

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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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. 10,595,731 (“The ’731 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 ’731 patent.

2. I have been asked to provide my independent analysis of the ’731 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 ’731 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 ’731 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, 7, 12, 13, 16, 17, 23-26 and 30 of the '731 patent are rendered obvious by Shmueli.
- **Ground 2:** Based upon my knowledge and experience and my review of the prior art publications in this declaration, I believe that claims 1, 2, 4, 7, 12-

14, 16-18, 20, 23-26 and 30 of the '731 patent are rendered obvious by Shmueli in view of Osorio.

- **Ground 3:** Based upon my knowledge and experience and my review of the prior art publications in this declaration, I believe that claims 13, 5, 6, 19, 21 and 22 of the '731 patent are rendered obvious by Shmueli in view of Osorio and Li 2012.
- **Ground 4:** Based upon my knowledge and experience and my review of the prior art publications in this declaration, I believe that claims 8-11 and 27-29 of the '731 patent are rendered obvious by Shmueli in view of Osorio and Kleiger 2005.
- **Ground 5:** Based upon my knowledge and experience and my review of the prior art publications in this declaration, I believe that claim 15 of the '731 patent is rendered obvious by Shmueli in view of Osorio and Chan.

IV. BACKGROUND KNOWLEDGE ONE OF SKILL IN THE ART WOULD HAVE HAD PRIOR TO THE PRIORITY DATE OF THE '731 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 '731 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 '731 patent ("POSITA"). Based on instruction from Counsel, I have applied March 14, 2014 ("Critical Date"), as the date of the alleged invention of the '731 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 '731 patent; my own knowledge and experiences gained from my work experience in the field of the '731 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. Pat. No. 10,595,731 to Gopalakrishnan (“the '731 patent”) (APPLE-

1001)

- Excerpts from the Prosecution History of the '731 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. Wittkamp, “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 (731 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)
- Aaron 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 the 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. Electrocardiography (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

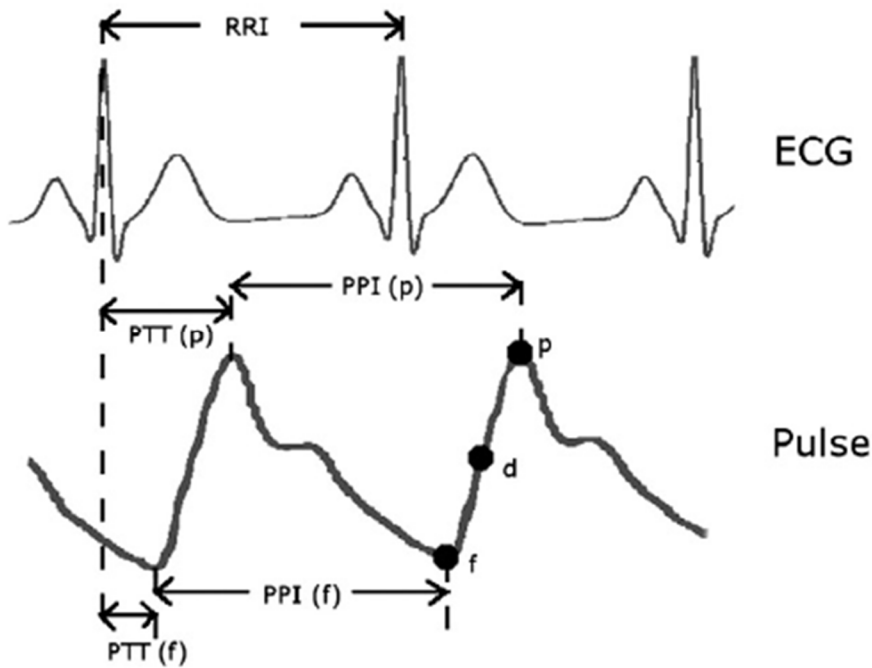
hospital to diagnose cardiac arrhythmias. APPLE-1016, p. 6080. As an irregular heartbeat caused by arrhythmia does not necessarily occur during examination at the hospital, a Holter ECG has been used for measuring one or more leads of an ECG in daily life. *Id.* A Holter ECG device is not ideal because 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 and 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 to help diagnose various types of arrhythmia. 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 ’731 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, 8:64-9:2 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

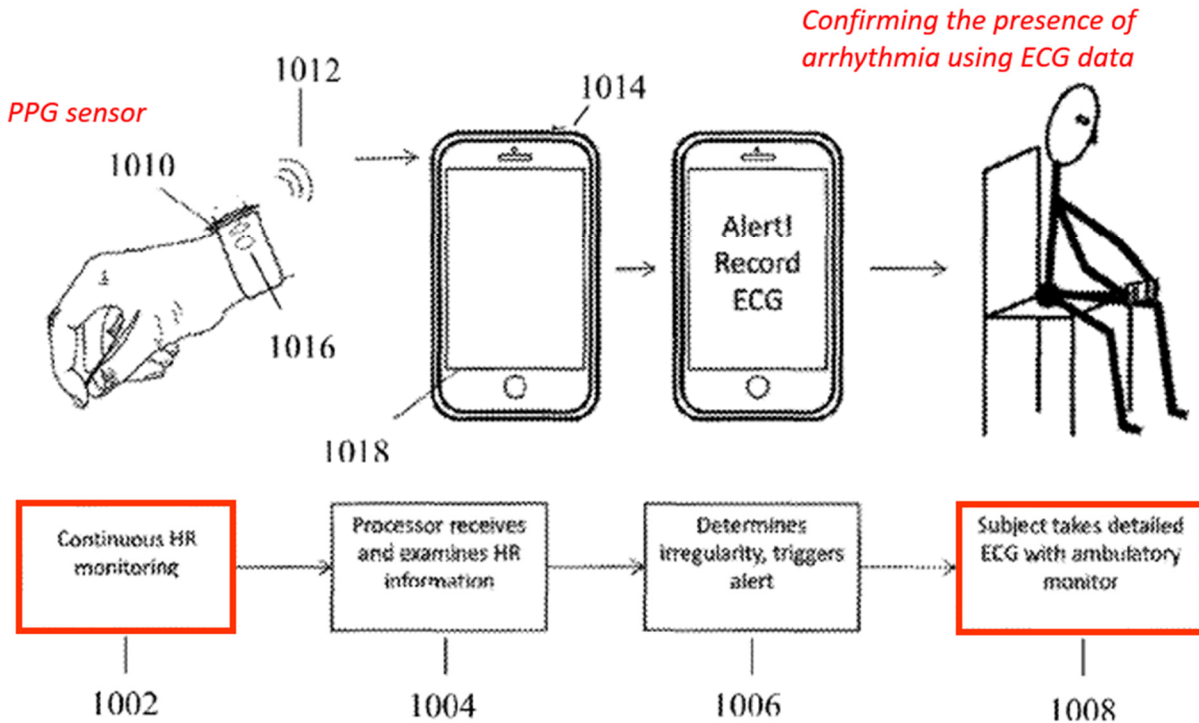
learning and statistical pattern recognition have been the subject of tremendous interest in the biomedical community because they offer promise for improving the sensitivity and/or specificity of detection and diagnosis of disease, while at the same time increasing objectivity of the decision-making 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 '731 PATENT

39. The '731 patent, titled "Methods and systems for arrhythmia tracking and scoring," claims a two-staged arrhythmia detection method where the first step uses a PPG monitor and the second step uses an ECG monitor. APPLE-1001, claim 1. Specifically, the '731 patent claims a method that includes: (1) receiving PPG data from a PPG sensor; (2) detecting arrhythmia based on the PPG data; (3) receiving ECG data from an ECG sensor, and (4) confirming arrhythmia based on the ECG data. *Id.*, claim 1. The '731 patent explains that the heart rate can be detected by using PPG. APPLE-1001, 8:51-55. The '731 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, 25:25-30.

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

detected using a heart rate monitor 1010 (e.g., PPG sensor), an irregularity is detected, and an alert is provided for the user to record an ECG. APPLE-1001, 23:22-34 (“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 16/588,201 (“the ’201 application”) on September 30, 2019. APPLE-1001, Cover. The ’201 application is a continuation application of U.S. Patent Application No. 16/153,446, filed on October 5, 2018, which is a continuation of U.S. Patent Application No. 15/393,077, filed on December 28, 2016, which is a continuation of U.S. Patent Application No. 14/730,122, filed on June 3, 2015, which is a continuation of U.S. Patent Application No. 14/569,513, filed on December 12, 2014, which claims priority to provisional application No. 62/014,516, filed on June 19, 2014,

provisional application No. 61/970,551, filed on March 26, 2014, provisional application No. 61/969,019, filed on March 21, 2014, provisional application No 61/953,616, filed on March 14, 2014, and provisional application No. 61/915,113,¹ filed on December 12, 2013. *Id.*

42. During prosecution of the '731 patent, the Examiner only issued a double-patenting rejection, which was overcome by filing a terminal disclaimer. APPLE-1002, pp. 73-78 (Non-Final Rejection dated November 25, 2019) and pp. 51-72 (Response dated January 8, 2020). During prosecution, the examiner did not consider Shmueli, Osorio, or Li.

43. Later, the Office allowed the application and noted in the Examiner's statement of reason for allowance that the cited reference fails to disclose the claimed invention having a smart watch and a method of determining a presence of arrhythmia comprising sensing an activity level with a motion sensor and comparing a heart rate variability to said activity level. APPLE-1002, 25-32 (Notice of Allowance, 2020-2-3). The '731 patent issued on March 24, 2020 and includes 30 claims, of which claims 1, 17 and 25 are independent. APPLE-1001, Cover and claims.

¹ The cover of the '731 patent lists provisional application No. 61/915,113 as “provisional application No. 61/915,115,” which I understand as a typo.

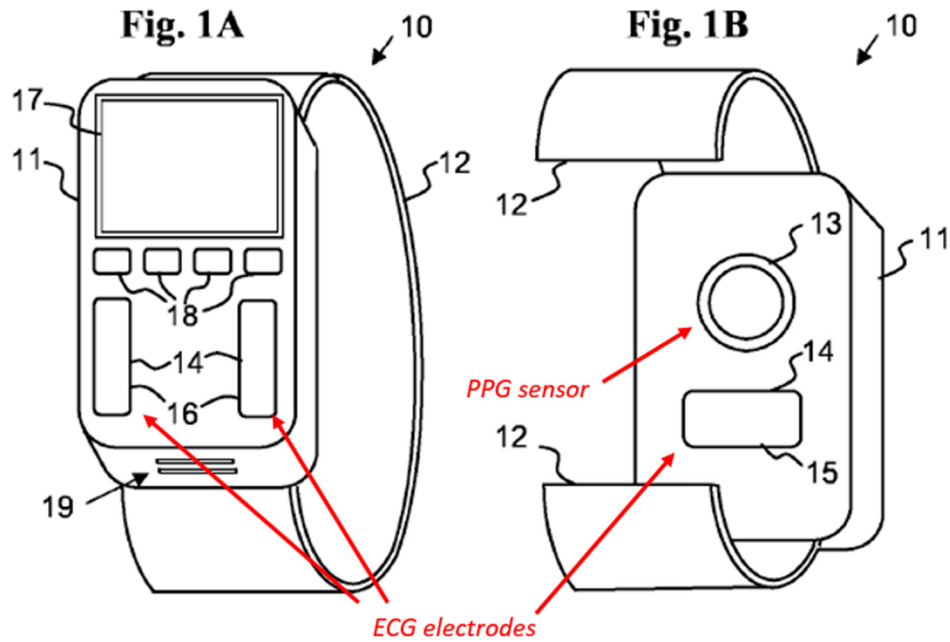
X. SUMMARY OF THE PRIOR ART

A. Shmueli

(a) Monitoring Device

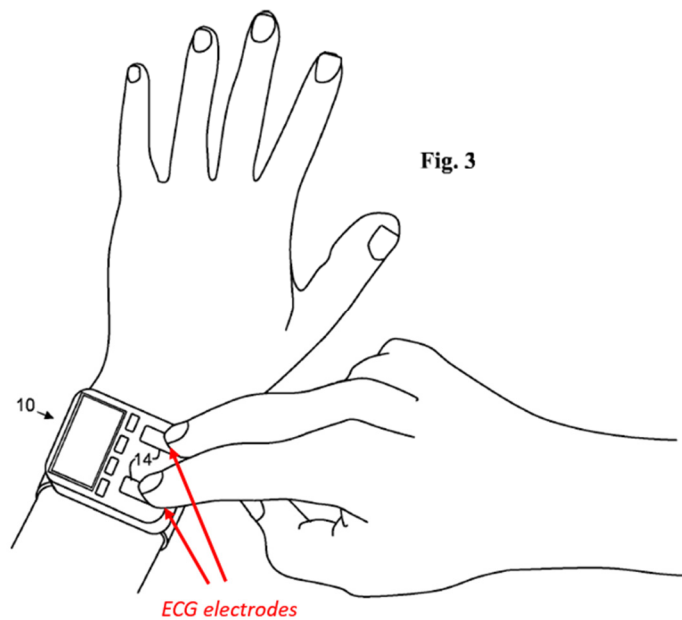
44. Shmueli is titled “Pulse oximetry measurement triggering ECG measurement.” APPLE-1004, Cover. Shmueli’s heart monitoring device includes an “oximetry measuring unit” for measuring oxygen saturation (SpO₂), which Shmueli describes as being the same as PPG. APPLE-1004, 7:25-27 (“In this document, unless 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.

45. 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)

46. 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*

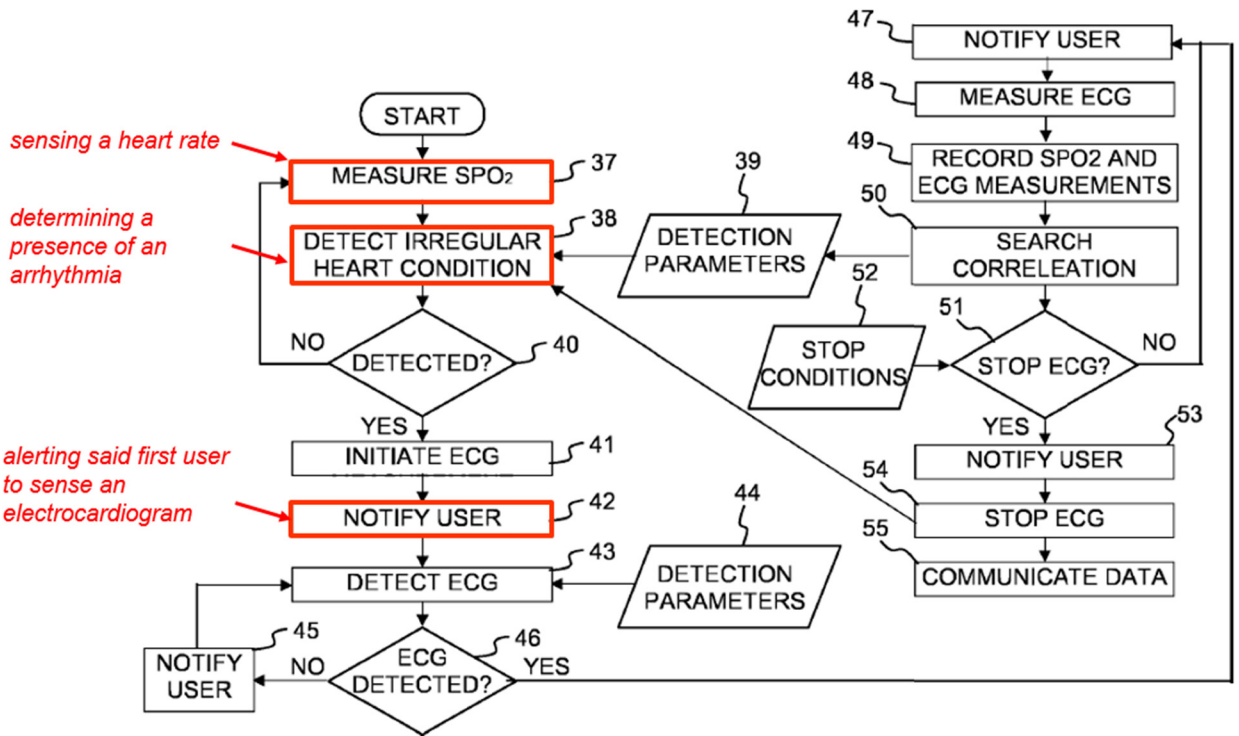
47. Shmueli's hearting monitoring device performs a monitoring technique that involves "continuously measuring [oxygen saturation (SpO₂)] at the wrist of the user, detecting an **irregular heart condition** from the SpO₂ measurement, notifying the user to perform an ECG measurement, and initiating the ECG measurement at least partially at the wrist." APPLE-1004, Abstract (emphasis added). PPG also is referred to as pulse oximetry SpO₂ (oxygen saturation). APPLE-1004, 7:25-27.

48. 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 ’731 patent describes arrhythmia as “a **cardiac condition** in which the electrical activity of the heart is **irregular**...” APPLE-1001, 1:40-42. 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.

49. Like the ’731 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)

50. 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.

51. 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

52. 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:

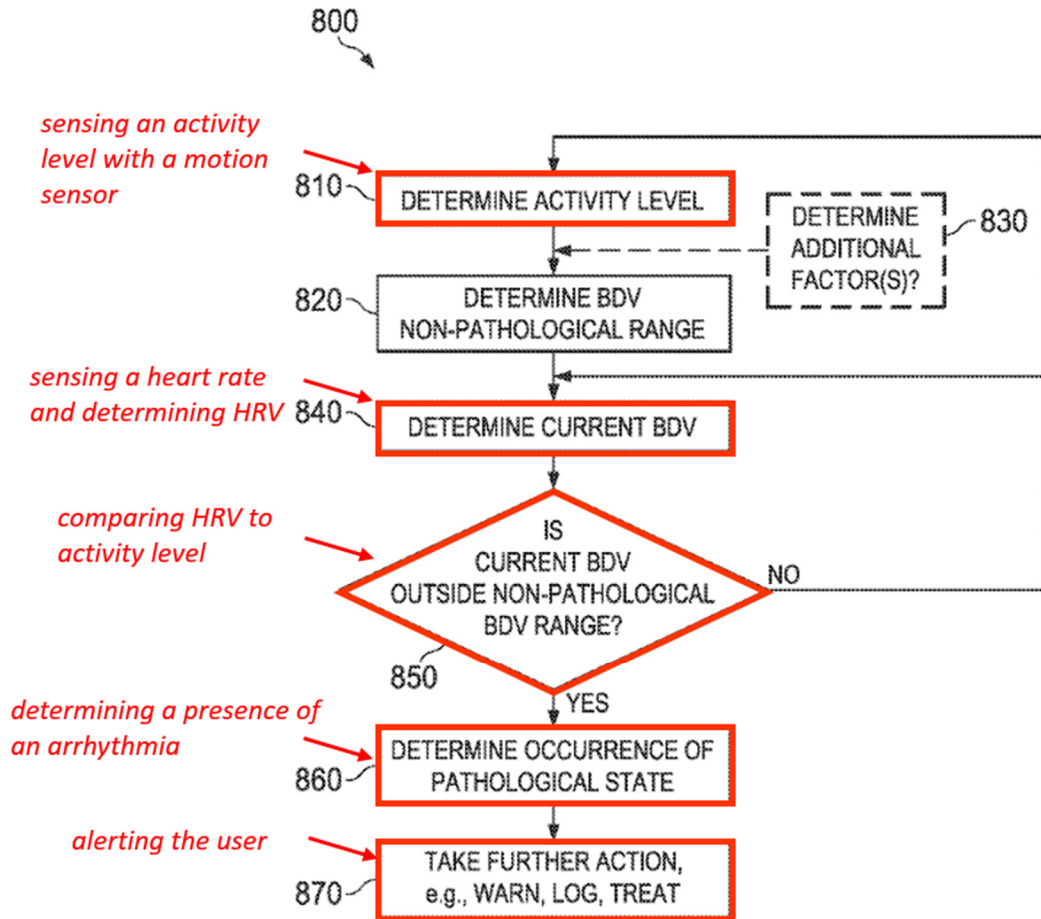


FIG. 8

APPLE-1005, Fig. 8 (annotated)

53. 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.*

54. 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.

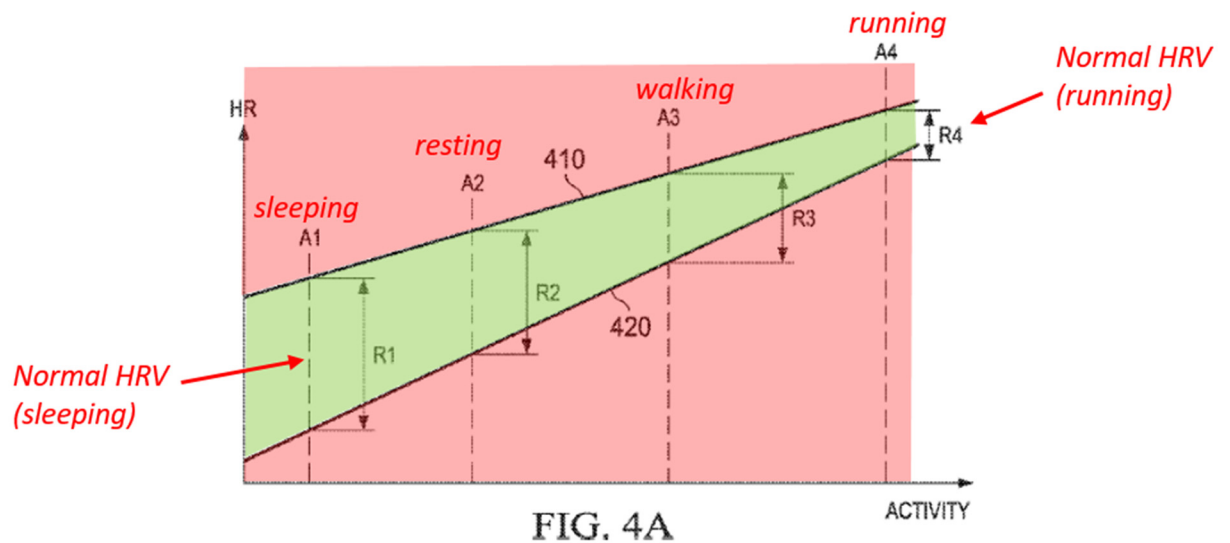
55. Osorio explains that accurate detection of a pathological condition (e.g., arrhythmia) based on a patient’s HR should also consider the patient’s activity level:

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].

56. 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.”).

57. 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:



APPLE-1005, Figs. 4A (annotated)

58. 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. Li 2012 Overview

59. Li 2012, titled “signal quality and data fusion for false alarm reduction in the intensive care unit,” discloses using a machine learning algorithm to detect arrhythmia based on PPG and ECG data. APPLE-1006, Abstract. Li 2012 explains that traditional arrhythmia detection was marred by false alarms due to a lack of

integration between different sensors. APPLE-1006, Abstract. To solve this problem, Li 2012 utilized a machine learning algorithm to combine up to 114 features extracted from PPG and ECG data. APPLE-1006, Abstract. 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.

D. Kleiger 2005 Overview

60. Kleiger 2005, titled “Heart rate variability: measurement and clinical utility,” is a review article on the common HRV measurements and their clinical utility. APPLE-1033, Title. Kleiger 2006 discloses that HRV, also referred to as RR interval variability, is useful for assessing risk of cardiovascular death or *arrhythmia* events. APPLE-1033, Abstract. Kleiger 2005 discloses that methods for quantifying HRV are categorized as: time domain, spectral or frequency domain, geometric, and nonlinear. APPLE-1033, p. 88.

(c) *Time domain HRV measures*

61. Kleiger 2005 explains that, in time domain analysis, the intervals between adjacent normal R waves (NN intervals) are measured over the period of recording. APPLE-1033, p. 88. Kleiger 2005 discloses common time domain HRV measures in Table 1:

Table 1. Time Domain Measures of HRV Calculated over 24 Hours

SDNN	Standard deviation of all normal to normal R-R (NN) intervals
SDANN	Standard deviation of 5-minute average NN intervals
ASDNN (index)	Mean of the standard deviations of all NN intervals for all 5-minute segments in 24 hours
rMSSD	Square root of the mean of the squares of successive NN interval differences
NN50	The number of NN intervals differing by >50 ms from the preceding interval
pNN50	The percentage of intervals >50 ms different from preceding interval
Night-day difference	Mean night R-R interval minus mean day R-R interval

APPLE-1033, Table 1.

