 7:6-13. These examples align with Shmueli's wrist-worn device that comprises a wristband and a heart rate sensor that attaches to the wristband to couple to a user's wrist.

133. Similarly, Osorio also discloses a body-worn device. APPLE-1005, [0060] ("Upper and lower non-pathological HR boundaries 430, 450 may be determined from patient population data and stored in a memory of an implantable or ***body-worn medical device***."). Thus, in the Shmueli-Osorio combination, it would have been obvious that the combined device is a wrist-worn device that includes a wristband as shown in Figs. 1A/1B and Fig. 3 above. Thus, the Shmueli-Osorio combination renders obvious [2.0].

D. Claim 3

[3.0] The method of claim 1, further comprising receiving biometric data of said first user from a biometric data sensor coupled to said first user.

134. It is my opinion that the Shmueli-Osorio combination renders obvious element [2.0].

135. The '499 patent generally describes the biometric data sensor as

including “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.” EX-1001, 4:48-52. The ’499 patent then describes the biometric data as including “an electrocardiogram (ECG), dietary information, stress level, **activity level**, gender, height, weight, age, body fat percentage, or blood pressure.” EX-1001, 4:57-61. Thus, both Shmueli’s PPG sensor and Osorio’s motion sensor are biometric data sensors within the meaning of the ’499 patent. Correspondingly, both the PPG data from Shmueli’s PPG sensor and the activity data from Osorio’s motion sensor are “biometric data” within the meaning of the ’499 patent.

136. As discussed for element [1.1], Shmueli discloses sensing a heart rate using Shmueli’s PPG sensor, which is coupled to the user through Shmueli’s wrist-worn device.

137. As discussed for element [1.4], the Shmueli-Osorio combination renders obvious sensing an activity level with a motion sensor (e.g., an accelerometer). As discussed in Section XI.A (above), in the Shmueli-Osorio combination, Shmueli is modified by incorporating Osorio’s motion sensor and activity level analysis. Thus, in the combined device, the motion sensor is also coupled to the user through Shmueli’s wrist-worn device.

138. As discussed in Section XI.A (above), in the Shmueli-Osorio combination, **Shmueli's PPG sensor** is used to determine heart rate information, and **Osorio's motion sensor** (e.g., an accelerometer) is used to determine the user's activity level. Then the combined device determines current HRV based on the heart rate information, determines the non-pathological HRV range based on the user's activity level and compares the HRV to the non-pathological HRV range to determine if there is an irregularity, as taught by Osorio. APPLE-1005, Fig. 8 and [0077]-[0080]; APPLE-1010, [0042]-[0050]. A POSITA would have understood that both Shmueli's PPG sensor and Osorio's motion sensor are biometric data sensors within the meaning of the '499 patent, and that the combined device receives biometric data from the PPG sensor and motion sensor coupled to the user. Thus, the Shmueli-Osorio combination renders obvious [3.0].

E. Claim 4

[4.0] 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.

139. It is my opinion that the Shmueli-Osorio combination renders obvious element [4.0].

140. As discussed in Section XI.A (above), in the Shmueli-Osorio combination, Shmueli is modified by incorporating Osorio's motion sensor and activity level analysis. Thus, in the combined device, the motion sensor is also

coupled to the user through Shmueli's wrist-worn device. Osorio discloses that its motion sensor can be an accelerometer. APPLE-1005, [0028] ("An activity level or state (e.g., awake or asleep) of the patient may in some embodiments be determined from a kinetic sensor such as an ***accelerometer***"); APPLE-1010, [0032] ("In one embodiment, the neurologic data acquisition unit 270 may contain a kinetic unit that may comprise an ***accelerometer***"). Similarly, the '499 patent also discloses a motion sensor in the form of an accelerometer. APPLE-1001, 25:5-9 ("For example, presently available smart watches include motion sensors such as pedometers. Pedometers can be based on an ***accelerometer***"). It was well-know that the accelerometer is an inertial sensor and measures motion based on inertial data. APPLE-1045, 1163 ("The basic principle of the ***accelerometer as an inertial sensor*** is very straightforward: the accelerometer measures acceleration and displacement is determined by double integrating the data."). Thus, a POSITA would have understood that Osorio's motion sensor measures "inertial data" within the meaning of the '499 patent.

141. As discussed in Section XI.A (above), in the Shmueli-Osorio combination, Shmueli's PPG sensor is used to determine heart rate information, and **Osorio's motion sensor** (e.g., an accelerometer) is used to determine the user's activity level. A POSITA would have understood that Osorio's motion sensor is a biometric data sensor within the meaning of the '499 patent, and that

the combined device receives biometric data in the form of inertial data from Osorio's motion sensor.. Thus, the Shmueli-Osorio combination renders obvious [3.0].

F. Claim 5

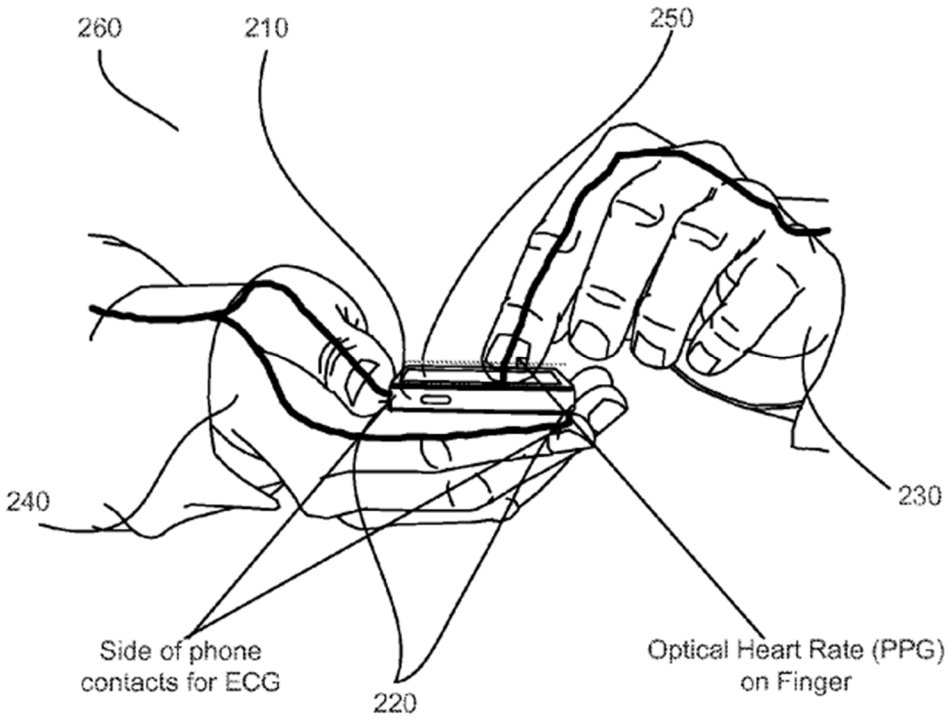
[5.0] The method of claim 1, wherein said mobile computing device comprises a smartphone.

142. It is my opinion that the Shmueli-Osorio combination renders obvious element [5.0].

143. Shmueli discloses "[a]lternatively, the wrist-mounted heart monitoring device may communicate with a gateway, such as a mobile gateway, such as a **cellular telephone**, that relays the data from the wrist-mounted heart monitoring device to the remote server." APPLE-1004, 14:19-21. A POSITA would have understood and found obvious that Shmueli's wrist-worn heart monitoring device may communicate with a smartphone because the majority of cell phones on the market were smartphones by 2013. APPLE-1043, p. 2 ("56% of American adults are now smartphone owners"). It would have been obvious to modify the wrist-mounted heart monitoring device so that it uses the processor and memory of a smartphone to carry out Shmueli's software program. A POSITA would have been motivated to modify Shmueli's device to use the processor and memory of a smartphone in order to simplify Shmueli's device.

144. A POSITA would also have had a reasonable expectation of success

to modify Shmueli's device to use the processor and memory of a smartphone. The concept of using a smartphone for heart rate monitoring was well-known at the Critical Date. For example, Martin discloses a smartphone connected to motion, PPG and ECG sensors that can detect motion sensor data, heart rate and HRV. *See* APPLE-1009, Figs. 2, 4 and 7, [0077] ("FIG. 7 is a flow diagram 700 illustrating a plurality of derived metrics 720 from a plurality of sensor metrics 710, according to some embodiments. The plurality of sensor metrics 710 may include, but is not limited to, PPG pulse measurement, accelerometer measurements, AC biometric impedance measurements, and 2-lead ECG heart rate measurements. These sensor metrics 710 may be obtained by taking measurements via the mobile device. Based on data from the sensor metrics 710, a plurality of derived metrics 720 may be derived. These derived metrics may include, but is not limited to, heart rate, heart rate variability, stress calculation, blood pressure, and hydration state") and [0099].



APPLE-1008, Fig. 2.

145. As discussed in Section XI.A (above), in the Shmueli-Osorio combination, Shmueli is modified by incorporating Osorio's motion sensor and activity level analysis. It would have been obvious that the mobile computing device in the Shmueli-Osorio combination can be a smartphone. Based on Shmueli's disclosure related to use of a cellular phone in conjunction with heart rate monitoring and a POSITA's general knowledge that cellular phones included smartphones by 2013 and that smartphones were used for heart rate monitoring by the Critical Date, it would have been obvious that the mobile computing device in the Shmueli-Osorio combination can be a smartphone that receives heart rate and motion sensor data and performs the operations identified in claim 1 as being

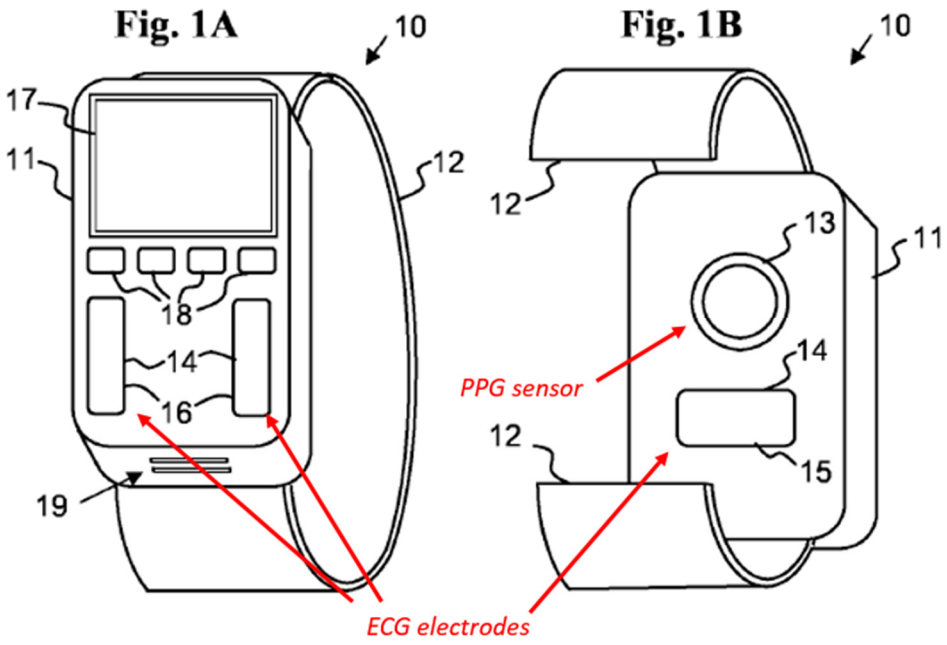
performed by the mobile computing device. Indeed, through Shmueli's disclosure of communication between its wrist-worn device and a cellular phone and a POSITA's general knowledge that smartphones often performed processing from wrist-worn devices (e.g., smartwatches), a POSITA would have found it obvious to use a smartphone to perform the operations described as being performed by Shmueli's wrist-worn computing device. Thus, the Shmueli-Osorio combination renders obvious [5.0].

G. Claim 6

[6.0] The method of claim 1, wherein said mobile computing device comprises a smartwatch.

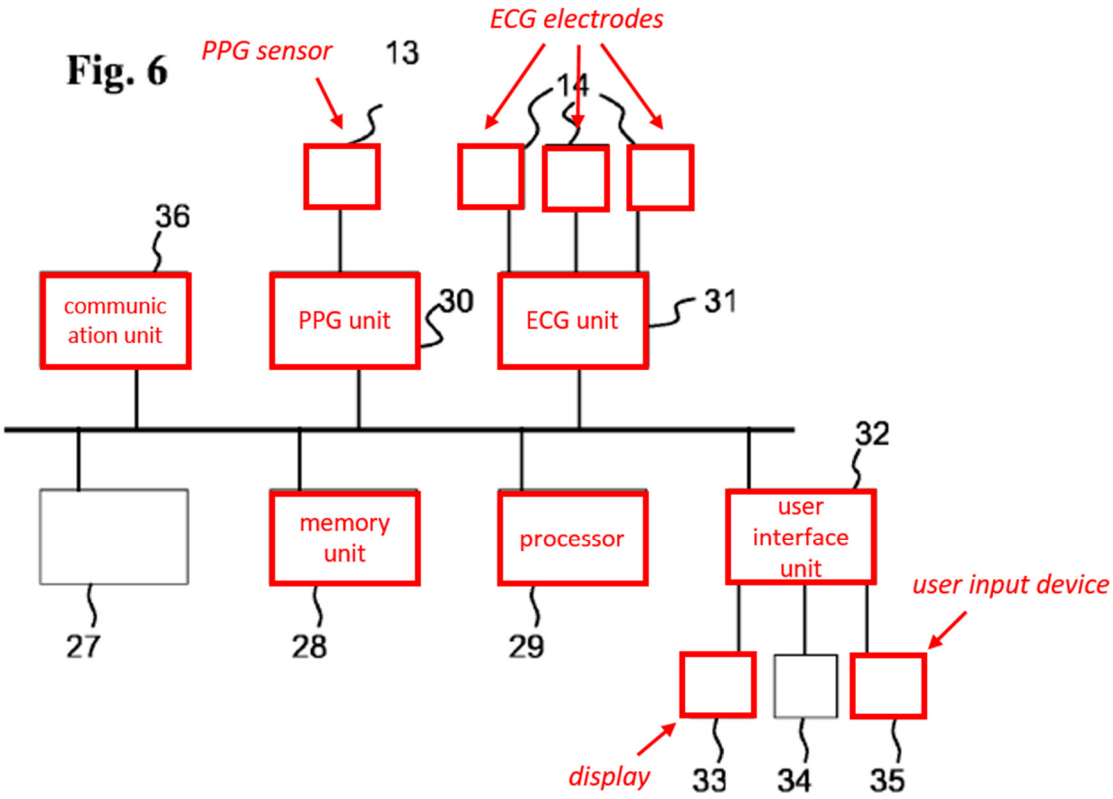
146. It is my opinion that the Shmueli-Osorio combination renders obvious element [6.0].

147. Figs. 1A and 1B illustrate an example of Shmueli's device.



APPLE-1004, Figs. 1A and 1B (annotated).

148. As shown in Fig. 6, Shmueli's device includes "a power supply unit such as a battery 27, a memory unit 28, a processor 29, an oximetry measuring unit 30 with the oximetry sensor 13, an ECG measuring unit 31 with three ECG contact sensors 14, a user interface unit 32 preferably containing output devices such as a display 33 and a sound producing device 34, and a user input device 35 for example including buttons, and optionally a communication unit 36." APPLE-1004, 11:10-15.



APPLE-1004, Fig. 6 (annotated). This is highly similar to the '499 patent's smartwatch that includes a heart rate monitor 1402, an activity monitor 1404, a processor coupled to a memory, an output device 1408. APPLE-1001, 24:58-25:4. Thus, a POSITA would have understood that Shmueli's mobile computing device is a "smartwatch" within the meaning of the '499 patent.

149. In addition, the concept of using a smartwatch for heart rate monitoring was well-known by the Critical Date and, to the extent Patent Owner argues that Shmueli's wrist-worn device is not a smartwatch, a POSITA would have found it obvious to implement Shmueli's wrist-worn device as a smartwatch. As early as 2000, there were commercial smart watch products that monitored

heart rate. APPLE-1044, p.7 ("Polar produces heart monitor watches (Smart Edge™, Beat™, Protrainer NV™, Lady Beat™, Target™, Pacer™).") and p. 8 (discussing the Casio VDU 200B™ watch with a touch screen). For example, Tran discloses a smartwatch that can detect arrhythmia with motion, PPG and ECG sensors. *See* APPLE-1007, Fig. 6A, [0280]-[0282], [0288], [0315], [0387]-[0389] and [0479]. Similarly, Yuen discloses a smartwatch that can detect heart rate with PPG and motion sensors. *See* APPLE-1008, Fig. 8, [0015], [0046] and [0182]. Yuen also discloses that the smartwatch includes various applications including a swimming app, bicycling app, a programmable or customizable watch face, stop watch, music player controller (e.g., mp3 player remote control), text message and/or email display or "notifier", navigational compass, bicycle computer display, weight lifting tracker, sit-up reps tracker, etc. APPLE-1008, [0180]-[0183]. Yuen also discloses that if a bluetooth-enabled smart phone comes within reach of the smartwatch, the smartwatch may transmit data to or receive data from the Internet through the smart phone's cell phone network. APPLE-1008, [0160]. As another example, Martin discloses a smartwatch with motion, PPG and ECG sensors that can be used to determine heart rate variability. APPLE-1009, Figs. 2-4, 7, [0067] and [0065] ("the multifunction button 320 may be integrated into a touch-screen of the wristwatch device 310"); APPLE-1054, [0021]. As discussed in an article published in 2000, there are various design options for the input device on the

smart watch including a keyboard, a touch-screen or a scrolling mechanism. APPLE-1044, p.8. The same article also indicates that the smart watch should include a user interface that allows for easy navigation between functions/applications including telling time, setting alarms, and personal information management (e.g., calendar, phone book, to dos). APPLE-1044, p.9. Known functions of a smart watch at the time included watch functions, personal information management (PIM) application (calendar, phone book, to dos), games, and an MP3 music player. APPLE-1004, p.10. Thus, a POSITA would have found it obvious to implement Shmueli's wrist-worn device in a smartwatch given the well-known nature of smartwatches and the visual and functional similarity between smartwatches and Shmueli's wrist-worn device.

150. Further, in a recently-filed Antitrust Complaint, AliveCor argues for a narrow definition of the term "smartwatch," alleging that a "smartwatch is a mobile computing device with a touchscreen display that is typically worn on the wrist." APPLE-1055, p.30. However, nothing in the '499 patent suggests that a smartwatch must have a touchscreen. Indeed, the '499 patent never uses the term "touchscreen" and does not describe a "touchscreen" as being a part of its example smartwatch. Apple-1001, 24:58-65 (describing smart watch 1400 as including heart rate monitor 1402, activity monitor 1404, and output device 1408). Moreover, as of the Critical Date, touchscreens were considered optional input

devices for smartwatches and there were smartwatches that did not employ a touchscreen. *See* APPLE-1044, p.7 (discussing the Polar smartwatches) and p.8 (discussing the RexPro 5-DS™ smartwatch). In fact, the relative size of a watch face and a human finger limited the number of distinguishable touch zones, and thus some smartwatches used other input devices, such as scrolling mechanisms. APPLE-1044, p.8. Thus, despite AliveCor's contentions in the Antitrust Complaint, no basis exists for limiting the claimed "smartwatch" to a device including a touchscreen. Nevertheless, even if the term "smartwatch" is construed narrowly to require a touchscreen, a POSITA would have found it obvious to use a touchscreen as the selected input device for the Shmueli-Osorio device. Specifically, a POSITA would have understood that a touchscreen was one of a few obvious input options for a smartwatch. APPLE-1009, [0065] ("the multifunction button 320 may be integrated into a touch-screen of the wristwatch device 310"); APPLE-1054, [0021]; APPLE-1044, p.8 (discussing the Casio VDU 200B™ watch with a touch screen). As evidenced by these references, a POSITA would have had the general knowledge that a touchscreen was an available input device for a watch device, like Shmueli's, and would have found it obvious to employ a touchscreen as the input device for the Shmueli-Osorio device. *Id.* AliveCor's Antitrust Complaint also alleges that a smartwatch has "the ability to use multiple types of apps and easily select between them." APPLE-1055, p.30.

Again, and similar to touchscreen, nothing in the ’499 patent suggests that a smartwatch must have this functionality. Indeed, the ’499 patent lacks disclosure of selecting among multiple types of apps and consistently refers only to a single “application.” Apple-1001, 2:35-40. Nevertheless, a POSITA would have found selection among multiple types of apps obvious to implement in the Shmueli-Osorio device based on a POSITA’s general knowledge of that type of functionality in smartwatches available as of the Critical Date. For example, Narayanaswami 2000 discloses that a smartwatch should include a user interface that allows for easy navigation between functions/applications including telling time, setting alarms, and personal information management (e.g., calendar, phone book, to dos). APPLE-1044, p.9. Yuen also discloses that the smartwatch includes various applications including a swimming app, bicycling app, a programmable or customizable watch face, stop watch, music player controller (e.g., mp3 player remote control), text message and/or email display or “notifier”, navigational compass, bicycle computer display, weight lifting tracker, sit-up reps tracker, etc. APPLE-1008, [0180]-[0183]. As evidenced by these references, a POSITA would have had the general knowledge that selection among multiple types of apps was well-known and would have found it obvious to employ in the Shmueli-Osorio device. Further, AliveCor’s Antitrust Complaint alleges that a smartwatch can act as an extension of a user’s smartphone. APPLE-1055, p.30. Although, again,

nothing in the ’499 patent suggests that this feature is required in a smartwatch, a POSITA would have found this feature obvious. For example, Shmueli discloses that the wrist-mounted heart monitoring device may communicate with a cell phone. APPLE-1004, 14:19-21. Yuen also discloses that if a Bluetooth-enabled smart phone comes within reach of the device, the device may transmit data to or receive data from the Internet through the smart phone's cell phone network. APPLE-1008, [0160]. Based on Shmueli’s disclosure and the knowledge of a POSITA that watch devices served as extensions of smartphones, a POSITA would have found it obvious that the Shmueli-Osorio device act as an extension of a user’s smartphone. As discussed in Section XI.A (above), in the Shmueli-Osorio combination, Shmueli’s smartwatch is modified by incorporating Osorio’s motion sensor and activity level analysis. Thus, the combined mobile computing device is still a smartwatch within the meaning of the ’499 patent. Thus, the Shmueli-Osorio combination renders obvious [5.0].

H. Claim 10

[10.0] 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.

151. It is my opinion that the Shmueli-Osorio combination renders obvious element [10.0].

152. FIG. 4A of Osorio shows a dynamic relationship between non-

pathological patient activity levels and an exemplary set of body data and BDV (heart rate and HRV). APPLE-1005, [0057] ("Fig. 4A shows a dynamic relationship between non-pathological patient ***activity levels (e.g., as determined from a tri-axial accelerometer)*** and an exemplary ***body data and BDV (e.g., heart rate and HRV***)."). The patient's activity level is shown on the x-axis, HR is on the y-axis, and HRV is represented by bars R1-R4. *Id*. Osorio discloses that this dynamic relationship between non-pathological HRVs and activity levels may be exploited to detect pathological states, such as tachycardia, by "determining when the patient's HRV is **incommensurate** with the patient's activity level and/or heart rate." APPLE-1005, [0066] ("The dynamic relationship between non-pathological HRVs and activity levels may be exploited to detect pathological states such as epileptic seizures by determining when the patient's HRV is incommensurate with the patient's activity level and/or heart rate."); APPLE-1010, [0042]-[0050] ("If the patient's activity level is determined at 920 not to be commensurate with one or more of the time of day, the patient's body data, or with one or more body indices appropriate for determining a non-pathological state, the pathological statement be confirmed (930)."). A POSITA would have understood that Osorio discloses detecting an irregularity when it sees an increase in heart rate variability without a corresponding increase in activity level.

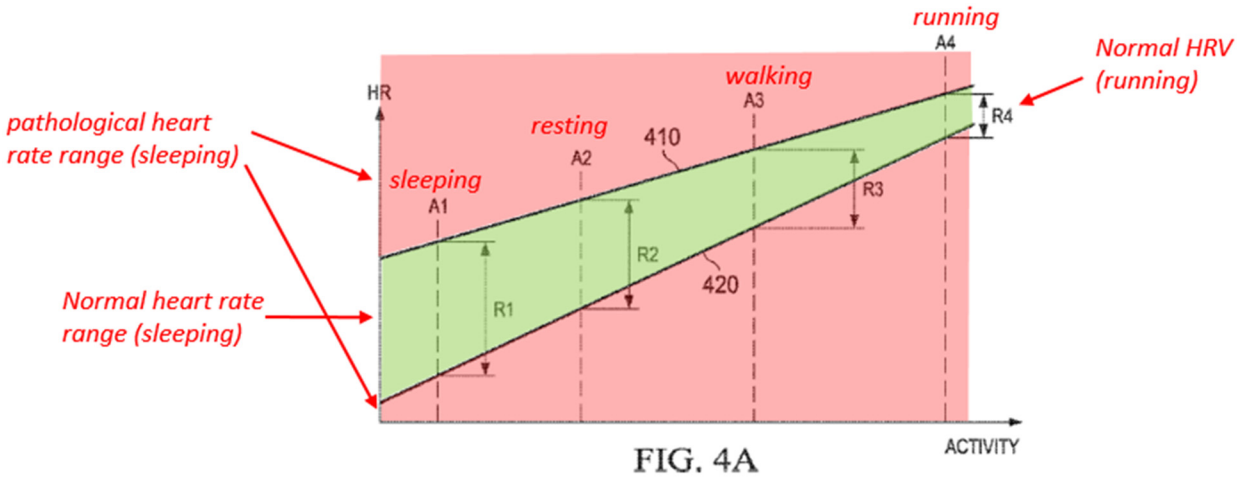


FIG. 4A

APPLE-1005, Fig. 4A (annotated).Fig. 8 shows an example of Osorio's method:

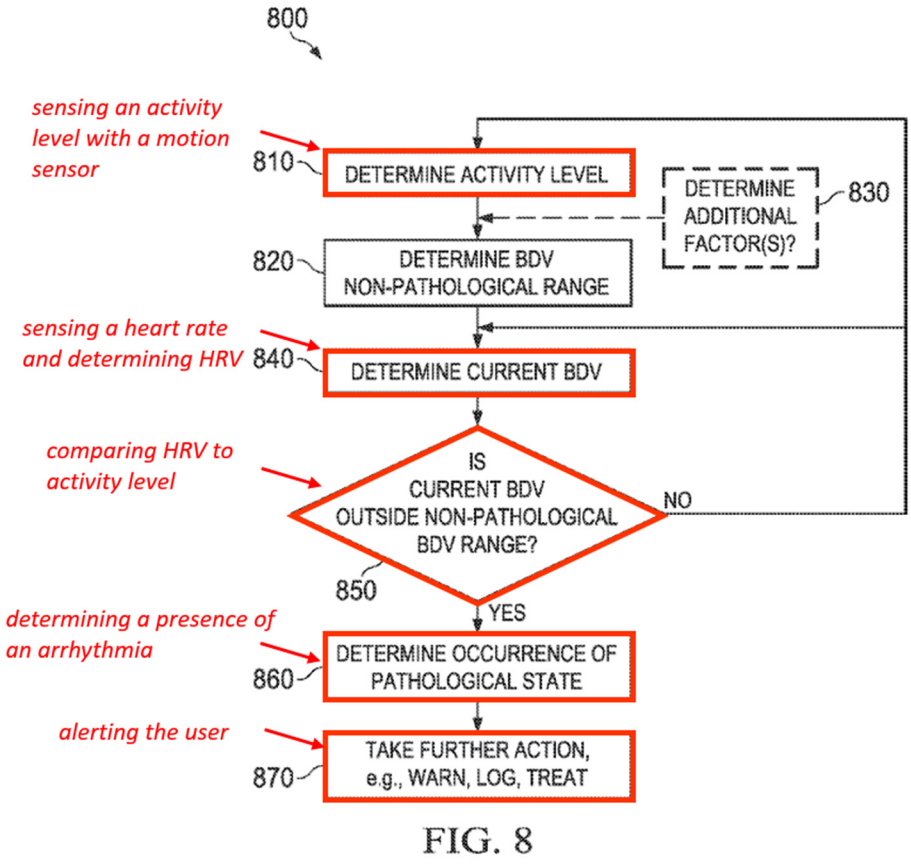


FIG. 8

APPLE-1005, Fig. 8 (annotated).