As one example, Kleiger 2005 discloses that SDNN, the standard deviation of all normal RR (NN) intervals during a 24-hour period, is the most commonly used time domain measure of HRV. APPLE-1033, p. 88.

(d) *Spectral or frequency domain HRV measures*

62. Regarding spectral or frequency domain HRV measures, Kleiger 2005 explains that either fast Fourier transformation or auto-regression techniques can be used to quantify cyclic fluctuations of R-R intervals. APPLE-1033, p. 89.

Traditionally, spectral analysis has been done in short-term laboratory studies; often standard 5-minute ECG segments are analyzed. *Id.* Two peaks are seen in 5-minute R-R interval power spectra, a HF peak between 0.15 and 0.40 Hz and a low frequency (LF) peak between 0.04 and 0.15 Hz. *Id.*

63. As shown below in Table 2, Kleiger 2005 explains that each of the 24-hour spectral measures has an equivalent time domain variable, which is highly correlated with it because both are influenced by the same physiologic inputs and because of mathematical relationships. APPLE-1033, p. 90.

Table 2. Highly Correlated Time and Spectral Measures of HRV

Time Domain	Frequency Domain
SDNN	Total power
SDANN	ULF power
ASDNN	VLf power
PNN50, rMSSD	HF power
<i>Highly Correlated Time Domain Measures</i>	
SDNN	SDANN
RMSSD	pNN50

APPLE-1033, Table 2.

(e) ***Geometric HRV measures***

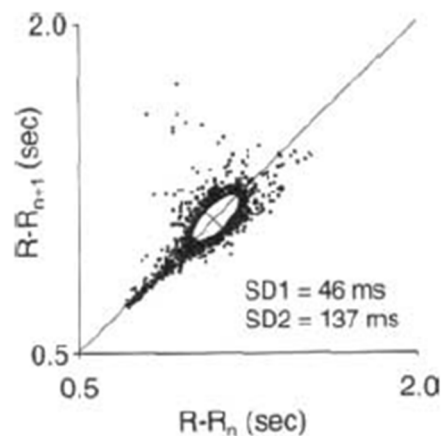
64. Regarding geometric HRV measures, Kleiger 2005 discloses that HRV triangular index, a geometric measure of HRV, has been used extensively by investigators at St. George’s Hospital in London. APPLE-1033, p. 91. In this method, the calculation of HRV index minimizes the influence of outlier R-R intervals, i.e., those much longer or shorter than the usual, thereby substantially reducing the influence of missed beats, artifact, and ectopic complexes. *Id.*

(f) ***Nonlinear HRV measures***

65. Although time and frequency domain measures of HRV quantify HRV on various time scales, nonlinear HRV measures attempt to quantify the structure or complexity of the R-R interval time series. APPLE-1033, p. 91. For example, a random series of R-R intervals, a normal series of R-R intervals and a totally periodic series of R-R intervals might have the exact same SDNN, but their

underlying “organization” would be completely different. *Id.* A large number of nonlinear measures of HRV have been studied, but only a few have shown clear utility in risk stratification. *Id.* These include the power law slope, the short- and long-term fractal-scaling exponent, and SD12, a measure derived from Poincare plots. *Id.*

66. Kleiger 2005 explains that the Poincare graph plots *each RR interval as a function of the next RR interval* and provides an excellent way to visualize patterns of R-R intervals. APPLE-1033, p. 92 and Fig. 2. Kleiger 2005 also explains that the Poincare plot is a *nonlinear* measure of the *RR interval fluctuations*. *Id.*, Fig. 2.



APPLE-1033, Fig. 2.

67. Poincare plots that reveal abnormal R-R interval patterns have been characterized as “complex.” APPLE-1033, p. 92. SD12 is determined by fitting an ellipse to the Poincare plot. *Id.* SD1 is the short axis of this ellipse and SD2 is the

long axis. *Id.* SD12 is their ratio. *Id.* As the plot becomes more complex, the relative magnitude of SD1 compared to SD2 increases and SD12 becomes larger. *Id.* In addition, if the plot is small and ball-shaped because of relatively constant R-R intervals, SD12 also will be large. *Id.*

E. Chan Overview

68. Chan is titled “device and method for measuring three-lead ECG in a wristwatch.” APPLE-1048, Cover. Chan discloses a “wristwatch worn by a user for measuring a three-lead ECG.” APPLE-1048, Abstract. Figs. 1A and 1B show front and back views of Chan’s device. APPLE-1048, 2:43-49. In the backside 1 of the watch, an electrode 3 is inserted for touching the hand that wears the watch. *Id.* The frontside 2 of the watch includes electrode 4 and electrode 6 for fingers from the other hand to press on. *Id.* A display 7, such as a liquid crystal display (LCD), is on the frontside 2 of the watch. *Id.* The display 7 can demonstrate in text 15, which includes time, heart rate, condition (normal or arrhythmia), and graph/animation, an event 13 and ECG waveforms 14. *Id.*

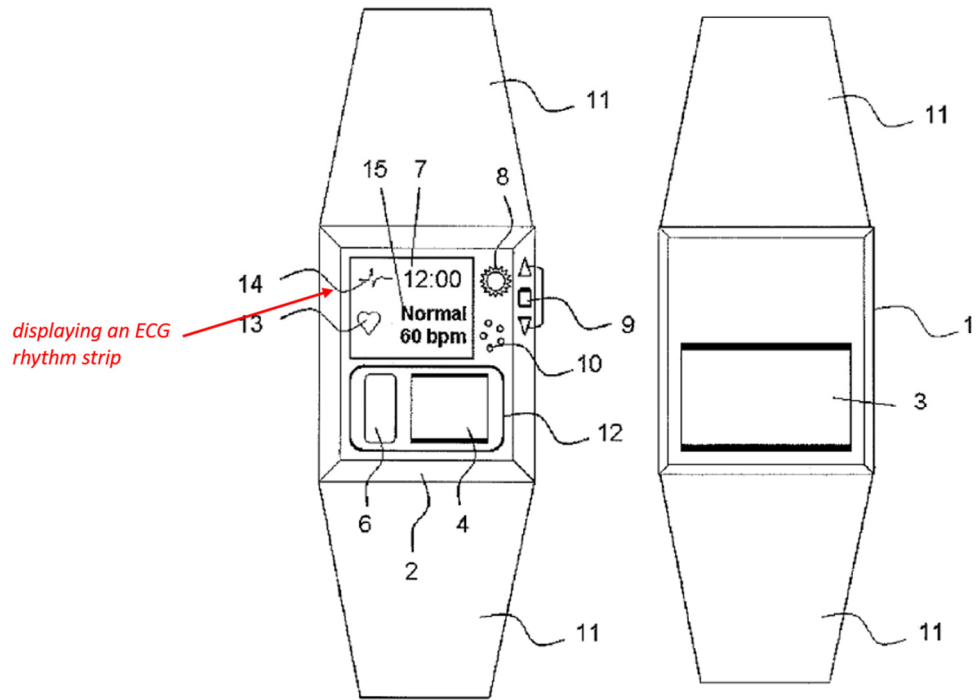
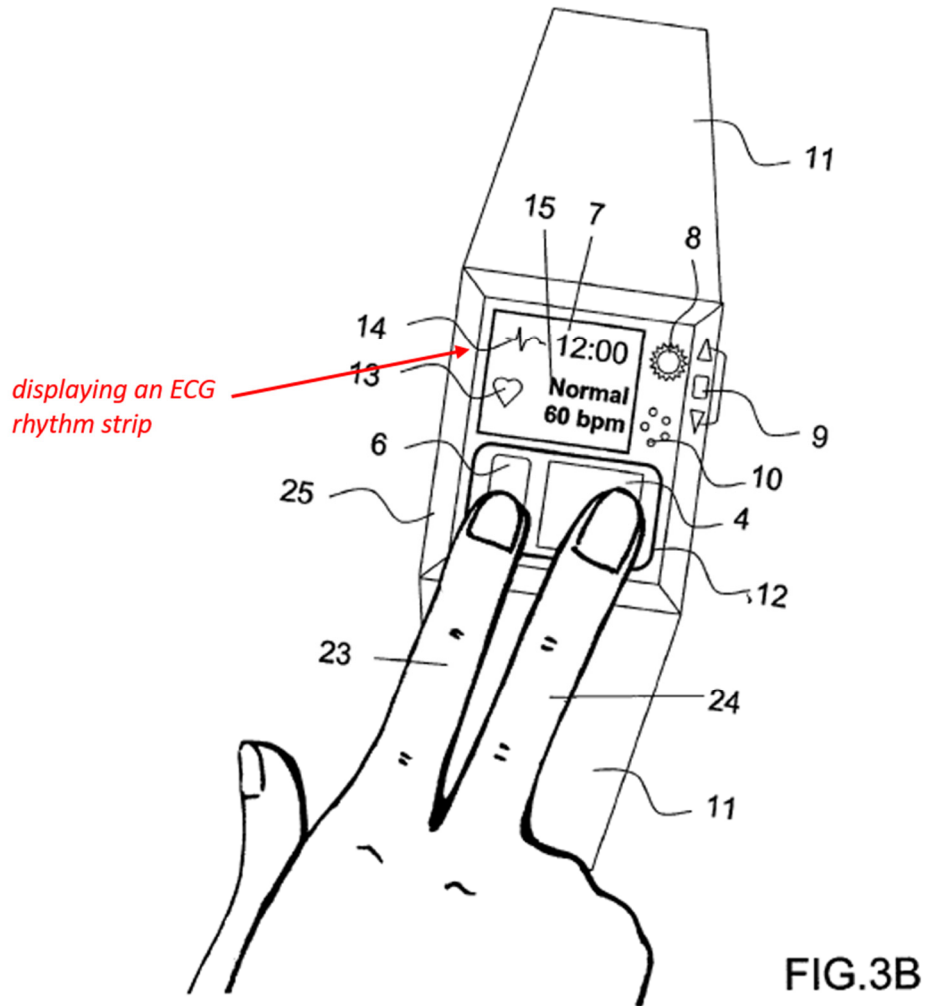


FIG.1A

FIG.1B

APPLE-1045, Figs. 1A and 1B (annotated).

69. Fig. 3B of Chan shows an example of using Chan's device to measure an ECG. APPLE-1048, Fig. 3B. In Fig. 3B, Chan's watch 25 is worn tightly on one hand and one finger 23 from the other hand 21 presses on the sensing element 6, and another finger 24 from the other hand 21 presses on the electrode 4 on the front 2 of the watch simultaneously. APPLE-1048, 3:5-13.



APPLE-1045, Fig. 3B (annotated).

XI. ANALYSIS OF SHMUELI

70. For the reasons articulated in detail below, and based on my review of the '731 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 provide all the elements of claims 1, 7, 12, 13, 16, 17, 23-26 and 30.

A. Claim 1

[1.0] A smart watch to detect the presence of an arrhythmia of a user, comprising:

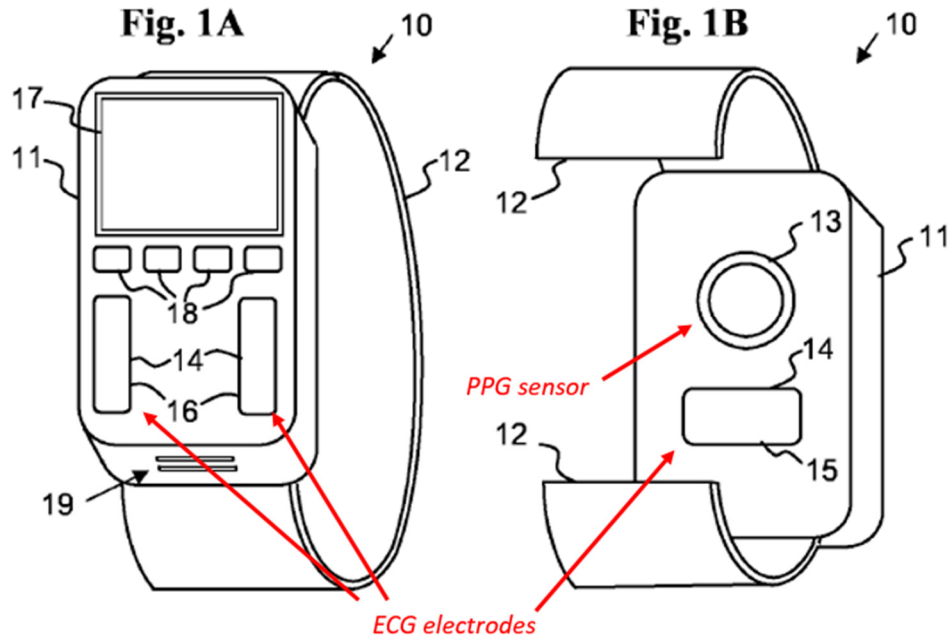
71. To the extent the preamble is limiting, it is my opinion that Shmueli renders obvious element [1.0].

72. Shmueli teaches “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.” 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. The ’731 patent also defines arrhythmia as an irregular heart condition. APPLE-1001, 1:40-42 (“Arrhythmia is a cardiac condition in which the electrical activity of the heart is irregular...”). Similarly, the Black Medical Dictionary lists arrhythmia as the first condition under the heading “Heart, Disease of.” APPLE-1047, pp. 320-321. Thus, 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.

73. 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 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 refers 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. 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 discloses and/or renders obvious that Shmueli's detection of irregular heart conditions using PPG data includes detection of arrhythmias. For example, Lee 2013 discloses using PPG data and ECG data to detect atrial fibrillation, one of the most common type 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

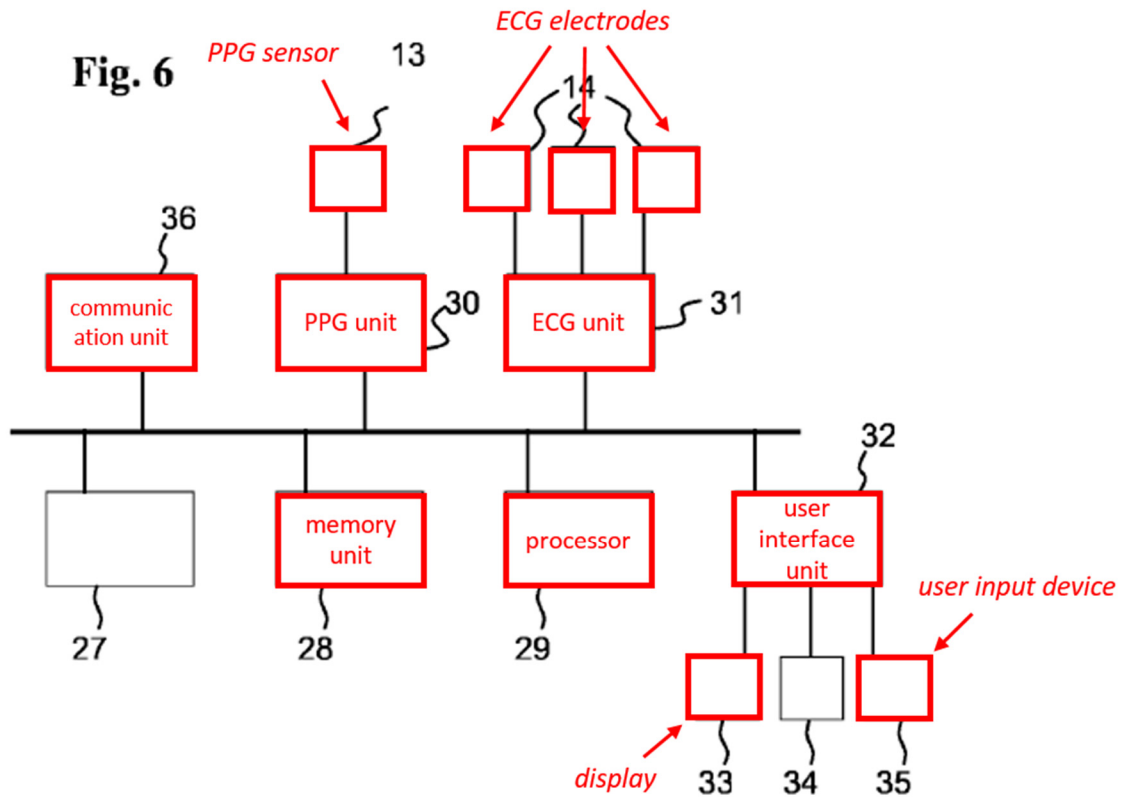
ECG measurements, Shmueli renders obvious a method of determining a presence of an arrhythmia of a first user.

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



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

75. 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).

76. This is highly similar to the '731 patent's smartwatch that includes a heart rate monitor 1402, an activity monitor 1404, a processor coupled to a memory, and an output device 1408. APPLE-1001, 24:66-25:6. Thus, a POSITA would have understood that Shmueli's mobile computing device is a "smartwatch" within the meaning of the '731 patent.

77. 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 instance, 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. Thus, Shmueli renders obvious [1.0].

78. 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 '731 patent suggests that a smartwatch must have a touchscreen. Indeed, the '731 patent never uses the term "touchscreen" and does not describe a "touchscreen" as being a part of its example smartwatch. Apple-1001, 24:66-25:12 (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.*

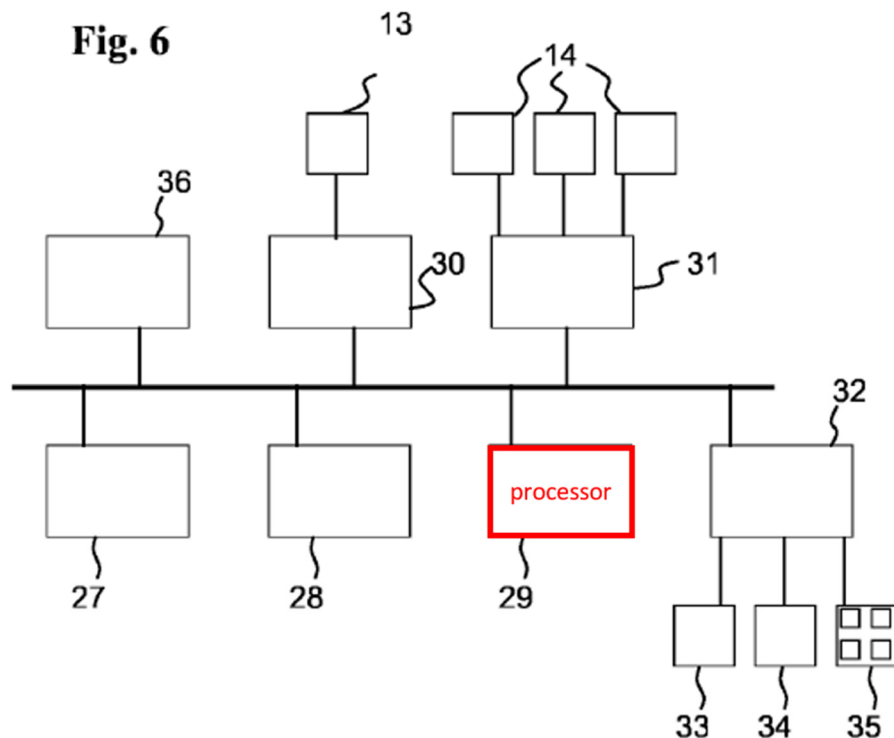
AliveCor's Antitrust Complaint also alleges that a smartwatch has "the ability to use multiple types of apps and easily select between them." APPLE-1055, p.30. Again, and similar to touchscreen, nothing in the '731 patent suggests that a smartwatch must have this functionality. Indeed, the '731 patent lacks disclosure of selecting among multiple types of apps and consistently refers only to a single "application." Apple-1001, 2:44-53. 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 '731 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.

[1.1] a processing device

79. It is my opinion that Shmueli renders obvious element [1.1]. Shmueli discloses a processing device. 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. A POSITA would have understood that Shmueli’s device contains a processing device because it has a **processor** operative to control both SpO2 and ECG measuring. APPLE-1004, 4:1-9 (discussing “a processor operative to control both the SpO2 measuring and the ECG measuring unit.”). Thus, Shmueli renders obvious [1.1].



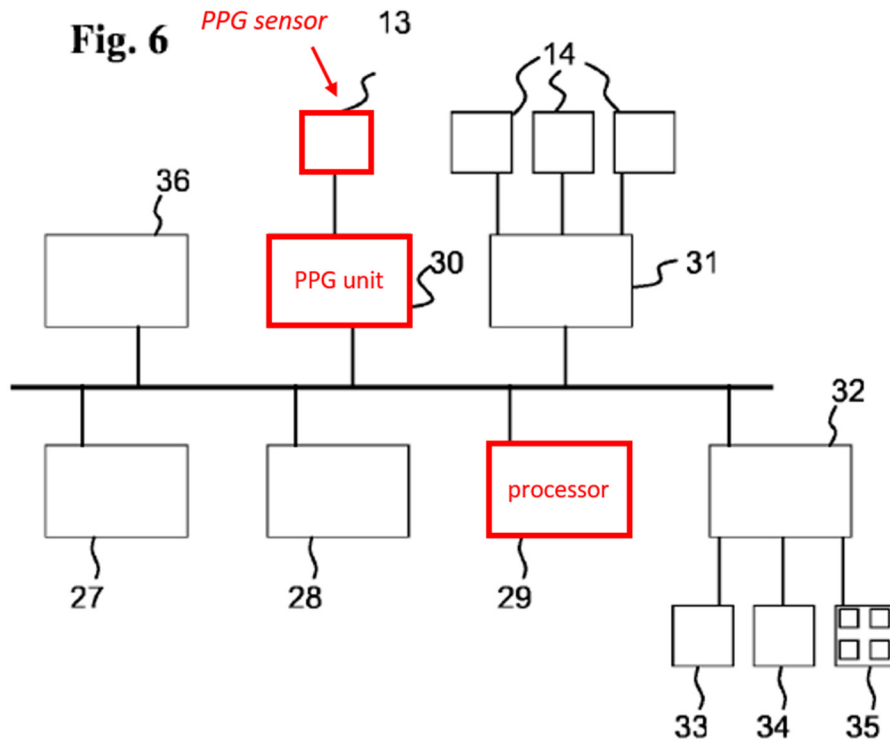
APPLE-1004, Fig. 6 (annotated).

[1.2] a photoplethysmography (“PPG”) sensor operatively coupled to the processing device;

80. It is my opinion that Shmueli renders obvious element [1.2].

81. Shmueli discloses a PPG sensor operatively coupled to the processing device. 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).

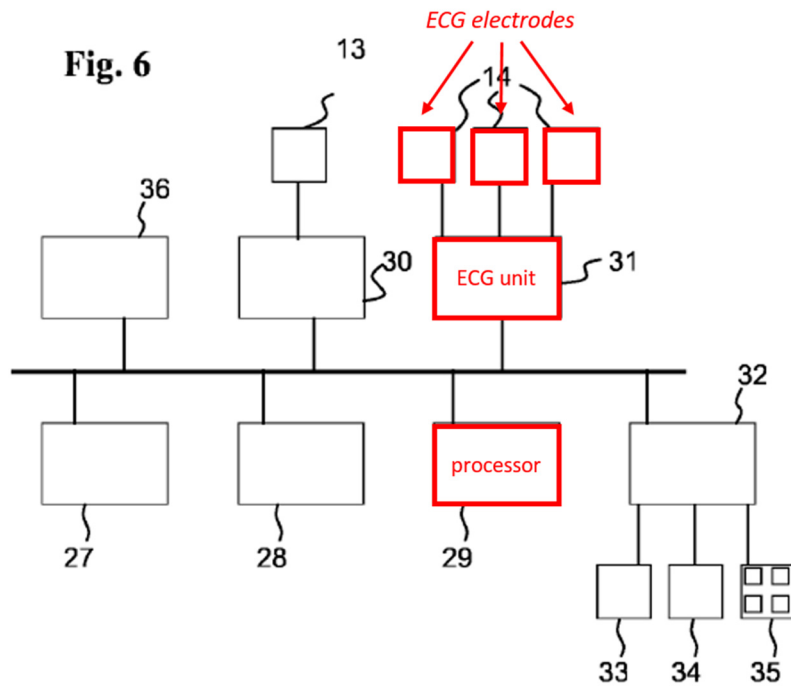
82. A POSITA would have understood that Shmueli’s device includes a PPG sensor operatively coupled to the processing device because it has an “**oximetry measuring unit 30 with the oximetry sensor 13**” that is under the control of processor 29. Shmueli discloses that the terms “**oximetry**” and

“**photoplethysmography**” (**PPG**) have the same meaning and may be used interchangeably. APPLE-1004, 7:25-31. Thus, Shmueli renders obvious [1.2].

[1.3] an ECG sensor, comprising two or more ECG electrodes, the ECG sensor operatively coupled to the processing device;

83. It is my opinion that Shmueli renders obvious element [1.3].

84. Shmueli discloses an ECG sensor operatively coupled to the processing device. 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).

85. Shmueli also discloses that the three ECG contact sensors are attached to different parts of the user's body:

Additionally according to another aspect of the present invention there is provided a wrist-mounted physiological parameters measuring device where the ECG measurement unit includes at least two separate conductive areas configured to measure electrical activity of the subject, where the at least three conductive areas arranged in one of the following configurations: a first conductive area configured to be in contact with at least a portion of the wrist, and second conductive area configured to be touched by a finger of a second hand of the subject, a first conductive area configured to be in contact with at least a portion of the wrist, and second and third conductive areas configured to be touched by two fingers of a second hand of the subject, and a first and a second conductive areas configured to be in contact with at least a portion of the first hand and a third conductive area configured to be touched by a second hand of the subject, *where the ECG signal is extracted from the three conductive areas by using the signal of one conductive area as a reference and amplifying the differential voltage*

between the other two conductive areas, and where the processor is operative to continuously convert the ECG signal to form medical information.

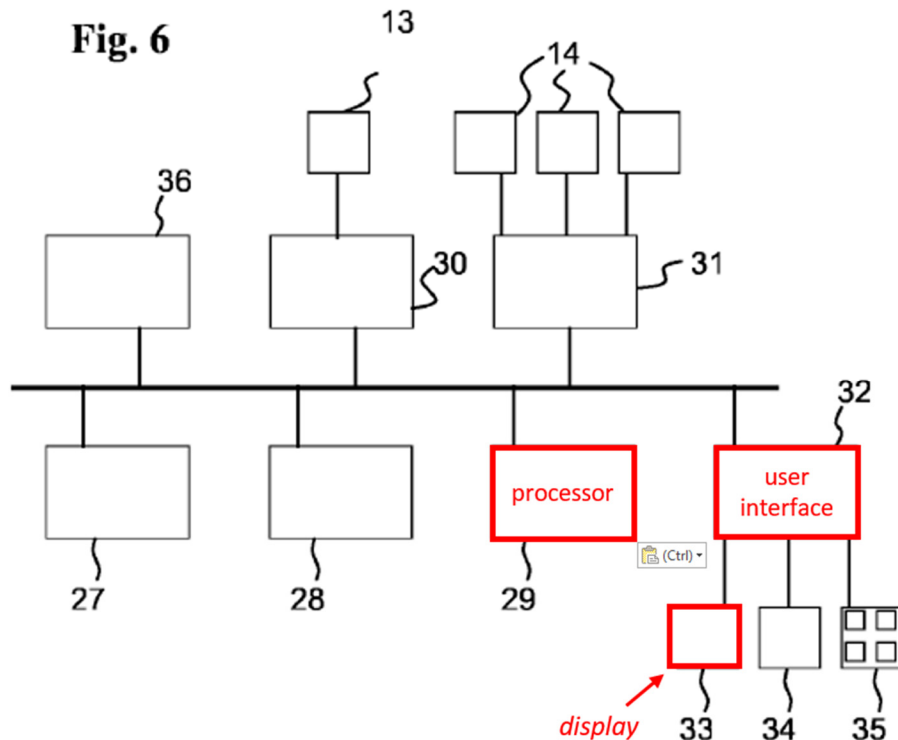
APPLE-1004, 5:6-20.

86. A POSITA would have understood that Shmueli's device includes an ECG sensor operatively coupled to the processing device and that the ECG sensor has three ECG electrodes because it has "an ECG measuring unit 31 with three ECG contact sensors 14" under the control of processor 29. Thus, Shmueli renders obvious [1.3].

[1.4] a display operatively coupled to the processing device; and

87. It is my opinion that Shmueli renders obvious element [1.4].

88. 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, **a user interface unit 32 preferably containing output devices such as a display 33.**" APPLE-1004, 11:10-15.



APPLE-1004, Fig. 6 (annotated).

89. Shmueli further discloses that “[t]he 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.” APPLE-1004, 14:4-8.

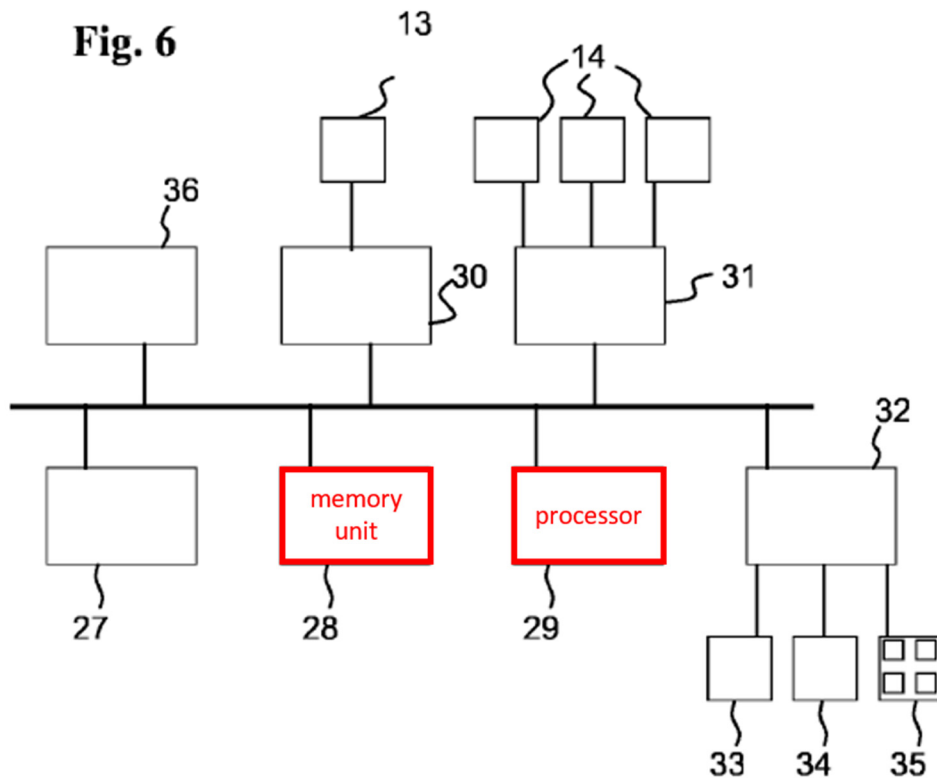
90. A POSITA would have understood that Shmueli’s device includes a display operatively coupled to the processing device because it has “a user interface unit 32 preferably containing output devices such as a display 33” that is

coupled to processor 29. Thus, Shmueli renders obvious [1.4].

[1.5] a memory, operatively coupled to the processing device, the memory having instructions stored thereon that, when executed by the processing device, cause the processing device to:

91. It is my opinion that Shmueli renders obvious element [1.5].

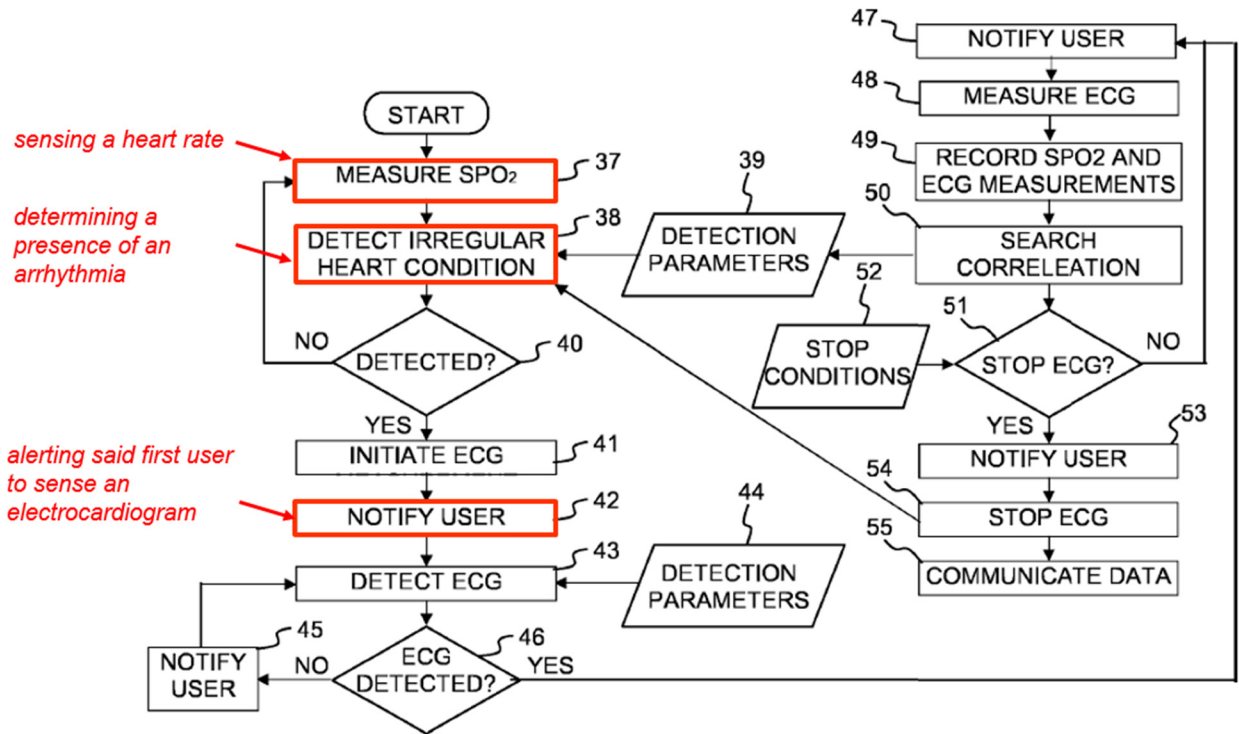
92. As shown in Fig. 6 below, Shmueli’s heart monitoring device includes “**a memory unit 28**, a processor 29, an oximetry measuring unit 30 with the oximetry sensor 13, an ECG measuring unit 31 with three ECG contact sensors 14.” APPLE-1004, 11:10-15. Shmueli further discloses “[t]he **memory unit 28 preferably contains software program containing instructions to be executed by the processor 29.**” APPLE-1004, 11:19-21.



APPLE-1004, Fig. 6 (annotated).

93. Shmueli further discloses in Fig. 7 a flow chart of a software program executed by the processor 29 of the wrist-mounted monitoring 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 and the present invention.”) and Fig. 7.

Fig. 7



APPLE-1004, Fig. 7 (annotated).

94. A POSITA would have understood that Shmueli’s device includes a memory operatively coupled to the processing device and that the memory has instructions to be executed by the processing device because it has “a memory unit

28” that is coupled to processor 29 and that “memory unit 28 preferably **contains software program containing instructions to be executed by the processor 29.**”

Thus, Shmueli renders obvious [1.5].

[1.6] receive PPG data from the PPG sensor;

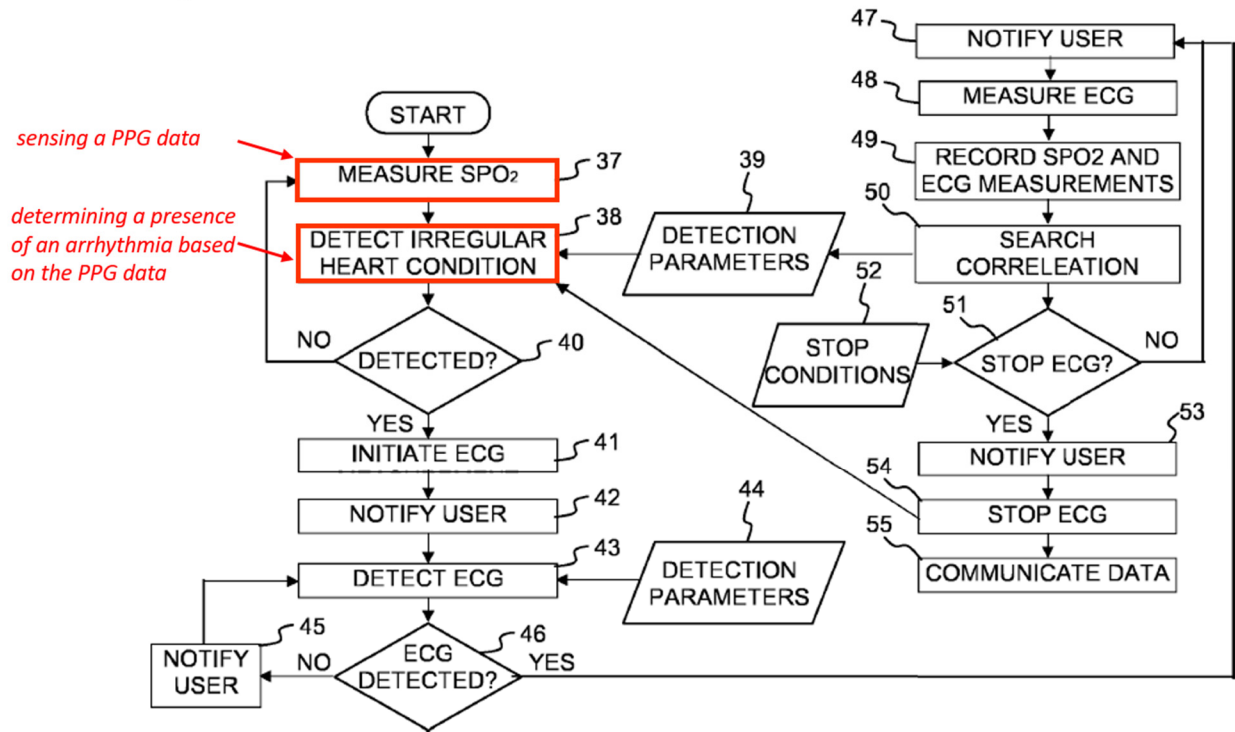
95. It is my opinion that Shmueli renders obvious element [1.6].

96. Shmueli discloses that “the software program contained in memory unit 28 preferably contains various procedures such as: Procedures for operating the oximetry measuring unit 30 and ECG measuring unit 31 including **procedures to continuously measure SpO2 signal**, and procedures to initiate ECG measurements. Procedures for operating the user-interface unit 32 and for interacting with the user including procedures for notifying the subject to perform an ECG measurement. **Procedures for analyzing oximetry measurements to detect various irregular heart conditions.**” APPLE-1004, 11:22-31. Shmueli also explains that the terms SpO2, oximetry and photoplethysmography (PPG) have the same meaning. APPLE-1004, 7:25-27.

97. Fig. 7 of Shmueli provides a flow chart of a software program executed by Shmueli’s processing device. APPLE-1004, 12:6-8. 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 “scans the derived physiological parameters to detect various

irregularities of the heart condition.” APPLE-1004, 12:9-17. As discussed above for element [1.0], a POSITA would have found it obvious that the term “irregular heart condition” in Fig. 7 refers to arrhythmia.

Fig. 7



APPLE-1004, Fig. 7 (annotated).

98. A POSITA would have understood that the software causes the processing device to receive PPG data from the PPG sensor because element 38 requires the processor to “derive from the SpO2 measurement physiological parameters” and to scan “the derived physiological parameters to detect various irregularities of the heart condition.” APPLE-1004, 12:9-17.

99. Shmueli further discloses that the oximetry (PPG) 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. APPLE-1004, 9:20-22. As shown in Fig. 5 below, the PPG measuring unit (i.e., heart rate sensor) is connected to Shmueli's wrist-worn device through an electrical cable 26. APPLE-1004, 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 worn 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.***") and Fig. 5. A POSITA would have understood that Shmueli's device is configured to receive PPG data from the oximetry (PPG) sensor through the electrical cable 26.

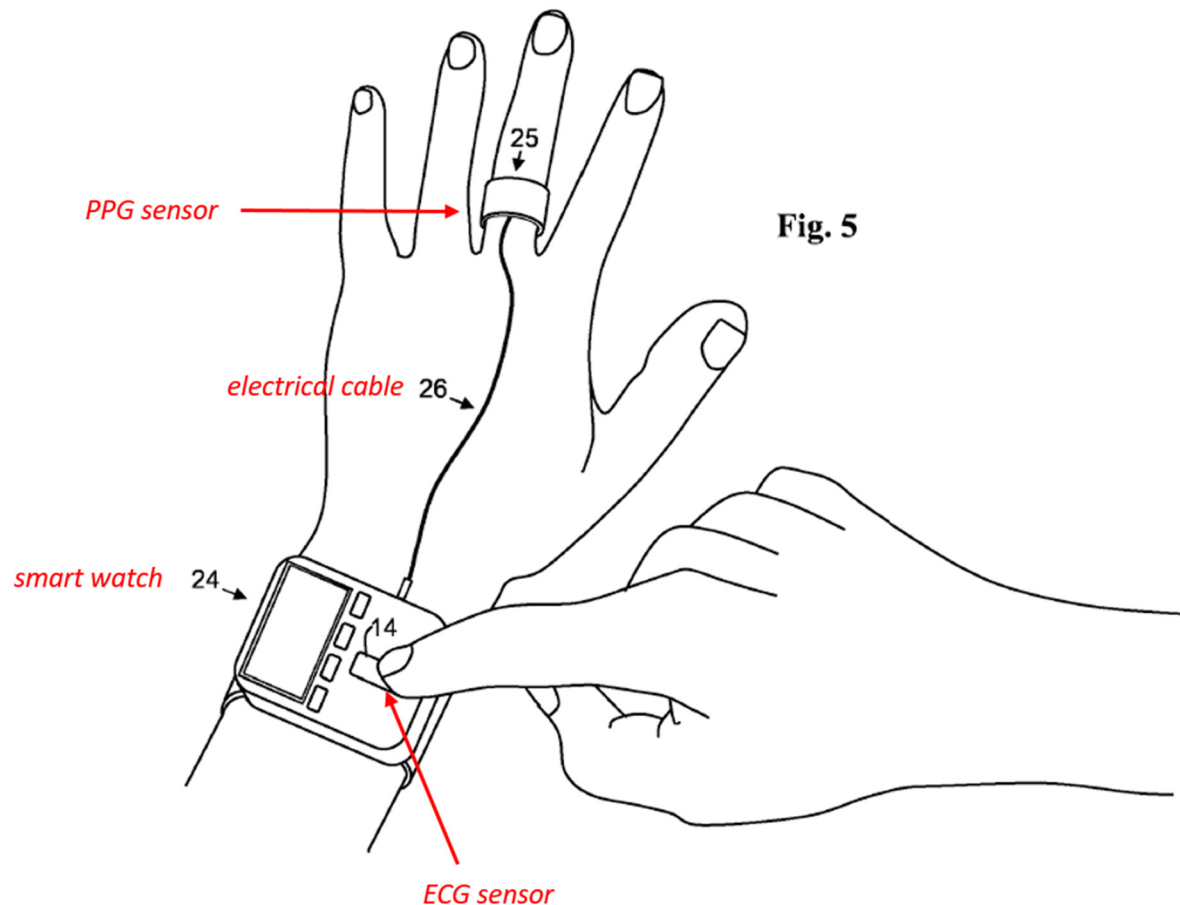


Fig. 5

APPLE-1004, Fig. 5 (annotated).

100. For the reasons discussed above, it is obvious that the processor is configured to receive PPG data from the PPG sensor. Thus, Shmueli renders obvious [1.6].

[1.7] detect, based on the PPG data, the presence of an arrhythmia;

101. It is my opinion that Shmueli renders obvious element [1.7].

102. Shmueli discloses that “the software program contained in memory unit 28 preferably contains various procedures such as: Procedures for operating the oximetry measuring unit 30 and ECG measuring unit 31 including procedures

to continuously measure SpO₂ signal, and procedures to initiate ECG measurements. Procedures for operating the user-interface unit 32 and for interacting with the user including procedures for notifying the subject to perform an ECG measurement. **Procedures for analyzing oximetry measurements to detect various irregular heart conditions.**” APPLE-1004, 11:22-31. Shmueli also explains that the terms SpO₂, oximetry and photoplethysmography (PPG) have the same meaning. APPLE-1004, 7:25-27.

103. Fig. 7 of Shmueli provides a flow chart of a software program executed by Shmueli’s processing device. APPLE-1004, 12:6-8. 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 **“scans the derived physiological parameters to detect various irregularities of the heart condition.”** APPLE-1004, 12:9-17.

electrocardiograph (ECG).”); APPLE-1020, Abstract (“The arrhythmia detecting apparatus of the present invention is provided with a pulse wave detecting means which non-invasively detects the pulse waveform, and an arrhythmia detecting means which detects arrhythmia by monitoring changes in the pulse waveform detected by the pulse wave detecting means.”). Thus, Shmueli renders obvious [1.7].

[1.8] receive ECG data from the ECG sensor; and

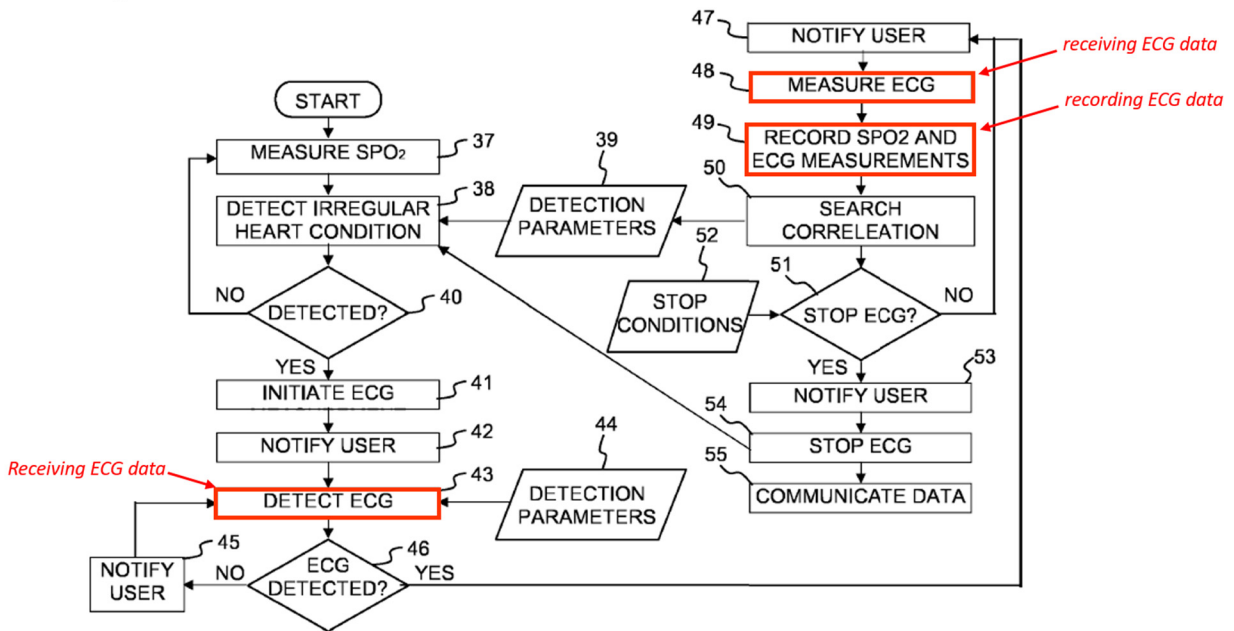
105. It is my opinion that Shmueli renders obvious element [1.8].

106. Shmueli discloses that “the software program contained in memory unit 28 preferably contains various procedures such as: Procedures for operating the oximetry measuring unit 30 and ECG measuring unit 31 including procedures to continuously measure SpO₂ signal, and **procedures to initiate ECG measurements**” and “**procedure for identifying correlations between SpO₂ measurement and ECG measurement of a particular subject to detect user-specific irregular heart conditions.**” APPLE-1004, 11:22-31.

107. Fig. 7 of Shmueli provides a flow chart of a software program executed by Shmueli’s processing device. APPLE-1004, 12:6-8. 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 “scans the derived physiological parameters to detect various

irregularities of the heart condition.” APPLE-1004, 12:9-17. Then, the software program “initiates ECG measurement, preferably by operating ECG measuring unit 31” and “proceeds to element 43 to detect and [sic] ECG signal.” APPLE-1004, 12:23-28. Next, 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 store them in the memory unit 28.” APPLE-1004, 13:10-12.

Fig. 7



APPLE-1004, Fig. 7 (annotated).

108. A POSITA would have understood that the software causes the processing device to receive ECG data from the ECG sensor at various steps including element 43, element 48, and element 49. Thus, Shmueli renders obvious [1.7].

[1.9] confirm the presence of the arrhythmia based on the ECG data.