153. As shown in Fig. 8, an activity level is determined at 810, and a non-pathological BDV range is determined at 820, based on the activity level. APPLE-1005, [0077]. A current BDV is determined at 840 and compared to the non-pathological BDV range. APPLE-1005, [0078]. If the current BDV is outside the non-pathological range, then a pathological state is determined at 860. APPLE-1005, [0078]. Osorio also discloses "the body index value may be heart rate and the BDV value may be HRV." APPLE-1005, [0080] ("***the body index value may be heart rate and the BDV may be HRV***."); APPLE-1010, [0035] ("For example, the body data variability module 165 may comprise an HRV module 310 configured ***to determine HRV from heart rate data***.").. Osorio also discloses: "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. APPLE-1005, [0066] ("The dynamic relationship between non-pathological HRVs and activity levels may be exploited to detect pathological states such as epileptic seizures by determining when the patient's HRV is incommensurate with the patient's activity level and/or heart rate."). A POSITA would have understood that Osorio's method detects an irregularity when it sees an increase in heart rate variability without a corresponding increase in activity level, because the HRV will fall outside the non-pathological range under the same activity level.

154. Correspondingly, Osorio Provisional discloses determining the user's activity level and determining whether the activity level is commensurate with the body data. APPLE-1010, [0042]-[0050] ("If the patient's activity level is determined at 920 not to be commensurate with one or more of the time of day, the patient's body data, or with one or more body indices appropriate for determining a non-pathological state, the pathological statement be confirmed (930).").

155. Fig. 11 of Osorio shows an example of comparing the patient's HRV to the non-pathological ranges dynamically determined based on the activity level. As shown in Fig. 11, HRV values that are below 0.5 bpm and above 4 bpm are [generally] always pathological in patients having normal physical fitness and is resting or walking. APPLE-1005, [0091] ("FIG. 11 shows a conceptual depiction of pathological and non-pathological BDV (e.g., HRV) value ranges. ***Certain HRV ranges, such as below 0.5 bpm and above 4 bpm, are essentially always pathological*** when seen in patients having normal levels of physical fitness and either resting or engaged in mild activity (e.g., walking). ***Intermediate HRV ranges, such as from 0.5-4 bpm, may be pathological, or may be non-pathological***, depending on the kinetic and/or emotional/ cognitive activity levels of the patient."). Intermediate HRV values (0.5-4 bpm) may be pathological depending on the activity level of the patient. *Id*. As shown in Fig. 11, an irregularity (i.e., a pathological state) is detected when the user's HRV increases

above 4 bpm without a corresponding increase in activity level (i.e., the user is still resting or walking). *Id*.

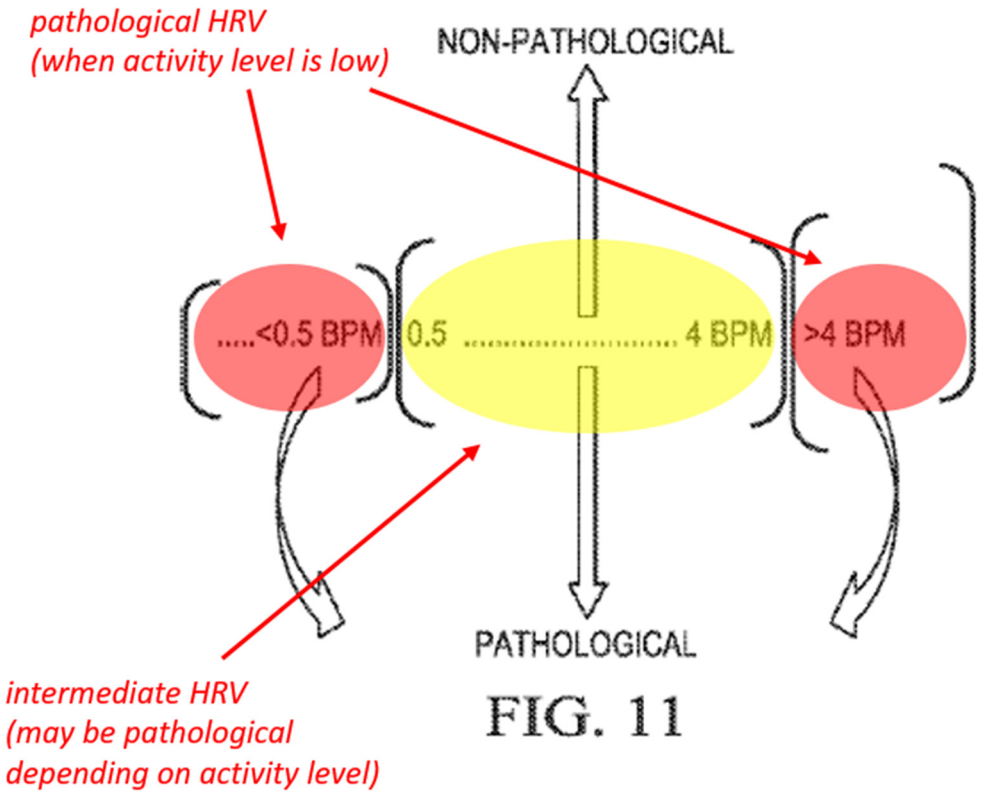


FIG. 11

APPLE-1005, Fig. 11 (annotated).

156. In addition, Osorio discloses in Fig. 12 a method that involves comparing HRV to activity level to determine "whether the patient's activity level is **commensurate** with the BDV." APPLE-1005, [0092] ("A non-pathological BDV range value may be determined (e.g., from patient data, and taken into account an assumed activity level of the patient) at 1210, and a current BDV may be determined at 1215. If the BDV is found to be inside the non-pathological range at 1220, flow returns to 1210. If the BDV value is found to be outside the range at

1220, then a determination may be made at 1230 whether the patient's activity level is commensurate with the BDV. If the activity level is commensurate, then the non-pathological BDV range may be (re)determined at 1210. If the activity level is not commensurate with the current BDV, then a detection of a pathological state may be issued at 1250, with flow then returning to 1215."). Note that Osorio discloses that the BDV can be HRV. APPLE-1004, [0080] ("***the body index value may be heart rate and the BDV may be HRV***."); APPLE-1010, [0035] ("For example, the body data variability module 165 may comprise an HRV module 310 configured ***to determine HRV from heart rate data***."). As shown in Fig. 12, the device determines a nonpathological BDV (e.g., HRV) range based on an assumed activity level at 1210, and determines a current BDV (e.g., HRV) at 1215. APPLE-1005, [0092]. If the BDV (e.g., HRV) is found to be outside the non-pathological BDV range at 1220, then a determination is made at 1230 on "whether the patient's activity level is commensurate with the BDV." *Id*. If the activity level is not commensurate with the current BDV (e.g., HRV), then a detection of a pathological state is issued at 1250. *Id*.

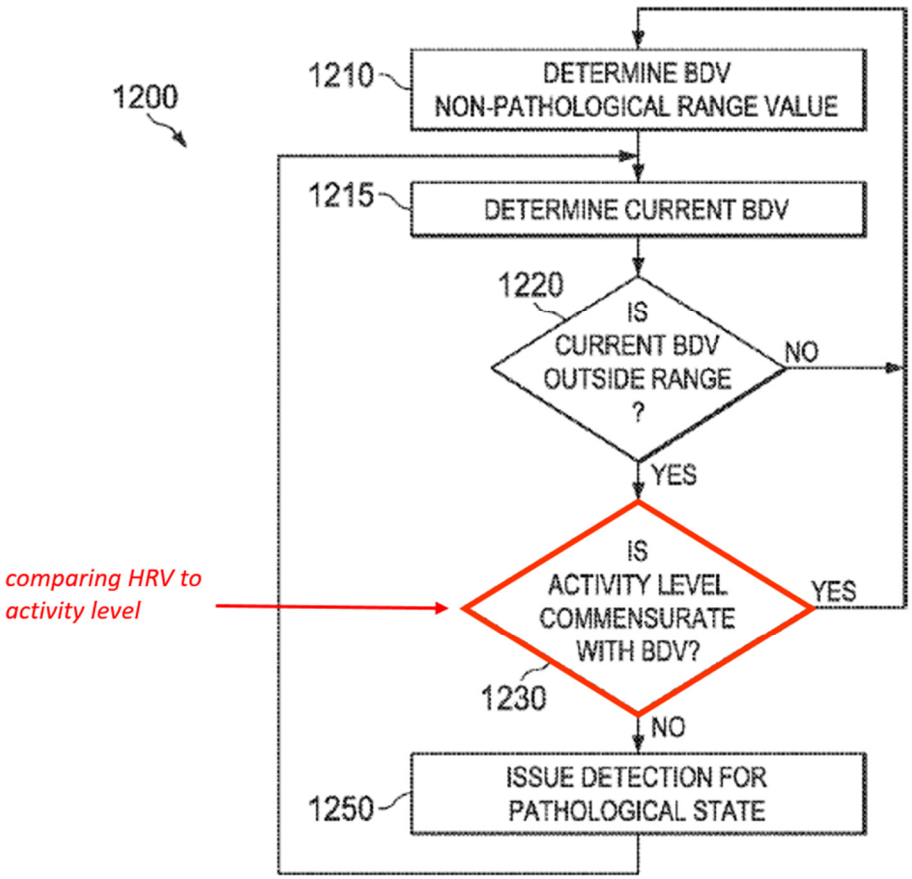


FIG. 12

APPLE-1005, Fig. 12 (annotated). A POSITA would have understood that Osorio's method in Fig. 12 also detects an irregularity when it sees an increase in heart rate variability without a corresponding increase in activity level, because the HRV will no longer be "commensurate" with the activity level.

157. Correspondingly, Osorio Provisional discloses determining the user's activity level and determining whether the activity level is commensurate with the body data. APPLE-1010, [0042]-[0050] ("If the patient's activity level is determined at 920 not to be commensurate with one or more of the time of day, the

patient's body data, or with one or more body indices appropriate for determining a non-pathological state, the pathological statement be confirmed (930).”)..

158. As discussed in Section XI.A (above), in the Shmueli-Osorio 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, determines the non-pathological HRV range based on the user’s activity level and compares the HRV to the non-pathological HRV range to determine if there is an irregularity, as taught by Osorio. APPLE-1005, Fig. 8 and [0077]-[0080]; APPLE-1010, [0042]-[0050]. A POSITA would have understood that Osorio’s method detects an irregularity when it sees an increase in heart rate variability without a corresponding increase in activity level, because the new HRV will fall outside the non-pathological range under the same activity level. Thus, the Shmueli-Osorio combination renders obvious [10.0].

I. Claim 11

[11.0] A system for determining the presence of an arrhythmia of a first user, comprising

159. It is my opinion that the Shmueli-Osorio combination renders obvious element [11.0].

160. To the extent the preamble of [11.0] is limiting, the Shmueli-Osorio combination renders the preamble obvious. Shmueli discloses “a wrist-mounted

physiological parameters measuring device including: an SpO2 measuring unit attached to a wrist of a subject the SpO2 measuring unit being operative to continuously measure SpO2 at the wrist of the subject, an ECG measuring unit attached to the wrist of the subject for measuring ECG signal at least partially at the wrist, and a processor operative to control both the SpO2 measuring and the ECG measuring unit, where the processor is operative **to detect an irregular heart condition** from the SpO2 measurement, to notify the subject to perform an ECG measurement upon detecting the irregular heart condition the, and to initiate the ECG measurement." APPLE-1004, 4:1-9. The Merriam-Webster Dictionary defines "heart disease" as "an abnormal condition of the heart or of the heart and circulation (such as coronary heart disease, arrhythmia, or heart-valve defect)." APPLE-1023, p.2. The '499 patent also defines arrhythmia as an irregular heart condition. APPLE-1001, 1:31-33 ("Arrhythmia is a cardiac condition in which the electrical activity of the heart is irregular…"). Thus, a POSITA would have understood the term "irregular heart condition" refers arrhythmia. In addition, a POSITA also would have understood the term "irregular heart condition" to refer to arrhythmia because Shmueli discloses detecting the irregular heart condition based on PPG data and then confirming it with an ECG measurement. APPLE-1004, Abstract ("The method including the steps of: ***continuously measuring SpO2*** at the wrist of the user, detecting an irregular heart condition from the SpO2

measurement, notifying the user to perform an ECG measurement, and ***initiating the ECG measurement*** at least partially at the wrist.") and Fig. 7. Indeed, Shmueli offers an expansive meaning for the term "irregular heart condition," explaining that "[i]t is expected that during the life of this patent many relevant methods and systems will be developed and the scope of the terms herein, particularly of the term 'irregular heart condition' are intended to include all such new technologies a priori." APPLE-1004, 15:3-5.

161. A POSITA would have known, based on his/her education, training, and experience by the Critical Date, and found it obvious to use Shmueli's SpO2 measurement to detect arrhythmia as the irregular heart condition because using PPG data to detect arrhythmia was well-known and arrhythmia was a well-known heart condition. For example, Suzuki 2009 discloses using PPG data to detect arrhythmia. APPLE-1016, p. 6081. In addition, Shmueli discloses both detecting the "irregular heart condition" based on PPG data and confirming the diagnosis with an ECG measurement. APPLE-1004, Abstract ("The method including the steps of: ***continuously measuring SpO2*** at the wrist of the user, detecting an irregular heart condition from the SpO2 measurement, notifying the user to perform an ECG measurement, and ***initiating the ECG measurement*** at least partially at the wrist.") and Fig. 8. Arrhythmia is one of the most obvious (if not the most obvious) types of "irregular heart condition[s]" that can be determined

using both PPG and ECG data. For example, both Amano and Lee 2013 disclose using PPG data to detect arrhythmia. APPLE-1011, Abstract; APPLE-1020, Abstract. Tran also discloses detecting arrhythmia using ECG data. APPLE-1007, [0479]. Li 2012 discloses detecting arrhythmia using both PPG and ECG data. APPLE-1006, Abstract. Suzuki 2009 explains that while arrhythmia is traditionally detected using ECG, it can also be detected using PPG. APPLE-1016, 6080. Other references explains that arrhythmia can be detected using HRV, which in turn can be derived from either PPG or ECG data. *See* APPLE-1012 (explaining detecting arrhythmia based on HRV derived from ECG data); APPLE-1013, Abstract ("Our results demonstrate that the parameters of PPGV are highly correlated with the parameters of HRV."); APPLE-1014, Abstract ("HRV can also be reliably estimated from the PPG based PP interval method."); and APPLE-1015, Abstract ("Our results confirm that PPG provides accurate interpulse intervals from which HRV measures can be accurately derived in healthy subjects under ideal conditions, suggesting this technique may prove a practical alternative to ECG for HRV analysis.") and APPLE-1018, Abstract (replacing ECG with PPG to detect HRV). For these reasons, based on Shmueli's disclosure of detecting an irregular heart condition from SpO2 and ECG measurements, Shmueli renders obvious a system for determining a presence of an arrhythmia of a user.

162. In addition, Osorio also discloses using heart rate data to determine

arrhythmia. APPLE-1005, [0046] (discussing detecting "a **tachycardia** episode."). Tachycardia is a form of arrhythmia. APPLE-1001, 1:31-33. Indeed, Osorio explicitly mentions detection of "cardiac arrhythmias." APPLE-1005, [0071].

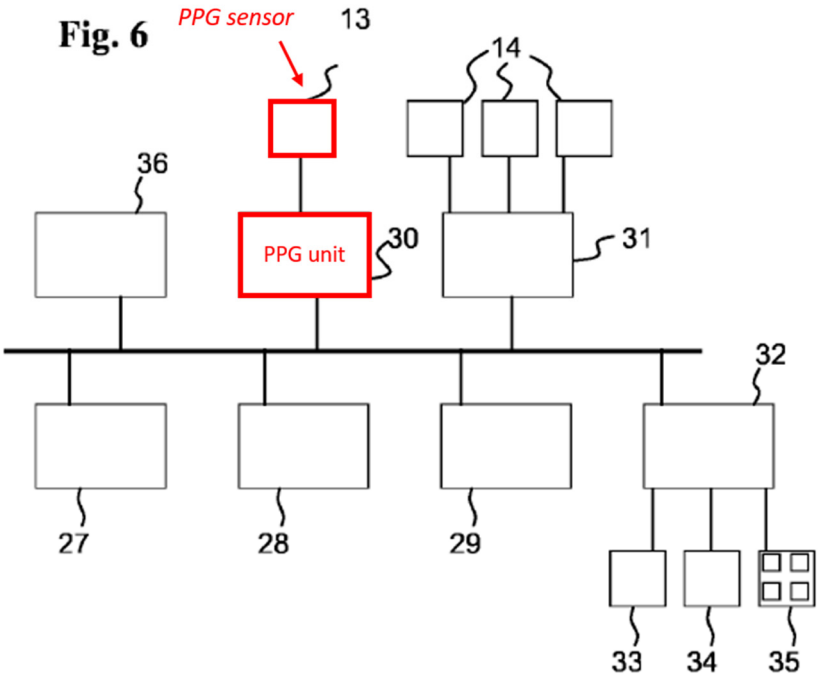
163. As discussed in Section XI.A (above), in the Shmueli-Osorio combination, Shmueli's PPG sensor is used to determine heart rate information, and Osorio's motion sensor is used to determine the user's activity level. Then the combined device determines current HRV based on the heart rate information and determines the non-pathological HRV range based on the user's activity level and compares the HRV to the non-pathological HRV range to determine if there is an irregularity (e.g., arrhythmia), as taught by Osorio. APPLE-1005, Fig. 8 and [0077]-[0080]; APPLE-1010, [0042]-[0050]. Thus, the Shmueli-Osorio combination renders obvious [11.0].

[11.1] a heart rate sensor coupled to said first user;

164. It is my opinion that the Shmueli-Osorio combination renders obvious element [11.1].

165. The '499 patent teaches sensing a heart rate with a PPG sensor. APPLE-1001, 8:41-45. During prosecution, Applicant distinguished prior art by arguing that the claimed "heart rate sensor" is different from the ECG sensor in the prior art. APPLE-1002, 342-347. Similar to the '499 patent, Shmueli discloses measuring SpO_2 with a PPG sensor. APPLE-1004, 9:8-10 (disclosing "an oximetry

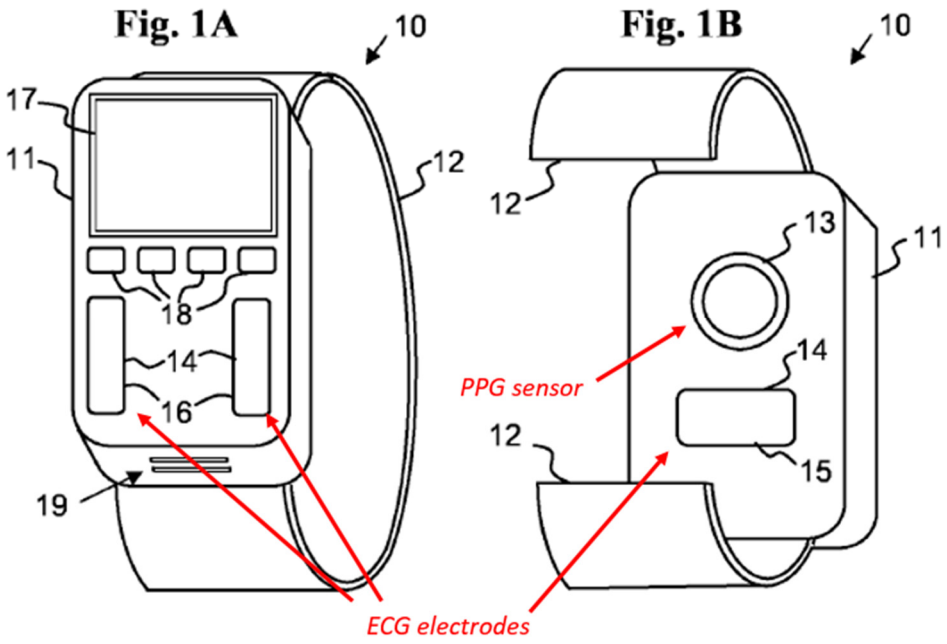
sensor"); 7:25-27 (explaining that the terms oximetry and photoplethysmography have the same meaning). In addition, Shmueli explains that "[d]eriving heart beat rate from oximetry" was known in the art. APPLE-1004, 8:11-13. As shown in Fig. 6 below, Shmueli's heart monitoring device includes "a memory unit 28, a processor 29, **an oximetry measuring unit 30 with the oximetry sensor 13**, an ECG measuring unit 31 with three ECG contact sensors 14." APPLE-1004, 11:10-15.



APPLE-1004, Fig. 6 (annotated). A POSITA would have understood that Shmueli's device contains a heart rate sensor within the meaning of the '499 patent because it has an "oximetry measuring unit 30 with the oximetry sensor 13."

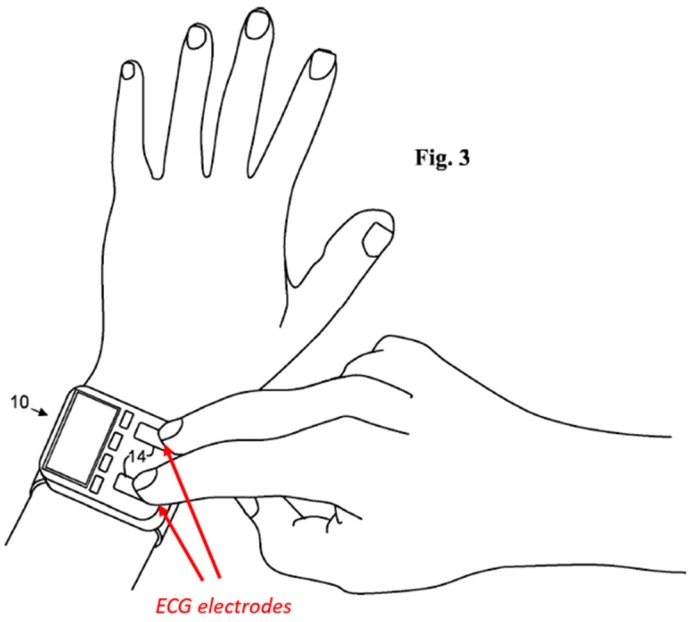
166. Shmueli also discloses that the PPG sensor is coupled to the user

through a wrist-worn device. APPLE-1004, 4:1-9 (discussing a "wrist-mounted physiological parameters measuring device including: an SpO2 measuring unit."). Figs. 1A and 1B illustrate an example of Shmueli's device.



APPLE-1004, Figs. 1A and 1B (annotated).

167. Fig. 3 of Shmueli shows an example of a user using the device of FIG. 1A/1B to take an ECG. As shown in Figs. 1A, 1B and 3, Shmueli's PPG sensor is coupled to the user through a wrist-mounted device.



APPLE-1004, Fig. 3 (annotated).

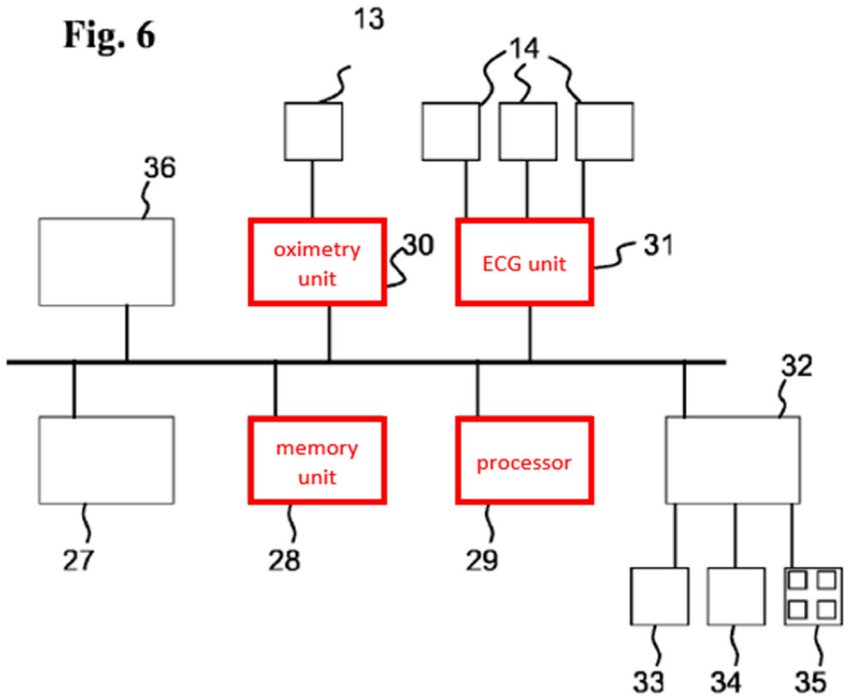
168. As discussed in Section XI.A (above), in the Shmueli-Osorio combination, ***Shmueli's PPG sensor, which is coupled to the user, is used to determine heart rate information***, and Osorio's motion sensor is used to determine the user's activity level. Thus, the Shmueli-Osorio combination renders obvious [11.1].

[11.2] 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

169. It is my opinion that the Shmueli-Osorio combination renders obvious element [11.2].

170. Shmueli discloses discloses a mobile computing device comprising a processor. APPLE-1004, 4:1-9 (discussing a "wrist-mounted physiological

parameters measuring device including: an SpO2 measuring unit," "an ECG measuring unit" and a "***processor*** operative to control both the SpO2 measuring and the ECG measuring unit."). As shown in Fig. 6 below, Shmueli's heart monitoring device includes "**a memory unit 28**, **a processor 29**, **an oximetry measuring unit 30 with the oximetry sensor 13**, **an ECG measuring unit 31 with three ECG contact sensors 14**." APPLE-1004, 11:10-15.



APPLE-1004, Fig. 6 (annotated).

171. As discussed above for element [11.1], a POSITA would have understood that Shmueli's PPG sensor is a heart rate sensor within the meaning of the '499 patent. Thus, Shmueli discloses a mobile computing device comprising a processor (i.e., processor 29), wherein said mobile computing device is coupled to

said heart rate sensor (i.e., an oximetry measuring unit 30 with the oximetry sensor 13), and wherein said mobile computing device is configured to sense an electrocardiogram (ECG) of the user (with ECG measuring unit 31).

172. As discussed in Section XI.A (above)., in the Shmueli-Osorio 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. ***The heart rate information is transmitted to the combined device, which is a mobile computing device coupled to the PPG sensor, to determine the current HRV***. Then the combined device determines the current HRV based on the heart rate information, determines the non-pathological HRV range based on the user's activity level and compares the current HRV to the non-pathological HRV range to determine if there is an irregularity, as taught by Osorio. APPLE-1005, Fig. 8 and [0077]-[0080]; APPLE-1010, [0042]-[0050]. Once an irregularity is detected in the Shmueli-Osorio combination, ***the user is notified to take an ECG at the wrist-worn device, which is configured to sense an ECG, as described by Shmueli***. APPLE-1004, Abstract ("The method including the steps of: ***continuously measuring SpO2*** at the wrist of the user, detecting an irregular heart condition from the SpO2 measurement, notifying the user to perform an ECG measurement, and ***initiating the ECG measurement*** at least partially at the wrist."), 12:23-13:9, and Fig. 7. The Shmueli-Osorio combination is configured to sense an ECG if an

irregularity is determined by the PPG and activity data. Thus, the Shmueli-Osorio combination renders obvious [1.2].

[11.3] a motion sensor

173. It is my opinion that the Shmueli-Osorio combination renders obvious element [11.3].

174. As discussed above in Section XI.A (above), a POSITA would have been motivated to add Osorio's motion sensor and activity level analysis to Shmueli's device because Osorio teaches that considering activity level improvise detection of a pathological condition (e.g., arrhythmia) based on heart rate. APPLE-1005, [0029] ("This disclosure recognizes that to determine (using body systems and their features) whether a body system is functioning pathologically or non-pathologically with a clinically worthwhile degree of accuracy and reliability, ***one must take into account the type and/or level of activity being performed*** by a subject at the time the pathological/non-pathological determination is made.").

175. Osorio discloses monitoring the user's activity level using a kinetic sensor. APPLE-1005, Abstract, [0003]-[0006] and [0028] ("a medical device capable of monitoring an **activity type and/or level** of a patient and dynamically determining a non-pathological BDV range based upon an activity type and/or level of the patient. … **An activity level or state (e.g., awake or asleep)** of the patient may in some embodiments be determined from a **kinetic sensor such as an**

accelerometer."), [0033] (discussing an activity sensor 212), [0057] ("Fig. 4A shows a dynamic relationship between non-pathological patient ***activity levels (e.g., as determined from a tri-axial accelerometer)*** and an exemplary ***body data and BDV (e.g., heart rate and HRV***)."), [0061] and Fig. 1; APPLE-1010, [0025]-[0026] ("The medical device 200 may comprise at least one ***activity level sensor(s)*** 114, each configured to collect at least one body signal from a patient relating to an activity level of the patient. For example, each activity level sensor(s) 114 may be selected from an ***accelerometer***…") and [0045]-[0050] ("In some embodiments, the method 700 may further comprise ***determining an activity level*** of the patient (not shown). In some embodiments, determining the activity level may comprise determining a kinetic index from an output of at least one of an ***accelerometer***…"). A POSITA would have understood that Osorio's "kinetic sensor" (e.g., accelerometer) is a motion sensor within the meaning of the '499 patent. For example, the '499 patent discloses "[a]n 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**." APPLE-1001, 25:19-22. Thus, as shown in Fig. 1 below, Osorio discloses a motion sensor.