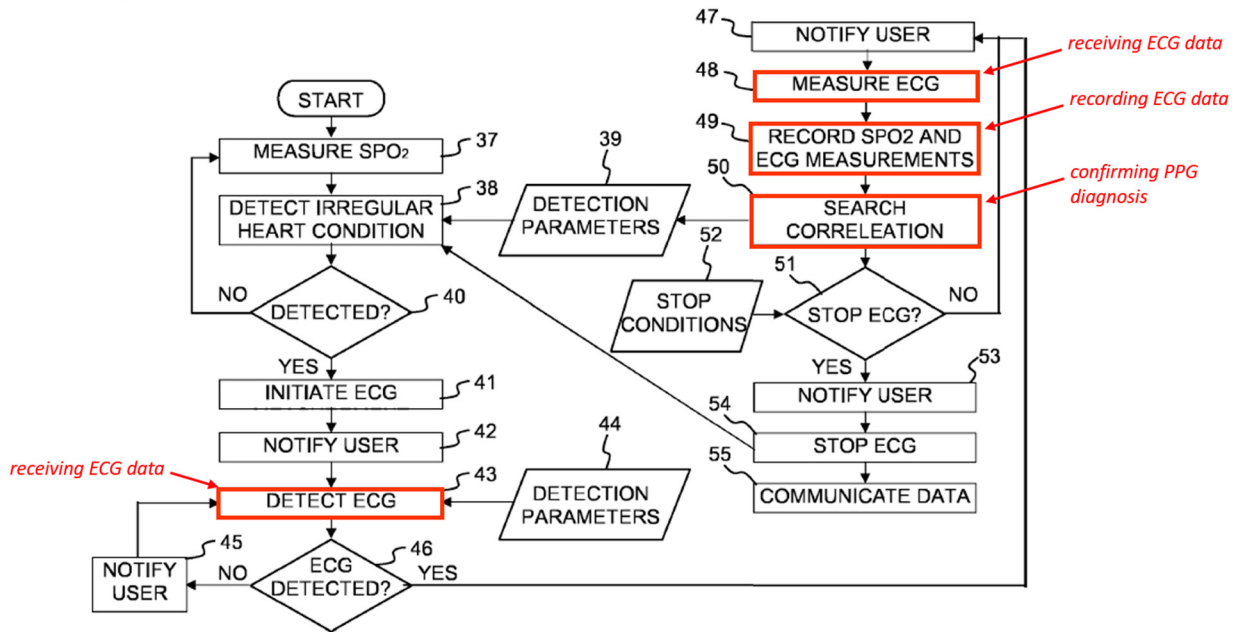
109. It is my opinion that Shmueli renders obvious element [1.9].

110. Shmueli discloses that “the software program contained in memory unit 28 preferably contains various procedures such as: Procedures for operating the oximetry measuring unit 30 and ECG measuring unit 31 including procedures to continuously measure SpO2 signal, and procedures to initiate ECG measurements” and “**procedure for identifying correlations between SpO2 measurement and ECG measurement of a particular subject to detect user-specific irregular heart conditions.**” APPLE-1004, 11:22-31.

111. Fig. 7 of Shmueli provides a flow chart of a software program executed by Shmueli’s device. APPLE-1004, 12:6-8. 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 “scans the derived physiological parameters to detect various irregularities of the heart condition.” APPLE-1004, 12:9-17. Then, the software program “initiates ECG measurement, preferably by operating ECG measuring unit 31” and “proceeds to element 43 to detect and [sic] ECG signal.” APPLE-1004, 12:23-28. Next, 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 store them in the memory unit 28.” APPLE-1004, 13:10-12. The software

program also proceeds to element 50 to search for **correlations between the SpO₂ signal and the ECG signal** to produce new detection parameters, or modify existing parameters, so as to **enhance the detection algorithms of the irregular heart conditions**. APPLE-1004, 13:16-19.

Fig. 7



APPLE-1004, Fig. 7 (annotated).

112. As discussed above for element [1.0], although Shmueli does not explicitly use the term arrhythmia, a POSITA would have found it obvious that the term “irregular heart condition” in element 38 of Fig. 7 refers to arrhythmias. As discussed above for element [1.6], a POSITA would have found it obvious that the software at element 38 causes the processing device to detect, based on the PPG data, the presence of arrhythmia. Thus, a POSITA would have understood that the software at element 50, element 39 and element 38 causes the processing device to

confirm the presence of the arrhythmia based on the ECG data, by searching for correlations between the PPG and ECG data, modifying detection parameters, and confirming the presence of arrhythmia. 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. 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 data. APPLE-1016, 6080. Other references explain 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.”); 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). Thus, based on Shmueli’s disclosure and the general knowledge of a POSITA, a POSITA would have understood that the software at element 50, element 39 and element 38 causes the processing device to confirm the presence of the arrhythmia based on the ECG data, by searching for correlations between the PPG and ECG data, modifying detection parameters, and confirming the presence of arrhythmia. Thus, Shmueli renders obvious [1.9].

113. In addition, after the software confirms the detected arrhythmia at element 50, element 39 and element 38 by searching for correlations between the PPG and ECG data, the software proceeds to element 51 to determine a set of stop conditions (element 52), such as whether “*the irregular heart condition has stopped.*” APPLE-1004, 13:22-29. Shmueli discloses that when the software program detects that “*the irregular heart condition has stopped*” (element 51), the software program notifies the user that the ECG measurement has stopped (element 53) and stops the ECG measurement (element 54). APPLE-1004, 13:22-29. A POSITA would have understood that determining whether “the irregular heart condition has stopped” also requires the software program to confirm the presence of arrhythmia using the ECG data.

B. Claim 7

[7.0] The smart watch of claim 1, wherein the processing device is further configured to: extract one or more features from the PPG data; and detect, based on the one or more features, the presence of the arrhythmia.

114. It is my opinion that Shmueli renders obvious element [7.0].

115. Shmueli teaches “continuously measuring SpO₂ at the wrist of the user, detecting an **irregular heart condition** from the SpO₂ measurement.”

APPLE-1004, Abstract. As discussed in element [1.0], a POSITA would have understood the term “irregular heart condition” refers to and includes arrhythmias.

Like the '731 patent, Shmueli's device first detects arrhythmia based on SpO₂ measurement, which is also known as photoplethysmography (“PPG”) or pulse

oximetry. APPLE-1004, Abstract and 7:25-31. As shown in Fig. 7 below,

Shmueli's software program “starts in element 37 by measuring SpO₂” and then

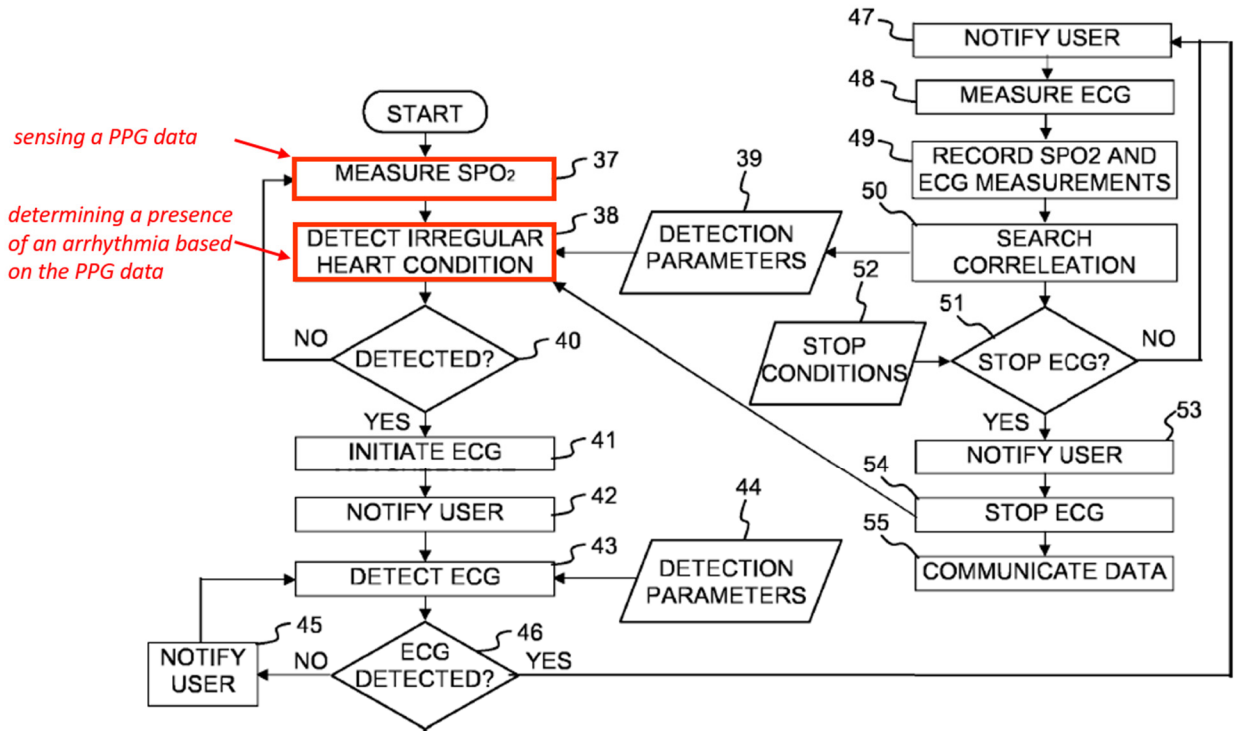
“proceeds to element 38 to derive from the SpO₂ measurement **physiological**

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.

Fig. 7



APPLE-1004, Fig. 7 (annotated).

116. As discussed above for element [1.7], a POSITA would have found it obvious that the software at element 38 causes the processing device to detect, based on the PPG data, the presence of arrhythmia. A POSITA would have found it obvious that a determination of arrhythmia based on PPG data involves extracting from the PPG data certain features, such as pulse rate, RR intervals and HRV. By the Critical Date, it was well-known that RR intervals and HRV can be extracted from either PPG data or the 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.”); 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). 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 (PPG) of blood to the periphery. APPLE-1014, p. 480. 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. In addition, a POSITA would have been motivated to extract HRV from the PPG 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. In addition, HRV analysis is more robust because it involves extracting the RR intervals and is less affected by noise. APPLE-1039, p. 52 (“This is a more robust method since the R-R time intervals are less affected by the noise.”).

117. In addition, by the Critical Date, machine learning algorithms were

the mainstream technique to detect arrhythmia based on various features (e.g., HRV) extracted from the heart rate data. APPLE-1040, p. 1928 (discussing neural networks, wavelet transforms, support vector machines, fuzzy logic and rule-based algorithms) and APPLE-1041, p. 74 (discussing fuzzy logic and neural networks). A POSITA would have understood that these machine learning algorithms involve extracting features from the underlying data. For example, Li 2012 discloses detecting arrhythmia using neural networks based on features extracted from PPG data. APPLE-1006, Abstract. In addition, Tsipouras 2004 discloses detecting arrhythmia using machine learning based on HRV features. APPLE-1012, Abstract.

118. Thus, although Shmueli does not specifically disclose how to detect arrhythmia based on PPG data, a POSITA would have found it obvious to extract certain features (e.g., RR intervals and HRV) from the PPG data and to determine arrhythmia based on these features.

C. Claim 12

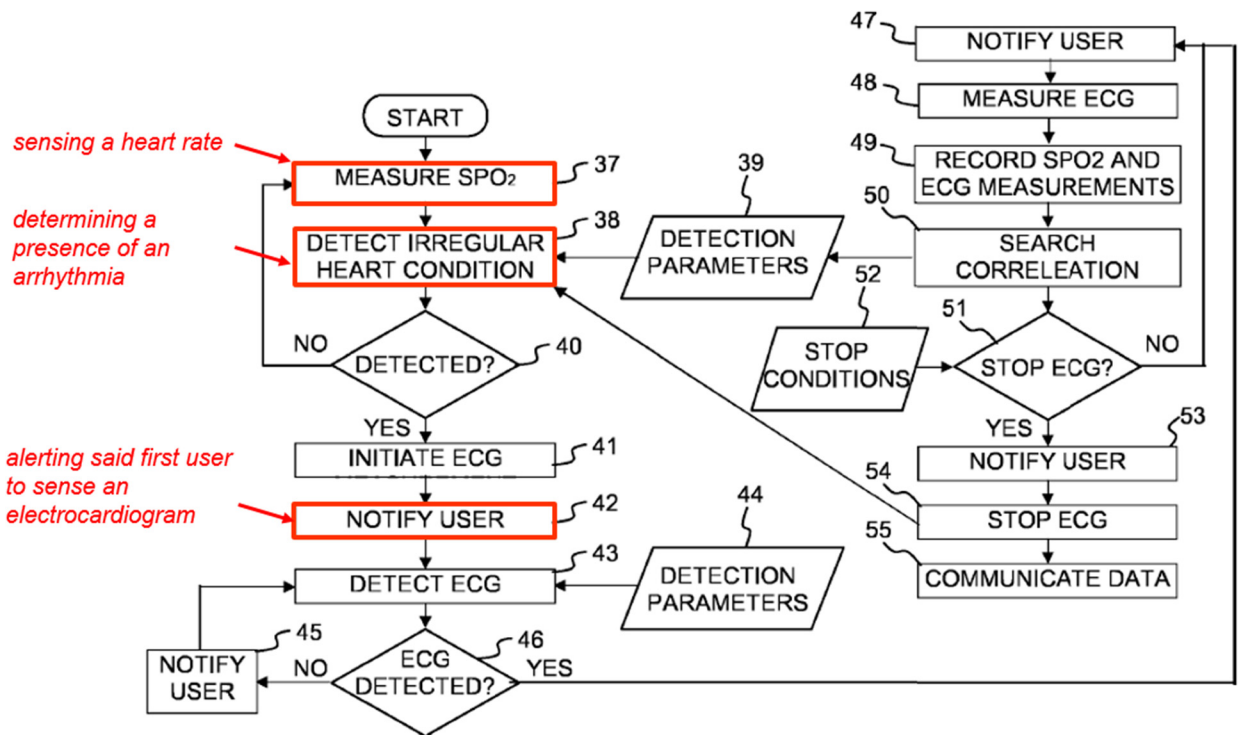
[12.0] The smart watch of claim 1, wherein the processing device is further configured to generate a notification of the detected arrhythmia.

119. It is my opinion that Shmueli renders obvious element [12.0].

120. As discussed above in Section X.A, Shmueli's method first detects arrhythmia based on the SpO2 measurement, which is also known as PPG or pulse oximetry. APPLE-1004, Abstract. 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).

121. 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. 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.* ("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”).

122. As discussed for element [1.4], Shmueli’s device includes a display operatively coupled to the processing device. Shmueli’s “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**, and to initiate the ECG measurement.” APPLE-1004, 4:6-9. Shmueli also discloses that such a notification may be visual, audible, graphic, textual, etc. APPLE-1004, 14:4-8. It would have been obvious that Shmueli’s processing device (processor 29) (APPLE-1004, Figure 6) is configured to generate a notification of the detected arrhythmia to notify the subject to perform an ECG. From Shmueli’s disclosure, a POSITA would have found it beneficial to notify the user of the detected arrhythmia because it allows the user to make an informed decision on whether to perform an ECG based on the PPG data. Thus, Shmueli renders obvious [12.0].

123. In addition, as shown in Fig. 7, after the ECG is detected (elements 48 and 49), Shmueli’s method “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 algorithm of the irregular heart conditions.” APPLE-1004, 13:16-19. Based on this

disclosure, it would have been obvious that Shmueli's device (processor 29) is configured to confirm the initial diagnosis based on the ECG and PPG data and to generate a notification of the confirmed arrhythmia. A POSITA would have found it beneficial to notify the user of the confirmed arrhythmia because it allows the user to make an informed decision on whether there is a need to seek medical help. Thus, Shmueli renders obvious generating both a notification of the initially detected arrhythmia based on PPG data and a second notification of the confirmed arrhythmia based on the PPG and ECG data. Thus, Shmueli renders obvious [12.0].

D. Claim 13

[13.0] The smart watch of claim 1, further comprising a biometric data sensor, wherein the processing device is further configured to: receive biometric data of the user from the biometric data sensor; and detect, based on the biometric data, the presence of the arrhythmia.

124. It is my opinion that Shmueli renders obvious element [13.0].

125. The '731 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." APPLE-1001, 4:57-61. Shmueli discloses that the terms "oxygen saturation in the blood," "blood oxygen saturation," "pulse oximeter," oximetry, SpO₂, and photoplethysmography have the same meaning and may be

used interchangeably. APPLE-1004, 7:25-31. Thus, a POSITA would have understood that Shmueli's PPG sensor, also known as a pulse oximeter sensor, is a biometric data sensor within the meaning of the '731 patent. Similarly, the PPG data from the PPG sensor is a biometric data within the meaning of the '731 patent.

126. As discussed for element [1.2], element [1.6] and element [1.7], Shmueli's device receives PPG data from the PPG sensor and detects, based on the PPG data, the presence of an arrhythmia. Thus, Shmueli renders obvious [13.0].

127. In addition, based on the '731 patent's explanation that an ECG sensor is also a biometric data sensor, a POSITA would have understood that Shmueli's ECG sensor is a biometric data sensor within the meaning of the '731 patent.

APPLE-1001, 4:57-61 (“The sensor may comprise one or more of a hand-held **electrocardiogram (ECG) sensor**, a wrist-worn activity sensor, a blood pressure monitor, a personal weighing scale, a body fat percentage sensor, a personal thermometer, **a pulse oximeter sensor**, or any mobile health monitor or sensor.”). Similarly, the ECG data from the ECG sensor is a biometric data within the meaning of the '731 patent.

128. As discussed above in element [1.3], element [1.8], and element [1.9], Shmueli's device receives ECG data from the ECG sensor and confirms, based on the ECG sensor, the presence of an arrhythmia. Thus, for this additional reason, Shmueli renders obvious [13.0].

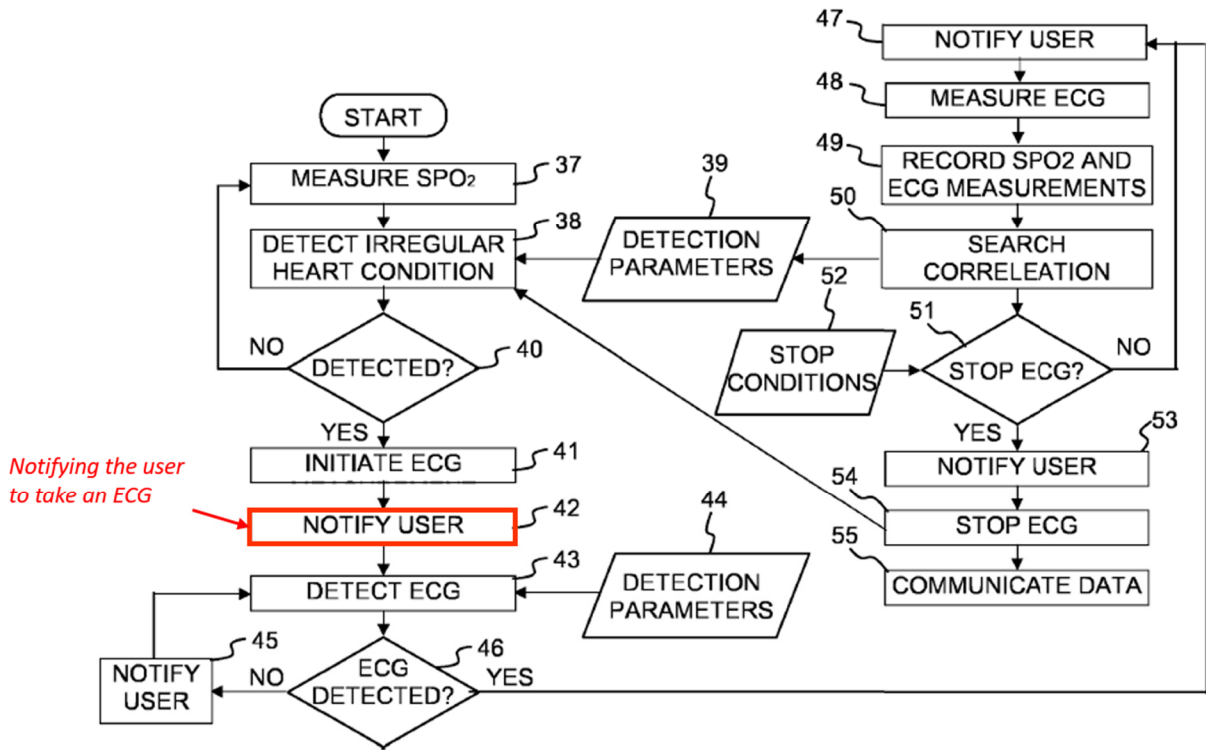
E. Claim 16

[16.0] The smart watch of claim 1, the processing device further to receive the ECG data from the ECG sensor in response to receiving an indication of a user action.

129. It is my opinion that Shmueli renders obvious element [16.0].

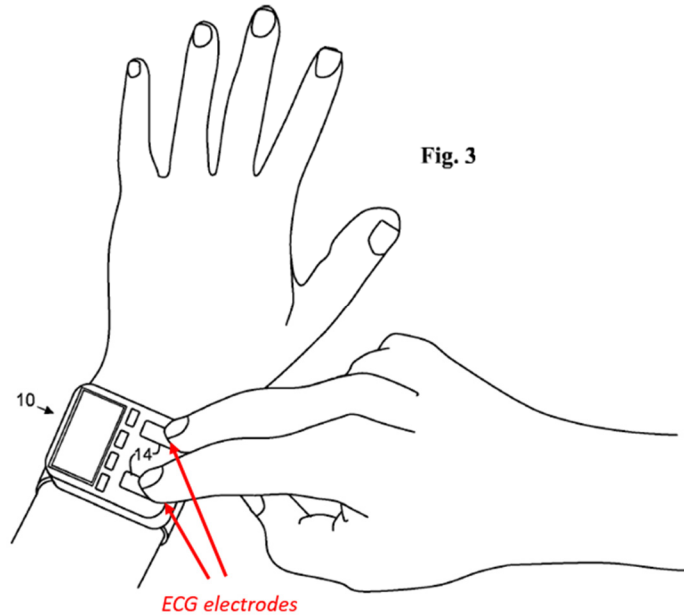
130. As discussed above in Section X.A, Shmueli's device first detects arrhythmia based on SpO2 measurement, which is also known as photoplethysmography ("PPG"). If the SpO2 measurement indicates arrhythmia, Shmueli's device then notifies the user to take an ECG measurement to confirm the arrhythmia detection. As discussed for element [1.8], Shmueli's processing device is configured to receive the ECG data from the ECG sensor. Fig. 7 shows an example of Shmueli's method:

Fig. 7



APPLE-1004, Fig. 7 (annotated).

131. A POSITA would have understood that the “notify user” step in element 42 requires the user to take an action to perform the ECG monitoring. Indeed, Shmueli discloses that the ECG measurement includes “contacting a first conductive area to at least a portion of the wrist, and a second conductive area to a finger of a **second hand** of the subject.” APPLE-1004, 3:14-19. Fig. 3 of Shmueli shows an example of a user using Shmueli’s device to take an ECG by touching the ECG sensors on the front of the device with a second hand.



APPLE-1004, Fig. 3 (annotated).

132. A POSITA would have understood that, in order to contact a second conductive area to a finger of a second hand of the subject, a user action (e.g., contacting with a second hand) is required. Thus, Shmueli renders obvious [16.0].

F. Claim 17

[17.0] A method to detect the presence of an arrhythmia of a user on a smart watch, comprising:

133. It is my opinion that Shmueli renders obvious element [17.0]. See [1.0].

[17.1] receiving PPG data from a PPG sensor of the smartwatch;

134. It is my opinion that Shmueli renders obvious element [17.1]. See [1.6].

[17.2] detecting by a processing device, based on the PPG data, the presence of an arrhythmia;

135. It is my opinion that Shmueli renders obvious element [17.2]. See [1.7].

[17.3] receiving ECG data from an ECG sensor of the smartwatch; and

136. It is my opinion that Shmueli renders obvious element [17.3]. See [1.8].

[17.4] confirming the presence of the arrhythmia based on the ECG data.

137. It is my opinion that Shmueli renders obvious element [17.4]. See [1.9].

G. Claim 23

[23.0] The method of claim 17, further comprising generating a notification of the detected arrhythmia.

138. It is my opinion that Shmueli renders obvious element [23.0]. See [12.0].

H. Claim 24

[24.0] The method of claim 17, further comprising receiving the ECG data from the ECG sensor in response to receiving an indication of a user action.