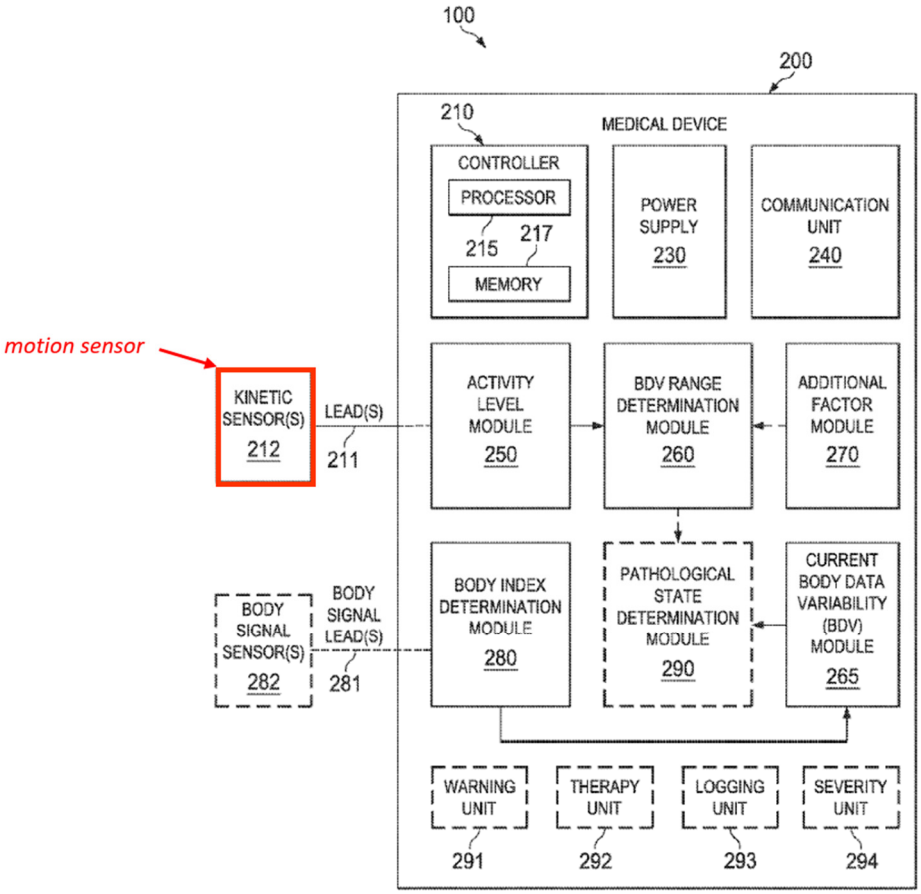


FIG. 1

APPLE-1005, Fig. 1 (annotated).

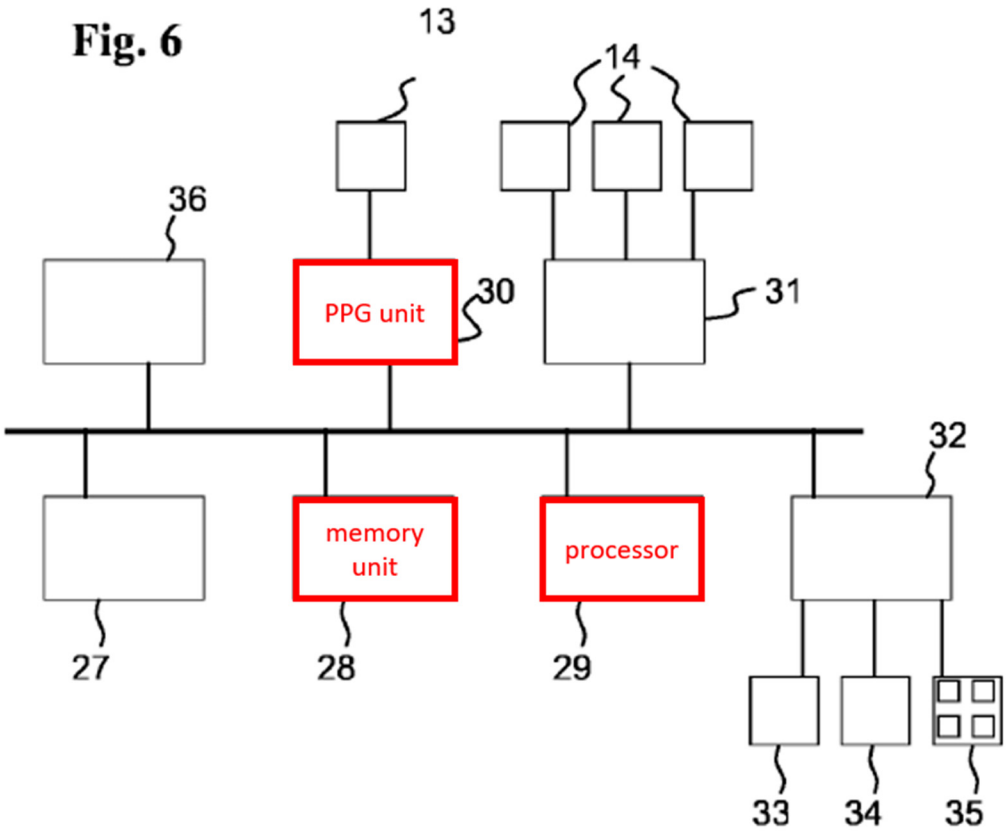
176. As discussed in Section XI.A (above), in the Shmueli-Osorio combination, Shmueli's PPG sensor is used to determine heart rate information, and ***Osorio's motion sensor is used to determine the user's activity level***. Thus, the Shmueli-Osorio combination renders obvious [11.3].

[11.4] 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,

177. It is my opinion that the Shmueli-Osorio combination renders obvious

element [11.4].

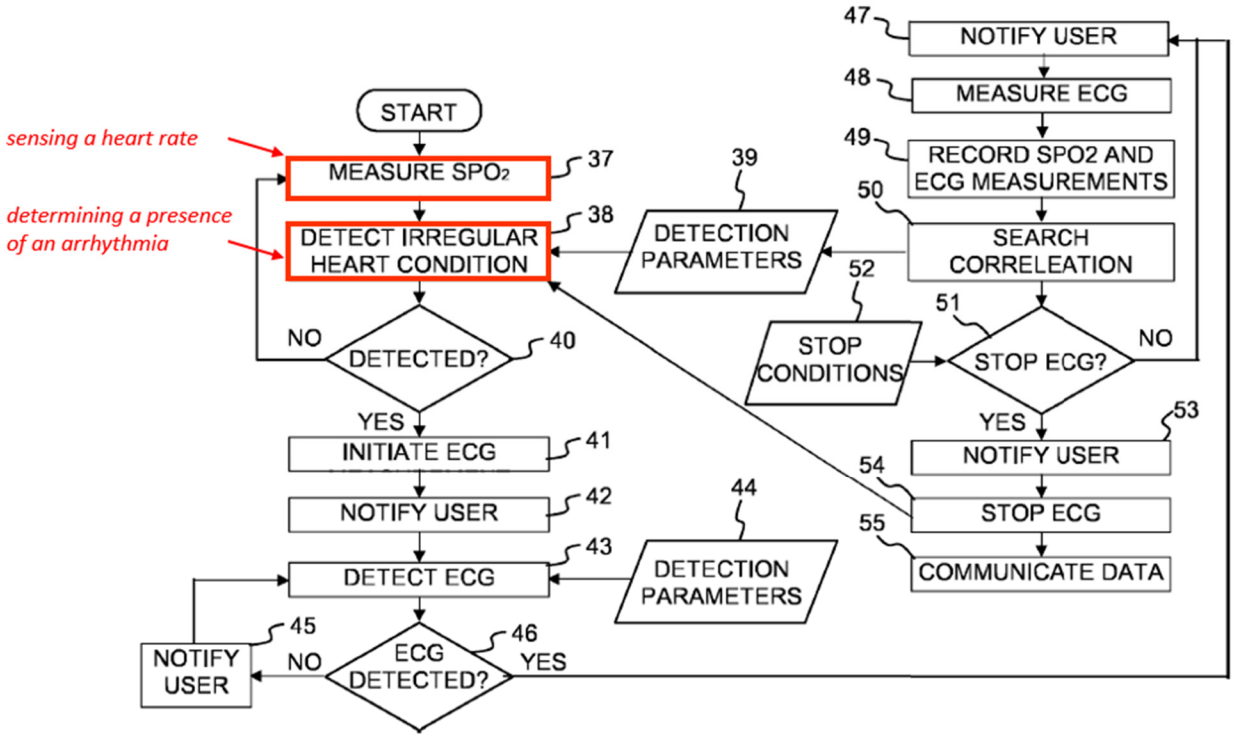
178. As shown in Fig. 6 below, Shmueli's heart monitoring device includes "**a memory unit 28**, **a processor 29**, **an oximetry measuring unit 30 with the oximetry sensor 13**, an ECG measuring unit 31 with three ECG contact sensors 14." APPLE-1004, 11:10-15. Shmueli further discloses "[t]he **memory unit 28 preferably contains software program containing instructions to be executed by the processor 29**." APPLE-1004, 11:19-21. Thus, Shmueli's memory 28 constitutes "a non-transitory computer readable medium encoded with a computer program including instructions."



APPLE-1004, Fig. 6 (annotated).

179. Fig. 7 provides a flow chart of a software program contained in memory unit 28 and executed by processor 29. APPLE-1004, 11:22-23 and 12:6-8. As shown in Fig. 7 below, the software program "starts in element 37 by measuring SpO2" and then "proceeds to element 38 to derive from the SpO2 measurement physiological parameters" and "to detect various irregularities of the heart condition." APPLE-1004, 12:9-17 ("The software program proceeds to ***element 38 to derive from the SpO2 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 scanning for an irregular heart condition preferably uses heart-irregularity detection parameters (element 39) stored in the memory unit 28. When an irregular heart condition is detected (element 40) the software program continues to element 41. However, the SpO2 measurement (element 37) preferably continues and optionally also the derivation of physiological parameters as well as the detection of irregular heart conditions (element 38)."). A POSITA would have known and understood that in order for the computing device to detect irregular heart condition, element 38 requires processor 29 to receive a heart rate from the heart rate sensor (PPG sensor). APPLE-1004, Fig. 7.

Fig. 7



APPLE-1004, Fig. 7 (annotated).

180. In the Shmueli-Osorio 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. The combined device has a memory encoded with a computer software to be executed by a processor to determine the current HRV based on the heart rate information, determines the non-pathological HRV range based on the user's activity level and compares the HRV to the non-pathological HRV range to determine if there is an irregularity, as taught by Osorio. APPLE-1005, Fig. 8 and [0077]-[0080]; APPLE-1010, [0042]-[0050]. Thus, the Shmueli-Osorio combination renders obvious [11.4].

[11.5] sense an activity level of said first user from said motion sensor,

181. It is my opinion that the Shmueli-Osorio combination renders obvious element [11.5]. *See* element [1.4].

[11.6] determine a heart rate variability of said first user based on said heart rate of said first user,

182. It is my opinion that the Shmueli-Osorio combination renders obvious element [11.6]. *See* element [1.3].

[11.7] compare and activity level of said first user to said heart rate variability of said first user, and

183. It is my opinion that the Shmueli-Osorio combination renders obvious element [11.7]. *See* element [1.5].

[11.8] alert said first user to record an electrocardiogram using said mobile computing device.

184. It is my opinion that the Shmueli-Osorio combination renders obvious element [11.8]. *See* element [1.6].

J. Claim 12

[12.0] The system of claim 11, wherein said heart rate sensor comprises one or more of a patch, a wristband, and an armband.

185. It is my opinion that the Shmueli-Osorio combination renders obvious element [12.0]. *See* element [2.0].

K. Claim 13

[13.0] 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.

186. It is my opinion that the Shmueli-Osorio combination renders obvious element [13.0]. *See* element [3.0].

L. Claim 14

[14.0] 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.

187. It is my opinion that the Shmueli-Osorio combination renders obvious element [14.0]. *See* element [4.0].

M. Claim 15

[15.0] The system of claim 11, wherein said mobile computing device comprises a smartphone.

188. It is my opinion that the Shmueli-Osorio combination renders obvious element [15.0]. *See* element [5.0].

N. Claim 16

[16.0] The system of claim 11, wherein said mobile computing device comprises a smartwatch.

189. It is my opinion that the Shmueli-Osorio combination renders obvious element [16.0]. *See* element [6.0].

O. Claim 20

[20.0] 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.

190. It is my opinion that the Shmueli-Osorio combination renders obvious

element [20.0]. *See* element [10.0].

XII. ANALYSIS OF SHMUELI IN VIEW OF OSORIO AND HU 1997

191. For the reasons articulated in detail below, and based on my review of the ’499 patent, the file history, and the prior art references cited here, it is clear that a POSITA would have readily understood that the teachings of Shmueli in view of Osorio and Hu 1997 provide all the elements of claims 7-9 and 17-19.

A. The Combination of Shmueli, Osorio and Hu 1997

192. As discussed in Section XI.A (above), in the Shmueli-Osorio 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, determines the non-pathological HRV range based on the user’s activity level and compares the HRV to the non-pathological HRV range to determine if there is an irregularity (e.g., arrhythmia), as taught by Osorio. APPLE-1005, Fig. 8 and [0077]-[0080].

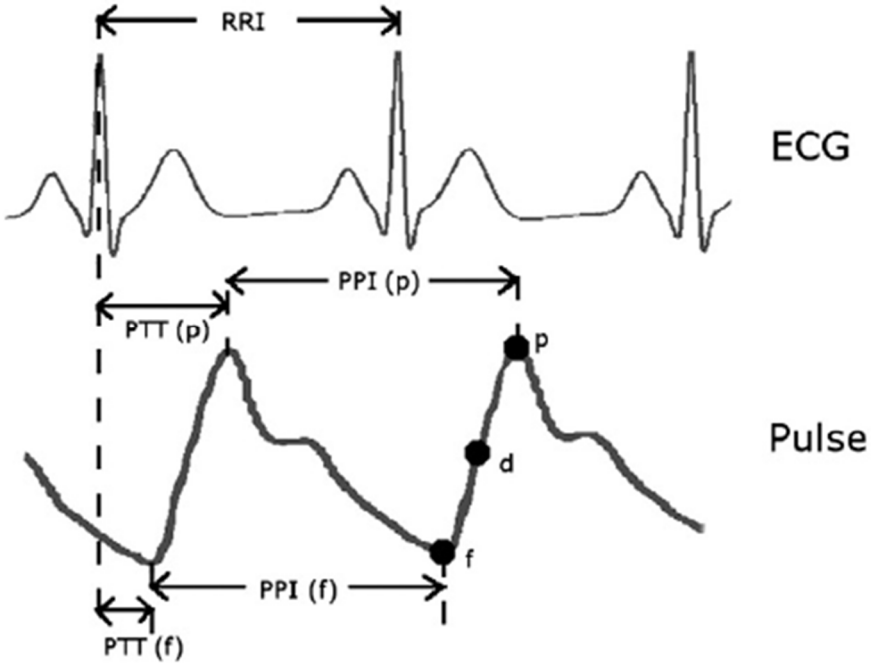
193. By 2009, examples of known arrhythmia detection techniques include: neural networks, wavelet transforms, support vector machines, fuzzy logic and rule-based algorithms. APPLE-1040, p. 1928. According a 2011 article, most of the recent algorithms developed for detecting ECG anomalies (e.g., arrhythmia) are based in fuzzy logic and Neural Network techniques. APPLE-1041, p. 74. A

POSITA would have understood that these algorithms are machine learning algorithms. APPLE-1001, 9:61-66 (listing neural networks and support vector machines as exemplary machine learning algorithms). Thus, by the Critical Date, machine learning algorithms were a well-known and popular technique to detect arrhythmia based on heart rate data. *Id*.

194. In the Shmueli-Osorio-Hu 1997 combination, a POSITA would have been motivated to employ a machine learning algorithm to detect arrhythmia based on known advantages of machine learning. For example, machine learning approaches offer superior performance when the inputs are complex, features of the input data cannot be readily discerned, or the relationships between input data are complex and nonlinear. Machine learning algorithms are sophisticated, automatic, and objective for analysis of high-dimensional and multimodal biomedical data. APPLE-1042, Abstract. Li 2012 also discloses that its machine learning algorithm increases the detection accuracy by reducing false alarms. APPLE-1006, Abstract. To achieve these benefits, a POSITA would have been motivated to apply a machine learning method to the heart rate analysis performed in the Shmueli-Osorio combination.

195. As the pulse period derived from PPG data is directly related to cardiac activity, the physiological information derived from RR intervals of ECG can also be derived from the pulse period of a PPG reading. APPLE-1014, p. 480.

This is because electrical activity of the heart (ECG) is followed by spread of the pulsatile wave of blood to the periphery (PPG). APPLE-1014, p. 480. Thus, a PPG signal includes information about both heart rate and heart rate variability. APPLE-1025, p. 16. Many studies verify the high correlation between RR intervals (RRI) obtained from ECG and PP intervals (PPI) obtained from PPG. APPLE-1025, p. 16; APPLE-1018, Fig. 1.



APPLE-1018, Fig. 1.

196. Thus, while Hu 1997 focuses on detecting arrhythmia using the ECG data, a POSITA would have known how to use same machine learning approach to detect arrhythmia based on PPG data in view of the high correlation between RRI obtained from ECG and PPI obtained from PPG.

197. Further, Osorio describes that the "BDV range determination module

260 may determine that the same BDV value (e.g., the same heart rate) in the same patient is either pathological or non-pathological based on the activity level, activity type, or other variables (e.g., fitness level)." APPLE-1005, [0036]. As discussed above in Section XI.A, in the Shmueli-Osorio combination, the combined device detects arrhythmia based on PPG data (and HR and HRV derived therefrom) and motion sensor data (and the activity level derived therefrom). A POSITA would have been motivated to optimize this multifactor analysis in Osorio using a machine learning algorithm.

198. In addition, after an ECG was measured as part of Shmueli's method, it would have been obvious for the combined device to detect arrhythmia using a machine learning algorithm based on the HRV data and motion sensor data. Shmueli discloses "[o]ptionally but preferably 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***." APPLE-13:16-19. A POSITA would have found it obvious that this disclosure covers machine learning, which "focuses on algorithms capable of learning and/or adapting their structure (e.g., parameters) based on a set of observed data." APPLE-1042, p. 538.

199. A POSITA also would have had a reasonable expectation of success

in using a machine learning algorithm to detect arrhythmia in this way. For example, 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. Tsipouras 2004 discloses detecting arrhythmia by training a machine learning algorithm (e.g., neural networks) with HRV data. APPLE-1012, Abstract. Tavassoli 2012 also discloses detecting arrhythmia by training a machine learning algorithm with HRV and ECG data. APPLE-1038, Abstract.

200. Thus, 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*** based on the PPG data, heart rate, HRV, motion sensor data and activity level.

201. Alternatively or in combination, in the Shmueli-Osorio-Hu 1997 combination, upon detection of the irregularity (e.g., arrhythmia), the combined device notifies the user to take an ECG measurement and detects arrhythmia ***using a machine learning algorithm*** based on the PPG data, heart rate, HRV, motion sensor data and the ECG data. APPLE-1006, Abstract; APPLE-1004, Fig. 7 and 12:6-30. As POSITA would have found it obvious to apply Hu 1997's machine

learning techniques to the initial stage of detection of irregularities (e.g., arrhythmias) using Shmueli's PPG data and/or to the confirmation stage of detection of irregularities (e.g., arrhythmias) using Shmueli's ECG data. Indeed, a POSITA would have found use of machine learning as being applicable to Shmueli's analysis of PPG data and/or ECG data because, as discussed above, machine learning was a well-known technique to improve arrhythmia detection using either PPG or ECG data or both.

B. Claim 7

[7.0] The method of claim 1, further comprising determining a presence of said arrhythmia using a machine learning algorithm.

202. It is my opinion that the Shmueli-Osorio-Hu 1997 combination renders obvious element [7.0].

203. As discussed in Section XII.A, 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*** based on the PPG data, heart rate, HRV, motion sensor data and activity level. Thus, the Shmueli-Osorio-Hu 1997 combination renders obvious [7.0].

204. Alternatively or in combination, in the Shmueli-Osorio-Hu 1997 combination, upon detection of the irregularity (e.g., arrhythmia), the combined

device notifies the user to take an ECG measurement and detects arrhythmia ***using a machine learning algorithm*** based on the PPG data, heart rate, HRV, motion sensor data, activity level and the ECG data. APPLE-1006, Abstract; APPLE-1004, Fig. 7 and 12:6-30.

C. Claim 8

[8.0] 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.

205. It is my opinion that the Shmueli-Osorio-Hu 1997 combination renders obvious element [8.0].

206. As discussed in [7.0], the Shmueli-Osorio-Hu 1997 combination renders it obvious to use a machine learning algorithm to determine arrhythmia.

207. Shmueli discloses "the software program proceeds to element 48 to perform the ECG measurement and to element 49 to record the SpO2 and the ECG measurements and preferably **store them in the memory unit 28**. Preferably, the SpO2 and the ECG signals are correlated and stamped with a time stamp." APPLE-1004, 13:10-13. In addition, Osorio discloses that "the BDV range determination module 260 may also use the patient's **historical health information** to generate a non-pathological range for one or more body indices." APPLE-1005, [0040]. In addition, as discussed above in Section X.C, Hu 1997 discloses that training the machine learning algorithm with both general population

data and user-specific data can significantly improve performance comparing to training with general population alone.

208. Thus, in the Shmueli-Osorio-Hu 1997 combination, it would have been obvious that the combined device stores historical heart rate and HRV data (derived from PPG and ECG measurements) from the same user to improve arrhythmia detection. In the combination with Hu 1997, a POSITA would have found it obvious to extend the Shmueli-Osorio patient data tracking to help the machine learning algorithm make a personalized arrhythmia detection based on the patient's historical health information. A POSITA would have been motivated to do so because different users have different heart rate rhythm patterns and one detection algorithm may not fit for all users. APPLE-1049, p. 891 (discussing "wild variations in the morphologies of ECG waveforms of different patients").

209. As discussed in Section XII.A, 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*** based on the PPG data, heart rate, HRV, motion sensor data and activity level. It would have been obvious that the combined device uses a machine learning algorithm ***that stores heart rate and heart rate variability data previously***

associated with arrhythmias in the same user to determine arrhythmia based on this stored user-specific heart rate and heart rate variability data. Thus, the Shmueli-Osorio-Hu 1997 combination renders obvious [8.0].

210. Alternatively or in combination, in the Shmueli-Osorio-Hu 1997 combination, upon detection of the irregularity (e.g., arrhythmia), the combined device notifies the user to take an ECG measurement and detects arrhythmia ***using a machine learning algorithm*** based on the PPG data, heart rate, HRV, motion sensor data, activity level and the ECG data. APPLE-1006, Abstract; APPLE-1004, Fig. 7 and 12:6-30. It would have been obvious that the combined device uses a machine learning algorithm ***that stores heart rate and heart rate variability data previously associated with arrhythmias in the same user to determine arrhythmia based on this stored user-specific heart rate and heart rate variability data***.

D. Claim 9

[9.0] 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.

211. It is my opinion that the Shmueli-Osorio-Hu 1997 combination renders obvious element [9.0].

212. As discussed in [7.0], the Shmueli-Osorio-Hu 1997 combination

renders it obvious to use a machine learning algorithm to determine arrhythmia.

213. In the Shmueli-Osorio-Hu 1997 combination, it would have been obvious that when the combined device needs to detect arrhythmia in a new user, the machine learning algorithm needs to determine arrhythmia based on the stored heart rate and HRV data associated with arrhythmias in a different user. Indeed, Shmueli discloses "the software program scans the derived physiological parameters to detect various irregularities of the heart condition. The scanning for an irregular heart condition preferably uses **heart-irregularity detection parameters (element 39) stored in the memory unit 28**." APPLE-1004, 12:16-19. In addition, as discussed above in Section X.C, Hu 1997 discloses that training the machine learning algorithm with both general population data and user-specific data can significantly improve performance comparing to training with general population alone. Thus, it would have been obvious to use known parameters from a second individual (or population of individuals) to help determine if a user of the device has an arrhythmia.

214. A POSITA would have been motivated to use a machine learning algorithm that stores heart rate and HRV data from a second user because when the combined device needs to detect arrhythmia in a new user, historical heart rate data for the new user is not available. A POSITA would have had a reasonable expectation of success. For example, Li 2012 trains a machine learning algorithm

with general population data and 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. In addition, Tsipouras 2004 also discloses training the machine learning algorithm using HRV data associated with arrhythmias in a second user in the MIT-BIH arrhythmia database. APPLE-1012, Abstract. Similarly, Asl 2008 also discloses training a machine learning algorithm using HRV data associated with arrhythmias in a second user in the MIT-BIH arrhythmia database. APPLE-1039, Abstract.

215. As discussed in Section XII.A, 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*** based on the PPG data, heart rate, HRV, motion sensor data and activity level. It would have been obvious that the combined device uses a machine learning algorithm ***that stores heart rate and heart rate variability data previously associated with arrhythmias in a second user to determine arrhythmia (in the first user) based on this stored heart rate and heart rate variability data***. Thus, the Shmueli-Osorio-Hu 1997 combination renders obvious [9.0].

216. Alternatively or in combination, in the Shmueli-Osorio-Hu 1997

combination, upon detection of the irregularity (e.g., arrhythmia), the combined device notifies the user to take an ECG measurement and detects arrhythmia ***using a machine learning algorithm*** based on the PPG data, heart rate, HRV, motion sensor data, activity level and the ECG data. APPLE-1006, Abstract; APPLE-1004, Fig. 7 and 12:6-30. It would have been obvious that the combined device uses a machine learning algorithm ***that stores heart rate and heart rate variability data previously associated with arrhythmias in a second user to determine arrhythmia (in the first user) based on this stored heart rate and heart rate variability data***.

E. Claim 17

[17.0] 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.

217. It is my opinion that the Shmueli-Osorio combination renders obvious element [17.0]. *See* element [7.0].

F. Claim 18

[18.0] 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.

218. It is my opinion that the Shmueli-Osorio combination renders obvious element [18.0]. *See* element [8.0].

G. Claim 19

[19.0] 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.

219. It is my opinion that the Shmueli-Osorio combination renders obvious element [19.0]. *See* element [9.0].

XIII. CONCLUSION

220. The findings and opinions set forth in this declaration are based on my work and examinations to date.

221. I may continue my examinations. I may also receive additional documentation and other factual evidence over the course of this IPR that will allow me to supplement and/or refine my opinions. I reserve the right to add to, alter, or delete my opinions and my declaration upon discovery of any additional information. I reserve the right to make such changes as may be deemed necessary.

222. In signing this declaration, I recognize that the declaration will be filed as evidence in an IPR before the PTAB. I also recognize that I may be subject to cross-examination in the case and that cross-examination will take place within the United States. If cross-examination is required of me, I will appear for cross-examination within the United States during the time allotted for cross-examination.

223. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: June 4 2021 By: Bernard Chaitman MD

Dr. Bernard R. Chaitman
St. Louis, Missouri

02/09/2021

Bernard Chaitman MD

Curriculum Vitae

Bernard R. Chaitman, M.D.