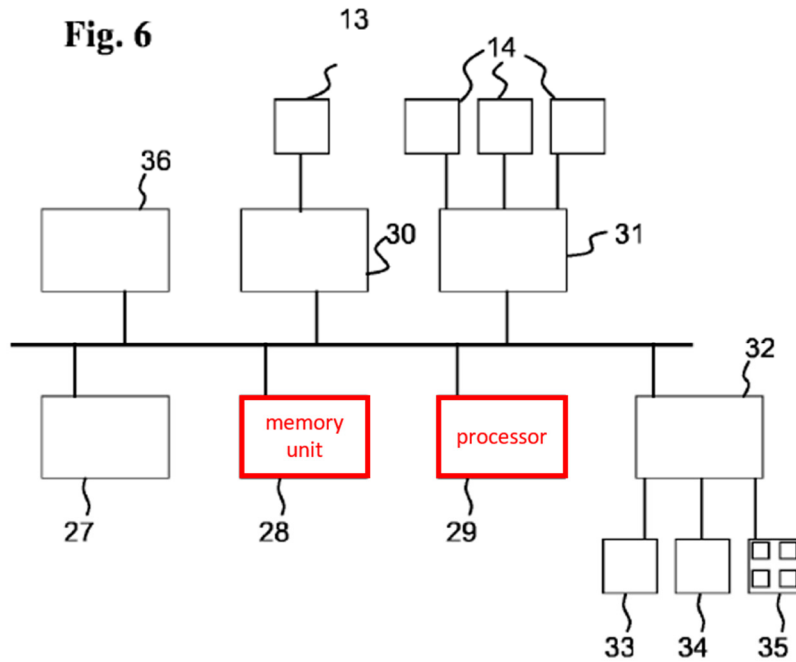
139. It is my opinion that Shmueli renders obvious element [24.0]. See [16.0].

I. Claim 25

[25.0] A non-transitory computer-readable storage medium including instructions that, when executed by a processing device, cause the processing device to:

140. It is my opinion that Shmueli renders obvious element [25.0].

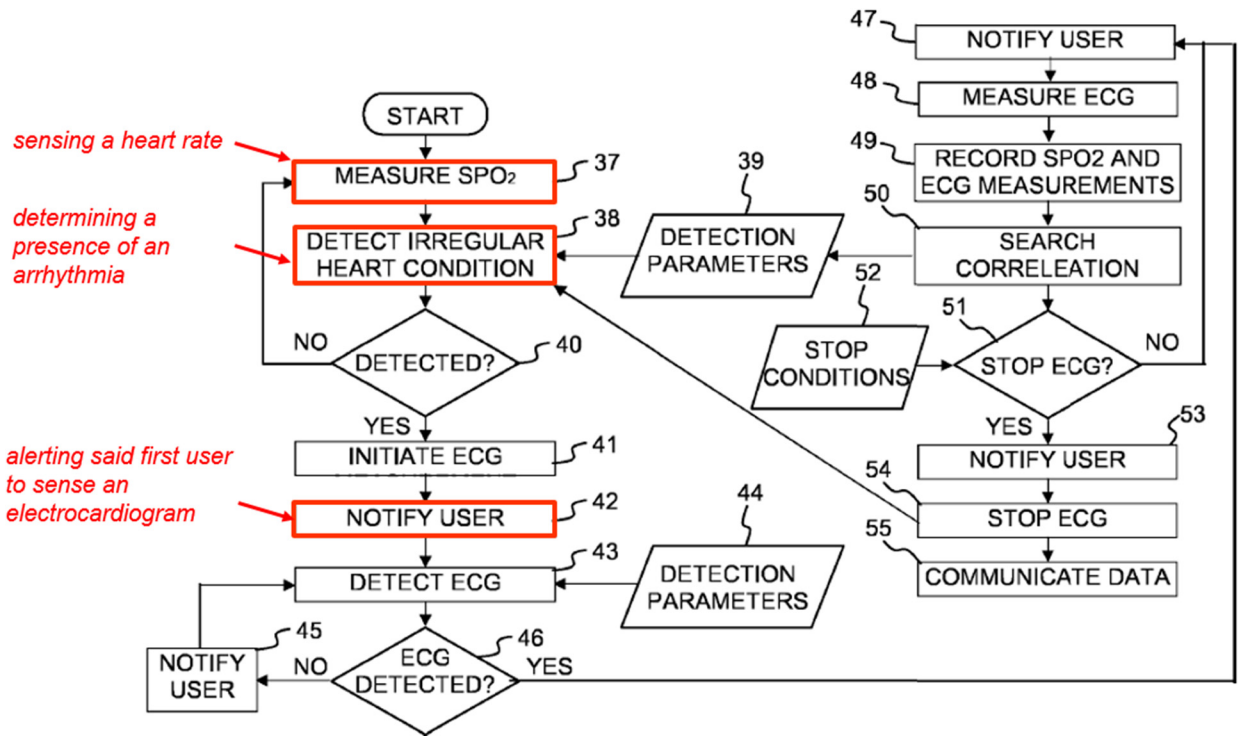
141. As shown in Fig. 6, Shmueli's heart monitoring device "includes a power supply unit such as a battery 27, **a memory unit 28**, a processor 29, an oximetry measuring unit 30 with the oximetry sensor 13, an ECG measuring unit 31 with three ECG contact sensors 14, a user interface unit 32 preferably 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. 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.



APPLE-1004, Fig. 6 (annotated).

142. Shmueli further discloses in Fig. 7 a flow chart of a software program executed by the processor 29 of the wrist-mounted monitoring 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 and the present invention.”) and Fig. 7.

Fig. 7



APPLE-1004, Fig. 7 (annotated).

143. A POSITA would have understood that Shmueli's memory 28 constitutes "a non-transitory computer-readable storage medium including instructions" to be executed by a processing device. Fig. 7 of Shmueli provides a flow chart of a software program contained in memory unit 28 and executed by processor 29. APPLE-1004, Figs. 6-7, 11:22-23 and 12:6-8. Thus, Shmueli renders obvious [25.0].

[25.1] receive PPG data from a PPG sensor of the smartwatch;

144. It is my opinion that Shmueli renders obvious element [25.1]. See element [1.6].

[25.2] detect by the processing device, based on the PPG data, the presence of an arrhythmia;

145. It is my opinion that Shmueli renders obvious element [25.2]. See element [1.7].

[25.3] receive ECG data from an ECG sensor of the smartwatch; and

146. It is my opinion that Shmueli renders obvious element [25.3]. See element [1.8].

[25.4] confirm the presence of the arrhythmia based on the ECG data.

147. It is my opinion that Shmueli renders obvious element [25.4]. See element [1.9].

J. Claim 26

[26.0] The non-transitory computer-readable storage medium of claim 25, wherein the processing device is further configured to: extract one or more features from the PPG data; and detect, based on the one or more features, the presence of the arrhythmia.

148. It is my opinion that Shmueli renders obvious element [26.0]. See element [7.0].

K. Claim 30

[30.0] The non-transitory computer-readable storage medium of claim 25, the processing device further to receive the ECG data from the ECG sensor in response to receiving an indication of a user action.

149. It is my opinion that Shmueli renders obvious element [30.0]. See element [16.0].

XII. ANALYSIS OF SHMUELI IN VIEW OF OSORIO

150. For the reasons articulated in detail below, and based on my review of the '731 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, 2, 4, 7, 12-14, 16-18, 20, 23-26 and 30.

A. The Combination of Shmueli and Osorio

151. 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].

152. 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*

153. 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].

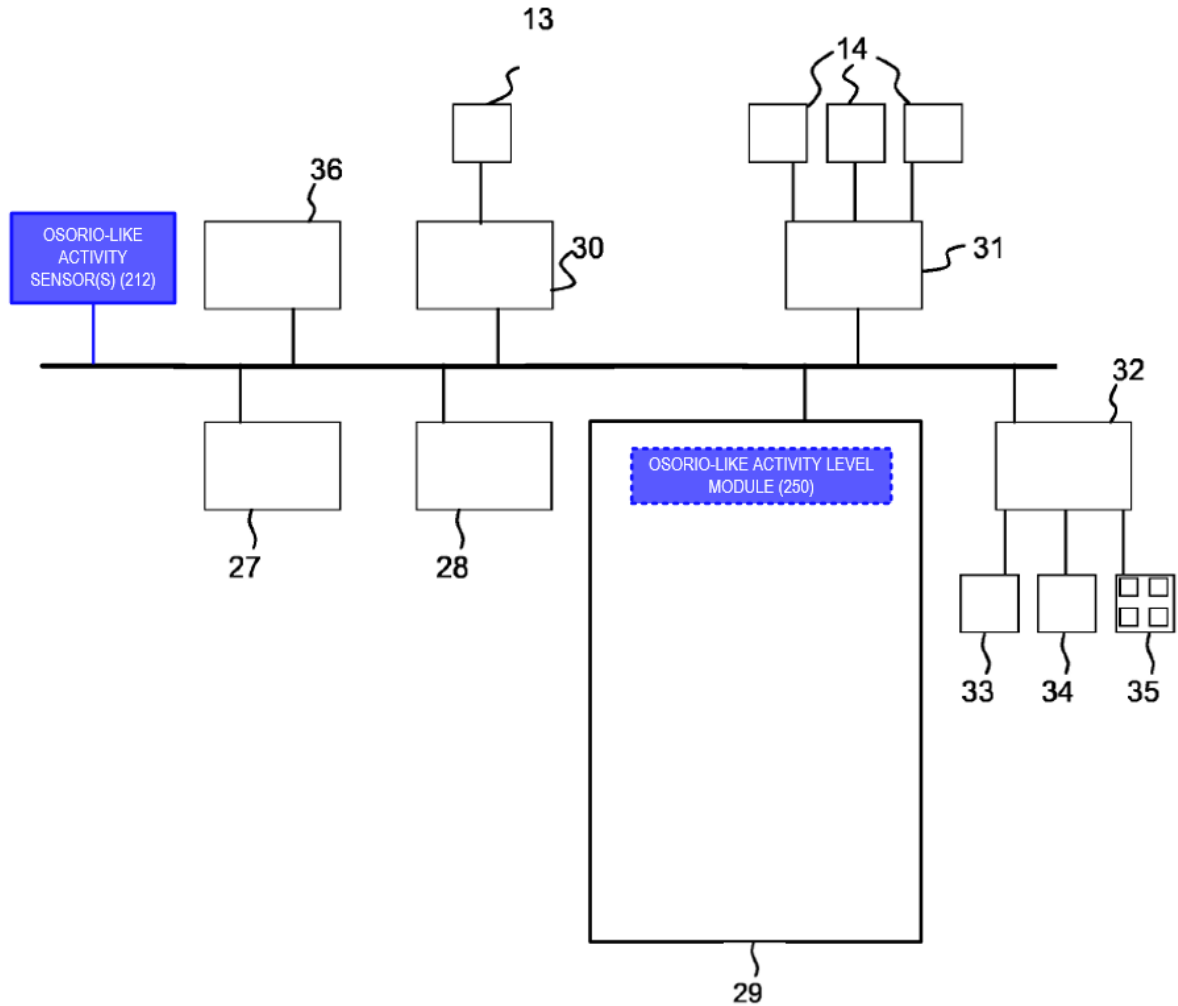
154. A POSITA would have found the modification of Shmueli’s heart monitoring device to incorporate Osorio’s activity level monitoring techniques to have been obvious since, by the Critical Date, it was well-known that activity level was related to HR and, therefore, activity level would have been considered 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.

155. 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.

156. 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)

157. 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.

158. 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 from 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 a 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.

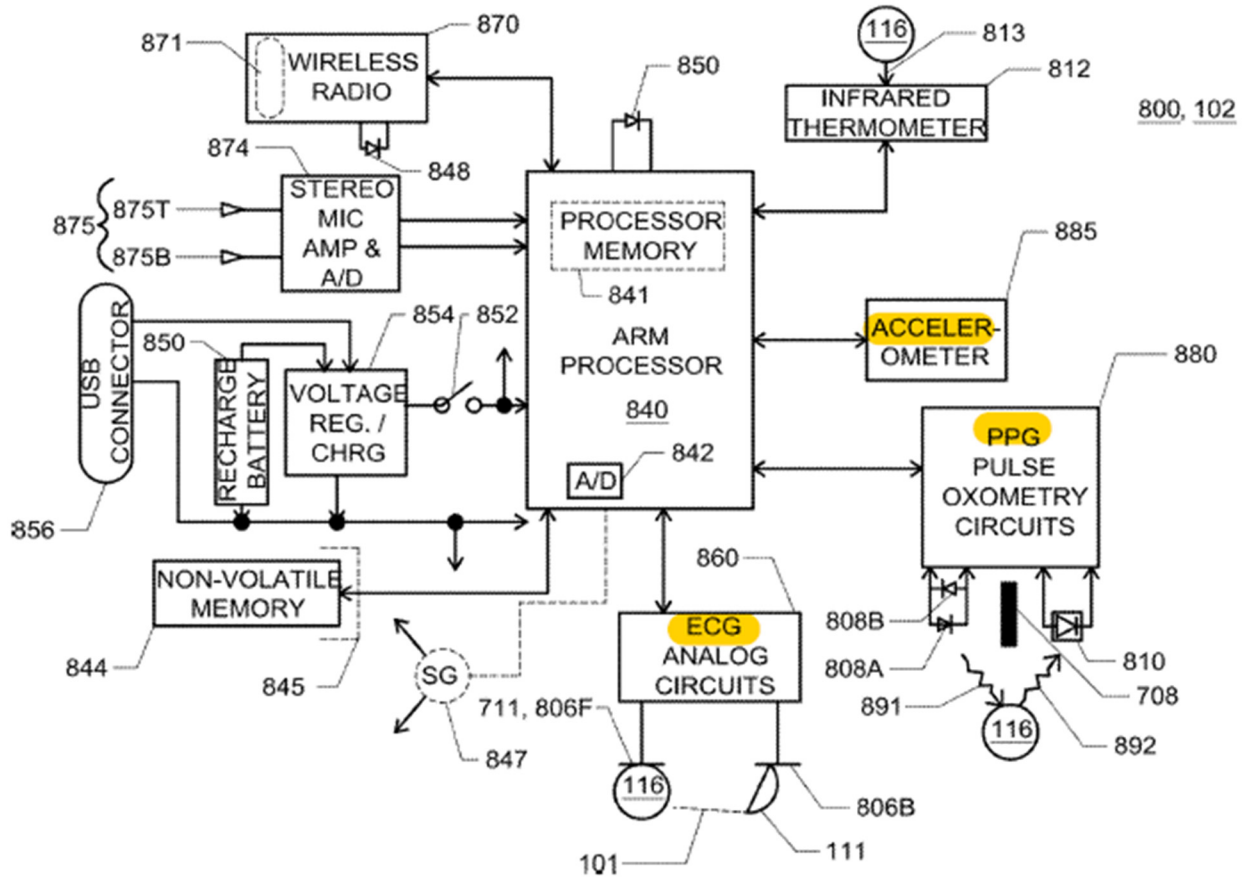


FIG. 8A

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.

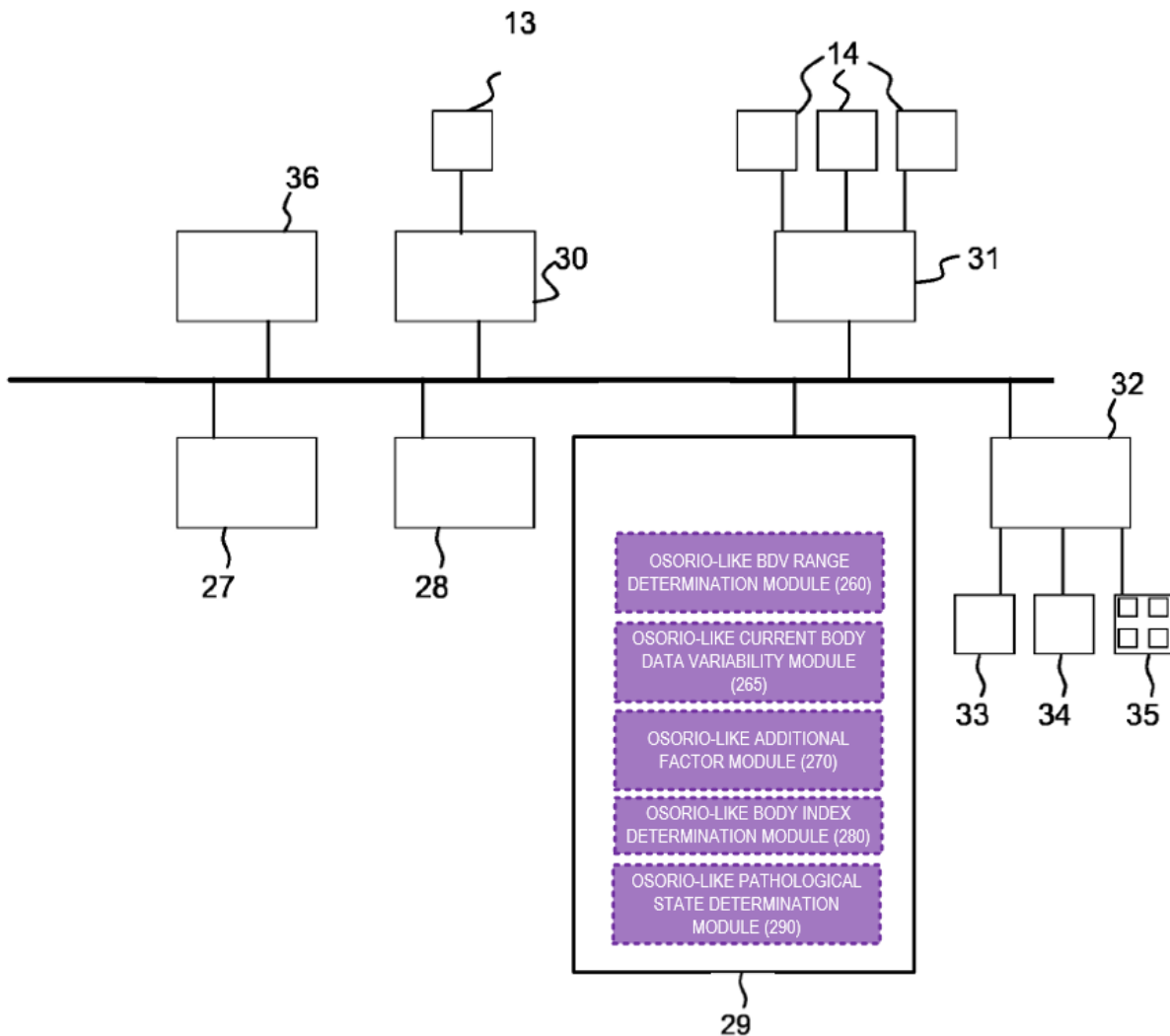
(b) *HRV Monitoring*

159. 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.”).

160. 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.

161. 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)

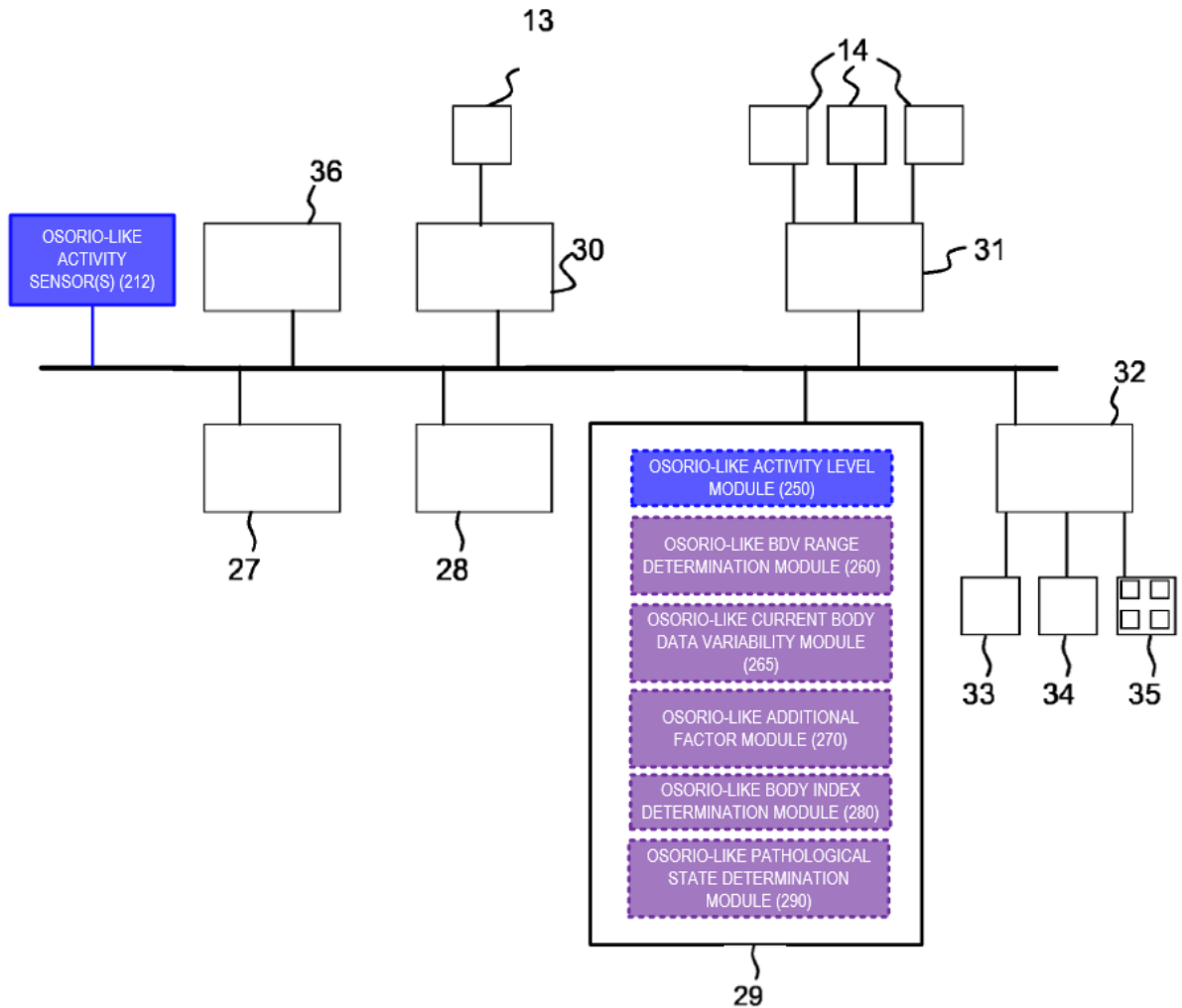
162. A POSITA would have been motivated to incorporate Osorio's software modules into Shmueli's heart monitoring device since doing so would have enabled use of HRV, which improves the pathological event detection capabilities compared to Shmueli's unmodified heart monitoring device. For example, although 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.

163. 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.

164. 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.

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



The Shmueli-Osorio Device

166. 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 have determined 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.

167. 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 smart watch to detect the presence of an arrhythmia of a user, comprising:

168. To the extent the preamble is limiting, it is my opinion that the Shmueli-Osorio combination renders obvious element [1.0].

169. As discussed above in Section XI.A, Shmueli discloses a smart watch to detect the presence of an arrhythmia of a user.

170. 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].

171. As discussed above in Section XII.A, in the Shmueli-Osorio combination, Shmueli is modified by incorporating Osorio’s motion sensor and activity level analysis. Thus, the Shmueli-Osorio combination renders obvious [1.0].

[1.1] a processing device

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

173. As discussed above in Section XI.A, Shmueli discloses a smart watch containing a processing device that controls the operations of Shmueli's PPG sensor and ECG sensor.

174. As discussed above in Section XII.A, in the Shmueli-Osorio combination, Shmueli is modified by incorporating Osorio's motion sensor and activity level analysis. Thus, the Shmueli-Osorio combination renders obvious [1.1].

[1.2] a photoplethysmography ("PPG") sensor operatively coupled to the processing device;

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

176. As discussed above in Section XI.A, Shmueli discloses a PPG sensor operatively coupled to the processing device.

177. As discussed above in Section XII.A, in the Shmueli-Osorio combination, Shmueli is modified by incorporating Osorio's motion sensor and activity level analysis. 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 [1.2].

[1.3] an ECG sensor, comprising two or more ECG electrodes, the ECG sensor operatively coupled to the processing device;

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

179. As discussed above in Section XI.A, Shmueli discloses an ECG sensor, comprising three ECG electrodes and operatively coupled to the processing device.

180. As discussed above in Section XII.A, in the Shmueli-Osorio combination, Shmueli is modified by incorporating Osorio's motion sensor and activity level analysis. 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 [1.3].