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Work: (314) 725-4668
Fax: (314) 725-2171
E-mail: bernard.chaitman@health.slu.edu
Personal Contact Information
Home: (314) 422-2096 (Mobile)
Fax: (314) 993-8539
E-mail: chaitman@swbell.net

Birth: Detroit, Michigan
December 23, 1943

Marital Status: Married, 3 children

Education: Premedical: McGill University
Montreal, Quebec, B.Sc., 1965
Medical: McGill University
Montreal, Quebec, M.D., C.M., 1969

Residency: Internal Medicine: McGill University
Royal Victoria Hospital
Montreal, Quebec, 1969-1972

Specialty: Cardiology: University of Oregon
University of Oregon Health Sciences Center
Portland, Oregon, 1972-1974

University of Montreal
Montreal Heart Institute
Montreal, Quebec, 1974-1975

Citizenship: United States/Canadian (dual)

Current Position: Emeritus Professor of Medicine
Director of Cardiovascular Research
St Louis University School of Medicine

Academic Appointments:

Saint Louis University School of Medicine	
Director, Cardiovascular Research	2000-
Medical Director, Core ECG/MI Classification Laboratory	1989-
Director, Division of Cardiology	1989-2000
Professor of Medicine	1983-2018
Professor Emeritus/Adjunct Professor	2018
University of Montreal Medical School	
Associate Professor of Medicine	1980-1983
Assistant Professor of Medicine	1976-1979

Hospital Appointments:

Saint Louis University Hospital:	
Attending Staff	1983-
Director of Exercise and Nuclear Cardiology Laboratories	1983-1989
Montreal Heart Institute:	
Director of Noninvasive Laboratory	1979-1983
Attending Staff	1976-1983

University/Hospital:

The Department of Internal Medicine Promotions and Tenure Committee	2012-
Executive Medical Director, *SoLUtions*, a Clinical Research Organization	2005-2010
Chairman, Search Committee, Chief of Cardiology, St. Louis University	2009-2010
SLU Cardiovascular Institute Planning Committee, Director	1999-
SLUCare New Business Initiatives Committee	1996-1997
Managed Care Contract Committee	1995-1997
Continuing Medical Education Advisory Committee Member	1995-1999
Business Plan Development Committee	1995
Search Committee Member, Chair of Opthamology	1997
Search Committee Member, Chief of Cardiology, Cardinal Glennon Hospital	1993-94
Clinical Service Database Planning Committee	1993-1994
Veterans Administration School of Medicine; Internal Medicine Shared Resource Committee	1989-1996
Internal Medicine Executive Committee Member	1989-2000
Department Design Team for Ambulatory Care Building	1991-1992
University Ad hoc Committee of the Educational Policy Committee	1990-1991
Search Committee Member, Physiology Chair	1988-1989
Radioactive Drug Research Committee Member	1987-1989
Chairman, Biomedical/Instrumentation Committee	1987
Committee Member, Quality Assurance Committee	1987
Liaison Committee on Medical Education	1986
University Hospital Forms Committee	1985

Professional Societies (Current and Former*):

Fellow of the American College of Cardiology

Fellow of the Clinical Council of the AHA	
Association of University Cardiologists*	
American Society of Nuclear Cardiology*	
American Society of Echocardiography*	
President, St. Louis Greater Division of the American Heart Association	1998-2000
Fellow of the Royal College of Physicians and Surgeons of Canada*	
Fellow, Academy of Science of St. Louis	
President, St. Louis Cardiac Society	1989-90

Board Certificates:

American Board of Internal Medicine	1973
American Board of Cardiovascular Disease	1975
Royal College of Physicians and Surgeons of Canada	1976
College of Physicians and Surgeons of Quebec	1975
National Board of Echocardiography	2001-2011
Diplomate of the Certification Board of Cardiovascular Computed Tomography	2009-2019

License: National Board of Medical Examiners 1970 (#103299)
Medical Council of Canada 1970 (#29980)
State of Missouri (#R8C62) (Active)
State of Florida (#ME120638) (Active)
State of Illinois (#036-074342) (Inactive)
State of New York (#246687) (Inactive)

Certifications: Good Clinical Practice – October, 2019
Conflict of Interest – August, 2019
Advance Cardiac Life Support – 1/6/21-1/6/23
Saint Louis University Annual Compliance Update
Fraud, Waste and Abuse –
Saint Louis University Information Security Awareness –
Saint Louis University Moderate Sedation

NIH Related Activities:

Research Grant Review Committees:

NHLBI NIH Challenge Grants in Health and Science Research (part of the American Recovery and Reinvestment Act of 2009), Grant Review Committee	2009
NIH/NHLBI Cardiothoracic Network Cardiopulmonary Exercise Core Lab Review Committee	2008
NHLBI Loan Repayment Program Review Committee for Health Careers in Research	2005
NHLBI Study Section: Clinical Trial Review Committee	1998-2002
NIH Ad Hoc Review Committee Member for the RFA applications Pathologic Effects of Impaired Myocardial function in Older Persons	1993
NHLBI Supplemental Scor Grant Review Committee	1987
NHLBI Scor Grant Review Committee	1986

Safety and Data Monitoring Board:

Safety Monitoring Committee for the National Institutes of Allergy and Infectious Diseases, National Institutes of Health, Division of Microbiology and Infectious Diseases study, "Randomized, Placebo-Controlled, Double-Blind, Dose-Escalation Phase I Study of the Safety, Tolerability and Pharmacokinetics of a Single Intravenous Dose of ETI-204 (Anthim^{TM})"	2008-09
Chairman DSMB, Women's Angiographic Vitamin and Estrogen (WAVE) Trial Protocol Review Committee, AC 11023, Award #NO1-HV-68165, D. Waters, PI.	1997-2004
Chairman, Data Safety and Monitoring Board for the Multicenter Unsustained Tachycardia Trial (MUSTT) A. Buxton, PI.	1992-1999
Chairman, Data Safety and Monitoring Board for "A Vascular Basis for the Treatment of Ischemia" Study, P. Stone, PI.	1996-

Clinical Event Committee Activity-Chairman (NIH unless otherwise specified):

WARRIOR Trial; Department of Defense
MINT 2 Trial
ISCHEMIA Trial
ISCHEMIA CKD Trial
AIM HIGH Trial
BARI-2 Diabetes Trial (ACS classification)
BARI Trial; Committee member
FOCUS Trial
MINT Trial
COURAGE (VA/MRC)
RESCUE CCTA Trial (ACRIN); Committee member

NIH Funded Activities:

Clinical Trials:

NHLBI, 1U01HL117904-01 International Study of Comparative Health Effectiveness with Medical and Invasive Approaches (ISCHEMIA) - CKD, Core Event and Rest ECG Analysis Laboratory	2013-2019
NHLBI, 1U01HL105462-01 International Study of Comparative Health Effectiveness with Medical and Invasive Approaches **(**ISCHEMIA), Core Event and Rest ECG Analysis Laboratory	2011-2019
NHLBI, SU01HL105561-03 International Study of Comparative Health Effectiveness with Medical and Invasive Approaches **(**ISCHEMIA) ETT, Core Event and Rest ECG Analysis Laboratory	2014-2019
NHLBI, 1U01HL133817-02 Myocardial Ischemia aNd Transfusion II (MINT) Trial	2016-2020
NHLBI, 1RC2HL101458 Myocardial Ischemia aNd Transfusion (MINT) Trial, A Pilot Study	2009-2012
Fred Hutchinson Cancer Center: HTVN and IAVI Vaccine Trials	2008-2018
Division of Microbiology and Infectious Diseases (NIAID/NIH): DMID	2009-
US Military HIV Research Programs	2009

NHLBI, U01HL081616-01; AIM HIGH Core Event and Rest ECG Analysis Laboratory, Executive Committee Member 2005-2011

NHLBI, U01HL073958-03S1 FOCUS Core Event and Rest ECG Analysis Laboratory, Executive Committee Member 2005-2009

NHLBI, NO1-RO1H1261746-01A1; BARI-2 Diabetes Trial Core ECG Laboratory, Executive Committee Member 2001-2009

NHLBI, NO1-HC-65149; Prevention of Events with Angiotensin Converting Enzyme Inhibitors (PEACE), PI; St. Louis University site; Multicenter Trial E. Braunwald, PI. 1997-2003

NHLBI, NO1-HV-18120; Asymptomatic Cardiac Ischemia Pilot (ACIP), Operations, Executive, Steering, and Publications Committees 1991-1993

NHLBI, RO1HL38504-03; Bypass Angioplasty Revascularization Investigation (BARI), Operations and Executive Committee Member; BARI Ancillary Study of Economic and Quality of Life 1987-1993

NHLBI, RO1; Thrombolysis in Acute Myocardial Infarction (TIMI) Phase III, PI; St. Louis University Site; Multicenter Trial (E. Braunwald, PI); Executive Committee and Steering Committee Member 1989-1991

NHLBI, Contract No. NO1-HV-68093; Thrombolysis in Acute Myocardial Infarction (TIMI II); PI, St. Louis University Site; Multicenter Trial (E. Braunwald, PI); Executive Committee Member, Steering Committee Member 1986-1989

NHLBI Coronary Artery Surgery Study (CASS), Co-Investigator, Executive Committee Member 1975-1988 1988-1992

Core Rest and Exercise ECG Laboratory:

NHLBI, 1U01HL117904-01 International Study of Comparative Health Effectiveness with Medical and Invasive Approaches (ISCHEMIA) - CKD Core Event and Rest ECG Analysis Laboratory 2013-2019

NHLBI, 1U01HL105462-01 International Study of Comparative Health Effectiveness with Medical and Invasive Approaches (ISCHEMIA), Core Event and Rest ECG Analysis Laboratory 2011-2019

NHLBI, SU01HL105561-03 International Study of Comparative Health Effectiveness with Medical and Invasive Approaches (ISCHEMIA) ETT, Core Event and Rest ECG Analysis Laboratory 2014-2019

NHLBI, 1RC2HL101458 Myocardial Ischemia aNd Transfusion (MINT) Trial: A Pilot Study, Core Event and Rest ECG Analysis Laboratory 2009-2012

NHLBI, U01HL081616-01 AIM HIGH Core Event and Rest ECG Analysis Lab 2005-2011

NHLBI, U01HL073958-03S1 FOCUS Core Event and Rest ECG Analysis Laboratory 2005-2009

NHLBI, NO1-RO1H1261746-01A1 BARI-2 Diabetes Trial Core ECG Laboratory 2001-2009

NHLBI, NO1-AG-6-2106 Dynamics of Health, Aging ECG Laboratory (NIH): and Body Composition (Health ABC). Core ECG Laboratory 1997-2004

NHLBI, N01-HC-55140, ENRICHD Core ECG Laboratory 1997-2001

NHLBI, RO1HL421245-04; BARI Core Rest Electrocardiogram and Exercise ECG Laboratory 1988-2001

NHLBI ACIP and PIMI Trial Core Rest and Exercise ECG Laboratory 1991-1994

NHLBI, RO1HL42419-03 TIMI Phase III A & B Core Rest and Exercise ECG Lab 1989-1993

NHLBI, TIMI II Core Exercise ECG Laboratory 1988-1989

Department of Defense Funded Activiies

Women's IschemiA TReatment Reduces Events In Non-ObstRuctive CAD (WARRIOR): CEC Chair — 2018-2024

Industry Sponsored Clinical Event Committee Work:
Chairman, CEC, Daiichi Sankyo Trials
Chairman, CEC, NovoNordisc Trials
Chairman, CEC, Relypsa Trials
Member, CEC, Merck Trials
Member, Jenssen (J&J) Trials
Chairman, CEC, Eli Lilly Trials
Chairman, CEC, Roche Trials
Chairman, CEC, Sanofi Aventis
Chair: CEC Bayer trials
Chairman, CEC, Sunovion Trials

Industry Sponsored Clinical DSMB Trials:
Chairman, DSMB, Relypsa Trial
Chairman, DSMB, Sanofi/Regeneron Trial
Member, Pfizer neuroscience trial
Chairman, DSMB, Atherogenics Trials
Chairman, DSMB, Sepracor Protocols
Chairman, DSMB, Pfizer Trials
Chairman, DSMB, Kendle International, Inc
Member, DSMB, Sanofi-Aventis Trials
Member OPUS TIMI 16 Trial

Core Rest and Exercise ECG Laboratory (other):

Women's IschemiA TReatment Reduces Events In Non-ObstRuctive CAD (WARRIOR): Department of Defense, CEC
Relypsa: Clinical Trials
NovoNordisk: Clinical Trials
Roche: Clinical Trials
COURAGE Trial: Evaluation of Aggressive Medical Therapy vs. Percutaneous Coronary Intervention: VA and MRC (Canada) clinical trial
Aventis: Clinical Trials
Pfizer: Clinical Trials
Bristol-Myers Squibb: Clinical Trials
Gilead/CV Therapeutics, Inc: Clinical Trials
Boston Scientific Scimed, Inc.: Clinical Trials
Schering-Plough: Clinical Trials
Eclipse Surgical Technologies, Inc.: Clinical Trials
Merck Pharmaceutical Research Group: Clinical Trials
Ohmeda, Inc.: Clinical Trials
Zeneca Pharmaceuticals: Clinical Trials
Berlex Pharmaceuticals: Clinical Trials
Gensia, Inc.: Clinical Trials
Genentech, Inc.: Clinical Trials
Smith Kline & French, Inc.: Clinical Trials

Ciba-Geigy Pharmaceuticals, Inc.: Clinical Trials
Biogen: Clinical Trials
Bayer Pharmaceuticals: Clinical Trials
Marshfield Medical Research Foundation, PI: Myocardial Ischemia/Infarct Classification Laboratory - Perioperative Myocardial Infarction Studies 1992-1995

Previous Funding, PI Unless Otherwise Specified:

CO Exposure in Cardiac Arrhythmias: Health Effects Institute (PI), Boston, MA Award #87-8 1987-1989
Ticlopidine; Prevention of Restenosis Post PTCA, Syntex Research, Palo Alto, CA 1984-1987
CO Exposure in CAD: Health Effects Institute, Boston, MA 1984-1987
Evaluation of Noninvasive techniques to diagnose CAD 1980-1983
Evaluation of the exercise polarcardiogram Canadian Heart Foundation 1980-1983
Prospective evaluation of Carpentier-Edwards porcine valves, Edwards Laboratory 1977-1983

Veterans Affairs Activities:

Safety and Data Monitoring Board, Department of Veterans Affairs, Cooperative Studies in Health Services ("The Diagnostic and Prognostic Value of the Computerized Exercise ECG") 1994-1997
Veterans Affairs Cardiovascular Disease Merit Review Board 1985-1987

Additional Research Grant Review Committees:

U.S. Agency for Health Care Policy and Research: AdhocReview Committee; Evaluation of the Ambulatory Ischemic Heart Disease Port 1994
Peer Reviewer, Clinical Practice Guideline on the Definition and Management of Unstable Angina (for Duke University and the U.S. Agency for Health Care Policy and Research) 1993-
American Heart Association, Missouri Affiliate 1984-1987
Cardiovascular Disease Section; National Veterans Administrative Merit Review Board 1984-1987
Medical Research Council of Canada 1979-1981
Canadian Heart Foundation 1979-1981