[1.4] a display operatively coupled to the processing device; and

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

182. As discussed above in Section XI.A, Shmueli discloses a display operatively coupled to the processing device.

183. As discussed above in Section XII.A, in the Shmueli-Osorio combination, Shmueli is modified by incorporating Osorio's motion sensor and activity level analysis. Thus, the Shmueli-Osorio combination renders obvious [1.4].

[1.5] a memory, operatively coupled to the processing device, the memory having instructions stored thereon that, when executed by the processing device, cause the processing device to:

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

185. As discussed above in Section XI.A, Shmueli discloses a memory operatively coupled to the processing device and having instructions to be executed by the processing device.

186. As discussed above in Section XII.A, in the Shmueli-Osorio combination, Shmueli is modified by incorporating Osorio's motion sensor and activity level analysis. Thus, the Shmueli-Osorio combination renders obvious [1.5].

[1.6] receive PPG data from the PPG sensor;

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

188. As discussed above in Section XI.A, Shmueli discloses a memory with instructions that cause the processing device to receive PPG data from the PPG sensor.

189. As discussed above in Section XII.A, in the Shmueli-Osorio combination, Shmueli is modified by incorporating Osorio's motion sensor and activity level analysis. 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 [1.6].

[1.7] detect, based on the PPG data, the presence of an arrhythmia;

190. It is my opinion that the Shmueli-Osorio combination renders obvious element [1.7].

191. As discussed above in Section XI.A, Shmueli discloses a memory with instructions that cause the processing device to detect, based on the PPG data, the presence of arrhythmia.

192. 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].

193. As discussed above in Section XII.A, in the Shmueli-Osorio combination, Shmueli is modified by incorporating Osorio's motion sensor and

activity level analysis. 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 sensor), 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 an arrhythmia, as taught by Osorio. APPLE-1005, Fig. 8 and [0077]-[0080]; APPLE-1010, [0042]-[0050]. Thus, the Shmueli-Osorio combination renders obvious [1.7].

[1.8] receive ECG data from the ECG sensor; and

194. It is my opinion that the Shmueli-Osorio combination renders obvious element [1.8].

195. As discussed above in Section XI.A, Shmueli discloses a memory with instructions that cause the processing device to receive ECG data from the ECG sensor.

196. As discussed above in Section XII.A, in the Shmueli-Osorio combination, Shmueli is modified by incorporating Osorio's motion sensor and activity level analysis. Upon detection of an arrhythmia, the combined device notifies the user to take an ECG measurement using Shmueli's ECG sensor. APPLE-1004, Fig. 7 and 12:6-30. Then the combined device confirms the detection of the arrhythmia using the ECG data. APPLE-1004, Fig. 7 and 13:16-19

(“Optionally 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.”). Thus, the Shmueli-Osorio combination renders obvious [1.8].

[1.9] confirm the presence of the arrhythmia based on the ECG data.

197. It is my opinion that the Shmueli-Osorio combination renders obvious element [1.9].

198. As discussed above in Section XI.A, Shmueli discloses a memory with instructions that cause the processing device to confirm the presence of the arrhythmia based on the ECG data.

199. As discussed above in Section XII.A, in the Shmueli-Osorio combination, Shmueli is modified by incorporating Osorio’s motion sensor and activity level analysis. Upon detection of the arrhythmia, the combined device notifies the user to take an ECG measurement using Shmueli’s ECG sensor. APPLE-1004, Fig. 7 and 12:6-30. Then, the combined device confirms the detection of the arrhythmia using the ECG data. APPLE-1004, Fig. 7 and 13:16-19 (“Optionally 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.”). Thus, the Shmueli-Osorio combination renders obvious [1.9].

C. Claim 2

[2.0] The smart watch of claim 1, further comprising a motion sensor operatively coupled to the processing device, wherein to detect the presence of the arrhythmia, the processing device is configured to:

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

201. As discussed above in Section XII.A, 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].

202. 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], [0061] and Fig. 1. *See also* APPLE-1010, [0025]-[0026] and [0045]-[0050].

203. A POSITA would have understood that Osorio’s “kinetic sensor” (e.g., accelerometer) is a motion sensor within the meaning of the ’731 patent. For example, the ’731 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, 25:13-15. Thus, as shown in Fig. 1 below, Osorio discloses a motion sensor. See APPLE-1005, Fig. 1; APPLE-1010, Fig. 1.

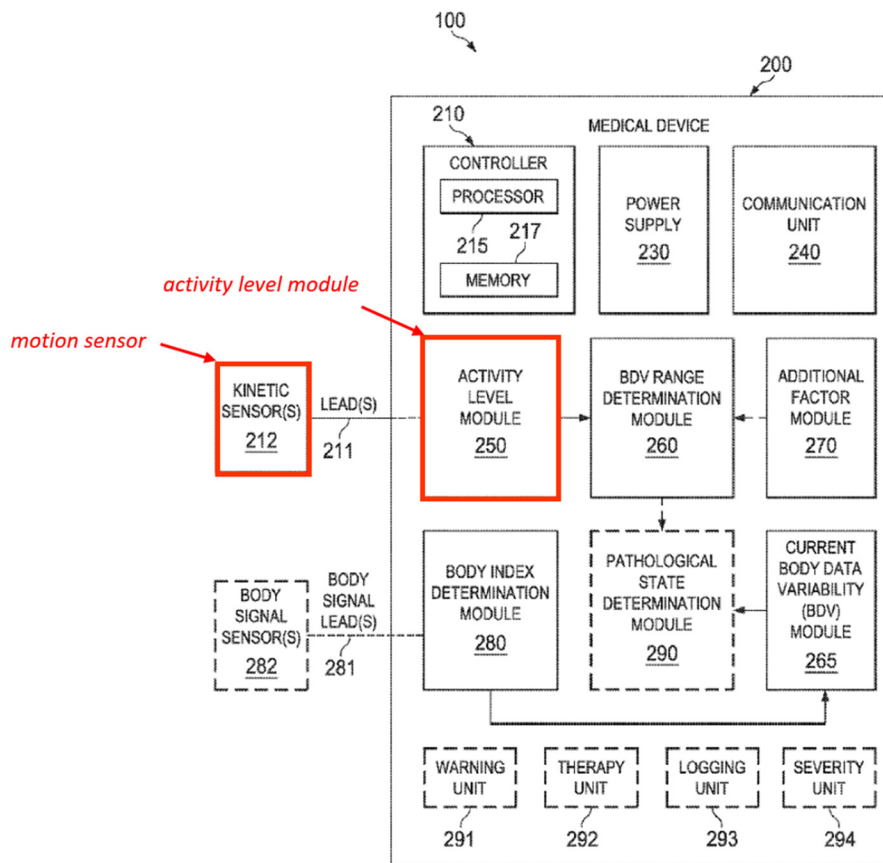


FIG. 1

APPLE-1005, Fig. 1 (annotated).

204. Osorio also discloses sensing an activity level using the activity level module 250. 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.”). 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. *See also*, APPLE-1010, [0025]-[0026] and [0045]-[0050].

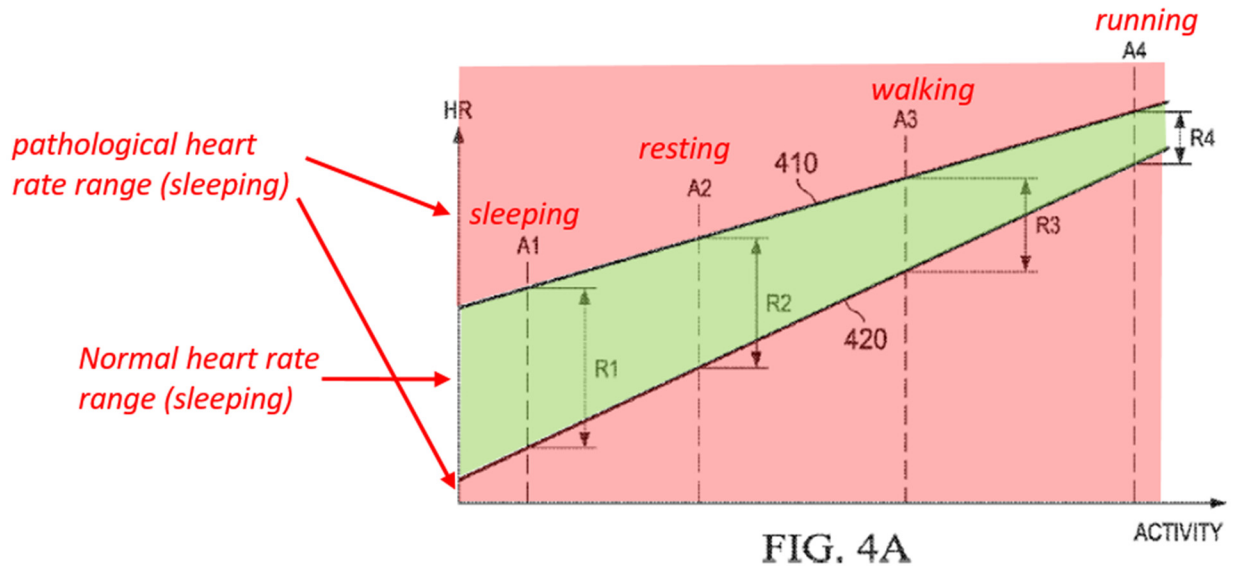
205. As discussed above in Section XII.A, in the Shmueli-Osorio combination, Shmueli is modified by incorporating Osorio’s motion sensor and activity level analysis. Shmueli’s PPG sensor is used to determine heart rate information, and *Osorio’s motion sensor is used to determine the user’s activity level.* Thus, the Shmueli-Osorio combination renders obvious [2.0].

[2.1] receive motion sensor data from the motion sensor; and

206. See element [2.0]. As discussed 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*. A POSITA would have understood that Shmueli's processing device is configured to receive motion sensor data from Osorio's motion sensor.

[2.2] determine, from motion sensor data, that the user is at rest.

207. Osorio discloses determining from the motion sensor data that the user is at rest. EX1005, [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.”). A POSTIA would have understood that the user is at rest when her activity level is low or when the user is asleep. As shown below in Fig. 4A, Osorio discloses “[b]oth the upper and lower bounds of the non-ictal [sic] HR region increase as activity level increases (e.g., from a sleep state to a **resting, awake state**) and reach their highest values for strenuous exertion... Another non-pathological HRV range R2 may be established by upper and lower boundaries 410 and 420 for **resting awake activity level A2**.” APPLE-1005, [0058].



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

208. Thus, Osorio discloses determining, from the motion sensor data, that the user is at rest (e.g., when the activity level is at A2).

209. As discussed above in Section XII.A, in the Shmueli-Osorio combination, Shmueli is modified by incorporating Osorio's motion sensor and activity level analysis. 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* including whether the user is at rest. Thus, the Shmueli-Osorio combination renders obvious [2.0].

D. Claim 4

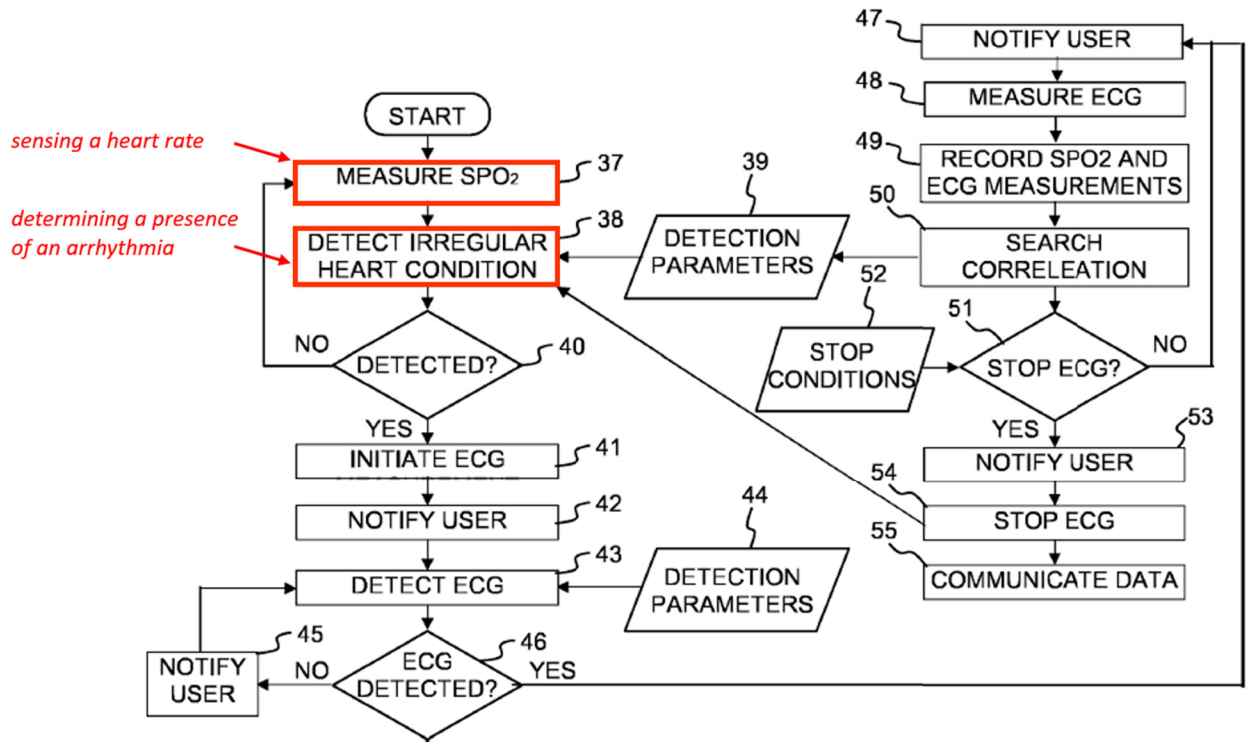
[4.0] The smart watch of claim 2, wherein to detect the presence of the arrhythmia, the processing device is configured to: determine heartrate

variability (“HRV”) data from the PPG data; and detect, based on the HRV data, the presence of the arrhythmia.

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

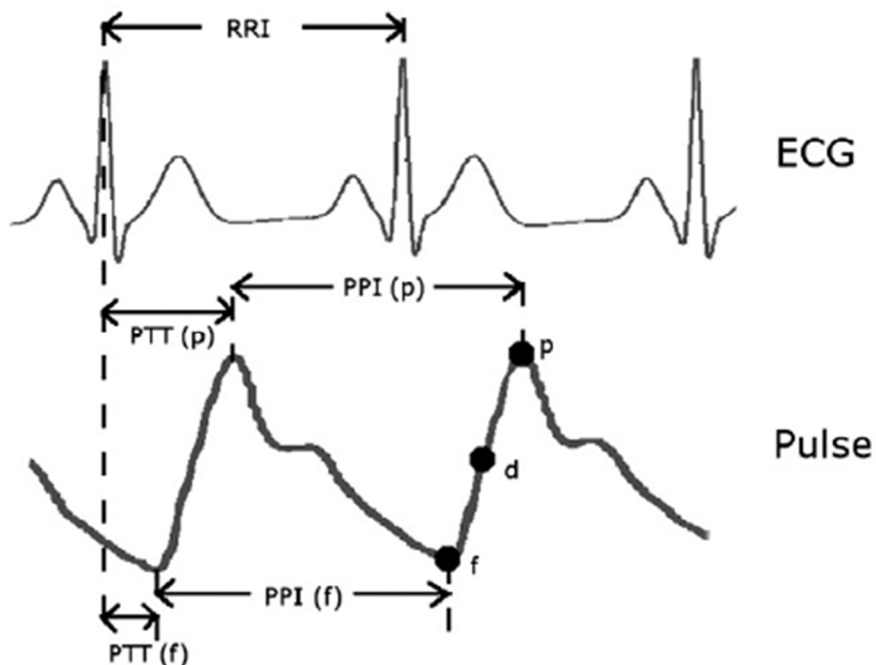
211. As discussed above in Section XII.A, in the Shmueli-Osorio combination, the combined device includes a mobile computing device that executes the software program in Fig. 7 to detect arrhythmia. As shown in Fig. 7 below, the software program “starts in element 37 by measuring SpO2” and then “proceeds 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. In element 38, Shmueli’s method derives the user’s pulse rate from the SpO2 measurement in element 37. *Id.*

Fig. 7



APPLE-1004, Fig. 7 (annotated).

212. As the pulse period derived from PPG data is directly related to the cardiac activity, the physiological information derived from RR intervals of ECG can also be derived from the pulse period of PPG. APPLE-1014, p. 480. This is because electrical activity of the heart (ECG) is followed by the contraction of the heart and 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.

213. Indeed, the '731 patent also discloses detecting heart rate using the 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 '731 patent, Shmueli discloses measuring heart rate 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. Thus, Shmueli discloses detecting heart rate using a heart rate sensor in the form of a PPG sensor.

214. A POSITA would have found it obvious that Shmueli’s method

derives HRV based on the heart rate data because HRV is a common physiological parameter derived from heart rate data to detect irregular heart conditions. APPLE-1012, p. 96 (“HRV analysis became a critical tool in cardiology for the diagnosis of heart diseases.”); APPLE-1039, p. 52 (“This is a more robust method since the R-R time intervals are less affected by the noise.”). In addition, a POSITA would have been motivated to determine HRV based on the 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.”). Thus, while Shmueli does not provide a detailed disclosure of how to detect 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 arrhythmia based on their knowledge, training, and experience in the field as of the Critical Date.

215. In addition, Osorio discloses detecting arrhythmia by determining HRV from the sensed heart rate from the heart rate sensor. APPLE-1005, Fig. 1, [0033], [0042], [0043], [0053] and [0080] (“*the body index value may be heart rate and the BDV may be HRV.*”). See also, 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] and [0043]. 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.*”). 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]. Thus, Osorio discloses determining HRV from the sensed heart rate from the heart rate monitor. See APPLE-1005, Fig. 1; 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.”).

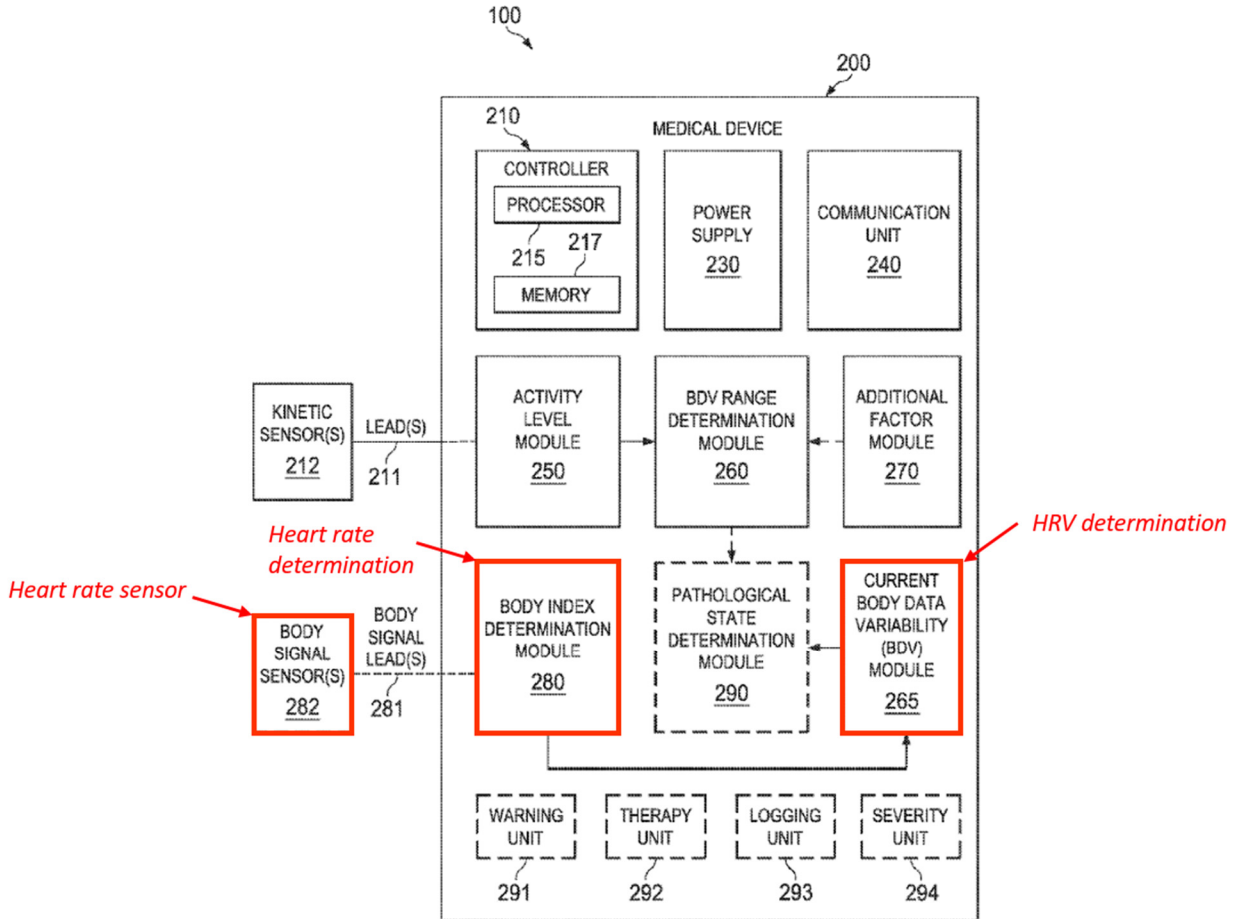


FIG. 1

APPLE-1005, Fig. 1 (annotated).

216. As discussed above in Section XII.A, a POSITA would have been motivated to combine Shmueli with Osorio because Shmueli does not disclose specifically how to detect an irregular heart condition (e.g., arrhythmia) based on heart rate data from the SpO2 measurement. Given the lack of details in Shmueli, a POSITA would have had reason to turn to other references, such as Osorio, that

disclose how to detect irregular heart conditions (e.g., arrhythmia) based on heart rate data. Specifically, Fig. 8 of Osorio discloses how to detect arrhythmia based on heart rate data:

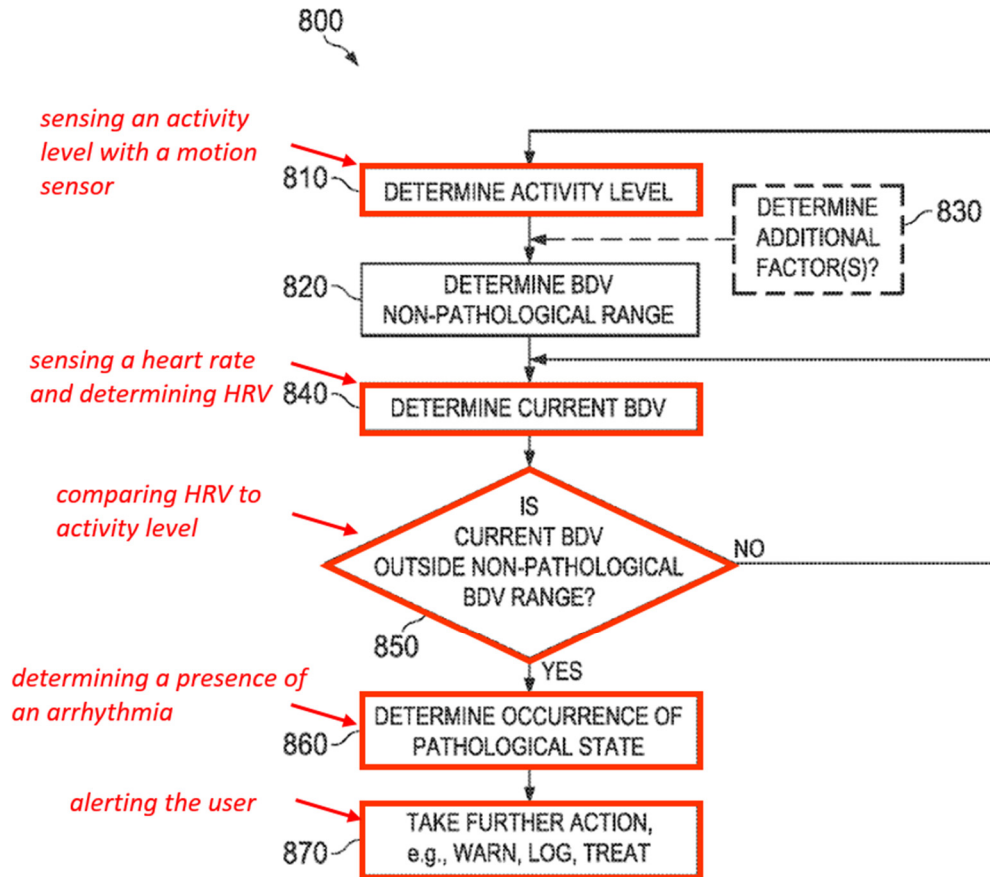


FIG. 8

APPLE-1005, Fig. 8 (annotated).