Committee Membership:

FDA/ACCF/AHA Cardiovascular Endpoints Data Standards Writing Committee 2013-
FDA Working Group on Clinical Event Committee Definitions and Processes, ACS Subcommittee member 2009-
Chairman, ECG working Group European Society of Cardiology / American Heart Association / American College of Cardiology / World Federation of Cardiology Task Force to prepare document on the Universal Definition of Myocardial Infarction 2007-
ACC Bethesda Conference Committee to rewrite the Sudden Cardiac Death in Athletes Report 2003
American College of Cardiology/American Heart Association/ European Society of Cardiology; Ventricular Arrhythmias and Sudden Cardiac Death Guidelines 2003

Writing Committee

FDA ad-hoc Committee on Electronic ECG Formatting - Aware Citation from FDA	2003
American Heart Association Council on Clinical Cardiology, Nominating Committee	2001-2003
American Heart Association Council on Clinical Cardiology, Scientific Program Committee	2001-2004
American College of Cardiology Foundation; Writing Committee for Task Force 6 to develop Concensus Report on Coronary Artery Disease	2003-2004
American College of Cardiology/American Heart Association Joint Subcommittee Writing Group to Revise the Report of the 1996 Exercise Test Guidelines	2000
American College of Cardiology Writing Group to Revise the Report of the 1995 Core Cardiology Training Symposium (COCATS)	2000
American College of Cardiology/American Heart Association Joint Subcommittee Writing Group to Revise the Report of the Guidelines for Evaluation of Patients Considered for Noncardiac Surgery	2000
Executive Committee Member, AHA Council on Clinical Cardiology	1998-2001
AHA Council on Clinical Cardiology: Chairman of Committee for Exercise, Cardiac Rehabilitation and Prevention	1998-2001
American College of Cardiology, Chairman, Constitution and Bylaws Committee	1998-2001
American College of Cardiology, Training Directors Committee	1991-1997
International Society for Electrocardiology	1997-
Accreditation and Curriculum Sub-Council, Association of Subspecialty Professors	1994-1997
Vice Chairman of the Committee for Exercise and Cardiac Rehabilitation; American Heart Association Council on Clinical Cardiology	1993-1998
American Heart Association Missouri Chapter, Vice-President and Board of Directors	1993-1995
American College of Cardiology, Chairman Nominating Committee, Missouri Chapter	1993
Regional Councilor, State of Missouri Chapter, American College of Cardiology	1992
ACGME: Cardiovascular Precertification Review Committee	1990-1996
Governor's Advisory Group, American College of Cardiology, State of Missouri	1989
European Society of Cardiology Working Group on Exercise Physiology, Physiopathology & Electrocardiography	1986-
AHA Abstract Review Committee, Scientific Sessions	1978-1979, 1984-present
American College of Cardiology Scientific Sessions Abstract Review Committee	1983-present
Abstract Review Committee, Scientific Sessions, Canadian Cardiovascular Society	1982
Scientific Review Committee, Consultant to International Symposium on Cardiac Bioprosthesis	1982
Abstract Review Committee, Scientific Sessions of the Royal College of Physicians and Surgeons of Canada	1979

Editorial Board (current): Journal of the American College of Cardiology
Circulation: Guest Editor
European Heart Journal
American Journal of Cardiology
Clinical Cardiology
Coronary Artery Disease
Journal of Cardiopulmonary Rehabilitation and Prevention
Journal of Cardiovascular Pharmacology and Therapeutics
Journal of Electrocardiology
Cardiology Today

Editorial Consultant: New England Journal of Medicine
Journal of the American Medical Association
Annals of Internal Medicine
Archives of Internal Medicine
Canadian Medical Association Journal
Chest
Journal of Arrhythmia (International Advisory Board)
Journal of Catheterization and Cardiovascular Diagnosis

Sabbaticals: Mount Sinai School of Medicine
New York, New York
September 1, 2008 to September 1, 2009
Advanced Cardiac Imaging: Cardiac CT Angiography

Washington University School of Medicine
St. Louis, Missouri
January 1 – June 30, 2001
Noninvasive Imaging: Advanced Echocardiography

Continuing Medical Education:

Cardiovascular Institute's 24th Annual Cardiology Update on "Clinical Management of Heart Disease 2017: Practical Approaches to the Diagnosis and Management of Cardiovascular Disease" Presented "Diabetes and Stable Ischemic Heart Disease" Philadelphia, PA — September 17, 2017

2nd Annual Endpoint Adjudication Conference: Streamline Data Collection Processes to Enable Efficient CEC Review and Regulatory Submissions Panelist: "Adjudicator Perspective - Critical Insights into Process Bottlenecks and Challenges" and "Key Tactics for Ensuring all Involved Parties Agree on Endpoint Approval" Philadelphia, PA — May 4-5, 2016

Harvard Medical School, Cardiovascular Grand Rounds "Myocardial Infarction Defined: A Clinical Trial Perspective" — October 15, 2015

Co-Chair, "Exercise Testing: Rationale of ETT and Comparison with Cardiac Imaging," American College of Cardiology Scientific Session — March 30, 2014

The Kilo Diabetes & Vascular Research Foundation Washington University School of Medicine: "The 39th Annual Symposium Current Topics in Diabetes, Endocrinology and Vascular Disease — November 18-19, 2011

Virginia Commonwealth University School of Medicine: "2011 Update on the Management and Treatment of Stable Ischemic Heart Disease — June 2, 2011

Albert Einstein College of Medicine: "2011 Update on Management and Treatment of Patients with Stable Ischemic Heart Disease" — March 8, 2011

Washington University School of Medicine Cardiology Grand Rounds "Optimal Choice of Initial Medical Therapy, PCI or CABG for Patients with Stable Ischemic Coronary Disease: A 2011 Perspective" — March 2, 2011

Saint Louis University School of Medicine, Internal Medicine Grand Rounds "Troponitis, Application of the ACC/AHA/ESC/WHF/WHO University MI Definition to Ruotine Clinical Care and Need for Downstream Testing" — March 4, 2011

Transcatheter Cardiovascular Therapies (TCT) 2010, Washington, DC — September 21-25, 2010
"BARI-2D Perspectives: Glass Half Empty or Glass Half Full for Revascularization?" & "Impact of Degree of Revascularization and Stent Type on Outcomes in BARI 2D"

The 15th Annual Meeting of the Japanese Association of Cardiac Rehabilitation (JACR), Tokyo, Japan — July 18-19, 2009

18th Cardiology Update Course sponsored by the Foundation for Cardiovascular Research and the European Society of Cardiology Davos, Switzerland — February 15-20, 2009

29th Panhellenic Annual Congress of Hellenic Cardiology Cardiologic Society Conference, Athens, Greece — October 30-November 1, 2008

17th Cardiology Update Course sponsored by the Foundation for Cardiovascular Research and the European Society of Cardiology Davos, Switzerland — February 12-16, 2007

"New Pharmacologic Approaches for the Treatment of Chronic Angina" — June 10, 2005
Department of Medicine, Chiba Hokusoh Hospital, Nippon Medical School Inba Chiba, Japan

The 9th Scientific Meeting for Pharmacotherapy of Cardiovascular Diseases — June 11, 2005
The University of Tokyo, Department of Anesthesiology, Tokyo, Japan

New Management Strategies for Chronic Angina: Harvard, Johns Hopkins Northwestern University — 2004-2005

Co-chair, symposium on Clinical Event Adjudication Committees — January 20-21, 2005
Duke University Medical Center, Duke Clinical Research Institute, Participation by FDA/University Consortium/Pharmaceutical Consortium

Multiple CME programs on Global Risk Factor Reduction and Guidelines to Reduce Atherosclerotic Burden — 2001-2003

Multiple CME programs on Prognostic Risk Stratification in Chronic Angina and its Treatment — 2001-2003

Changing Diagnosis of Acute Myocardial Infarctions – Implications for Practicing Clinical Investigations, "Cardiac Markers – Post CABG" — January 25-27, 2001
Duke University Medical Center, Duke Clinical Research Institute, Vienna Virginia

Cardiology Update for the Primary Caregiver: BR Chaitman, Chair — October 28, 2000
Ritz Carlton Hotel, St. Louis, MO

The Cardiovascular Board Review: For Certification & Recertification. — 2000-2005
"Exercise/Stress Testing," sponsored by American College of Cardiology Hyatt Regency O'Hare, Chicago, IL

Symposium on Chocolate, Antioxidants, Polyphenols and Cardiovascular Health: sponsored by XXII Congress of The European Society of Cardiology, B.R. Chaitman, Moderator; Amsterdam, The Netherlands — August 26-30, 2000

National Institutes of Health/U.S. Food and Drug Administration
"Biomarkers and Surrogate Endpoints: Advancing Clinical Research and Applications,""ECG in Acute Coronary Syndromes" and "The Electrocardiogram as a Biomarker for Myocardial Ischemia in Chronic Ischemic Heart Disease" Bethesda, Maryland — April 15-16, 1999

University of Florida-Gainesville: "Value of ETT in Women with Suspect Ischemic Heart Disease," "Perspective View of Future Directions in Cardiology: Canadian vs. USA," "Diabetes in Cardiovascular Disease" — March 5-6, 1998

St. Luke's Episcopal Hospital/Texas Heart Institute Cardiology Grand Rounds — February 13, 1998

"Diabetes and Heart Disease", Houston, Texas,

University of Virginia Health Sciences Center Cardiology Grand Rounds January 20, 1998
"Cardiovascular Diseases in the Diabetic Patient," Charlottesville, VA

Michigan Heart and Vascular Institute Cardiology Grand Rounds December 9, 1997
"Revascularization Options in Patients with Multi-Vessel Disease PTCA or CABG", Ypsilanti, Michigan

Fifth Annual Meeting of the Missouri Chapter of the American College of Cardiology, "Silent Ischemia in the ACIP Trial", St. Louis, Missouri September 27, 1997

Update in Diabetes and Endocrinology. "Heart Disease in the Diabetic Patient," St. Louis, Missouri September 26, 1997

The Philadelphia Board Review Course October 15-20, 1995, November 2-7, 1997
Course in Cardiovascular Diseases, Philadelphia Heart Institute, The Graduate Hospital, and the American Heart Association; Philadelphia, PA

Current Concepts in Cardiology '97, Presentation: "The Impact of Gender on the Diagnostic & Prognostic Utility of Noninvasive Cardiac Testing for Suspect of Proven Ischemic Heart Disease," Long Island Jewish Medical Center, New Hyde Park, NY May 7, 1997

University of Southern California, Los Angeles, CA Grand Rounds December 20, 1994

New Frontiers in Cardiac Imaging: sponsored by American Society of Nuclear Cardiology; Dallas, Texax November 13, 1994

Symposium on Ischemic Heart Disease Controversies: sponsored by the Spanish Society of Cardiology and European Society of Cardiology Marbella, Spain June 16-17, 1994

How to Become a Clinical Cardiovascular Investigator: sponsored by the Council on Clinical Cardiology of the American Heart Association; American College of Cardiology; National Heart, Lung, and Blood Institute; Bethesda, Maryland. May 6-7, 1994

International Therapeutic Symposium: sponsored by the Japanese Heart Association, Tokyo, Japan November 6, 1993

Clinical Applications of Exercise Testing in Cardiac Disease: American College of Cardiology, Bethesda, Maryland, Program Director 1986-1995

Clinical Exercise Physiology and Cardiac Rehabilitation Conference: American College of Cardiology, Palo Alto, CA, Program Director 1993-1995

Midwest Clinical Molecular Cardiology Conference: B.R. Chaitman and D. Douglas Miller-Moderators, St. Louis, Missouri September 1992-1994

International Conference on Ischemic Syndromes: B.R. Chaitman, D.G. Caralis Program Directors, Athens, Greece June 15-17, 1992

Management Strategies for Hypertensive Patients/Patients with Selective Cardiac Problems, Program, Director, St. Louis, MO August 24, 1991

New Concepts in the Management of Acute Myocardial Infarction: B.R. Chaitman, M. Kern, B.E. Sobel, P. Ludbrook, St. Louis and Washington Universities, St. Louis, Missouri May 25, 1990

Clinical Cardiology: A Practical approach. B.R. Chaitman, A.J. Labovitz Program Directors, St. Louis, Missouri May 19, 1989

The Initial Six Hours after Acute Myocardial Infarction. B.R.Chaitman, P. Ludbrook Directors, St. Louis and Washington Universities, St. Louis, MO May 1987

AHA and ACC Annual Scientific Sessions: Symposia Speaker, Fireside Panel, Meet the Expert Session

Invited lectures not listed

Postdoctoral Fellows:

Akira Kurita, M.D., Associate Professor of Medicine, 1st Department of Internal Medicine
National Defense Medical College, Saitama, Japan
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Jorge Hernandez, M.D., Private practice, St. Louis, Missouri
Yogesh Shah, M.D., Private practice, New Jersey
Mark D. Wittry, M.D., Assistant Professor of Medicine, Nuclear Medicine Division
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Leonardo R. Maitas, M.D., Attending Cardiologist; Hospital Miguel Perez Carreno
Caracas, Venezuela
Norbert Lingling Uy, M.D., Assistant Professor of Internal Medicine, University of the East,
Ramon Magsaysay Memorial Hospital, Manila, Philippines
Beaver R. Tamesis, M.D., Clinical Instructor, University of the Philippines, Manila,
College of Medicine Philippine General Hospital
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Yasuhiro Yokoyama, M.D., St. Marianna University School of Medicine, Kawasaki, Japan
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Acknowledgments:

American Heart Association Heartland affiliate Arthur E. Strauss Award 2005

Awarded the Food and Drug Administration's Commissioner's Special Citation Award for the development of a format for regulatory submission of annotated electrocardiographic wave form data to meet FDA's needs in assessing the pro-arrhythmic potential of drugs (October 2003)

Listed in the directory *America's Top Doctors*, published by Castle Connolly Medical Ltd., 2001 first edition, 2005-2017

Listed in the directory *The Best Doctors in America* published by Woodward/White, Inc., Aiken, S.D.; edited by Luch Stec, 1992, 1994, 1996, 1999, 2004, 2005-2006, 2009-2017

Life Member; National Registry of Who's Who, copyright 2000; registration number 110341

Keyword Descriptions: Exercise Testing
Coronary Artery Disease
Coronary Bypass Surgery
Valvular Prosthesis

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