217. 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]. Thereafter, a further action, such as **warning**, treating, or logging the occurrence and/or severity of the pathological state is taken at 870. APPLE-1005, [0078]. Osorio further discloses “the body index value may be heart rate and the BDV value may be HRV.” APPLE-1005, [0080]. 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]. Accordingly, as an additional reason to combine Shmueli and Osorio, a POSITA would have found it obvious to employ, in Shmueli’s detection of an irregular heart condition, Osorio’s process of comparing HRV to a non-pathological HRV range (dynamically selected based on activity level) to identify irregular heart conditions (e.g., arrhythmia). HRV is a well-known parameter used to detect heart irregularities and a POSITA would have readily appreciated the benefits of using HRV and a non-pathological HRV range to perform the detection of an irregular heart condition in Shmueli, particularly given the lack of details offered in Shmueli’s disclosure. ; APPLE-1012, p. 96 (“HRV analysis became a critical tool in cardiology for the diagnosis of heart diseases.”); APPLE-1039, p. 52 (“This is a more robust method since the R-R time intervals are less affected by the noise.”). With Shmueli’s lack of details, use of Osorio’s HRV analysis in Shmueli would have been seen as a simple application of a known technique to a known

device to yield predictable results. Indeed, a POSITA would have found 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, p. 52. A POSITA would have been motivated to choose HRV analysis because it is less affected by noise. APPLE-1039, p. 52 ("This is a more robust method since the R-R time intervals are less affected by the noise."). In addition, a POSITA 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, one of the most common cardiac arrhythmia) requires HRV analysis.

218. As discussed above in Section XII.A, 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 an arrhythmia*, as taught by Osorio. APPLE-1005, Fig. 8 and [0077]-[0080]; APPLE-1010, [0042]-[0050]. Thus, the Shmueli-Osorio combination renders obvious [4.0].

E. Claim 7

[7.0] The smart watch of claim 1, wherein the processing device is further configured to: extract one or more features from the PPG data; and detect, based on the one or more features, the presence of the arrhythmia.

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

220. As discussed above in Section XI.B, although Shmueli does not specifically disclose how to detect arrhythmia based on PPG data, a POSITA would have found it obvious to extract certain features (e.g., RR intervals and HRV) from the PPG data and to determine arrhythmia based on these features.

221. As discussed above in Section XII.A, in the Shmueli-Osorio combination, Shmueli is modified by incorporating Osorio's motion sensor and activity level analysis. Shmueli's PPG sensor is used to determine heart rate information (a feature extracted from the PPG data), and Osorio's motion sensor is used to determine the user's activity level. The combined device then determines current HRV (a feature extracted from the PPG data) 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 an arrhythmia, as taught by Osorio. APPLE-1005, Fig. 8 and [0077]-[0080]; APPLE-1010, [0042]-[0050]. In other words, the combined device extracts *features including the heart rate and the HRV* from the PPG data and detects arrhythmia based on these extracted features. Thus, the Shmueli-Osorio combination renders obvious [7.0].

F. Claim 12

[12.0] The smart watch of claim 1, wherein the processing device is further configured to generate a notification of the detected arrhythmia.

222. It is my opinion that the Shmueli-Osorio combination renders obvious element [12.0].

223. As discussed above in Section XI.C, Shmueli's processing device is configured to generate a notification of the detected arrhythmia. Shmueli renders obvious generating both a notification of the initially detected arrhythmia based on PPG data and a second notification of the confirmed arrhythmia based on the PPG and ECG data.

224. In addition, Osorio also discloses generating a notification of the detected arrhythmia. APPLE-1005, [0071] (discussing “declaring a pathological state” and “issuing a warning to the patient or a caregiver regarding the pathological state ... the emergence of one or more cardiac arrhythmias”). Fig. 1 of Osorio also shows a “warning unit 291” that is used to issue such notifications:

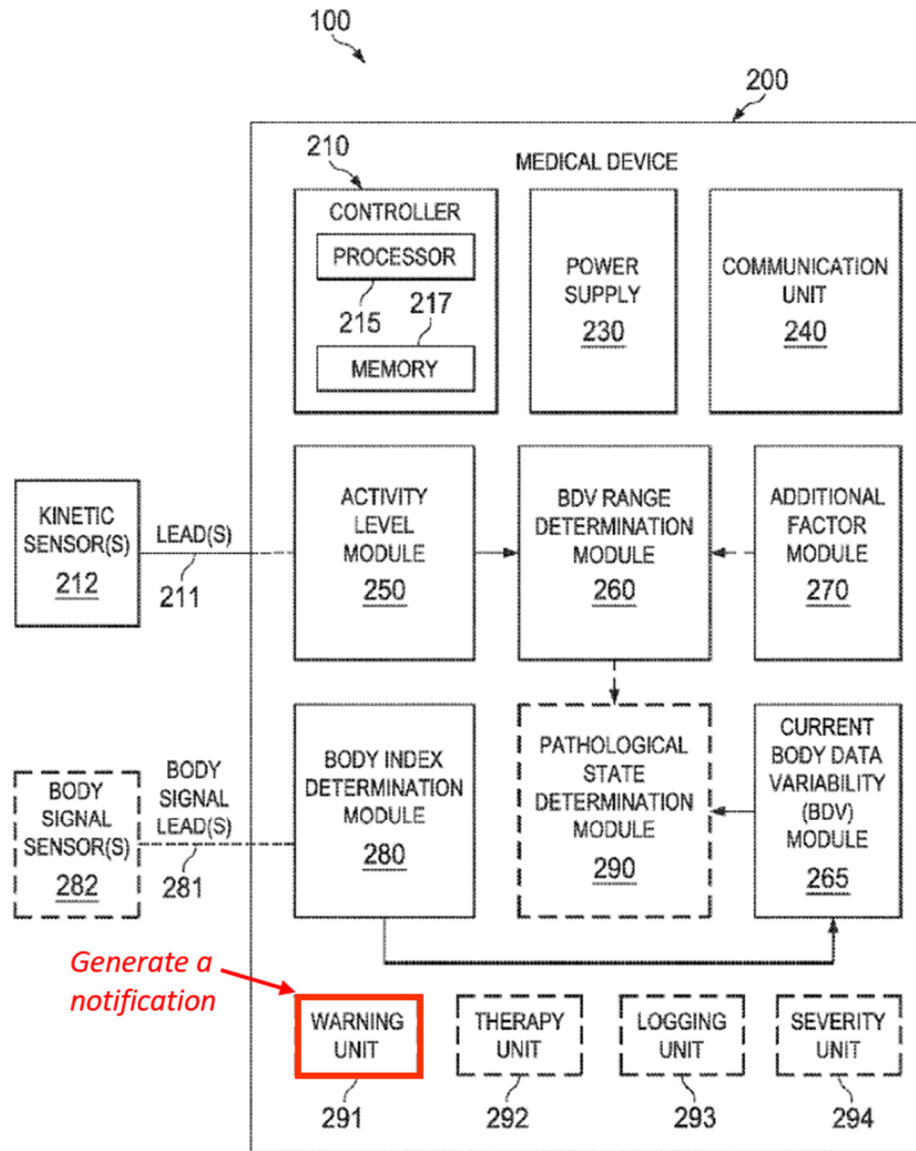


FIG. 1

APPLE-1005, Fig. 1 (annotated).

225. As discussed above in Section XII.A, in the Shmueli-Osorio combination, Shmueli is modified by incorporating Osorio's motion sensor and activity level analysis. Upon detection of an arrhythmia, *the combined device notifies the user of the detected arrhythmia* to prompt the user to take an ECG

measurement using Shmueli's ECG sensor. APPLE-1004, Fig. 7 and 12:6-30.

After the ECG is measured, the combined device confirms the presence of arrhythmia based on the ECG and PPG data and notifies the user of the confirmed arrhythmia. APPLE-1004, 13:16-19 ("Optionally 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."). Thus, the Shmueli-Osorio combination renders obvious [12.0].

G. Claim 13

[13.0] The smart watch of claim 1, further comprising a biometric data sensor, wherein the processing device is further configured to: receive biometric data of the user from the biometric data sensor; and detect, based on the biometric data, the presence of the arrhythmia.

226. It is my opinion that the Shmueli-Osorio combination renders obvious element [13.0].

227. As discussed above in Section XI.D, Shmueli's smart watch comprises a biometric data sensor (PPG sensor or ECG sensor), wherein the processing device is configured to receive biometric data (PPG data or ECG data) from the biometric sensor and detect the presence of arrhythmia based on the biometric data.

228. In addition, the '731 patent describes its 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.” APPLE-1001, 4:57-61. Thus, a POSITA would have understood that Osorio’s motion sensor also is a biometric data sensor and that the motion sensor data is biometric data within the meaning of the ’731 patent.

229. As discussed above in Section XII.A, in the Shmueli-Osorio combination, Shmueli is modified by incorporating Osorio’s motion sensor and activity level analysis. 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 (as determined based on the motion sensor data)*, and compares the HRV to the non-pathological HRV range to determine an arrhythmia, as taught by Osorio. APPLE-1005, Fig. 8 and [0077]-[0080]; APPLE-1010, [0042]-[0050]. Thus, the Shmueli-Osorio combination renders obvious [13.0].

H. Claim 14

[14.0] The smart watch of claim 13, wherein the biometric data comprises at least one of: a temperature, a blood pressure, or an inertial data of the user.

230. It is my opinion that the Shmueli-Osorio combination renders obvious element [14.0].

231. The ’731 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.” APPLE-1001, 4:57-61. Thus, a POSITA would have understood that Osorio’s motion sensor also is a biometric data sensor and that the motion sensor data is biometric data within the meaning of the ’731 patent.

232. As discussed above in Section XII.A, 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 arrhythmia based on heart rate. APPLE-1005, [0029]. Osorio discloses monitoring the user’s activity level using a kinetic sensor, such as an accelerometer. APPLE-1005, Abstract, [0003]-[0006], [0028], [0033], [0057], [0061] and Fig. 1. *See also* APPLE-1010, [0025]-[0026] and [0045]-[0050]. The ’731 patent also discloses a motion sensor in the form of an accelerometer. APPLE-1001, 25:5-9. It was well-known that the accelerometer is an inertial sensor and measures motion based on inertial data. APPLE-1045, 1163. Thus, a POSITA would have understood that Osorio’s “kinetic sensor” (e.g., accelerometer) measures “inertial data” within the meaning of the ’731 patent.

233. As discussed above in Section XII.A, in the Shmueli-Osorio combination, Shmueli’s PPG sensor is used to determine heart rate information,

and *Osorio's motion sensor (e.g., accelerometer) is used to determine the user's activity level (based on an inertial data from the motion sensor)*. A POSITA would have understood that Osorio's motion sensor is a biometric data sensor within the meaning of the '731 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 [14.0].

I. Claim 16

[16.0] The smart watch of claim 1, the processing device further to receive the ECG data from the ECG sensor in response to receiving an indication of a user action.

234. It is my opinion that the Shmueli-Osorio combination renders obvious element [16.0].

235. As discussed above in Section XI.E, Shmueli's processing device is configured to receive ECG data from the ECG sensor in response to receiving an indication of a user action.

236. As discussed above in Section XII.A, in the Shmueli-Osorio combination, Shmueli is modified by incorporating Osorio's motion sensor and activity level analysis. Upon detection of an arrhythmia, ***the combined device notifies the user to take an ECG and detects an ECG in response to a user action.*** APPLE-1004, 3:14-19, Figs. 4 and 7. Thus, the Shmueli-Osorio combination renders obvious [16.0].

J. Claim 17

[17.0]. A method to detect the presence of an arrhythmia of a user on a smart watch, comprising:

237. To the extent the preamble is limiting, it is my opinion that the Shmueli-Osorio combination renders obvious element [17.0]. See element [1.0].

[17.1] receiving PPG data from a PPG sensor of the smartwatch;

238. It is my opinion that the Shmueli-Osorio combination renders obvious element [17.1]. See element [1.6].

[17.2] detecting by a processing device, based on the PPG data, the presence of an arrhythmia;

239. It is my opinion that the Shmueli-Osorio combination renders obvious element [17.2]. See element [1.7].

[17.3] receiving ECG data from an ECG sensor of the smartwatch; and

240. It is my opinion that the Shmueli-Osorio combination renders obvious element [17.3]. See element [1.8].

[17.4] confirming the presence of the arrhythmia based on the ECG data.

241. It is my opinion that the Shmueli-Osorio combination renders obvious element [17.4]. See element [1.9].

K. Claim 18

[18.0] The method of claim 17, wherein detecting the presence of the arrhythmia comprises:

242. It is my opinion that the Shmueli-Osorio combination renders obvious element [18.0]. See element [2.0].

[18.1] receiving motion sensor data from a motion sensor of the smartwatch; and

243. It is my opinion that the Shmueli-Osorio combination renders obvious element [18.1]. See element [2.1].

[18.2] determine, from motion sensor data, that the user is at rest.

244. It is my opinion that the Shmueli-Osorio combination renders obvious element [18.2]. See element [2.2].

L. Claim 20

[20.0] The method of claim 18, wherein detecting the presence of the arrhythmia comprises: determining heartrate variability (“HRV”) data from the PPG data; and detecting, based on the HRV data, the presence of the arrhythmia.

245. It is my opinion that the Shmueli-Osorio combination renders obvious element [20.0]. See element [4.0].

M. Claim 23

[23.0] The method of claim 17, further comprising generating a notification of the detected arrhythmia.

246. It is my opinion that the Shmueli-Osorio combination renders obvious element [23.0]. See element [12.0].

N. Claim 24

[24.0] The method of claim 17, further comprising receiving the ECG data from the ECG sensor in response to receiving an indication of a user action.

247. It is my opinion that the Shmueli-Osorio combination renders obvious element [24.0]. See element [16.0].

O. Claim 25

[25.0] A non-transitory computer-readable storage medium including instructions that, when executed by a processing device, cause the processing device to:

248. It is my opinion that the Shmueli-Osorio combination renders obvious element [25.0].

249. As discussed above in Section XI.I, Shmueli's device includes a non-stationary computer-readable storage medium including instructions to be executed by Shmueli's processing device.

250. As discussed above in Section XII.A, in the Shmueli-Osorio combination, Shmueli is modified by incorporating Osorio's motion sensor and activity level analysis. Thus, the Shmueli-Osorio combination renders obvious [16.0].

[25.1] receive PPG data from a PPG sensor of the smartwatch;

251. It is my opinion that the Shmueli-Osorio combination renders obvious element [25.1]. See element [1.6].

[25.2] detect by the processing device, based on the PPG data, the presence of an arrhythmia;

252. It is my opinion that the Shmueli-Osorio combination renders obvious element [25.2]. See element [1.7].

[25.3] receive ECG data from an ECG sensor of the smartwatch; and

253. It is my opinion that the Shmueli-Osorio combination renders obvious element [25.3]. See element [1.8].

[25.4] confirm the presence of the arrhythmia based on the ECG data.

254. It is my opinion that the Shmueli-Osorio combination renders obvious element [25.4]. See element [1.9].

P. Claim 26

[26.0] The non-transitory computer-readable storage medium of claim 25, wherein the processing device is further configured to: extract one or more features from the PPG data; and detect, based on the one or more features, the presence of the arrhythmia.

255. It is my opinion that the Shmueli-Osorio combination renders obvious element [26.0]. See element [7.0].

Q. Claim 30

[30.0] The non-transitory computer-readable storage medium of claim 25, the processing device further to receive the ECG data from the ECG sensor in response to receiving an indication of a user action.

256. It is my opinion that the Shmueli-Osorio combination renders obvious element [30.0]. See element [16.0].

XIII. ANALYSIS OF SHMUELI IN VIEW OF OSORIO AND LI 2012

257. For the reasons articulated in detail below, and based on my review of the '731 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 Li 2012 provide all the elements of claims 3, 5, 6, 19, 21 and 22.

A. The Combination of Shmueli, Osorio and Li 2012

258. As discussed above in Section XII.A, 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] ("*the body index value may be heart rate and the BDV may be HRV.*").

259. 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 all 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.*

260. In the Shmueli-Osorio-Li 2012 combination, a POSITA would have been motivated to employ a machine learning algorithm to detect arrhythmia based on its many advantages. 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 can increase the detection accuracy by reducing false alarms. APPLE-1006, Abstract.

261. Osorio discloses detecting arrhythmia based on the motion sensor data, the body index and BDV. APPLE-1005, [0046] and [0071]. Osorio discloses that body index may be heart rate and the BDV may be HRV. APPLE-1004, [0080]. 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]. A POSITA would have been motivated to optimize this multifactor analysis in Osorio using a machine learning algorithm, in order to detect arrhythmia based on PPG data (and the heart rate and HRV derived therefrom) and the motion sensor data (and the activity level derived therefrom). A POSITA would have also been motivated to employ HRV

analysis because it is less affected by noise. APPLE-1039, p. 52 (“This is a more robust method since the R-R time intervals are less affected by the noise.”).

262. In addition, after an ECG was measured following Shmueli’s method, it is obvious for the combined device to detect arrhythmia using a machine learning algorithm based on the PPG data (and the heart rate and HRV derived therefrom), motion sensor data (and the activity level derived therefrom) and ECG data.

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 understood that this disclosure refers to machine learning, which “focuses on algorithms capable of learning and/or adapting their structure (e.g., parameters) based on a set of observed data.”

APPLE-1042, p. 538;

263. A POSITA would also have had a reasonable expectation of success in using a machine learning algorithm to detect arrhythmia in this way. For example, Li 2012 discloses detecting arrhythmia based on PPG and ECG 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. 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.

264. Thus, in the Shmueli-Osorio-Li 2012 combination, Shmueli's PPG sensor is used to determine heart rate information, and Osorio's motion sensor is used to determine the user's activity level. Then the combined device determines current HRV based on the heart rate information (from the PPG data), and detects arrhythmia *using a machine learning algorithm* based on the PPG data, heart rate, HRV, motion sensor data and activity level.

265. Alternatively or in combination, in the Shmueli-Osorio-Li 2012 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.

B. Claim 3

[3.0] The smart watch of claim 2, wherein to detect the presence of the arrhythmia, the processing device is configured to input the PPG data into a machine learning algorithm trained to detect arrhythmias.

266. It is my opinion that the Shmueli-Osorio-Li 2012 combination renders

obvious element [3.0].

267. As discussed above in Section XIII.A, in the Shmueli-Osorio-Li 2012 combination, Shmueli's PPG sensor is used to determine heart rate information, and Osorio's motion sensor is used to determine the user's activity level. Then the combined device determines current HRV based on the heart rate information (from the PPG data) and detects arrhythmia *using a machine learning algorithm* based on the PPG data, heart rate, HRV, motion sensor data and activity level. It would have been obvious that the processing device is configured to input the PPG data into a machine learning algorithm trained to detect arrhythmias. Thus, the Shmueli-Osorio-Li 2012 combination renders obvious [3.0].

268. Alternatively or in combination, in the Shmueli-Osorio-Li 2012 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 5

[5.0] The smart watch of claim 4, wherein to detect the presence of the arrhythmia, the processing device is configured to input the HRV data into a machine learning algorithm trained to detect arrhythmias.

269. It is my opinion that the Shmueli-Osorio-Li 2012 combination renders

obvious element [5.0].

270. Osorio discloses detecting arrhythmia based on the motion sensor data, the body index and BDV. APPLE-1005, [0046] and [0071]. Osorio discloses that body index may be heart rate and the BDV may be HRV. APPLE-1004, [0080]. 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]. A POSITA would have been motivated to optimize this multifactor analysis in Osorio using a machine learning algorithm, in order to detect arrhythmia based on PPG data (and the heart rate and HRV derived therefrom) and the motion sensor data (and the activity level derived therefrom). A POSITA would have also been motivated to employ HRV analysis because it is less affected by noise. APPLE-1039, p. 52.

271. As discussed above in Section XIII.A, in the Shmueli-Osorio-Li 2012 combination, Shmueli’s PPG sensor is used to determine heart rate information, and Osorio’s motion sensor is used to determine the user’s activity level. Then the combined device determines current HRV based on the heart rate information (from the PPG data) and detects arrhythmia *using a machine learning algorithm* based on the PPG data, heart rate, HRV, motion sensor data and activity level. It would have been obvious that the processing device is configured to input the

HRV data into a machine learning algorithm trained to detect arrhythmias. Thus, the Shmueli-Osorio-Li 2012 combination renders obvious [5.0].

272. Alternatively or in combination, in the Shmueli-Osorio-Li 2012 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;

D. Claim 6

[6.0] The smart watch of claim 5, wherein to detect the presence of the arrhythmia, the processing device is further configured to input the motion sensor data with the HRV data into the machine learning algorithm trained to detect arrhythmias.

273. It is my opinion that the Shmueli-Osorio-Li 2012 combination renders obvious element [6.0].

274. Osorio discloses detecting arrhythmia based on the motion sensor data, the body index and BDV. APPLE-1005, [0046] and [0071]. Osorio discloses that body index may be heart rate and the BDV may be HRV. APPLE-1004, [0080]. 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]. A POSITA would have

been motivated to optimize this multifactor analysis in Osorio using a machine learning algorithm, in order to detect arrhythmia based on PPG data (and the heart rate and HRV derived therefrom) and the motion sensor data (and the activity level derived therefrom). A POSITA would have also been motivated to employ HRV analysis because it is less affected by noise. APPLE-1039, p. 52.

275. As discussed above in Section XIII.A, in the Shmueli-Osorio-Li 2012 combination, Shmueli's PPG sensor is used to determine heart rate information, and Osorio's motion sensor is used to determine the user's activity level. Then the combined device determines current HRV based on the heart rate information (from the PPG data) and detects arrhythmia *using a machine learning algorithm* based on the PPG data, heart rate, HRV, motion sensor data and activity level. It would have been obvious that the processing device is configured to input the motion sensor data and the HRV data into a machine learning algorithm trained to detect arrhythmias. Thus, the Shmueli-Osorio-Li 2012 combination renders obvious [3.0].

276. Alternatively or in combination, in the Shmueli-Osorio-Li 2012 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.

E. Claim 19

[19.0] The method of claim 18, wherein detecting the presence of the arrhythmia comprises inputting the PPG data into a machine learning algorithm trained to detect arrhythmias.

277. It is my opinion that the Shmueli-Osorio-Li 2012 combination renders obvious element [19.0]. *See* element [3.0].

F. Claim 21

[21.0] The method of claim 20, wherein detecting the presence of the arrhythmia comprises inputting the HRV data into a machine learning algorithm trained to detect arrhythmias.

278. It is my opinion that the Shmueli-Osorio-Li 2012 combination renders obvious element [21.0]. *See* element [5.0].

G. Claim 22

[22.0] The method of claim 21, wherein detecting the presence of the arrhythmia comprises inputting the motion sensor data with the HRV data into the machine learning algorithm trained to detect arrhythmias.

279. It is my opinion that the Shmueli-Osorio-Li 2012 combination renders obvious element [22.0]. *See* element [6.0].

XIV. ANALYSIS OF SHMUELI IN VIEW OF OSORIO AND KLEIGER 2005

280. For the reasons articulated in detail below, and based on my review of the '731 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 Kleiger 2005 provide all the elements of claims 8-11 and 27-

29.

A. The Combination of Shmueli, Osorio and Kleiger 2005

281. As discussed above in Section XII.A, in the Shmueli-Osorio combination, Osorio's motion sensor (e.g., accelerometer) is added to Shmueli's device to detect a user's activity level, which in combination with PPG data is used to detect arrhythmia with increased accuracy based on activity level. APPLE-1005, [0029]. 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 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 the presence of arrhythmia, as taught by Osorio. APPLE-1005, Fig. 8 and [0077]-[0080] ("*the body index value may be heart rate and the BDV may be HRV.*").

282. Thus, Shmueli and Osorio determine HRV based on the heart rate information. As discussed in Section X.D, Kleiger provides a detailed disclosure of how to determine HRV based on heart rate information. Since Shmueli and Osorio do not provide a detailed disclosure on how to determine HRV based on the heart rate information, a POSITA would have been motivated to look to Kleiger 2005 for such details. In the Shmueli-Osorio-Kleiger 2005 combination, the

combined device applies the common HRV measures described in Kleiger 2005 to determine HRV from the heart rate information. A POSITA would have had a reasonable expectation of success because Kleiger 2005's HRV measures were standard techniques that had been used in the field.

283. Thus, in the Shmueli-Osorio-Kleiger 2005 combination, the combined device determines HRV based on the heart rate information from the PPG data using the HRV measures described in Kleiger 2005.

B. Claim 8

[8.0] The smart watch of claim 7, wherein the one or more features correspond to an HRV signal analyzed in a time domain.

284. It is my opinion that the Shmueli-Osorio-Kleiger 2005 combination renders obvious element [8.0].

285. As discussed above in Section XIV.A, in the Shmueli-Osorio-Kleiger 2005 combination, the combined device determines HRV based on the heart rate information from the PPG data using the HRV measures described in Kleiger 2005.

286. Kleiger 2005 discloses extracting HRV from the heart rate information using time domain measures of HRV (HRV signal analyzed in a time domain). APPLE-1033, p. 88 (“In time domain analysis, the intervals between adjacent normal R waves (NN intervals) are measured over the period of recording.”). Thus, in the Shmueli-Osorio-Kleiger 2005 combination, it would

have been obvious that the combined device determines HRV based on HRV signal analyzed in a time domain. Thus, the Shmueli-Osorio-Kleiger 2005 combination renders obvious [8.0].

C. Claim 9

[9.0] The smart watch of claim 7, wherein the one or more features comprise a nonlinear transform of R-R ratio or R-R ratio statistics with an adaptive weighting factor.

287. It is my opinion that the Shmueli-Osorio-Kleiger 2005 combination renders obvious element [9.0].

288. The '731 patent does not define the term "R-R ratio." Although this term is not defined, a POSITA would have understood that term to refer to the ratio of consecutive RR intervals, or the ratio of one RR interval versus the previous RR interval, and that this is a measure of RR interval fluctuations. Kleiger 2005 discloses that the Poincare graph plots *each RR interval as a function of the next RR interval*. APPLE-1033, p. 92. Kleiger 2005 also explains that the Poincare plot is a *nonlinear* measure of the *RR interval fluctuations*. *Id.*, Fig. 2. Based on this disclosure and a POSITA's knowledge, training, and experience in the field as of the Critical Date, a POSITA would have understood that the Poincare plot involves a nonlinear transform of R-R ratio (e.g., a ratio of consecutive RR intervals).

289. As discussed above in Section XIV.A, in the Shmueli-Osorio-Kleiger 2005 combination, the combined device determines HRV based on the heart rate

information from the PPG data using the HRV measures described in Kleiger 2005. Kleiger 2005 discloses extracting HRV from the heart rate information using nonlinear measures of HRV including the Poincare plot. APPLE-1033, pp. 91-92 (“The Poincare graph plots each R-R interval as a function of the next R-R interval (Fig. 2, top panel) and provides an excellent way to visualize patterns of R-R intervals.”). In the Shmueli-Osorio-Kleiger 2005 combination, it would have been obvious that the combined device determines HRV based on the Poincare plot. Thus, the Shmueli-Osorio-Kleiger 2005 combination renders obvious [9.0].

D. Claim 10

[10.0] The smart watch of claim 7, wherein the one or more features are features of an HRV signal analyzed geometrically.

290. It is my opinion that the Shmueli-Osorio-Kleiger 2005 combination renders obvious element [10.0].

291. As discussed above in Section XIV.A, in the Shmueli-Osorio-Kleiger 2005 combination, the combined device determines HRV based on the heart rate information from the PPG data using the HRV measures described in Kleiger 2005.

292. Kleiger 2005 discloses extracting HRV from the heart rate information using geometric measures (HRV signal analyzed geometrically). APPLE-1033, p. 91 (“Heart rate variability triangular index, a geometric measure of HRV, has been used extensively by investigators at St. George’s Hospital in

London.”). Thus, in the Shmueli-Osorio-Kleiger 2005 combination, it would have been obvious that the combined device determines HRV based on HRV signal analyzed geometrically. Thus, the Shmueli-Osorio-Kleiger 2005 combination renders obvious [10.0].

E. Claim 11

[11.0] The smart watch of claim 7, wherein the one or more features are features of an HRV signal analyzed in the frequency domain.

293. It is my opinion that the Shmueli-Osorio-Kleiger 2005 combination renders obvious element [11.0].

294. As discussed above in Section XIV.A, in the Shmueli-Osorio-Kleiger 2005 combination, the combined device determines HRV based on the heart rate information from the PPG data using the HRV measures described in Kleiger 2005.

295. Kleiger 2005 discloses extracting HRV from the heart rate information using spectral or frequency domain measures (HRV signal analyzed in the frequency domain). APPLE-1033, pp. 89-91 (“Either fast Fourier transformation or autoregression techniques can be used to quantify cyclic fluctuations of R-R intervals.”). Thus, in the Shmueli-Osorio-Kleiger 2005 combination, it would have been obvious that the combined device determines HRV based on HRV signal analyzed in the frequency domain. Thus, the Shmueli-Osorio-Kleiger 2005 combination renders obvious [11.0].

F. Claim 27

[27.0] The non-transitory computer-readable storage medium of claim 26, wherein the one or more features correspond to an HRV signal analyzed in a time domain.

296. It is my opinion that the Shmueli-Osorio-Kleiger 2005 combination renders obvious element [27.0]. See element [8.0].

G. Claim 28

[28.0] The non-transitory computer-readable storage medium of claim 26, wherein the one or more features comprise a nonlinear transform of R-R ratio or R-R ratio statistics with an adaptive weighting factor.

297. It is my opinion that the Shmueli-Osorio-Kleiger 2005 combination renders obvious element [28.0]. See element [9.0].

H. Claim 29

[29.0] The non-transitory computer-readable storage medium of claim 26, wherein the one or more features are features of an HRV signal analyzed geometrically or in the frequency domain.

298. It is my opinion that the Shmueli-Osorio-Kleiger 2005 combination renders obvious element [29.0]. See element [10.0].

XV. ANALYSIS OF SHMUELI (OR SHMUELI AND OSORIO) IN VIEW OF CHAN

299. For the reasons articulated in detail below, and based on my review of the '731 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 Chan, or Shmueli in view of Osorio and Chan provide all the elements of

claim 15.

A. The Combination of Shmueli (or Shmueli and Osorio) and Chan

300. As discussed above in Section X.A and Section A.E, both Shmueli and Chan disclose similar wrist-worn devices that monitor the user's ECG in order to detect irregular heart conditions, such as arrhythmia. As discussed above in Section XII.A, in the Shmueli-Osorio combination, Shmueli's device is modified by incorporating Osorio's motion sensor and activity level analysis.

301. As discussed above in Section X.E, Chan discloses a "wristwatch worn by a user for measuring a three-lead ECG." APPLE-1048, Abstract. Figs. 1A and 1B show front and back views of Chan's device. APPLE-1048, 2:43-49. In the backside 1 of the watch, an electrode 3 is inserted for touching the hand that wears the watch. *Id.* The frontside 2 of the watch includes electrode 4 and electrode 6 for fingers from the other hand to press on. *Id.* A display 7, such as a liquid crystal display (LCD), is on the frontside 2 of the watch. *Id.* The display 7 can demonstrate in text 15, which includes time, heart rate, condition (normal or arrhythmia), and graph/animation, an event 13 and ECG waveforms 14. *Id.*

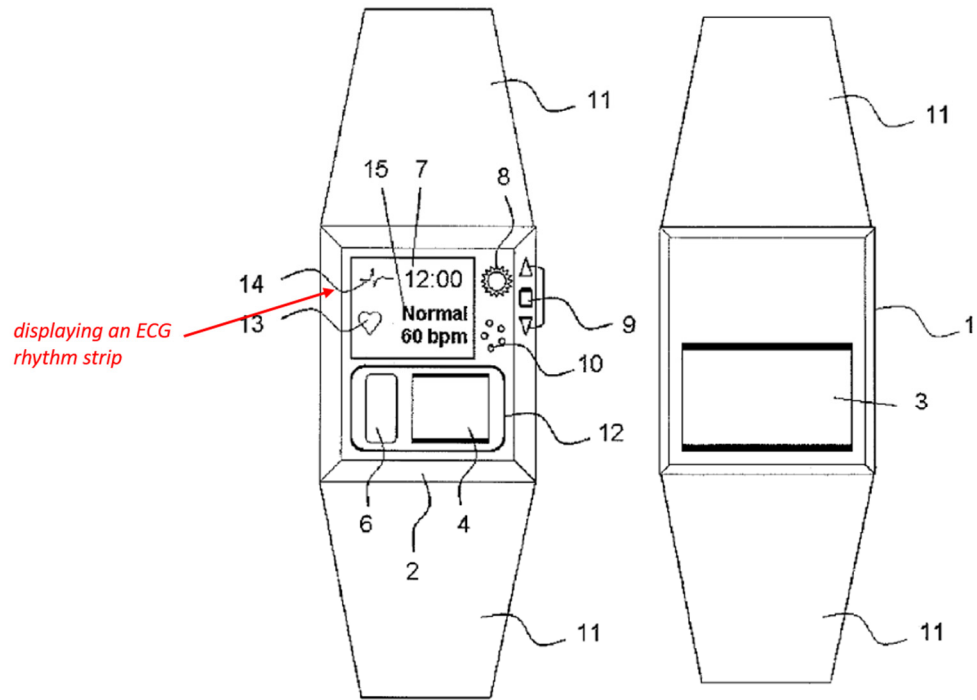


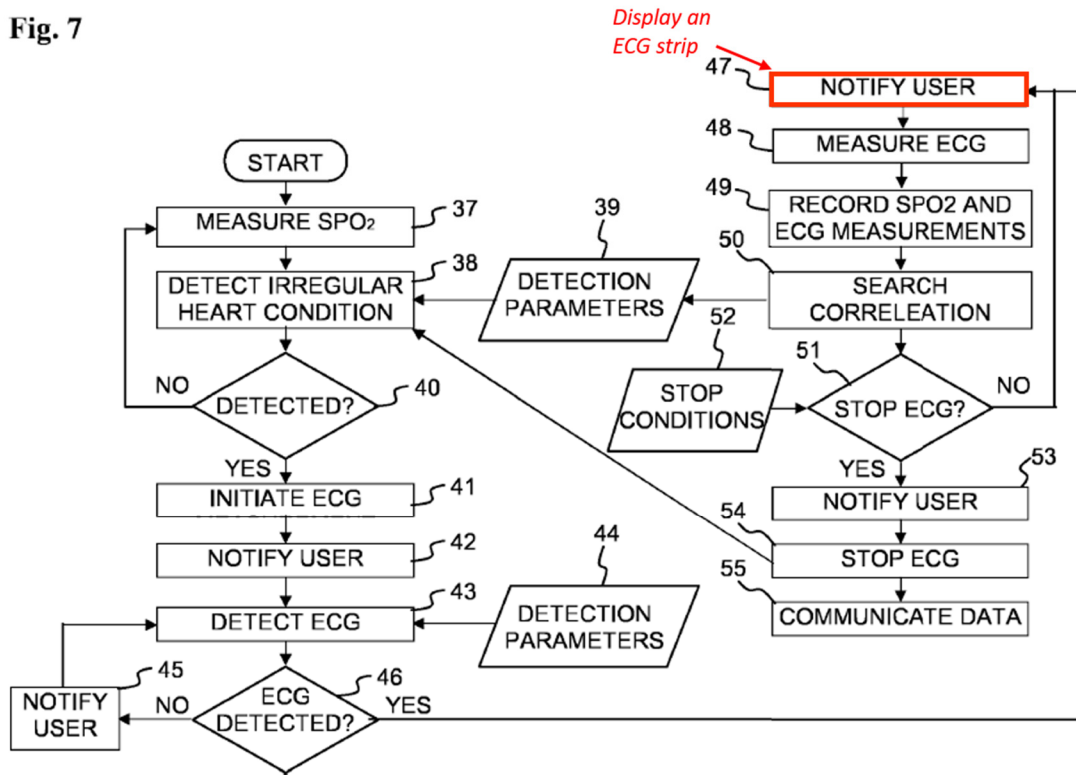
FIG.1A

FIG.1B

APPLE-1045, Figs. 1A and 1B (annotated).

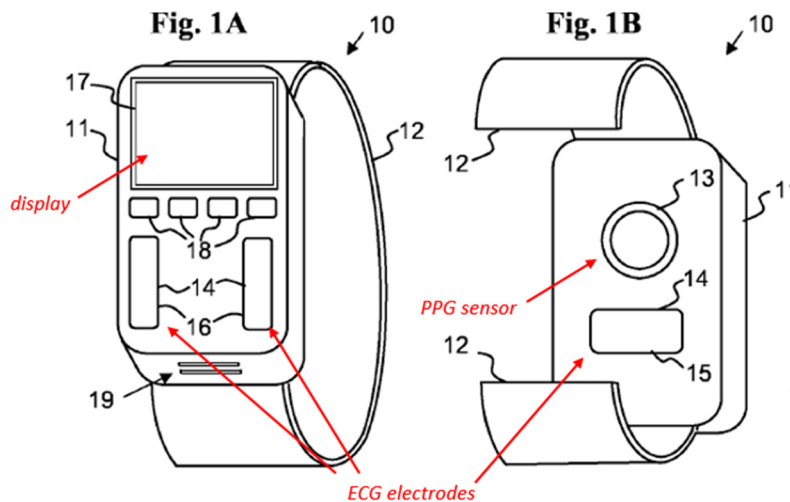
302. As discussed above in Section X.A, Shmueli's device also includes an ECG sensor and a display. Shmueli's device first detects arrhythmia based on SpO2 measurement. APPLE-1004, Abstract and 7:25-31. If the SpO2 measurement indicates arrhythmia, Shmueli's device then takes an ECG measurement to confirm the arrhythmia detection and notifies the user of the detected ECG. *Id.* Fig. 7 shows an example of Shmueli's method:

Fig. 7



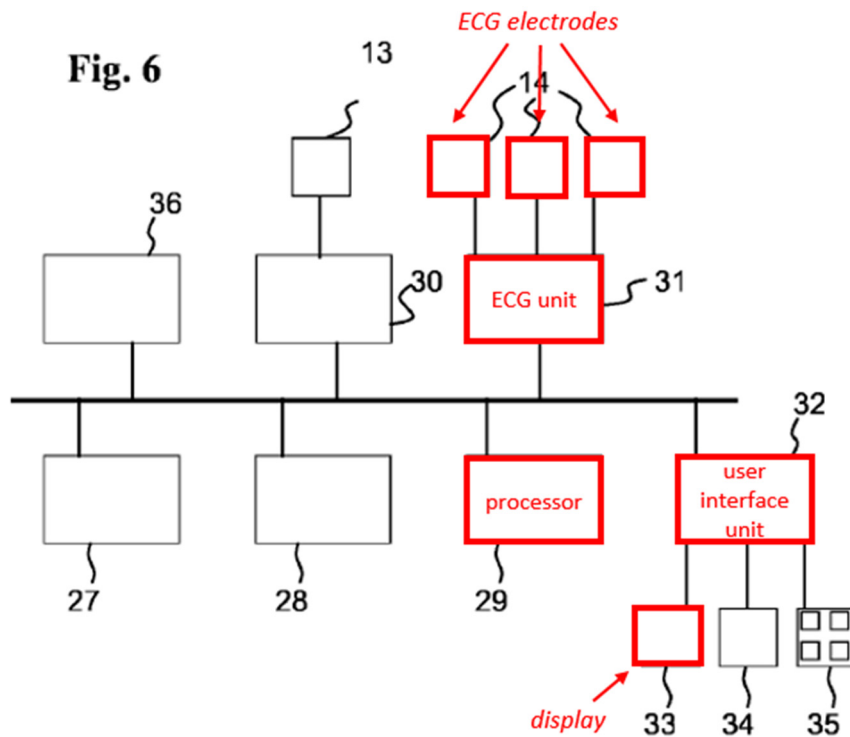
APPLE-1004, Fig. 7 (annotated).

303. Similar to Chan, Shmueli also discloses that the wrist-worn device includes a display. APPLE-1004, APPLE-1004, 9:26-28, 11:10-15 (“preferably containing output devices such as a display 33”), Figs. 1A and 6.



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

304. 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, **a user interface unit 32 preferably containing output devices such as a display 33.**” APPLE-1004, 11:10-15.



APPLE-1004, Fig. 6 (annotated).

305. Shmueli further discloses that “[t]he 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.” APPLE-1004, 14:4-8. Shmueli further discloses that “[t]he 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...” APPLE-1004, 14:4-8. A POSITA would have understood that there are only a finite number of ways to notify the user of “ongoing ECG measurement” and “that the ECG measurement has stopped.” In view of Chan, a POSITA would have recognized that one obvious method to provide ECG information is to display the ECG rhythm strip. A POSITA would have been motivated to display the ECG waveforms because it allows the user to see the *ongoing ECG measurement (element 47)* in real time, and also get notified *when the ECG measurement has stopped (element 53)*.

306. In addition, although Shmueli does not contain a detailed disclosure on what information is provided on its display, a POSITA would have found it obvious to turn to Chan for such details because Shmueli and Chan describes similar wristworn devices that monitor ECG and detect irregular heart conditions, such as arrhythmia. Indeed, Shmueli discloses that its “invention is capable of other embodiments or of being practiced or carried out in various ways.” APPLE-1004, 7:16-17.

307. In the Shmueli-Chan or Shmueli-Osorio-Chan combination, the combined device employs Chan's display that demonstrates in text, information including time, heart rate, condition (normal or arrhythmia), and also demonstrates in graph/animation, information including ECG waveforms. APPLE-1048, 2:43-49;

B. Claim 15

[15.0] The smart watch of claim 1, the processing device further configured to display an ECG rhythm strip from the ECG data.

308. It is my opinion that the Shmueli-Chan combination or Shmueli-Osorio-Chan combination renders obvious element [15.0].

309. As shown in Fig. 1A, Chan discloses that its display 7 can demonstrate in text 15, which includes time, heart rate, condition (normal or arrhythmia), and graph/animation, an event 13 and ***ECG waveforms 14***. APPLE-1048, 2:43-49.

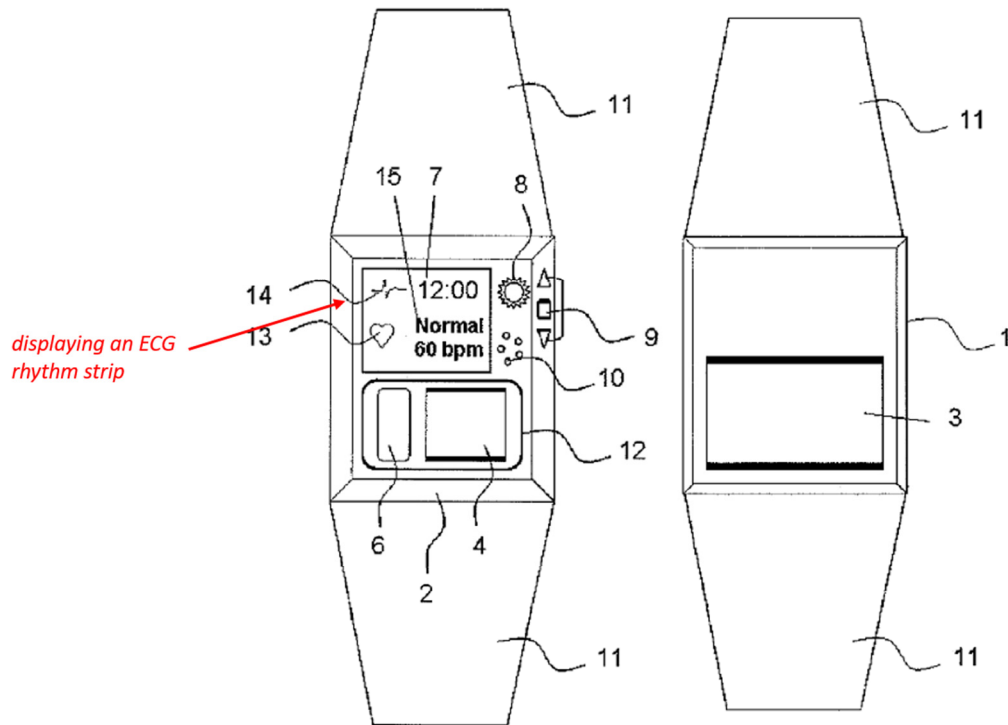


FIG.1A

FIG.1B

APPLE-1045, Figs. 1A and 1B (annotated).

310. Although the '731 patent does not define the term “ECG rhythm strip,” a POSITA would have understood the term “ECG rhythm strip” to refer to ECG waveforms.

311. As discussed above in Section XV.A, in the Shmueli-Chan combination or Shmueli-Osorio-Chan, the combined device employs Chan’s display that demonstrates, in graph/animation, *ECG waveforms*. It would have been obvious that Chan’s ECG waveforms include an ECG rhythm strip from the ECG data within the meaning of the '731 patent. Thus, the Shmueli-Chan combination renders obvious [15.0].

XVI. CONCLUSION

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

313. 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.

314. 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.

315. 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

Bernard Chaitman MD

Curriculum Vitae

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Personal Contact Information

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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, <i>SoLUtions</i> , 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 Ophthalmology	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 2009
 American Recovery and Reinvestment Act of 2009), Grant Review Committee
 NIH/NHLBI Cardiothoracic Network Cardiopulmonary Exercise Core Lab 2008
 Review Committee
 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 1993
 Effects of Impaired Myocardial function in Older Persons
 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 (Anthem™)”	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 Activities

Women's Ischemic 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, Janssen (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 Ischemic 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" September 17, 2017
Presented "Diabetes and Stable Ischemic Heart Disease" Philadelphia, PA
2nd Annual Endpoint Adjudication Conference: Streamline Data Collection Processes to Enable Efficient CEC Review and Regulatory Submissions May 4-5, 2016
Panelist: "Adjudicator Perspective - Critical Insights into Process Bottlenecks and Challenges" and "Key Tactics for Ensuring all Involved Parties Agree on Endpoint Approval" Philadelphia, PA
Harvard Medical School, Cardiovascular Grand Rounds October 15, 2015
"Myocardial Infarction Defined: A Clinical Trial Perspective"
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 November 18-19, 2011
Washington University School of Medicine: "The 39th Annual Symposium Current Topics in Diabetes, Endocrinology and Vascular Disease"
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 March 2, 2011
"Optimal Choice of Initial Medical Therapy, PCI or CABG for Patients with Stable Ischemic Coronary Disease: A 2011 Perspective"
Saint Louis University School of Medicine, Internal Medicine Grand Rounds March 4, 2011
"Troponitis, Application of the ACC/AHA/ESC/WHF/WHO University MI Definition to Routine Clinical Care and Need for Downstream Testing"

- 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 Cardiological 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” Department of Medicine, Chiba Hokusoh Hospital, Nippon Medical School Inba Chiba, Japan June 10, 2005
- The 9th Scientific Meeting for Pharmacotherapy of Cardiovascular Diseases The University of Tokyo, Department of Anesthesiology, Tokyo, Japan June 11, 2005
- New Management Strategies for Chronic Angina: Harvard, Johns Hopkins Northwestern University 2004-2005
- Co-chair, symposium on Clinical Event Adjudication Committees Duke University Medical Center, Duke Clinical Research Institute, Participation by FDA/University Consortium/Pharmaceutical Consortium January 20-21, 2005
- 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” Duke University Medical Center, Duke Clinical Research Institute, Vienna Virginia January 25-27, 2001
- Cardiology Update for the Primary Caregiver: BR Chaitman, Chair Ritz Carlton Hotel, St. Louis, MO October 28, 2000
- The Cardiovascular Board Review: For Certification & Recertification. “Exercise/Stress Testing,” sponsored by American College of Cardiology Hyatt Regency O’Hare, Chicago, IL 2000-2005
- 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, Texas	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
Bonpei Takase, M.D., Assistant Professor of Medicine, Major of Japan Ground Self Defense Force
1st Department of Internal Medicine, National Defense Medical College, Saitama, Japan
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
St. Louis University School of Medicine
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
Liwa T. Younis, M.D., Ph.D., Private practice, St. Louis, Missouri
Naohiko Osada, M.D., St. Marianna University School of Medicine, Kawasaki, Japan
Yasuhiro Yokoyama, M.D., St. Marianna University School of Medicine, Kawasaki, Japan
Shunta Sakai, M.D., Chiba Hokusoh Hospital, Nippon Medical School, Chiba, Japan
Junko Sano, M.D., Chiba Hokusoh Hospital, Nippon Medical School, Chiba, Japan

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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